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Original Articles

**Evaluation of zinc as an adjunct in chlorhexidine containing toothpaste on gingival and plaque index**  
Mohadeseh Arabsolghar MD, Majid Roshanzamir DDS, Mahsayeh Lashkarizadeh DDS ..... (115-120)

**Absorbed dose of sensitive organs in maxillofacial region by different radiographic techniques: Panoramic, Waters, Caldwell and cone-beam computed tomography**  
Seyed Hosein Hoseini-Zarch DDS, MSc, Mohammad Taghi Bahreyni PhD, Fatemeh Akbari MSc, Nasim Khaki PhD, DDS, MD, Mona Poorazad DDS ..... (121-129)

**Assessment of systemic effects of ginger on salivation in patients with post-radiotherapy xerostomia**  
Goli Chamani DDS, MSc, Mohammad Reza Zarei DDS, MSc, Mitra Mehrabani, Nozar Nakhaee MD, Bita Kalaghchi MD, Mahdi Aghili MD, Arezoo Alaei DDS ..... (130-137)

**Does health literacy affect women's oral health self-care behavior? A cross-sectional study in health centers of Tabriz, North West of Iran**  
Raheleh Soltani MSc, Ahmad Ali Eslami PhD, Najmeh Akhlaghi DDS, Behzad Mahaki PhD, Mohammad Vahedian-Shahroodi PhD, Gholamreza Sharifirad PhD ..... (138-144)

**Clinical evaluation of the effect of gingival thickness on increasing the width of keratinized and attached gingiva with and without preserving periosteum in an animal study**  
Saeedeh Ebrahimi DDS, MSc, Jalil Abshenas DVM, DVSC, Mohammad Mehdi Molaei DVM, DVSC, Mohammad Mohammadi DDS, MSc, Nastaran Karimi DDS, MSc ..... (145-150)

**Evaluating the life quality of patients with diseases of oral mucosa referred to Kerman Dental School, Kerman, Iran, in 2014-2015**  
Mina Farhang DDS, Nader Navabi DDS, MSc, Shahla Kakoie DDS, MSc, Maryam Alsadat Hashemipour DDS, MSc ..... (151-158)

**Comparison of transportation and centering ability using RECIPROC and iRace: A cone-beam computed tomography study**  
Bahareh Dadresanfar DDS, MDS, Nahid Mohammadzadeh-Akhlaghi DDS, MDS, Shahriar Shahab DDS, MDS, Shima Shahbazian DDS, Masoud Parirokh DMD, MSc ..... (159-164)

**Dental caries status and its associated factors in pregnant women, Shiraz, Iran, 2014**  
Soheila Shaghaghian MD, MPH, Leila Malekmakan MD, MPH, Vahid Rahimian DDS, Najmeh Savadi DDS ..... (165-172)

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# Table of Contents

## Original Articles

- Evaluation of zinc as an adjunct in chlorhexidine containing toothpaste on gingival and plaque index**  
Mohadeseh Arabsolghar MD, Majid Roshanzamir DDS, Mahsayeh Lashkarizadeh DDS .....(115-120)
- Absorbed dose of sensitive organs in maxillofacial region by different radiographic techniques: Panoramic, Waters, Caldwell and cone-beam computed tomography**  
Seyed Hosein Hoseini-Zarch DDS, MSc, Mohammad Taghi Bahreyni PhD, Fatemeh Akbari MSc, Nasim Khaki PhD, DDS, MD, Mona Poorazad DDS .....(121-129)
- Assessment of systemic effects of ginger on salivation in patients with post-radiotherapy xerostomia**  
Goli Chamani DDS, MSc, Mohammad Reza Zarei DDS, MSc, Mitra Mehrabani, Nozar Nakhaee MD, Bita Kalaghchi MD, Mahdi Aghili MD, Arezoo Alaei DDS .....(130-137)
- Does health literacy affect women’s oral health self-care behavior? A cross-sectional study in health centers of Tabriz, North West of Iran**  
Raheleh Soltani MSc, Ahmad Ali Eslami PhD, Najmeh Akhlaghi DDS, Behzad Mahaki PhD, Mohammad Vahedian-Shahroodi PhD, Gholamreza Sharifirad PhD .....(138-144)
- Clinical evaluation of the effect of gingival thickness on increasing the width of keratinized and attached gingiva with and without preserving periosteum in an animal study**  
Saeedeh Ebrahimi DDS, MSc, Jalil Abshenas DVM, DVSC, Mohammad Mehdi Molaei DVM, DVSC, Mohammad Mohammadi DDS, MSc, Nastaran Karimi DDS, MSc .....(145-150)
- Evaluating the life quality of patients with diseases of oral mucosa referred to Kerman Dental School, Kerman, Iran, in 2014-2015**  
Mina Farhang DDS, Nader Navabi DDS, MSc, Shahla Kakoie DDS, MSc, Maryam Alsadat Hashemipour DDS, MSc.... (151-158)
- Comparison of transportation and centering ability using RECIPROC and iRace: A cone-beam computed tomography study**  
Bahareh Dadresanfar DDS, MDS, Nahid Mohammadzadeh-Akhlaghi DDS, MDS, Shahriar Shahab DDS, MDS, Shima Shahbazian DDS, Masoud Parirokh DMD, MSc .....(159-164)
- Dental caries status and its associated factors in pregnant women, Shiraz, Iran, 2014**  
Soheila Shaghaghian MD, MPH, Leila Malekmakan MD, MPH, Vahid Rahimian DDS, Najmeh Savadi DDS ..(165-172)

## Evaluation of zinc as an adjunct in chlorhexidine containing toothpaste on gingival and plaque index

*Mohadeseh Arabsolghar MD<sup>1</sup>, Majid Roshanzamir DDS<sup>2</sup>,  
Mahsayeh Lashkarizadeh DDS<sup>3</sup>*

### Original Article

#### Abstract

**BACKGROUND AND AIM:** Bacterial plaque is the uppermost element in periodontal diseases. Chlorhexidine (CHX) is one of the utmost influential materials in chemical plaque control and ORTHOKIN is a toothpaste claimed to encompass CHX. Although there are various studies on efficacy of different types of CHX formulation in toothpaste, no literature has focused on the anti-plaque effects of toothpaste with CHX when zinc acetate is introduced in to chemical formula. Therefore, in the present study, we compared Crest ANTI-Cavity toothpaste with KIN gingival and ORTHOKIN toothpastes that contained CHX.

**METHODS:** This controlled clinical trial study was conducted on 30 patients with gingivitis. To compare the anti-plaque activity and bleeding on probing (BOP) index of the toothpastes, the average BOP and plaque index percent was recorded 14-day post-brushing. BOP index and plaque index were measured by an experienced dentist blind to the study and were recorded at pre-scaling, post-scaling and post-brushing for each group. Analysis of variance and paired t-test was used to analyze the data.

**RESULTS:** The average BOP in the 3<sup>rd</sup> meeting for the ORTHOKIN, Crest ANTI-Cavity and KIN gingival toothpastes was 10.54%, 12.15% and 10.60%, and the plaque index in the 3<sup>rd</sup> meeting was 32.22%, 50.35% and 27.80%, respectively. In these 3 groups, BOP did not have a reduction while the plaque index significantly differed between ORTHOKIN and KIN gingival compared to Crest ANTI-Cavity ( $P < 0.05$ ).

**CONCLUSION:** These results showed that the reduction of gingival inflammation in CHX contained toothpastes was the same as the toothpaste without CHX. The addition of zinc had no effect on the effectiveness of CHX.

**KEYWORDS:** Fluoride; Toothpaste; Chlorhexidine; Dental Plaque; Zinc

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In human, the utmost prevalent infectious diseases of oral cavity such as periodontal inflammation, caries, and gingivitis are caused by dental plaque.<sup>1</sup> Dental plaque, containing more than 500 bacterial species, is a complex biofilm that accumulates on the surface of the teeth and is the uppermost element in periodontal diseases.<sup>2</sup> Adequate self-performed mechanical plaque control is an important means to improve periodontal

health. Because of the well-known limitations of the mechanical plaque control methods such as difficult access to distal aspect of third upper molar or interproximal surfaces and difficulty to perform these methods in aged patients with hand mobility limitation and dexterity, chemical materials are used as supplements.<sup>3</sup> The addition of antimicrobial/antiplaque chemical for preparing the toothpaste has gained much attention to maintain dental health and

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enhance the efficacy of self-performed mechanical tooth-cleaning.<sup>4</sup>

Toothpastes are formulated by different active agents that are antimicrobial in nature, to provide a therapeutic effect to control plaque and microorganisms accumulation that cause periodontal disease. It is well established that antibacterial toothpastes and mouth rinses are effective in decreasing tooth surface plaque.<sup>5</sup> Enzymes, amine alcohols, natural products, triclosan, bisbiguanides [chlorhexidine (CHX)], quaternary ammonium compounds [cetylpyridinium chloride (CPC) and different metal salts (zinc salts, stannous fluoride, and stannous fluoride with amine fluoride) are active agents that have been included in toothpastes.<sup>6</sup>

There are large varieties of toothpastes for different purposes such as caries and gingivitis prevention, anti-calculus, dentin hypersensitivity prevention and tooth whitening, with a wide range of active and non-active ingredients. CHX is a cationic antiseptic with action against a few lipophilic viruses, a wide spectrum of bacteria including gram negative and gram positive bacteria and dermatophytes. A significant reduction of its antiplaque potential may be observed when it is formulated into toothpaste.<sup>7</sup> Owing to inactivation of CHX by anionic ingredients, formulation of a toothpaste including CHX is a challenging task.<sup>8</sup> Numerous studies have been conducted to evaluate the efficacy of toothpastes containing CHX. A systematic review in 2012 showed the effectiveness of CHX toothpaste in reduction of bleeding index and plaque index in patients with gingivitis for a 4-week period while there was not any substantial decrease in bleeding index and plaque index for CHX dentifrice.<sup>9</sup>

Although various studies were conducted to evaluate the efficacy of different types of CHX formulation in toothpaste, no study has been carried out to consider the anti-plaque effects of toothpaste with CHX when zinc acetate is combined in to chemical formula. Allegedly in this toothpaste, combination of

CHX and zinc shows and enhanced antimicrobial activity compared to any one of these substances alone. It can be stated that the antimicrobial efficacy of chemical agents in a toothpaste could be lowered or inactivated when mixed with other ingredients. The main goal of the present work was to investigate and compare the antibacterial and anti-plaque activity of a toothpaste without CHX with dentifrice with CHX or a toothpaste containing CHX and zinc acetate.

## Methods

The Ethics Committee of The Faculty of Dental School, Kerman University of Medical Sciences, Kerman, Iran, approved the study (ethical code: K/91/378, IRCT: IRCT2016101330289N1). Written informed consent was obtained from all patients.

This prospective, controlled clinical trial was conducted on 30 patients (13 men and 17 women) with gingivitis who referred to Periodontology Department of Dental Clinic of Kerman University of Medical Sciences. The patients were randomly (block randomization) divided into three groups (each group containing 10 subjects), in which anti-plaque activity of three toothpastes including one without CHX (Crest ANTI-Cavity, Procter & Gamble, Germany), one with CHX (KIN gingival, McCabes Pharmacy, Spain), and one containing CHX and zinc acetate (ORTHOKIN, McCabes Pharmacy, Spain) was investigated.

Inclusion criteria were patients with gingivitis that had a minimum of 24 natural permanent teeth with gingival index II [defined as moderate inflammation, redness, edema and glazing, bleeding on probing (BOP)]. Exclusion criteria were smoking, dental prosthesis or orthodontic devices, taking antibiotics or anti-inflammatory drugs and having any systemic disease.

At the start point, all participants underwent oral examination through which clinical indices including BOP and dental plaque index were recorded and oral health

**Table 1.** Bleeding on probing (BOP) index and standard deviation of three toothpastes

Toothpastes/BOP index	Pre-scaling	Post-scaling	After treatment
ORTHOKIN (mean $\pm$ SD)	30.54 $\pm$ 15.94	24.80 $\pm$ 12.64	10.54 $\pm$ 5.86
Crest (mean $\pm$ SD)	34.97 $\pm$ 8.35	23.77 $\pm$ 10.92	12.15 $\pm$ 4.54
KIN gingival (mean $\pm$ SD)	40.81 $\pm$ 13.04	23.60 $\pm$ 15.13	10.60 $\pm$ 8.63

SD: Standard deviation; BOP: Bleeding on probing

was given. Clinical examination of the patients was carried out by an experienced dentist who was blind to the treatment groups. Subsequently, scaling and root planning (SRP) was performed with Gracey Curettes (Hu-Friedy, Chicago, IL) and an ultrasonic scaler (PS, miniPiezon, EMS Piezon Systems, Nyon, Switzerland). During the 14-day study, subjects were asked to brush twice per day with their assigned dentifrice using a standard manual toothbrush (Oral-B P35 Indicator) for three minutes. At day 14, the subjects were examined for BOP, plaque index and stain index.

Data analyses were done using the SPSS software (version 20, IBM Corporation, Armonk, NY, USA) package. Standard deviation (SD) of all data was  $\pm$  1. After performing Shapiro-Wilk normality test to ensure the normality of pairwise differences, the mean values of data were calculated and statistical significance was determined with ANOVA to compare the effect of anti-plaque activity of three toothpastes. P-value < 0.05 was considered significant. Intra-group differences were analyzed using repeated measure ANOVA.

## Results

The average age of the patients was 29.5 years (18-43), and the majority (56.6%) was women. The mean  $\pm$  SD BOP values for ORTHOKIN group were 30.54  $\pm$  15.94, 24.80  $\pm$  12.64 and 10.54  $\pm$  5.86 percent when measured pre-scaling, post-scaling and post treatment (at day 14), respectively. The

recorded value of the BOP index for any three toothpastes at each time is demonstrated in table 1. BOP index was reduced at post-scaling as well as 14-day post-treatment in three toothpaste groups. The lowest mean percent of BOP index was seen with ORTHOKIN toothpaste compared to KIN gingival and Crest toothpaste groups. However, there was no significant difference in BOP index between the three groups of toothpastes ( $P > 0.050$ ). In all three groups, brushing resulted in significant decrease in BOP index compared to pre- ( $P = 0.003$ ) and post-scaling ( $P = 0.010$ ).

At day 14, the mean plaque index values for KIN gingival, Crest and ORTHOKIN gingival were 32.22  $\pm$  13.24, 50.35  $\pm$  9.41, and 27.80  $\pm$  10.61 percent, respectively (Table 2). Plaque index was reduced at post-scaling as well as 14-day post-treatment in three toothpaste groups. The smallest amount of plaques belonged to the ORTHOKIN group compared to KIN gingival and Crest groups.

Nonetheless, this difference in plaque index of the three toothpastes was negligible and insignificant ( $P > 0.050$ ). In the ORTHOKIN and KIN gingival, brushing resulted in significant decrease in plaque index compared to pre- ( $P = 0.010$ ) and post-scaling ( $P = 0.030$ ). Crest toothpaste resulted in non-significant decrease in plaque index compared to pre- and post-scaling ( $P > 0.050$ ).

## Discussion

Claims of plaque and BOP control benefits

**Table 2.** Plaque index of three toothpastes

Toothpastes/plaque index	Pre-scaling	Post-scaling	After treatment
ORTHOKIN (mean $\pm$ SD)	77.50 $\pm$ 12.08	54.08 $\pm$ 11.03	27.80 $\pm$ 10.61
Crest (mean $\pm$ SD)	80.75 $\pm$ 11.40	55.48 $\pm$ 7.45	50.35 $\pm$ 9.41
KIN gingival (mean $\pm$ SD)	76.88 $\pm$ 13.50	49.91 $\pm$ 11.74	32.22 $\pm$ 13.42

SD: Standard deviation

are common among marketed toothpastes, but comparative in vivo clinical testing is infrequent. The primary aim of this clinical study was to investigate and compare the anti-plaque activity and BOP control of a toothpaste without CHX (Crest) with toothpastes containing CHX (KIN gingival) or CHX in combination with zinc acetate (ORTHOKIN). To compare the anti-activity plaque and BOP of the toothpastes, the average BOP and plaque index percent was calculated for each patient at 14-day post-brushing. BOP index and plaque index were measured by an experienced dentist blind to the study and recorded at pre-scaling, post-scaling and post-brushing for each group.

This study demonstrated a difference in plaque inhibitory performance by the three dentifrices. KIN gingival dentifrice inhibited the rate of plaque formation at 14-day post-brushing to a greater degree than that of Crest (as negative control) and lower than that of ORTHOKIN (containing zinc acetate). Albeit this diversity of plaque formation inhibition between the three toothpaste groups was negligible and insignificant. Various studies using different toothpastes have failed to show significant differences between the efficacy of the test and control toothpastes, although gingival index and plaque index were reduced compared with baseline values.<sup>10,11</sup> ORTHOKIN dentifrice inhibited the rate of plaque formation at 14-day post-brushing to a greater degree than those of KIN gingival and Crest. This might be due to tooth brushing with zinc citrate formulation that was shown to result in significant reductions in oral bacteria from all of the intraoral locations.<sup>12</sup> However, the results of plaque index of ORTHOKIN toothpaste showed a little and inconsequential decrease at 14-day post-brushing compared to KIN gingival and Crest toothpastes. CHX is a cationic antiseptic with action against a wide spectrum of bacteria. However, a significant reduction of its antiplaque potential may be observed when it is formulated into toothpaste and

formulating a toothpaste containing CHX have also difficulties. Possibly the main reason for no significant reduction in plaque index in 3 toothpastes could be the interaction between CHX and anionic components.<sup>7</sup> It has been demonstrated that toothpastes containing fluorides and other antimicrobials including triclosan and zinc citrate are more effective on plaque index and gingival bleeding.<sup>5</sup> Junevicius et al. have shown that the "Blend-A-Med Complete 7 Extra fresh" toothpaste containing zinc nitrate had more antimicrobial effect compared to silver and gold dentifrice.<sup>13</sup>

There was significant decrease in plaque index of KIN gingival and ORTHOKIN toothpastes at 14-day post-brushing compared to pre- and post-scaling. While there was no significant decrease in plaque index of Crest at 14-day post-brushing compared to pre- and post-scaling. After pellicle formation on fresh tooth surface following brushing, different population of microorganisms adhere to the polysaccharides matrix of pellicle and dental plaque is formed.<sup>2,14</sup> It has been shown that CHX as an ingredient of dentifrices is able to reduce the number of anaerobic supragingival plaques.<sup>15</sup> CHX is widely accepted to be one of the gold standard chemical inhibitors of plaques.<sup>9</sup> It has been illustrated that CHX has greater instant anti-pathogenic outcome and in vivo durability effect than other mouthwashes used as topical agents in mouth and is one of the most useful and impressive antimicrobial agents for plaque control.<sup>16</sup> Because of the binding properties of the CHX molecule, its effect sustains in the mucosal surface and on teeth and progressively results in a broad bactericidal and bacteriostatic spectrum of action after 8 hours.<sup>9</sup> In addition, CHX has a high substantivity of up to 12 hour within the oral cavity.<sup>17</sup> The patients were asked to brush twice per day. The twice daily application of a toothpaste formulation containing CHX as main ingredient has been demonstrated to have statistically significant

effectiveness in reducing gingival inflammation over a 3-month period.<sup>18,19</sup> Bellamy et al. reported that toothpaste containing stannous fluoride is significantly more effective in alleviating plaque formation than Lacalut Aktive toothpaste containing CHX.<sup>20</sup> There are discrepancies in results on efficacy of toothpastes containing CHX. The induce of innate and unplanned factors on the anti-pathogenic behavior of CHX or the substantivity of CHX after performing routine daily activities, such as eating, swallow, or mastication was demonstrated.<sup>17</sup> This may explain the possible reason of this discrepancy.

The data on BOP index illustrated that the mean percent of BOP in KIN gingival was lower than ORTHOKIN and greater than Crest. However, no statistically significant differences in BOP index were found between the three toothpaste groups.

In a clinical study which was based on home use lasting for 6 months, both CHX alone and CHX/fluoride formulations were more effective than placebo in reducing plaques, gingival inflammation and bleeding.<sup>21</sup> Comparable clinical results were reported by others concerning the effectiveness of CHX in toothpaste formulations.<sup>14,15</sup> In agreement with our results, Wara-aswapati et al. reported that three toothpaste containing antiplaque and anti-inflammatory agents can reduce gingival

bleeding index and plaque index, albeit nonsignificant.<sup>3</sup>

Regardless of the type of toothpaste, our results showed that scaling and root planning is effective in alleviating plaque formation and BOP (Table 1). However, no obvious difference was found in the average amount of plaque index and BOP between pre- and post-scaling in any of the three groups.

### Conclusion

In conclusion, CHX and zinc in ORTHOKIN toothpaste had a greater but non-significant anti-plaque and anti-gingival bleeding effect than KIN gingival and Crest toothpastes containing CHX alone or without CHX, respectively. More studies are needed to further determine that the combination of CHX and zinc can enhance antimicrobial activity of any one of these substances alone. Toothpastes containing CHX alone and in combination with zinc can reduce plaque index and BOP when comparing pre- and post-scaling.

### Conflict of Interests

Authors have no conflict of interest.

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## Absorbed dose of sensitive organs in maxillofacial region by different radiographic techniques: Panoramic, Waters, Caldwell and cone-beam computed tomography

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** Due to increasing use of X-rays in diagnosis and treatment of diseases, this study aimed to measure and compares the absorbed dose in a number of sensitive organs of head and neck in different radiographic techniques.

**METHODS:** Thermoluminescence dosimeter (TLD) and a male equivalent RANDO phantom were used to measure the absorbed dose in organs. The dosimeters were set in certain sites of phantom related to eye, parotid, thyroid gland, occipital area and temporomandibular joint (TMJ). Panoramic and Caldwell techniques with two different exposure conditions as well as Waters technique with three different exposure conditions were performed. Cone-beam computed tomography (CBCT) was applied in low and normal resolutions with different field of view (FOV), and the mean absorbed dose was calculated and compared by the dosimeters related to each of the organs.

**RESULTS:** The panoramic imaging technique revealed the lowest dose for the eyes, but interestingly higher doses for the parotid gland and the occipital area. In total, Waters and Caldwell imaging techniques indicated that the occipital area and the parotid gland absorbed a higher dose than other organs. In the majority of CBCT scans the parotid region received the highest dose. However, during sinus CBCT (both in low-dose and high-dose modes), the TMJ and eye areas absorbed the highest dose. Investigation of the use of thyroid shield on the absorbed dose in this organ in CBCT showed an average 22% reduction in dose.

**CONCLUSION:** In total, panoramic, Waters and Caldwell imaging techniques indicated that the occipital area and the parotid gland absorbed a higher dose than other organs. In the majority of CBCT scans, the parotid region received the highest dose.

**KEYWORDS:** Radiation Dosimeters; Absorption; Radiation; Cone-Beam Computed Tomography; Panoramic Radiography

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After discovery of X-ray in 1895, application of this beam expanded quickly in all fields, without much precautionary protection or worries about its possible harmful effects. However, the damaging effects of this type of radiation soon began to show up and raise concerns.

Consequently, X-ray and radioactive materials are currently used with extra care, although the application of X-ray is ever more expanding in the medical domain due to its capacity for diagnosis and treatment of diseases.<sup>1</sup>

The knowledge of the biological effects of

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ionizing radiation and realizing the fact that the corresponding dosage impacts the presentation of these effects led to increased protection for patients and radiographers during application. In this context, dosimetry becomes an essential measure both in radiography and radiotherapy.

By definition, dosimetry is concerned with determining the quantity of radiation exposure or dose. The term "absorbed dose" is used to specify the amount of energy absorbed by a given unit of material within the target region.<sup>2</sup>

Thermoluminescence dosimetry (TLD) is used as an appropriate method for measurement of dose in diagnostic radiology.<sup>3</sup> The greatest advantages of TLD materials are their small size and their flexibility, which allow for their insertion into the target material in order to measure the absorbed dose without significantly changing the radiation field. They are quite robust and do not require any connector or wiring.<sup>4</sup> In vivo insertion of dosimetry material is impossible in many cases, and therefore the measurement of dose is restricted to superficial organs such as testes, thyroid and crystalline lenses. For these cases, the TLD material is attached to the skin at the region of the desired organ. In view of the limitations, anthropomorphic physical phantoms can be employed to accurately measure the dose for internal organs. The amount of beam absorption and scattering of these phantoms is similar to that of natural tissues in human body.<sup>5</sup>

The panoramic imaging technique, used for screening radiography, is rapidly gaining popularity among dentists for routine dental examination. Also, Waters and Caldwell techniques have traditionally been used for screening radiography when evaluating the paranasal sinuses. Recently, however, Cone-Beam Computed Tomography (CBCT) has been introduced as a superior technique, and various studies have indicated a lower dose during application of this technique compared with computed tomography (CT).

Besides, the quality of sinus radiographs obtained from CBCT is much higher than that produced by conventional radiography. This study aimed to evaluate and compare the absorbed dose resulting from these different techniques, while noting the advantages and drawbacks of each technique.

## Methods

In this descriptive study, 100 cubic LiF: Mg, Ti TLDs (Thermoluminescent dosimeters) were used (TLD-100, Harshaw Company, USA).

TLDs were calibrated with diagnostic X-ray beams at 70 kVp using a Radcal-type calibrated ionization chamber, specialized for diagnostic X-ray beams. TLDs require annealing during the calibration procedure, and thus they were initially placed in the furnace at 400 °C for one hour. Then, they were removed from the furnace and left to cool slowly. Once again, they were put in the furnace at 100 °C for 2 hours, followed by a second cooling period. Upon completion of annealing, and once the TLDs were coded during calibration, they were placed in their plastic cassettes to shield them from any contamination.

In order to use TLDs for each new radiation, the possible residual energy from previous exposures had to be eliminated. For this purpose, an electric furnace (1200 model, Exciton Company, Iran) was deployed, which resided in the Medical Physics Research Center of Mashhad University of Medical Sciences, Mashhad, Iran.

RANDO phantoms (Figure 1) are specialized tools available for treatment planning in radiotherapy and can also be used in diagnostic radiology. The phantom is generally composed of 35 slices (0 to 34) and includes head and trunk (Figure 2). Each phantom slice comprises bone, red bone marrow, soft tissue and skin. The diagram of each slice features vertical and horizontal axes which define the anterior and posterior positions.<sup>6</sup>

Phantom slices are tightly held together by aluminum plates secured on the uppermost (0) and lowermost (34) slices.



**Figure 1.** RANDO phantom of the head and neck (Model 706-C; Computerized Imaging Reference Systems Inc., Norfolk, VA)

The phantoms come in two models of average size, a male and a female type, designed with the following specifications:

- The female phantom: 163 cm tall weighing 54 kg.
- The male phantom: 175 cm tall weighing 73.5 kg.

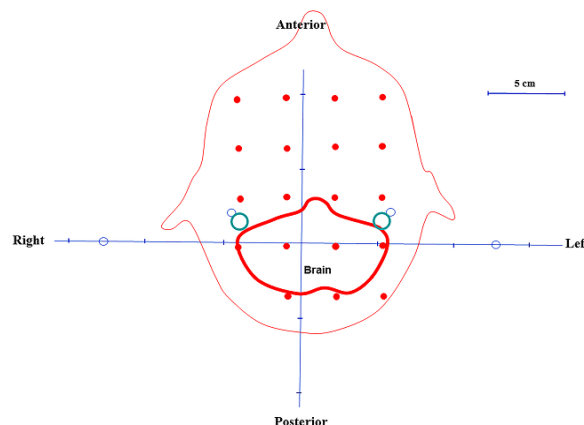


**Figure 2.** Different slices of phantom

Both phantoms contain an anthropomorphic skeleton stuffed with tissue-like materials.<sup>6</sup>

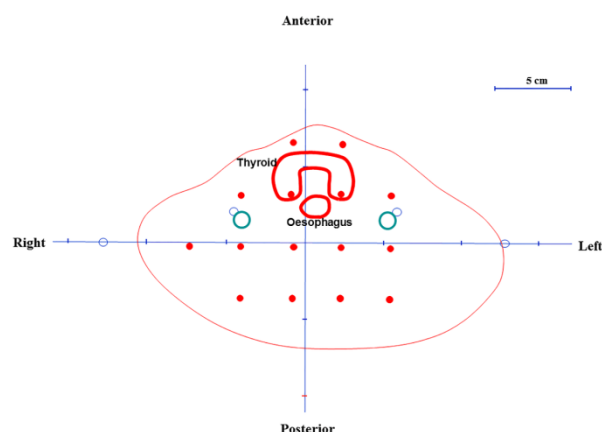
This study utilized a male RANDO phantom to ensure smooth application of TLDs in the region of each intended organ. Only the head and neck segments of the phantom were used, since all target organs of the study were located in this region. After consultation with anatomy specialists of MUMS and review of pertinent literature, the dosimeters corresponding to the occipital area and the temporomandibular joint (TMJ)

were placed in slices No. 8 and No. 4 of the phantom, respectively and those related to the thyroid (Figure 3), eyes and the parotid region were placed in slices No. 9, 3 and 6, respectively (Figure 4-6).

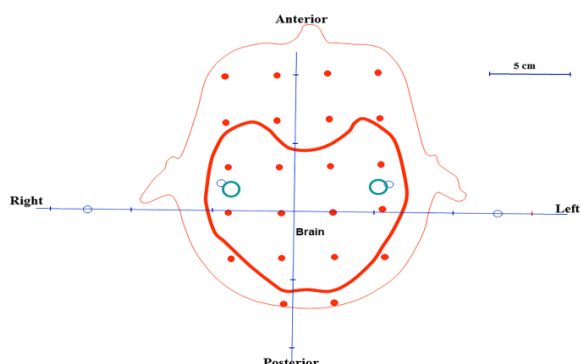


**Figure 3.** Schematic view of the fourth slice for the location of the thermoluminescent dosimeters (TLD)

Four TLD chips were registered within the anterior region of slice No. 9 for the thyroid gland and 2 TLD chips within slice No. 8 for the occipital area. One TLD chip was positioned in each side of the TMJ, the parotid gland and the eyes in the corresponding slices (No. 4, 6 and 3, respectively), and the mean of the doses recorded by each pair of the corresponding TLDs was calculated in order to establish the dose these organs received.

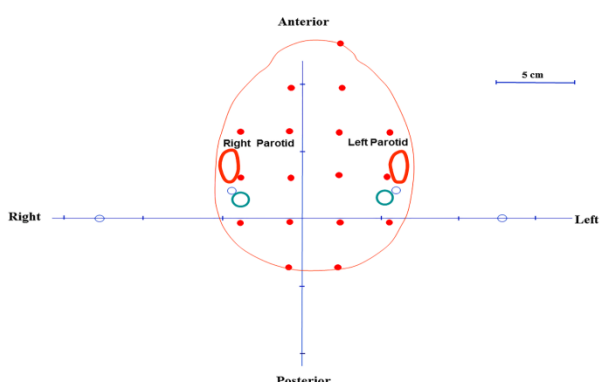


**Figure 4.** Schematic view of the ninth slice for the location of the thermoluminescent dosimeters (TLD)



**Figure 5.** Schematic view of the third slice for the location of the thermoluminescent dosimeters (TLD)

For Waters and Caldwell radiographic examinations, the phantom was fixed in place using the machine's bars and then set at the desired angle. During panoramic radiography and CBCT, the phantom's head was laid straight without any angle on a legged table.



**Figure 6.** Schematic view of the sixth slice for the location of the thermoluminescent dosimeters (TLD)

Panoramic imaging as well as Waters and Caldwell radiography were conducted using the Planmeca machine (ProlineXC 2007 model, Finland). Waters and Caldwell techniques were carried out employing the cephalometric arm of the panoramic device. The images were digitalized using a

computed radiography (CR) machine with pixel size of 86  $\mu\text{m}$  (CR-110, Konica). The device features rectangular collimation and its total filtration is equivalent to 2.5 mm of aluminum. Exposure conditions of the conventional techniques are presented in table 1.

Three-dimensional tomography was conducted using a Planmeca machine (ProMax3D 2009 model, Finland), which offers a resolution of 320  $\mu\text{m}$  on the low-dose mode and 160  $\mu\text{m}$  on the normal mode. The field of view (FOV) of the machine was as follows: large (8 cm  $\times$  14 cm), medium (8 cm  $\times$  8 cm, single jaw: 8 cm  $\times$  5 cm) and small (5 cm  $\times$  4 cm). This device boasts rectangular collimation and its total filtration is equivalent to 2.5 mm of aluminum and 0.5 mm of copper.

The following configurations were used when employing the CBCT device: mA = 8 and kVp = 80. The radiation beams covered four regions: maxilla, mandible, maxilla and mandible together, and the maxillary sinus. Radiography was performed for all four regions in both normal and low-dose modes. As for sinus CBCT, the Stitch technique with FOV = 8 cm  $\times$  14 cm was applied to increase the radiation field (Table 2). CBCT imaging was performed under three varied conditions with normal resolution and with three different FOVs: using a thyroid shield (CBCT images 7, 8 and 9) to measure the thyroid dose and compare it with similar positions; and also without the thyroid shield (CBCT images 1, 3 and 5). At the end of each radiography session performed according to a specific exposure setting, the TLDs were removed and replacement TLDs were prepared and placed again in the set regions of the organ so as to be radiated according to different exposure conditions.

**Table 1.** Exposure conditions of conventional techniques

Radiography technique	Setting		
	First time	Second time	Third time
Panoramic	mA = 5, kVp = 66, t = 18	mA = 10, kVp = 66, t = 18	-
Waters	mA = 6, kVp = 78, t = 1.2	mA = 12, kVp = 78, t = 1.2	mA = 12, kVp = 80, t = 2.3
Caldwell	mA = 12, kVp = 76, t = 1	mA = 12, kVp = 80, t = 2.6	-

**Table 2.** Exposure conditions in cone-beam computed tomography (CBCT) radiography

Organs	mA, kVp	CBCT	Resolution	Time (s)	Thyroid shield	FOV (cm)
Maxilla and mandible (full)	8, 80	CBCT 1	N	12.0	-	8 × 8
		CBCT 2	LD	2.8	-	
Maxilla	8, 80	CBCT 3	N	12.0	-	8 × 5
		CBCT 4	LD	2.8	-	
Mandible	8, 80	CBCT 5	N	12.0	-	8 × 5
		CBCT 6	LD	2.8	-	
Maxilla and mandible (full)	8, 80	CBCT 7	N	12.0	+	8 × 8
Maxilla	8, 80	CBCT 8	N	12.0	+	8 × 5
Mandible	8, 80	CBCT 9	N	12.0	+	8 × 5
Sinus	8, 80	CBCT 10	N	36.0	-	8 × 14 (stitch)
		CBCT 11	LD	8.5	-	

CBCT: Cone-beam computed tomography; N: Normal; LD: Low dose; FOV: Field of view

WinREMS software was used to read, process, and store the dosimetry data achieved in this study.

After transferring the TLDs to the Physics Research Center of MUMS, the doses absorbed by TLDs, matched to each organ and achieved from the various techniques, were obtained and the intended comparisons were performed.

## Results

In this study, the absorbed doses of the five sensitive organs in the head and neck region including the thyroid gland, the occipital area, the parotid gland, the TMJ and the eyes were measured using the panoramic, Waters, Caldwell and CBCT radiography techniques. The two panoramic imaging techniques revealed the lowest dose for the eyes, but interestingly higher doses for the parotid gland and the occipital area (Table 3).

In total, Waters and Caldwell imaging techniques, as likewise observed in the panoramic technique, indicated that the

occipital area and the parotid gland absorbed a higher dose than other organs (Table 3).

Table 4 summarizes the absorbed dose of organs for CBCT units in this study. In the techniques of CBCT 1-6, 10 and 11, the highest absorbed dose belonged to the parotid gland, occipital area and TMJ. By using the thyroid shield, the thyroid gland had the lowest absorbed dose in the CBCT 8 technique. In the majority of CBCT scans, the parotid region received the highest dose. However, during sinus CBCT (both in low-dose and high-dose modes), the TMJ and eye areas absorbed the highest dose.

## Discussion

The aim of this study was to compare the doses absorbed by a number of sensitive organs within the head and neck region, including the eyes, the thyroid gland, the parotid gland, the TMJ and the occipital area during certain radiography techniques, namely panoramic imaging, Waters, Caldwell and CBCT.

**Table 3.** Absorbed dose of organs in  $\mu\text{Gy}$  in radiographies

Organs	Pan 1	Pan 2	Wat 1	Wat 2	Wat 3	Caldw 1	Caldw 2	Wat 1 + Caldw 1 (A)	Wat 2 + Caldw 2 (B)	Wat 3 + Caldw 2 (C)
Thyroid	198.40	596.02	167.90	170.23	177.97	161.48	245.88	329.38	400.78	408.75
Occipital	820.12	1069.60	151.52	354.14	455.40	272.90	473.67	424.42	1027.64	1129.54
Parotid	2038.62	4187.73	279.32	303.57	339.50	231.85	344.99	511.17	588.96	625.46
TMJ	174.15	289.90	55.65	79.54	131.90	92.90	141.24	148.55	209.61	262.51
Eye	43.10	55.24	130.00	126.00	161.50	124.55	189.71	254.55	338.46	302.96

TMJ: Temporomandibular joint; Pan: Panoramic; Wat: Waters; Caldsw: Caldwell

**Table 4.** Absorbed dose by organs in  $\mu\text{Gy}$  in cone-beam computed tomography (CBCT) radiographs

Organs	CBCT 1	CBCT 2	CBCT 3	CBCT 4	CBCT 5	CBCT 6	CBCT 7*	CBCT 8*	CBCT 9*	CBCT 10	CBCT 11
Thyroid	495.45	285.63	223.93	106.18	533.08	271.05	365.60	199.20	381.82	322.84	212.44
Occipital	1338.68	649.10	1175.53	611.40	641.70	340.95	-	-	-	727.19	273.29
Parotid	2821.45	651.08	2514.45	628.85	930.53	293.53	-	-	-	1287.19	415.04
TMJ	340.10	116.68	284.05	201.80	66.93	47.43	-	-	-	4271.19	817.24
Eye	204.05	28.93	304.30	231.35	220.28	109.33	-	-	-	3799.19	743.19

CBCT: Cone-beam computed tomography; TMJ: Temporomandibular joint

\*In these three radiographs, only the effect of thyroid shield on the absorbed thyroid dose was considered; therefore, the dose absorbed by other organs was not calculated

The highest absorbed dose occurred at the occipital and parotid areas during panoramic, Waters and Caldwell radiography techniques, where the phantom was exposed to radiation at the back of the head. The parotid glands, which are situated along the two lateral axes of rotation, received the highest dose during the panoramic radiography approach. In light of these results, it is fair to say that during the majority of Waters and Caldwell scans, the parotid region absorbed the second-highest dose after the occipital area, possibly because of the beam radiation angle. Among the studied organs, the lowest absorbed dose during panoramic radiography was observed in the eye region, which could be explained by two factors: the focus and the movement of the X-ray tube in the inferior and posterior areas of the head.

The highest increase in the absorbed doses resulting from CBCT was observed in the TMJ and eye regions, compared with the total absorbed dose during Caldwell and Waters techniques. When a shield was used for the thyroid region, the variation of dose reduction ranged from 11% to 28% compared to similar conditions where no shield was used. The average reduction in dose was approximately 22%. Results from all CBCT imaging modes, which were classified according to normal or low-dose resolution and compared pairwise (i.e. CBCT 1 and 2, CBCT 3 and 4, CBCT 5 and 6 and CBCT 10 and 11), pointed out that the absorbed dose of all organs was lower during the low-dose mode.

The study by Pauwels et al.<sup>7</sup> evaluated the effective dose resulted from different CBCT devices using TLDs and anthropomorphic

phantoms. Fourteen different CBCT imaging systems were studied and the results were classified into three groups based on radiation zone. Using the Promax 3D machine at low resolution, the exposure conditions of the present study were almost identical to those of the Pauwels et al.<sup>7</sup> Accordingly, the dose absorbed by the salivary and the thyroid glands were roughly equal in the two studies. However, in the current study, the exposure conditions of the device at normal resolution were nearly half of those in the study of Pauwels et al., and thus the absorbed dose of the thyroid amounted to approximately half of the dose absorbed by this organ in Pauwels et al.'s study.<sup>7</sup>

In the study by Pauwels et al.<sup>7</sup>, the dose absorbed by the thyroid gland was lower than that of the salivary gland for all applied devices. According to the current study, the thyroid gland received a lower dose in comparison with the parotid gland, which can suggest that during CBCT the organs which are not located within the radiation field will only be subject to scattered radiation and will therefore receive considerably lower doses.

The overall conclusion obtained in Pauwels et al.'s study was that, as far as dental practice was concerned, the effective dose resulting from various CBCT devices was higher than that achieved from two-dimensional radiography techniques.<sup>7</sup> The findings of the present study, however, indicated that during all CBCT scans the absorbed dose was not higher than the dose resulting from panoramic, Waters or Caldwell techniques, especially during low-

dose CBCT scans, which delivered a much lower dose in some cases compared to two-dimensional radiographs.

Comparison of the dose absorbed by the TMJ during a pantomography technique using simple films in the study by Christiansen et al.<sup>8</sup> with the dose absorbed by the same organ during a panoramic imaging technique in the present study showed a lower dose of absorption in the latter study (0.17-0.29 mGy in the latter study vs. 0.3-0.4 mGy in the former study). This lower dose could have been caused by the different exposure settings of the devices used, but could also be attributed to factors such as utilizing more advanced devices with higher technology and employing digital receptors in the present study.

In the current study, the highest dose absorbed by TMJ when using CBCT techniques was related to normal resolution sinus CBCT, which was interestingly lower (nearly 12-15 times) compared to the dose received by the same organ during high resolution CT technique in the study by Christiansen et al.<sup>8</sup>

There have been few studies concerned with dosimetry involving Waters and Caldwell radiography. However, in the study by Nadas et al.,<sup>9</sup> the total dose of absorption in sensitive organs during radiographic examination of paranasal sinuses using conventional two-dimensional techniques such as Waters, Caldwell, Lateral and Hirtz was substantially lower than the dose absorbed by organs during high resolution CT. In the present study, the dose absorbed by eyes and TMJ during normal resolution CBCT proved to be higher than the dose these organs absorbed during Waters and Caldwell scans combined.

In the current study, the total dose absorbed by eyes, the thyroid gland and TMJ during Waters and Caldwell scans combined was considerably lower than the total dose these organs were reported to have received during four standard sinus radiography scans (Waters, Caldwell, lateral and Hirtz) in the study by Nadas et al.<sup>9</sup> This seems justifiable when considering the four

standard sinus radiography scans performed in the latter study versus only two radiography scans conducted in the present study. However, a more plausible explanation for this remarkable difference could be based on a number of factors that can lead to a considerable increase in dose, including the fact that the older radiography techniques tended to utilize unsophisticated receptors with relatively lower speed, as opposed to sophisticated high-speed digital receptors currently in use, and that the devices used formerly were not as efficient as the digital devices employed today.

Jadu et al.<sup>10</sup> compared the effective dose obtained during sialography using conventional two-dimensional radiographic techniques versus CBCT. In conclusion, they reported that the effective dose received by submandibular and parotid glands during CBCT at low FOV, mA and kVp settings was not considerably different from the dose resulting from conventional radiography techniques such as panoramic and lateral cephalometric radiography. However, the results of the present study indicated that using the lowest settings of the CBCT machine (mA = 7, kVp = 78 and low-dose resolution), the dose absorbed by the parotid gland turned out to be considerably lower than the corresponding dose when panoramic imaging techniques were employed; and was also approximately equivalent to the total dose received by this organ combining the results of the two techniques of Waters and Caldwell. With regards to the absorbed dose of the parotid gland, the small gap observed in the study by Jadu et al.<sup>10</sup> between the results of CBCT radiography and two-dimensional techniques such as panoramic imaging is likely to have been due to higher exposure conditions of CBCT compared to the current study.

Qu et al.<sup>11</sup> compared the effective radiation dose generated by Promax 3D CBCT machine in various dental protocols. They radiated the beam during different stages marked by changing the device settings: from a minimum



of 8 up to a maximum of 16 mA; using low, normal and high resolutions; and adjusting image size as small (sextants of both jaws), medium (maxilla or mandible) and large (encompassing both jaws). Their results concerning the impact of increasing exposure parameters of the device were consistent with the findings of the present study. Subject to almost identical device settings, the doses absorbed by the thyroid and parotid glands were found to be lower in the present study compared with the study by Qu et al.,<sup>11</sup> which might have been caused by a few factors including possible minor differences in the position of dosimeters, differences in the anthropomorphic phantoms used, and lower exposure conditions in the current study such as lower mA and kVp values.

Hidalgo et al.<sup>5</sup> investigated the effect of using thyroid shields on reducing the absorbed dose of this organ during production of dental CBCT images with high FOV using phantoms. They achieved a dramatic reduction in the dose received by the thyroid gland. Likewise, in the present study, the use of thyroid shields during CBCT 7, 8 and 9 sessions revealed a reduction in the dose absorbed by this organ (22%) compared to CBCT1, 3 and 5 techniques, conducted with same FOV and exposure conditions but without thyroid shields.

In the study by Silva et al.<sup>6</sup> the dose absorbed by all of the studied organs during radiography using i-CAT and NewTom CBCT devices was considerably higher than the dose resulting from panoramic and lateral cephalometric techniques. Such relationship was not observed in the doses absorbed by any of the organs the present study assessed using panoramic imaging and CBCT, while exposure conditions in the two CBCT techniques employed by Silva et al.<sup>6</sup> were much higher than the present study's exposure conditions (kVp = 120 and mA = 23.87 for the i-CAT device and kVp = 110 and mA = 5.4 for the NewTom device) and the power output of their panoramic device was lower than that of the present study.

The relationship observed between the corresponding doses absorbed by the thyroid gland, eyes and the parotid gland using digital panoramic imaging technique (kVp = 67, mA = 5 and t = 8.1) versus CBCT imaging (kVp = 70, mA = 5, t = 7.4) in the study by Garcia Silva et al.<sup>12</sup> was consistent with the findings related to the same organs in the present study which low-dose panoramic imaging and CBCT 1 technique were used (mapping both jaws at low-dose). The mentioned techniques were chosen for the purpose of comparison due to the presence of roughly similar conditions.

The results of the studies by Palomo et al.<sup>13</sup>, Ludlow et al.<sup>14</sup> and Walker and van der Putten<sup>15</sup> which noted the direct influence of, first, decreasing exposure parameters-including radiation area, kVp and mA- on the absorbed dose, and second, observing the ALARA (As Low As Reasonably Achievable) principle on reducing the dose absorbed by patients, were consistent with the findings of the current study.

One study concluded that the use of digital receptors or application of F-speed films instead of D-speed films, besides utilizing rectangular collimation and manipulating exposure settings of the devices can collectively lead to a substantial reduction in the dose received by patients.<sup>14</sup> Similarly, the present study evaluated the effects of different exposure settings as well as the application of thyroid shields on the absorbed dose using modern digital devices and digital receptors.

The present study followed the recommendations set by American Dental Association (ADA) in 2012, including the use of thyroid shields and digital sensors, application of filtration and appropriate exposure conditions (to obtain high-quality images while causing minimal absorbed dose), employment of modern digital devices, etc., in order to investigate the effects of these conditions on the absorbed dose. The aim was to suggest refined guidelines for conducting various radiography techniques

based on the achieved results and in line with the three principles of feasibility, optimization and dose limitation.

### Conclusion

In total, panoramic, Waters and Caldwell imaging techniques indicated that the occipital area and the parotid gland absorbed a higher dose than other organs. In the majority of CBCT scans, the parotid region received the highest dose. CBCT dose varied substantially depending on the device, FOV and selected technique. In CBCT, reducing the height of the FOV and shielding the thyroid are advisable methods and must be implemented to lower the exposure dose. Having acquired the dosimetric data for site-specific imaging using CBCT and

conventional radiography, a future goal is to optimize the exposure parameters that will balance the absorbed dose to the patient. Selection of the most appropriate imaging modality should be performed in view of the absorbed doses, required image quality and the clinical circumstances.

### Conflict of Interests

Authors have no conflict of interest.

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## Assessment of systemic effects of ginger on salivation in patients with post-radiotherapy xerostomia

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** Our aim was to assess the clinical efficacy of ginger capsule (Zintoma herbal capsule) in the relief of symptoms in patients with post-radiotherapy xerostomia.

**METHODS:** This study was a randomized double-blind, parallel clinical trial of ginger usage in patients with post-radiotherapy xerostomia. Sixty-one subjects were selected from patients with xerostomia of Imam Khomeini Cancer Institute, Tehran, Iran. Subject-based dry mouth scores derived from 100 mm visual analogue scales (VAS) were recorded at baseline. Patients also completed a questionnaire on the first visit regarding the symptoms of xerostomia. The patients received ginger capsule (30 persons) or placebo (31 persons) three times daily over a 2-weeks period. At the end of day 14, dry mouth scores derived from VAS were recorded again and patients responded to the additional variables regarding dry mouth symptoms and quality of life issues.  $P < 0.05$  was considered significant. Data were analyzed using SPSS.

**RESULTS:** The mean treatment effect on day 14 was  $33.7 \pm 20.9$  mm in the ginger group and  $23.6 \pm 17.3$  mm in the placebo group. The analysis indicated marginally significant improvement of xerostomia with ginger prescription ( $P = 0.057$ ). At the end of intervention there was no significant difference between the two groups regarding improvement of quality of life or dry mouth symptoms.

**CONCLUSION:** It seems that ginger could be helpful in the treatment of xerostomia. Since ginger is considered a safe herbal medicine with only few and insignificant adverse/side effects further studies in larger group of patients are recommended to provide the effect of ginger on different complaints of xerostomia.

**KEYWORDS:** Ginger, Radiation, Xerostomia

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Saliva is the production of major and minor salivary glands dispersed in the oral cavity. The subjective report of oral dryness is termed xerostomia.<sup>1</sup>

Several factors can cause xerostomia, but radiation therapy is one of the main causes. Radiation therapy of the head and neck region is used for treatment of primary and recurrent tumors in the upper aerodigestive

tract and squamous cell carcinoma (SCC) of oral cavity and sinuses, salivary gland tumors and nasopharynx carcinoma.<sup>2</sup> Radiotherapy is an effective treatment for head and neck cancer, but because traditional radiotherapy treatment fields frequently include the major salivary glands, xerostomia is a common late toxic effect of radiation therapy in patients with head and neck

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cancers.<sup>2-4</sup> It has been proved that radiation exposure has its own side effects such as disordering the salivary function, microbial infections, tastelessness and osteoradionecrosis of the jaw.<sup>5</sup>

Treatment of salivary hypofunction and xerostomia is primarily palliative and can be accomplished by multiple approaches<sup>6</sup> such as chewing gum,<sup>7</sup> sugar free lozenges,<sup>8,9</sup> salivary substitutes,<sup>10</sup> Biotène products, Oral balance products,<sup>11,12</sup> and toothpastes.<sup>13</sup> Amifostine has been approved by the Food and Drug Administration (FDA) to relief the incidence and severity of radiation-induced xerostomia, but it requires parenteral administration, has potential side effects, and is not universally available.<sup>14</sup> Electro-stimulation of tongue and palate, hyperbaric oxygen therapy and herbal medications are used by researchers to improve xerostomia.<sup>13,15</sup>

It is important to have a wide variety of products that can help modify the xerostomia symptoms. These products should be convenient to use, safe, with minimal side effects, and tested for safety and efficacy in controlled clinical trials.<sup>7</sup> The superior trait of saliva is its oral immunologic protection, therefore can never be replaced by any other synthetic substitute.<sup>16</sup>

Nowadays, there are various successful herbal drugs in clinical trials for alleviating xerostomia, Bakumondo-to, LongoVital, and linseed extract Salinum are examples of these drugs.<sup>15</sup>

Chamani et al. showed that salivation after injection of ginger extract was significantly higher than that of other herbal extracts and the negative control group in rats ( $P < 0.010$ ).<sup>13</sup> According to some research on herbal drugs, ginger has excellent chronological effect on post-synaptic M3 receptors.<sup>13,17</sup> Extracts and fractions of ginger (*Zingiber officinale*) have been shown to protect against chemically-induced tissue damage. The radioprotective effect of ginger extract has also been confirmed.<sup>18-23</sup> Ginger is not only known as a safe herbal medicine but also as an anti-cancer, anti-clotting, and

anti-inflammatory agent that has analgesic activities.<sup>24</sup>

In this study, we evaluated the effect of ginger on increasing salivation and improvement of quality of life and dry mouth symptoms in patients with post-radiotherapy xerostomia.

## Methods

This study was a randomized double-blind, parallel clinical trial of ginger usage in patients with post-radiotherapy xerostomia. This proposal had been evaluated by the Ethics Committee of Kerman University of Medical Sciences, Kerman, Iran (code K/87/103). The participants read and signed an official consent form. Sixty-one subjects were selected from patients with xerostomia from the Imam Khomeini Cancer Institute, Tehran, Iran. Registration ID of IRCT was IRCT138807012227N2.

In this research, the patients were minimum 18 years old with a history of radiotherapy treatment for neck cancer who had major and minor salivary glands disorders and experienced symptoms such as dry mouth when taking foods orally.

Exclusion criteria included any treatment for cancer in the last three months, patients who had not received the determined radiotherapy course completely, those who were pregnant, smokers, diabetics, those with recurrences of cancer or terminal cancer, Sjogren's syndrome, cancer of the salivary glands and other causes of xerostomia and those taking anticoagulant medication or nifedipine.<sup>25</sup>

A pharmacognosist prepared drug packages in the same type with two different codes, A and B (patients and examiner were blinded to the packages' ingredients), which consisted of starch capsule and Zintoma herbal capsule. Participants were randomly allocated by random digit numbering in two groups, received the package one by one until the sample size was completed. Patients of the experimental group (30 persons) were given the ginger capsule (Goldaru Company, Zintoma herbal capsule, Iran) three times

daily and patients of the control group (31 persons) received placebo three times daily over a 2-week period. Starch was used as placebo (Figure 1).

Participants who signed the consent form were obligated not to use any other products or medicine for treatment of dry mouth, but were permitted to use frequent small sips of water or any other mouth care products for the relief of dry mouth as needed (e.g. topical analgesics, topical antiseptics, and antifungal treatments).

To determine the presence of xerostomia in the study population, each patient was evaluated using the Fox questionnaire.<sup>26</sup> In this way the patients were enrolled by their scores derived from 100 mm visual analogue scales (VAS) registered on day 0 and 14 of a 2-weeks period. We categorized the patients into two groups according to their pre-intervention (baseline) VAS score: a. patients with significant xerostomia ( $x > 63.3$  mm) and b. patients with non-significant

xerostomia ( $x < 63.3$  mm).

The patients received ginger capsule or placebo three times daily over a 2-weeks period. At the end of day 14, dry mouth scores derived from VAS were recorded again. The mean dry mouth VAS score on day 14 was considered as mean treatment effect in each group.<sup>25</sup>

Patients also completed a questionnaire including continuous variables on the first visit regarding the symptoms of xerostomia such as speech, chewing and swallowing difficulties, bad taste and burning sensation. At the end of day 14, patients responded to the additional dichotomous variables regarding dry mouth symptoms and quality of life issues (Table 1).

The Student's t-test and chi-square test were used to compare initial group differences for continuous and categorical dates, respectively. To compare the xerostomia score, two-way analysis of variance (ANOVA) was used<sup>27</sup> with

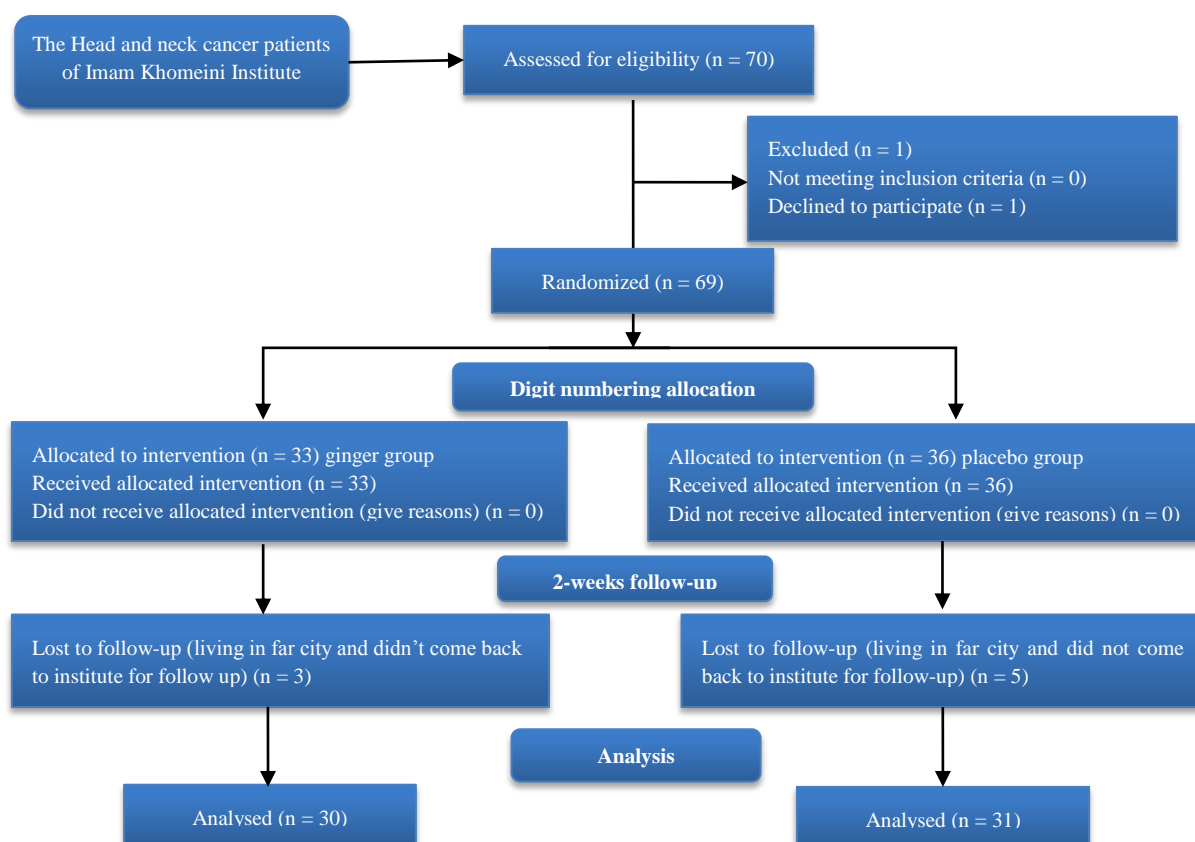


Figure 1. Flow diagram of the study

**Table 1.** Patient questionnaire completed on day 0 and day 14\*

How dry is your mouth? (0 = not dry at all, 100 = worst imaginable dryness)
Do you have difficulty chewing because of your dry mouth? (0 = no difficulties at all, 100 = very severe difficulties with chewing)
Do you have difficulty swallowing because of your dry mouth? (0 = no difficulties at all, 100 = very severe difficulties swallowing)
Is speech difficult because of your dry mouth? (0 = no difficulties at all, 100 = very severe difficulties with speech)
Is taste affected by your dry mouth? (0 = not affected at all, 100 = very severe alteration of taste)
Do you have a burning sensation in your mouth? (0 = no burning at all, 100 = very severe burning mouth)
Did the drug make your dry mouth better? Yes/No
Was the drug most useful in the night? Yes/No
Did the drug stop you waking in the night? Yes/No
Did the drug improve your sensation of taste? Yes/No
If you wear denture, did the drug help with the retention of the denture? Yes/No
Did you meet people more than you used to? Yes/No
Did you speak to people more than you used to? Yes/No
Did you get out of the house more than you used to? Yes/No
Did the drug make chewing easier? Yes/No
Did the drug make swallowing easier? Yes/No
Did the drug make talking easier? Yes/No
If you have a burning mouth, did the product improve the burning sensation? Yes/No
Did the drug make your dry mouth better? (0 = not dry at all, 100 = worst imaginable dryness)

\*Questions 1-6 were asked on day 0, and questions 7-18 were mentioned on day 14

treatment as one factor and the category of baseline xerostomia severity as the other.

$P < 0.05$  was considered significant. Data were analyzed using SPSS software (version 17, SPSS Inc., Chicago, IL, USA).

## Results

Sixty-one patients participated in this study. After breaking the prescribed drug code, it was determined that 30 patients used ginger (Zintoma herbal capsule) and 31 patients used the placebo.

The patients in both groups were compared together in different characteristics, such as age, sex and elapsed mean time after last radiotherapy. There was no significant difference between them (Table 2).

Because exact categorization between the

two groups for radiotherapy dose, the site and type of cancer was not possible, there was no estimation for type and site of cancer between both groups.

Using the VAS patients were questioned about xerostomia before ginger or placebo prescription. The mean treatment effect on day 14 (considering the categorization of patients in two groups with significant and non-significant xerostomia) was  $33.7 \pm 20.9$  mm VAS score in the ginger group and  $23.6 \pm 17.3$  mm VAS score in the placebo group (Figure 2).

The two-way ANOVA test indicated marginally significant improvement of xerostomia with ginger prescription ( $P = 0.057$ ). Meanwhile, there was no interaction between the ginger group and significant xerostomia ( $P = 0.930$ ).

**Table 2.** Comparison of baseline characteristics between the two groups

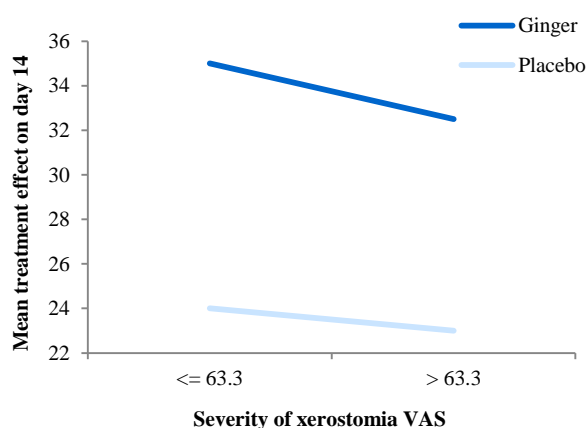
Characteristic	Ginger	Placebo	P
Sex			
Male [n (%)]	22 (73.3)	24 (77.4)	0.711
Female [n (%)]	8 (26.7)	7 (22.6)	
Age (year) (mean $\pm$ SD)	51.5 $\pm$ 18.4	54.4 $\pm$ 15.6	0.506
Time elapsed after last radiotherapy (month) (mean $\pm$ SD)	25.3 $\pm$ 24.4	24.1 $\pm$ 57.3	0.915
Systemic disease [n (%)]			
Yes	11 (36.7)	9 (29.0)	0.525
No	19 (63.3)	22 (71.0)	

SD: Standard deviation

**Table 3.** Comparison of dry mouth symptoms measured by visual analogue scales (VAS) score between the two groups before intervention

Symptom	Ginger	Placebo	P
	mean $\pm$ SD	mean $\pm$ SD	
Difficulty chewing	41.03 $\pm$ 27.70	51.48 $\pm$ 31.30	0.173
Difficulty swallowing	49.80 $\pm$ 26.40	48.02 $\pm$ 32.60	0.816
Speech difficulty	40.75 $\pm$ 27.01	39.52 $\pm$ 23.85	0.851
Affecting taste ability	24.73 $\pm$ 25.80	37.27 $\pm$ 32.90	0.104
Burning sensation in the mouth	18.62 $\pm$ 21.02	22.89 $\pm$ 23.76	0.461

SD: Standard deviation

**Figure 2.** This figure shows that xerostomia has improved in the ginger group (with significant and non-significant xerostomia), when compared to the placebo group  
VAS: Visual analogue scales

The severity of major symptoms of xerostomia (difficulty with chewing, swallowing and speech, affecting taste ability, and burning sensation in the mouth)

were compared between both groups and there was no significant difference. The findings indicated that both groups were the same before the intervention (Table 3). Patients were questioned about the effect of treatment on their quality of life and improvement of dry mouth symptoms on day 14 (end of intervention) (Table 1). The questions were yes/no type. The chi-square test showed that there was no significant differences between the two groups regarding improvement of dry mouth symptoms (including speech, chewing and deglutition difficulties and burning sensation) and quality of life issues such as dry mouth throughout the day, dry mouth throughout the night, awakening in the night due to dry mouth, affecting taste ability, decreased denture retention, meeting less people, speaking less to people, and going out less than before (Table 4).

**Table 4.** The effect of treatment on improvement of dry mouth symptoms and quality of life

Item	Response	Ginger			Placebo			P
		Yes [n (%)]	No [n (%)]	Total [n (%)]	Yes [n (%)]	No [n (%)]	Total [n (%)]	
Did the drug make chewing easier?		18 (60.0)	12 (40.0)	30 (100)	10 (40.0)	15 (60.0)	25 (100)	0.140
Did the drug make swallowing easier?		18 (60.0)	12 (40.0)	30 (100)	11 (44.0)	14 (56.0)	25 (100)	0.237
Did the drug make talking easier?		17 (56.7)	13 (43.3)	30 (100)	10 (40.0)	15 (60.0)	25 (100)	0.218
If you have a burning mouth, did the product improve the burning sensation?		8 (26.7)	22 (73.3)	30 (100)	3 (12.0)	22 (88.0)	25 (100)	0.176
Did the drug make your dry mouth better?		23 (82.1)	5 (17.9)	28 (100)	18 (62.1)	11 (37.9)	29 (100)	0.092
Did the drug most useful in the night?		14 (56.0)	11 (44.0)	25 (100)	12 (46.2)	14 (53.8)	26 (100)	0.482
Did the drug stop you waking in the night?		8 (44.4)	10 (55.6)	18 (100)	9 (39.1)	14 (60.9)	23 (100)	0.732
Did the drug improve your sensation of taste?		2 (22.2)	7 (77.8)	9 (100)	5 (50.0)	5 (50.0)	10 (100)	0.210
If you wear denture, did the drug help with the retention of the denture?		4 (28.6)	10 (71.4)	14 (100)	5 (38.5)	8 (61.5)	13 (100)	0.586
Did you meet people more than you used to?		5 (38.5)	8 (61.5)	13 (100)	5 (35.7)	9 (64.3)	14 (100)	0.883
Did you speak to people more than you used to?		3 (27.3)	8 (72.7)	11 (44.0)	5 (41.7)	7 (58.3)	12 (40.0)	0.469
Did you get out of the house more than you used to?		2 (50.0)	2 (50.0)	4 (28.6)	2 (25.0)	6 (75.0)	8 (61.5)	0.386

However, concerning one question (dry mouth throughout the day) 82% of patients in the ginger group and 62% of patients in the placebo group felt improvement and this difference was marginally significant ( $P < 0.100$ ).

Following drug consumption, some patients reported some side effects. In the ginger group, 1 patient had constipation, 2 patients had vertigo, and 2 had dyspepsia. In the placebo group, 2 patients had headache and 2 patients had dyspepsia. Because the side effects were few, it was probable that other elements caused these problems, rather than ginger or placebo consumption.

Before the study was done, patients inquired about the use of saliva substitute or other products to decrease dry mouth. No one reported using artificial saliva. Four patients (6.5%) were using BioXtra gel. These patients agreed to discontinue using BioXtra gel in order to join the study.

### Discussion

Some researchers conducted on the ginger plant have indicated parasympathomimetic effect.<sup>13,17,28</sup> In researches conducted by Ghayur and Gilani, ginger was shown to have spasmolytic effect through blocking calcium channels<sup>27</sup> and was involved in activation of postsynaptic muscarinic M3 receptors in the stomach of rats.<sup>17</sup> Chamani et al. discovered that ginger derivate was effective in increasing saliva of rats.<sup>13</sup>

The result of the recent study indicates that dry mouth improvement in patients who used ginger was marginally more significant than in patients in the placebo group. The statistical analysis showed that there was no significant difference in severity of symptoms of xerostomia between two groups and both groups of patients were similar in age, gender and time elapsed after last radiotherapy. This issue indicates that not only the two groups before the study were completely identical, but also it insists on the power of intervention and true randomly chosen sampling.

In this study, the improvement of xerostomia after ginger usage was marginally significant ( $P = 0.057$ ). To achieve the best reliable results, the patients were divided into two groups with significant and non-significant xerostomia. The improvement of dry mouth was assessed based on this categorization. If this division was not done and all of the patients who had significant and non-significant xerostomia in the ginger or placebo group were assessed together, the results of the comparison between control and study groups were completely significant by the t-test ( $P = 0.044$ ). In this study focus was placed on the two-way ANOVA test, to attain the most reliable results ( $P = 0.057$ ).

Because the decrease in xerostomia through ginger usage was marginally significant as compared to the placebo, it is proposed that in future researches, more attention should be placed to increase sample size to gain the best absolute results.

Despite the improvement of xerostomia there was no meaningful difference between two groups regarding improvement of dry mouth symptoms and quality of life issues on day 14. It is probable that non-significant results were related to the small sample size and the psychological effect of the placebo.

It is not deniable that the range of radiation side effects depends on several factors such as scope, dose and volume of radiation actors rather than the ordinary performance of the salivary gland.<sup>29</sup> By consulting the radiotherapist-oncologist, there was no chance to differentiate the patients based on these factors, so it is probable that such factors in small sample could have biased the research results.

The radiotherapist-oncologist advised the patients to use water and liquids, to have good oral hygiene, and to use nystatin and chlorhexidine mouthwashes, and fluconazole during treatment. This advice about liquid consumption could have some effects on dry mouth. We had no remedy to omit this confounder factor, because it is necessary to



advise patients to use water and liquid based on moral rules.

For evaluation of severity of xerostomia and the treatment effect, dry mouth scores derived from VAS were recorded on days 0 and 14 in this study.

The best treatment for decreased salivation is protection. Advances in technology in the field of therapeutic radiation spares a portion of the major salivary glands from destruction.<sup>7,12</sup> Great efforts were also made to develop radioprotective medications to decrease side effects of radiotherapy. By systemic application of amifostine, salivary gland function could be improved after therapy.<sup>29</sup>

One reliable alternative to treat radiotherapy-induced hyposalivation is stem cell replacement. The recent identification of stem and progenitor cell populations will aid with future research, but a better understanding of cell turnover in salivary glands is still needed.<sup>30</sup>

However, some patients who are going under radiotherapy are still suffering from the complications of xerostomia and more studies are needed to find new solutions for this problem.

#### Limitations

There was some limitation in our study such as different culture and language barrier

(participants spoke Turkish, Kurdish, etc.) that made some difficulties in answering the examiner's question, and low number of patients for treatment follow-up because of living distant from the institute which made sample size small to review. So, further studies in larger group of patients are recommended to provide the effect of ginger on various complaints of xerostomia.

#### Conclusion

This study showed that ginger decreased the severity of dry mouth in patients with post-radiation xerostomia, but it did not improve dry mouth symptoms or patients' quality of life. Conducting more research on this plant in the future, with attention to special characteristics (low cost, availability, safety) is advised.

#### Conflict of Interests

Authors have no conflict of interest.

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## Does health literacy affect women's oral health self-care behavior? A cross-sectional study in health centers of Tabriz, North West of Iran

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** In public health, health literacy (HL) is rather a new conception. In this regard, oral health as a critical public health issue that affects women's health. The objective of the present study was to determine oral health self-care behavior and its relationship with HL.

**METHODS:** This cross-sectional study was performed on 232 women who referred to health centers of Tabriz, Iran, in 2015. Data were collected using a self-administered questionnaire including demographic characteristics, oral health behavior, and HL [assessed using the Newest Vital Sign (NVS) scale]. Data were analyzed by one-way analysis of variance, independent samples t-test, and multiple regressions.

**RESULTS:** The mean age of the subjects was 33.4 years [standard deviation (SD) = 8.2; range = 18-49]. The mean  $\pm$  SD of oral health self-care behavior and HL score was  $4.4 \pm 1.9$  and  $3.3 \pm 2.0$ , respectively. Totally, 24.6% of the participants had limited HL (57/232). Only 19.4% (45/232) of participants brushed their teeth twice daily or more, and 28.9% (67/232) had dental check-up less than 6 months ago. The HL had positive association with oral health self-care behavior ( $\beta = 0.37$ ,  $P < 0.001$ ). In multiple linear regression models, oral health self-care behavior was associated with HL and education level ( $P < 0.001$ ). HL and education level explained 19.5% of the variance in behavior.

**CONCLUSION:** The findings of this study suggest that HL was a predictor of oral health self-care behavior in women. However, more studies are needed to confirm the results of this study. Hence, promoting oral health interventions and designing effective educational materials based on HL might be beneficial to improve oral health behavior and status.

**KEYWORDS:** Health Literacy; Brushing; Oral Health Behavior; Newest Vital Sign; Oral Self-Care

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The term "health literacy (HL)" was first used in the health education background about 30 years ago.<sup>1</sup>

HL-a relatively new concept-has a leading role in health promotion and is critical to empowerment.<sup>2,3</sup>

The World Health Organization (WHO) explains HL as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to understand and use information in ways which promote and maintain good health".<sup>3</sup> HL is linked to

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access, understand, and practice health information.<sup>1</sup> In dentistry field, awareness about the importance of HL has increased for the past 10 years. Hence, numerous efforts have been focused on adapting the concept of HL to dental practice and studies.<sup>4</sup> Oral health is integral not only to general health but also to well-being and quality of life.<sup>5</sup> Dental caries and periodontal disease are main dental disease and oral health problems.<sup>6</sup> In a study, decayed, missing, and filled teeth (DMFT) score was 4.7 for 18-year-old and 11 for 35- to 44-year-old Iranian women.<sup>7</sup> Also, the DMFT score was 5.4 in pregnant women.<sup>8</sup> A study indicated that 25.0% of women had never brushed their teeth and 80.1% had never flossed.<sup>9</sup>

HL is a well-known intermediary between socio-economic factors, and healthy behaviors and oral health consequences in different populations.<sup>10</sup> Some studies demonstrated that low HL was associated with oral hygiene status and oral health behaviors, and periodontal disease.<sup>11,12</sup>

Women's HL and oral health behavior are essential because they affect both the women's personal health and the health of the family.<sup>13</sup> Studies reported that low HL in mothers was associated with poor oral health status in their children.<sup>14</sup> The understanding of HL and oral health behaviors are important determinant factors not only to develop health promotion programs but also to communicate skills among clients referring to health care centres. HL is the inseparable part of health care organization, however; there are relatively few researches in this field.

This study attempted to investigate effects of HL on oral health self-care behavior among women having referred to health centers.

## Methods

The current cross-sectional study was carried out in health centers in Tabriz, north-west of Iran, from January to March 2015. The participants included women who were receiving routine maternal and child preventive care like checking and monitoring

child growth and immunization. The service of providing primary health care has been developed in Iran since 1970.<sup>15</sup> Tabriz is the third largest city in Iran and the center of East Azerbaijan province.<sup>16</sup>

The sample size was calculated 270 participants based on 20% prevalence of limited HL (from pilot study), level of confidence ( $Z_{\alpha/2} = 1.96$ ), 5% level of precision, and non-response rate (estimated to be 20%).

The inclusion criteria were willingness to take part in this survey, age  $\geq 18$  years, being skillful at reading and writing, and not experiencing specific emotional and mental diseases.

The applied sampling method was random multi-stage stratified to select participants. Firstly, 8 centers were randomly chosen from 4 districts of Tabriz (north, south, east, west). Secondly, from each center, 20 to 35 eligible women were randomly included based on the ratio of women referred to each center. Finally, 270 representative eligible women participated in this study.

All of the women participated voluntarily, and the participants were provided with an explanation about the objective of the study, and informed written consent was obtained. To avoid any data collection bias, a trained public health nurse had the responsibility for data collection. Isfahan University of Medical Sciences, Isfahan, Iran, approved the study's protocol. A three-section self-administered questionnaire was used to collect data. It consisted of demographic characteristics, oral health self-care behavior, and HL. Demographic characteristics included age, education level (primary school, middle school, high school, diploma, and university), occupation, marital status, self-reported economic status (poor, average, good), and the number of residents at home.

The oral self-care behavior was measured with three items derived from the available literature.<sup>15,17</sup> The items included "frequency of tooth brushing" (0 = irregularly or never, 1 = less than once daily, 2 = once daily, 3 = twice daily or more ), "frequency of

flossing" (0 = irregularly or never, 1 = less than once daily, 2 = once daily or more), and "time of your last dental check-up" (0 = never/do not remember/more than two years ago, 1 = one to two years ago, 2 = six months to one year ago, 3 = within six months). The score ranged from 0 to 8. Moreover, a higher score meant a higher oral self-care behaviour. Ten expert panels confirmed the content validity of study questionnaire.

The mean content validity index (CVI) and the mean content validity ratio (CVR) were 0.71 and 0.80, respectively. HL was measured using the Newest Vital Sign (NVS) instrument developed by Weiss et al.<sup>18</sup> The NVS consisted of six items. Every correct response was scored 1, and the incorrect or "do not know" responses were scored 0. Scores were summed to give a total range from 0 to 6. The NVS scores were divided into three HL categories: limited HL (range: 0-1), intermediate (range: 2-3), and adequate (range: 4-6).<sup>19</sup> In the Persian version of NVS which was culturally adapted by Javadzade et al.,<sup>20</sup> Cronbach's alpha for reliability was 0.71. In this study, scale reliability (Cronbach's alpha) was 0.80. According to recommendations, the NVS is relatively acceptable to assess HL in health care setting. It is a fast screening test for assessment of HL and simple to administer in different health-related settings.<sup>18,21</sup>

In a pilot study, the questionnaire reliability was assessed by test-retest (2-week interval) method among 50 eligible women in a health center, and the obtained data were not included in the final analysis. The test-retest reliability coefficient was 0.77 and each questionnaire completion took approximately 6 min.

SPSS software (version 16, SPSS Inc., Chicago, IL, USA) was applied to analyse the data. Descriptive statistics were performed to examine the data (the frequency and mean). Chi-square test was used to associate between items of oral health self-care behavior and HL level. Independent samples t-test and ANOVA were applied to explore the health self-care

behaviour score in groups of categorical variables. Pearson's correlation coefficient was used to explore the relationship between HL and oral health self-care behaviour. To control confounding variables, multiple linear regression was implemented. The significance level of  $\alpha$  was assumed 0.05 to all tests.

## Results

The final analysis sample involved 232 women from 270. Thirty-eight questionnaires were omitted due to missing data. Participation rate was 86%. As shown in table 1, the mean age of the subjects was 33.4 [standard deviation (SD) = 8.2 years; median = 33 years; range = 18-49 years]. Twenty-three participants (9.9%) had primary education and sixty-four participants (27.6%) had higher education and 78.3% were unemployed. The mean  $\pm$  SD scores of oral health self-care behavior and HL were  $4.4 \pm 1.9$  and  $3.3 \pm 2.0$ , respectively.

This study revealed that, 24.6% of the participants had limited HL [95% confidence interval (CI) 19.1-30.1], 58 participants (25.0%) had intermediate HL (95% CI 19.4-30.6), and 50.4% had adequate HL (95% CI 43.9-56.8).

The association between oral health self-care behavior score and socio-demographic characteristics (groups of categorical variables) is presented in table 1. Oral health self-care behavior score of the women was statistically associated with HL, oral health status, education level, and employment status. Furthermore, no significant relationship was found between oral health self-care behavior and marital status.

Table 2 shows the oral health self-care behavior index and the distribution of each item. According to the results, 31.5% of participants brushed their teeth less than once daily, and 28.9% had dental check-up less than 6 months ago. Also, the results of Pearson's correlation analysis between HL and oral health showed that HL was significantly and positively associated with oral health self-care behavior ( $R = 0.349$ ,  $P < 0.001$ ).

**Table 1.** Distribution of socio-demographic characteristics, mean  $\pm$  standard deviation (SD) oral health self-care behaviour scores, and their associated factors (n = 232)

Variables	Category	n (%)	95% CI	Mean $\pm$ SD	f or t	P
Education	Primary	23 (9.9)	6.0-13.7	3.4 $\pm$ 1.9	15.90	< 0.001
	Middle school	32 (13.8)	9.4-18.2	3.8 $\pm$ 2.0		
	High school	26 (11.2)	7.2-15.3	4.1 $\pm$ 2.0		
	Diploma	87 (37.5)	31.3-43.7	4.9 $\pm$ 2.1		
	University	64 (27.6)	21.9-33.4	6.8 $\pm$ 2.7		
Employment	Employed	50 (21.7)	16.4-27.1	6.1 $\pm$ 2.5	3.40	0.003
	Unemployed	182 (78.3)	72.9-83.6	4.8 $\pm$ 2.1		
Marital status	Single/divorced	10 (4.3)	1.7-6.9	5.5 $\pm$ 2.3	0.36	0.530
	Married	222 (95.7)	94.4-98.9	5.2 $\pm$ 2.0		
The number of residents at home	1 to 3	28 (12.1)	7.9-16.3	5.7 $\pm$ 3.3	0.83	0.430
	4 to 5	176 (75.8)	70.4-81.4	4.9 $\pm$ 2.6		
	5 more	28 (12.1)	7.9-16.3	5.0 $\pm$ 2.9		
Economic status	Poor	35 (15.0)	10.4-19.6	4.4 $\pm$ 2.3	4.50	0.011
	Average	116 (50.0)	43.6-56.4	4.7 $\pm$ 2.5		
	Good	81 (35.0)	28.9-41.2	5.8 $\pm$ 2.9		
Self-rated oral health status	Poor	13 (5.6)	2.6-8.6	3.4 $\pm$ 1.8	7.50	< 0.001
	Fair	59 (25.5)	19.7-31.0	3.8 $\pm$ 2.2		
	Good	130 (56.0)	49.6-62.4	5.4 $\pm$ 2.8		
	Very good	24 (10.3)	6.4-14.2	6.5 $\pm$ 2.8		
	Excellent	6 (2.6)	0.6-4.7	6.6 $\pm$ 2.4		
Health literacy	limited	57 (24.6)	19.1-30.1	3.7 $\pm$ 1.6	14.20	< 0.001
	Intermediate	58 (25.0)	19.4-30.6	4.1 $\pm$ 1.7		
	Adequate	117 (50.4)	43.9-56.8	5.3 $\pm$ 2.2		
Variables						Range
Health literacy				3.3 $\pm$ 2.0		0-6
Oral health behavior				4.4 $\pm$ 1.9		0-8
Age (year)				33.4 $\pm$ 8.2		18-49

SD: Standard deviation; CI: Confidence interval

As shown in table 3, the HL explained 12.7% of the oral health self-care (Model 1). The multiple linear regressions (Model 2), HL and education level ( $P < 0.001$ ) were associated with oral health self-care

behavior, and explained 19.5% of the variance in behavior. The women's oral health self-care behavior was not significantly associated with other background variables.

**Table 2.** Showing the score of each oral health self-care item oral health behavior (OHB) index (n = 232)

Items of oral health self-care	Weight	n (%)	Health literacy (category)			P
			Inadequate [57 (24.6)]	Intermediate [58 (25.0)]	Adequate [117 (50.4)]	
Frequency of teeth brushing						< 0.001
Never or irregularly	0	7 (3.0)	5 (71.4)	1 (14.3)	1 (14.3)	
Less than once daily	1	73 (31.5)	22 (30.1)	27 (37.0)	24 (32.9)	
Once daily	2	107 (46.1)	24 (22.4)	26 (24.3)	57 (53.3)	
Twice daily or more	3	45 (19.4)	6 (13.3)	4 (8.9)	35 (77.8)	
Frequency of flossing teeth						0.002
Never or irregularly	0	107 (46.1)	35 (32.7)	33 (30.8)	39 (36.5)	
Less than one day	1	53 (22.9)	10 (18.9)	13 (24.5)	30 (56.6)	
Once daily or more	2	72 (31.0)	12 (16.7)	12 (16.7)	48 (66.6)	
Last dental check-up						0.110
More than 2 years	0	41 (17.6)	11 (26.8)	14 (34.2)	16 (39.0)	
1-2 years ago	1	50 (21.6)	16 (32.0)	13 (26.0)	21 (42.0)	
6-12 months	2	74 (31.9)	20 (27.0)	17 (23.0)	37 (50.0)	
Less than 6 months	3	67 (28.9)	10 (14.9)	14 (20.9)	43 (64.2)	

**Table 3.** Regression analysis to investigate relationship between oral health behaviors (dependent variable) and health literacy adjusting for socio-demographic characteristics (n = 232)

Model	Variables	Unstandardized coefficients		P	95% CI for B	VIF	Adjusted R <sup>2</sup>
		B	SE				
1	Health literacy	0.370	0.063	0.001	0.32-0.64	1.0	0.127
2	Health literacy	0.222	0.067	0.002	0.12-0.47	1.2	0.195
	Education	0.470	0.124	0.001	0.32-0.92	1.7	

SE: Standard error; CI: Confidence interval; VIF: Variance inflation factor

Model 1 = health literacy, Model 2 = health literacy and demographic characterize factors: age, education, economic status, number of members in household, employment and marital status (insignificant factors were not presented)

## Discussion

We found the clear effects of HL on participants' oral health self-care behavior. The present study showed that HL was associated with oral health self-care behavior. This finding confirms several previous studies in this field.<sup>22</sup> A study in Japan reported the relationship between participant's oral health behaviors and oral HL.<sup>4</sup> Also, according to some studies, level of HL was associated with the patient-dentist communication, dental care patterns and the dental neglect among women in North Carolina.<sup>11,23</sup>

This finding is inconsistent with pervious study that reported no relationship between participants' oral health self-care behavior and HL.<sup>24</sup> This dissimilarity is probably due to using different HL instruments. Also, the majority of participants (68.7%) had adequate HL in comparison to participants of the present study.

In line with the results of other research studies,<sup>11,23,25</sup> this study showed that the oral health self-care behavior was associated with education level and economic status. This finding indicated the positive effect of demographic factors on oral health. Another study also reported that sociocultural factors-education and income-are risk factors in dental caries.<sup>26</sup> Hence, to improve oral health status, both education and income need to be considered much further in prevention programs and public health practice by health care organizations.

This study revealed that women's oral health self-care behavior was associated with oral health status. This finding confirms the

previous study conducted by Naghibi Sistani et al. that reported the frequency of tooth brushing was associated with self-reported oral health status in adults aged 18-65 years.<sup>25</sup> Another study showed a positive correlation between dental care patterns (R = 0.38) and oral health status.<sup>11</sup> Another study found that oral health behavior (regular check-up, application of fluoride, and daily frequency of tooth brushing) was associated with oral health status in Japanese young adults.<sup>27</sup>

This study revealed that 31.5% of participants brushed their teeth less than once daily. This result is consistent with those of previous study that showed unfavorable oral health behaviors, and revealed that "oral hygiene is in alarming situation in Iran".<sup>9</sup> In oral health programs, health education is a vital component.<sup>4</sup> Hence, appropriate programs are seriously needed to promote oral health behavior.

To our knowledge, this investigation was one of the few health center-based studies that investigated the HL and oral self-care behavior in the women.

This study was not without limitations. Firstly, data were collected via self-reported questionnaire which might be subject to recall and response bias. Secondly, cross-sectional investigation cannot lead to casual conclusions about HL and oral self-care. Third, the dependent variable (oral health self-care) was measured by self-reported measures and there were no clinical examinations. Despite limitations, self-assessment is a suitable, easy, valid, and cost-effective method of data collection in dental field on adolescents and adults.<sup>27-29</sup>

### Conclusion

HL was a determinant of oral health self-care behavior in the participants. Based on this predictor, educational intervention seems essential to improve oral self-care behavior. Also, health professionals need to assess clients' HL in health centers, and provide appropriate educational programs through HL strategies (simply understood materials) to promote oral health behaviors.

### Conflict of Interests

Authors have no conflict of interest.

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## Clinical evaluation of the effect of gingival thickness on increasing the width of keratinized and attached gingiva with and without preserving periosteum in an animal study

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** The present study was performed in order to assess the effect of gingival thickness on amount of gingival augmentation with and without preserving periosteum.

**METHODS:** The study was conducted on 8 ecotype dogs aged 1-5 years. At the beginning, clinical probing depth and keratinized and attached gingiva width were measured. Totally, 64 sites were operated in this study. Periosteal fenestration and denuded beds were randomly created on opposite sides of upper and lower jaws (4 sites each side). The thickness of gingiva was measured in mucogingival junction after preparation of the beds. The clinical parameters were evaluated 2 months after the surgery. The data were analyzed by Mann-Whitney U, Wilcoxon, and Pearson correlation tests.

**RESULTS:** The results showed the average increased width of keratinized and attached gingiva was 1.8 mm and 2 mm in periosteal fenestration sites and 1.9 mm and 2.3 mm in denudation sites, respectively at 2 months post-surgery. The difference between the width of keratinized gingiva and attached gingiva before and 2 months after operation was significant in both groups ( $P < 0.001$ ). However, no significant difference was shown between the two groups in terms of attached and keratinized gingival width ( $P = 0.100$  and  $P = 0.720$ , respectively). There was no correlation between the thickness of gingiva and the amount of increased width of keratinized and attached gingiva.

**CONCLUSION:** A gingival thickness of 0.8 to 2 mm does not affect the increment of the attached and keratinized gingival width with and without preserving periosteum.

**KEYWORDS:** Gingiva; Denudation; Surgery

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In the field of periodontology, a minimum width of attached gingiva is necessary for maintaining health of periodontium, particularly in orthodontic or prosthetic treatments to increase the removal of plaque around the gingival margin, improve esthetic, and reduce

inflammation around the restored teeth.<sup>1</sup> In people with poor oral hygiene, sufficient width of keratinized gingiva and vestibular depth help keep oral hygiene.<sup>2</sup> Sufficient attached gingiva is essential around the abutment teeth of the fixed or removable partial prosthesis.<sup>3</sup> Teeth with restorations involving subgingival

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margins and narrow attached gingiva are shown to be more inflamed than similar teeth with wide attached gingiva.<sup>4</sup>

Over the years, periodontists have introduced numerous techniques for gingival augmentation around the teeth. These techniques include, denudation, periosteal retention and fenestration, free gingival and connective tissue grafts and also alloderm and tissue engineering techniques.<sup>5-13</sup>

Various studies have shown that gingival thickness is effective for successful root coverage and regenerative treatments.<sup>14,15</sup> Because of the complications of free soft tissue graft techniques<sup>16</sup> and the high costs of tissue engineering techniques for preparing gingival grafts in terms of time and money,<sup>17,18</sup> it is preferred to find a simple technique that does not require the graft donor site and with predictable results. Periosteal fenestration technique and denudation technique are simple techniques introduced to increase the width of keratinized and attached gingiva, but with unpredictable results.<sup>8,19</sup> In some cases, other techniques are used today such as frenectomy. For example, after frenectomy, we should decide to use a soft tissue graft to increase the attached gingiva or not. Therefore, if the thickness of gingiva is an effective factor on gingival augmentation in periosteal fenestration and denudation techniques, we can make a decision about the kind of technique (a bed without graft or with graft). However, because, the factors affecting the clinical results of these two techniques have not yet been evaluated, this study was conducted to determine the effect of gingival thickness on increasing the width of attached and keratinized gingiva.

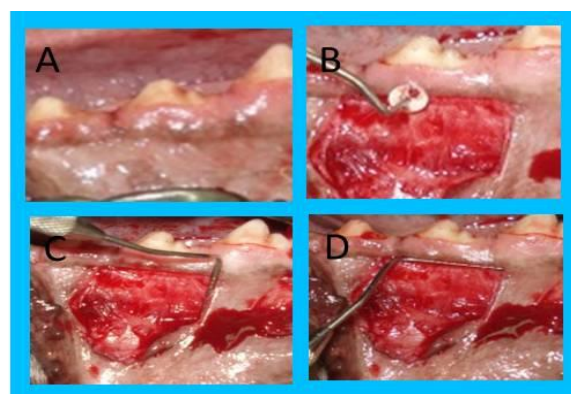
### Methods

The present research was an animal study. Considering that the dogs' periodontium is clinically and histologically similar to that of humans, this study was conducted on dogs.<sup>20</sup> The study population consisted of 8 ecotype dogs (4 females and 4 males) aged 1 to 5 years

that received rabies vaccine and antiparasitic treatments one month prior to the beginning of the study in order to meet the inclusion criteria. The appropriate ethical license (No. 698) was obtained from the Ethics Committee of Kerman University of Medical Sciences, Kerman, Iran.

The keratinized gingival width (the distance between the gingival margin and the mucogingival junction) at the mid-buccal area and also the mid-buccal probing depth of the examined tooth (mandibular and maxillary second and fourth premolars) were measured by a clinician who was blind to the study, using a Williams probe (Jooya, Tehran, Iran) with 1 mm accuracy. The attached gingival width at the mid-buccal area was measured by subtracting the probing depth from the keratinized gingiva width of the examined teeth. These measurements were performed on the dogs before the surgery and 2 months after operation.

The attached gingival thickness at the mid-facial area was measured at the mucogingival junction using a Williams probe with a rubber stop. The gingival thickness was then measured to the tenth of a millimeter using a caliper. The gingival thickness was measured during surgery after making an incision in the mucogingival junction and pushing the apical tissue aside for preparing the bed (Figure 1).



**Figure 1.** Clinical view before surgery (A), measuring of gingival thickness using a periodontal probe with rubber stop at mucogingival junction (B), vertical dimension of prepared bed (10 mm) (C), horizontal dimension of prepared bed (15 mm) (D)

**The surgical operation:** All surgical operations were performed in Department of Clinical Sciences, School of Veterinary Medicine, Shahid Bahonar University of Kerman. The dogs under study were anesthetized using 15 mg/kg of sodium pentobarbital (Chemidarou, Tehran, Iran) and then 1%-2.5% of halothane (Iran-Daroo, Tehran, Iran). During the surgery, the dogs were administered an intravenous dose of ringer lactate serum (5 ml/kg/hour). After general anesthesia, the sites of operation were anesthetized with lidocaine 2% containing epinephrine 1/80000 (Aburaihan, Tehran, Iran).

Overall, 64 sites (32 sites with preservation of periosteum and 32 sites with denudation technique) underwent the surgery. In design of this study, 2 sites in each quadrant of the mouth of dogs (4 sites in each side of the mouth of dogs) were operated. One side with periosteal fenestration technique and the other side with denudation technique (Figure 2). The operated sides were selected with throwing a coin (simple randomization). The periosteal fenestration technique was used to prepare the bed for half of the sites under study. While maintaining the marginal gingiva, a coronal (submarginal) incision was made by a surgical scalpel blade No. 15 in the mucogingival junction and vertical incisions at 15 mm intervals were made to both ends of the horizontal incision (Figure 1). The partial thickness flap was elevated and periosteal fenestration was performed at 6 mm distance of the coronal margin of the recipient bed on the preserved periosteum. An aluminum foil of the same dimensions was placed on the prepared bed. A crisscross horizontal mattress suture was then stitched to stabilize the aluminum foil. For the other sites, denudation technique was used. Similar to periosteal fenestration technique, the bed was prepared but without preserving the periosteum (Figure 2). With a periosteal elevator, a blunt dissection was performed to expose the bone. After this step, an aluminum foil with appropriate size was

placed on the bed and sutured. All surgical procedures were done by a periodontist who was not blind to this study.



**Figure 2.** Periosteal fenestration bed (A) and denuded bed (B)

**Postoperative care:** The dogs went on a soft food diet for two weeks after the surgery. After the two-week period ended, the dogs returned to their normal diet. At the first day of surgery, 20 mg/kg of cefazolin sodium (Dana, Tabriz, Iran) was injected intramuscularly. Oral hygiene was maintained through weekly application of 0.2% chlorohexidine solution (Shahredaru, Tehran, Iran) to control infection for one month.

**Postoperative measurements:** The postoperative evaluation was performed 3 months after the surgery. The examined dogs were anesthetized using 15 mg/kg of sodium pentobarbital and then 1%-2.5% mg/kg of halothane. The keratinized gingival width at the mid-buccal area and the depth of the gingival sulcus restored after treatment on the mid-buccal area were measured by a clinician who was blind to this study, using a Williams probe with 1 mm accuracy. The attached gingiva width on the mid-buccal area was measured by subtracting the depth of the gingival sulcus from the keratinized gingiva width of the area.

The mean and standard deviation of pre-treatment data and post-treatment results were calculated. The data were not distributed normally as demonstrated by one sample Kolmogorov-Smirnov test. Therefore, Wilcoxon test was used to analyze the data before and after operation in each group and Mann-Whitney U test was used to analyze the clinical parameters between the two groups.

**Table 1.** Clinical parameters before and 2 months after surgery

Technique	Clinical parameter (mm)	Baseline	Two months after surgery	P
		(mean ± SD)	(mean ± SD)	
Periosteal fenestration	Width of keratinized gingiva	4.80 ± 1.42	6.60 ± 1.84	< 0.001
	Probing depth	1.50 ± 0.76	1.20 ± 0.47	0.100
	Width of attached gingiva	3.30 ± 1.60	5.30 ± 1.94	< 0.001
Denudation	Width of keratinized gingiva	4.70 ± 1.36	6.60 ± 1.89	< 0.001
	Probing depth	1.40 ± 0.61	1.10 ± 0.39	0.090
	Width of attached gingiva	3.20 ± 1.47	5.50 ± 2.00	< 0.001

SD: Standard deviation

Spearman rank correlation test was used to assess the correlation between the thickness of gingiva and the width of keratinized and attached gingiva in each group two months after surgery.

### Results

The values of clinical parameters involving probing pocket depth, width of keratinized gingiva and width of attached gingiva at baseline and 2 months post-surgery are shown in table 1 and comparison of post-surgery clinical parameters between the two techniques is reported in table 2. These results showed the average of the increased width of keratinized and attached gingiva was 1.8 mm and 2 mm in periosteal fenestration sites, and 1.9 mm and 2.3 mm in denudation sites, respectively at 2 months post-surgery. The difference between the width of keratinized gingiva and attached gingiva before and 2 months after the surgery in both groups was significant ( $P < 0.001$ ) (Table 1). The comparison between post-surgery width of keratinized and attached gingiva between these two techniques did not show any statistical difference ( $P = 0.100$ ,  $P = 0.720$ , respectively) (Table 2).

The thickness of gingiva evaluated in this study was 0.8-2 mm. Based on the correlation analysis, there was not any correlation between the thickness of gingiva before

surgery and the amount of increased width of attached and keratinized gingiva after 2 months of surgery in periosteal fenestration and denuded sites.

### Discussion

This study was conducted in order to assess the effect of gingival thickness on increasing the width of keratinized and attached gingiva.

The results of this study reported that significant increased width of keratinized and attached gingiva was obtained 2 months post-surgery with performing both denudation and periosteal fenestration techniques ( $P < 0.001$ ).

Carranza and Carraro revealed an increased width of keratinized gingiva of  $2.30 \pm 0.38$  mm using periosteal fenestration, which was more than the 1.8 mm augmentation rate obtained in the present study.<sup>21</sup> Given that their study was also performed on dogs, the difference might be due to the larger dimensions of their prepared bed (15-20 mm vertical incision from the gingival margin); and removal of a 3-6 mm wide strip from the apical periosteum of the prepared bed.

Allen and Shell examined changes in keratinized gingival width in addition to vestibular depth through periosteal fenestration.<sup>22</sup>

**Table 2.** Comparison of post-surgery clinical parameters between the two techniques

Clinical parameter	Post-surgery (mean ± SD)		P
	Periosteal fenestration	Denudation	
Width of keratinized gingiva	6.60 ± 1.84	6.60 ± 1.89	0.720
Probing depth	1.20 ± 0.47	1.10 ± 0.39	0.560
Width of attached gingiva	5.30 ± 1.94	5.50 ± 2.00	0.100

SD: Standard deviation

They revealed a keratinized gingival extension rate of 2.3 mm 40 weeks after periosteal fenestration, which was higher than the keratinized gingival extension rate of 1.8 mm obtained in the present study. This difference might be the bed prepared in their study that involved the entire mandibular anterior sextant (a horizontal incision on the mucogingival junction and two 10 mm vertical incisions on the mandibular canine area). Therefore, the dimensions of their prepared bed were larger than the one in the present study.

Bowers reported an attached gingival extension rate of 2.3 mm after periosteal fenestration which was almost similar to this study (2 mm).<sup>23</sup>

In the study conducted by Mohammadi et al. the attached gingival extension rate after periosteal fenestration was reported 1.9 mm.<sup>13</sup> The attached gingival extension rate after periosteal fenestration was reported 2 mm in the present study. Given the studies performed periosteal fenestration, results of the study conducted by Mohammadi et al. closely resembled the results of the present study, which might be due to similar conditions of preparing the surgery bed. Mohammadi et al.<sup>13</sup> performed periosteal fenestration on humans, while the present study performed the technique on dogs. The dimensions of the recipient bed may be a factor affecting clinical results of periosteal fenestration technique. The reason might be that larger dimensions of the prepared bed, in particular the vertical dimension, help the fibroblast cells of the keratinized tissue to have more time for their apical motion on the prepared bed. Moreover, muscle attachment for developing vestibular depth will probably take longer too. The outcome of these two events is the formation of more keratinized and attached tissue.

Carraro et al. evaluated the effect of bone denudation in mucogingival surgery in a human study.<sup>19</sup> They concluded that the increased width of attached gingiva in sites with preserved periosteum is significantly

more than the denuded sites.<sup>19</sup> The difference of the width of the attached gingiva between denuded sites and periosteal retention sites was 0.6 mm, but this difference in present study was 0.1 mm. The difference in coronal incision (marginal in the mentioned study but submarginal in our study) can explain this. Based on the results of these two studies, when we have a marginal incision along with denudation, less attached gingiva will be created because of bone resorption and gingival recession, in comparison with periosteal retention sites. But in prepared sites with submarginal incisions, the amount of new created attached gingiva in denuded and periosteal retention sites is similar. These results show that the apical migration of mucogingival line is similar in both studies.

On one hand, thick gingiva has a larger amount of extracellular matrix, collagen and fibroblast cells compared to thin gingiva; on the other, it has a larger volume of blood vessels.<sup>24-26</sup> The larger volume of blood vessels causes higher tissue oxygenation, higher and better elimination of toxic products, better immune response and migration of more growth factors in the tissue.<sup>24-26</sup> Given the tissue properties of thick gingiva, the researchers decided to examine the effect of the thickness of gingiva on the amount of gingival augmentation with and without preservation of periosteum. The results of the present study did not show any correlation between gingival thickness and the amount of increased width of attached and keratinized gingiva in both groups within 2 months of the surgery. The gingival thickness evaluated in the present study was between 0.8 and 2 mm in both groups. Given results of the present study and also the fact that no similar studies have yet been performed on this topic, it can be concluded that a gingival thickness of 0.8 to 2 mm does not affect attached and keratinized gingival extension rates.

### Conclusion

Based on the results of this study, there is not any correlation between the gingival thickness of 0.8-2 mm at mucogingival

junction and the amount of increased width of keratinized and attached gingiva in periosteal fenestration and denuded sites.

### Conflict of Interests

Authors have no conflict of interest.

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## Evaluating the life quality of patients with diseases of oral mucosa referred to Kerman Dental School, Kerman, Iran, in 2014-2015

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** This study evaluated the quality of life (QOL) of patients with diseases of oral mucosa referred to Kerman Dental School, Kerman, Iran during 2014-2015.

**METHODS:** Total of 101 patients seen in the Kerman Department of Oral Medicine with chronic oral mucosal diseases were included in the study. They completed the designed questionnaire to assess their QOL. After the final edit, the questionnaire was filled by the subjects. Data were analyzed by t-test, chi-square, Pearson's correlation, analysis of variance, and post-hoc analysis using SPSS. The level of significance for all data analysis was  $< 0.05$ .

**RESULTS:** In this study, 101 patients with oral lesions were studied, [57 women (56.4%) and 44 men (43.6%)]. The patients' age range was 19-65 years and the average age was  $32.4 \pm 5.6$  years. Patients older than 35 years of age reported significantly lower QOL in the domain of social and emotional status. Significant age-related differences in QOL were not observed in other domains. Men reported significantly better oral health-related QOL in pain and functional limitation than women. Significant differences were observed between the disease groups only for recurrent aphthous ulcers and pemphigus.

**CONCLUSION:** The present study indicated that chronic oral mucosal diseases affect patients' QOL. Therefore, it seems that oral disease specialists play a key role in the treatment of these patients, including the disease management and symptomatic treatment, and in managing all issues affecting patients' living conditions.

**KEYWORDS:** Quality of Life; Chronic Diseases; Mouth Mucosa

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Chronic oral mucosal diseases include autoimmune and inflammatory diseases, diseases of the soft tissues of the mouth, mouth ulcers and lichenoid lesions. These conditions, like other mouth diseases, can lead to significant adverse physical, social and psychological consequences for patients.<sup>1</sup> Patients with these disorders have to be frequently examined for oral diseases in a clinical setting and usually be monitored for a long time. Some of these diseases can potentially lead to

development of life-threatening conditions<sup>2</sup> and such chronic conditions of the oral mucosa can not only influence patients' daily life, but also lead to long and expensive treatments. In addition, side effects of these treatments can also affect patients' daily lives.<sup>3</sup>

Studies have shown that oral diseases have a tremendous impact on people's everyday life and are associated with physical, economic, social and psychological consequences as well.<sup>4-6</sup> Hegarty et al.<sup>2</sup>

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examined the effect of oral diseases on quality of life (QOL) and priority of oral health specific measures that are not widely used for oral diseases.<sup>7</sup>

Although many QOL-related tools have been developed for the general population, they do not usually assess small significant clinical changes that lead to the development of a specific disease. Disease-specific questionnaires report the health aspects considered by patients or doctors to have the highest degree of importance. These questionnaires are very sensitive to change and compared to generic measures, predict clinical changes more precisely.<sup>8</sup> Although life quality scales have progressed and reported to a large extent, no sequence scale in the field of oral diseases has been progressed.<sup>9,10</sup> Streiner and Norman have proposed a specific and generic questionnaire to measure the QOL.<sup>11</sup>

Ni Riordain and McCreary reported that oral health-related life quality is the most commonly used health-related life quality for oral diseases.<sup>3</sup> Although the questionnaire is a valid and reliable scale, it is not void of faults and defects.<sup>4</sup> Allen and Locker have stressed some objections regarding the scale, including the disproportionate application of this scale in some population groups, its significant effects and poor response.<sup>12</sup>

Reports on the evaluation of treatment of oral diseases are limited.<sup>13-16</sup> Studies conducted on the impacts of chronic oral mucosal diseases on people's daily life by Ni Riordain et al.<sup>17,18</sup> indicated that patients' viewpoints can be correlated with biopsychosocial issues, therapeutic limitations and side effects, unpredictable conditions, the possibility of malignant lesions, and issues related to health care. The purpose of this study was to evaluate the QOL of patients with chronic oral mucosal diseases referred to Kerman Dental School, Kerman, Iran.

## Methods

In this cross-sectional analytic-descriptive study (ethical code K-125-94), the appended

questionnaire was used to assess the QOL of patients with chronic oral mucosal diseases. In this study, 124 questionnaires were distributed, of which 101 (81.5%) were returned. The demographic information such as age, gender, and occupation were recorded. The questionnaire contains 24 items. Patients selected the appropriate responses to the items among options classified according to a Likert-type scale (1 = never, 2 = little, 3 = moderate, 4 = relatively high, 5 = very high) and finally patients' QOL was determined based on their score. Score of questionnaire ranged from 24 to 120. Different items and their scoring were as follows: items related to pain and limited function (items 1 to 9, score 1-45), the use of medication and treatment (items 10 to 15, score 1-30), the social and psychological effects (items 16 to 22, score 1-35) and patient support (items 23 to 26, score 20).

The diagnosis of a chronic oral mucosal disease was established based on the history, clinical examination and hematological and histological investigations (biopsy of white, pigmented, exophytic lesions, and laboratory examinations of oral aphthous ulcers). In this study, 101 subjects aged over 18 years of age who suffered from oral lesions, including ulcers and white and exophytic lesions were examined. They were selected from patients referred to the dental school. Before each examination, the study aim was described and, if desired, the forms were offered to the individual. Meanwhile, all the subjects were assured that obtained information will remain confidential and will only be used for statistical analysis.

The questionnaire was designed based on the qualitative research studies conducted by Ni Riordain et al.<sup>17</sup> and Habib Aghahi et al.<sup>19</sup> To validate the questionnaire, it was rated by seven experts from Kerman Dental School and they were asked to score the questions from totally appropriate to totally inappropriate and the level of each question and its comprehensibility was discussed by the subjects. After this step, 11 questions were rated appropriate and two

questions were removed due to their inappropriateness. To obtain reliability of the questions, the questionnaire was filled by 10 subjects within 2 weeks. Cronbach's Alpha was 0.78 which was good and reliability of the questions was 0.74 to 0.85. After the final edit, the questionnaire was filled by the subjects. Data were analyzed by t-test, chi-square, Pearson correlation, ANOVA, post hoc analysis using SPSS software (version 21, IBM Corporation, Armonk, NY, USA). The level of significance for all analysis was  $P < 0.05$ .

### Results

In this study, 101 patients with oral lesions were studied, [57 women (56.4%) and 44 men (43.6%)]. The patients' age range was 19-65 years and the average age was  $32.4 \pm 5.6$  years (men  $36.6 \pm 7.4$  and women  $31.5 \pm 4.8$ ). Table 1 represents the demographic features of the subjects. Sixty-five patients (64.3%), in this study, reported that their disease was diagnosed with deferment.

In the current study, 63 subjects reported taking medication. Drugs was recommended by dentists rather than oral medicine specialist. The most commonly used drugs included chlorhexidine, benzydamine and corticosteroid. The study indicated that almost all patients were concerned about their disease getting worse (98.0% and 97.2%) and no significant correlation was reported between gender, education, and age and concerns about the disease getting worse over time ( $P = 0.120$ ,  $P = 0.230$ ,  $P = 0.190$ , respectively).

The scores obtained by the patients on items related to pain and limited function (items 1 to 9), the use of medication and

treatment (items 10 to 15), the social and psychological effects (items 16 to 22) and support (items 23 to 26) are shown in table 2. The present study indicated that scores obtained by the patients on the subscales of pain and limited function, social and psychological effects and family members' and friends' support were average. Considering drugs and their side effects, the scores were low. A significant association was observed between medicinal treatment and social and psychological status of patients and their pain and limited function (Table 3).

**Table 1.** Demographic characteristics of the patients

Characteristics	n (%)
Sex	
Male	44 (43.6)
Female	57 (56.4)
Occupation	
Employed	3 (6.8)
Unemployed	98 (93.2)
Education	
< Diploma	29 (28.7)
$\geq$ Diploma	72 (71.3)
Type of disease	
Pemphigus	10 (9.9)
Lichen planus	22 (21.7)
Oral aphthous	32 (31.7)
Leukoplakia	9 (9.0)
Exophytic lesions	28 (27.7)

Scores of the questionnaire ranged from 24 to 120. The mean score of the questionnaire was  $89.23 \pm 12.11$  (women  $90.13 \pm 9.41$  and men  $85.33 \pm 5.10$ ). This study indicated a significant correlation between the scores on the questionnaire and gender and age, i.e. women and men younger than 35 years old gained higher scores ( $P = 0.010$  and  $P = 0.020$ , respectively).

**Table 2.** The overall score and scores obtained by the patients in the questionnaire subscales

Questionnaire subscales	Mean $\pm$ SD	Total average questionnaire score (%)	Scores domain	Severity level*
Pain and functional limitation	$26.53 \pm 4.15$	58.90	1-40	Moderate
Medication and treatment	$24.32 \pm 5.25$	81.06	36-2	Mild
Social and emotional	$26.03 \pm 5.10$	74.37	35-2	Moderate
Patient support	$12.35 \pm 3.05$	61.20	20-2	Moderate
Total	$89.23 \pm 17.57$	67.70	125-1	Moderate

\*Score 0-25 percent: excellent quality of life, score 26-50 percent: good quality of life, score 51-75 percent: moderate quality of life, score 76-100 percent: poor quality of life, SD: Standard deviation

**Table 3.** Pearson correlations between questionnaire subscales

Karl Pearson correlation coefficient		Pain and functional limitation	Medication and treatment	Social and emotional	Patient support	Total
Pain and functional limitation	R	-	0.625*	0.741	0.155	0.825*
	P	-	< 0.001	< 0.001	0.134	< 0.001
Medication and treatment	R	0.625*	-	0.675*	0.195	0.754*
	P	< 0.001	-	< 0.001	0.125	< 0.001
Social and emotional	R	0.712*	0.675*	-	0.345*	0.890*
	P	< 0.001	< 0.001	-	0.015	< 0.001
Patient support	R	0.155	0.195	0.345*	-	0.395*
	P	0.134	0.125	0.015	-	0.001
Total	R	0.825*	0.754*	0.890*	0.395*	-
	P	< 0.001	< 0.001	< 0.001	0.001	-

\*A correlation is significant at the 0.01 level (two-tailed)

Moreover, comparison of the age groups revealed a significant relationship between age and lower scores on the social and psychological status subscale (Table 4).

Patients with diseases such as oral aphthous and pemphigus obtained higher scores on the questionnaire ( $92.55 \pm 17.54$  and  $91.25 \pm 18.60$ , respectively), and these diseases were found to have a greater impact

on patients' QOL (Tables 5 and 6).

**Table 4.** Correlation between scores on the questionnaire subscales and age

Pearson's correlation coefficient	R	P
Pain and functional limitation	0.251	0.060
Medication and treatment	0.108	0.120
Social and emotional	0.275	0.010*
Patient support	0.230	0.07
Total	0.274	0.020*

\*Statistically significant ( $P < 0.05$ )

**Table 5.** Scores on the questionnaire subscales according to the type of the disease

Conditions	n	Mean $\pm$ SD	ANOVA
Pain and functional limitation			
Oral lichen planus	22	23.33 $\pm$ 5.12	3.458
RAS	32	28.21 $\pm$ 6.12	
Pemphigus	10	29.12 $\pm$ 5.15	
Leukoplakia	9	19.12 $\pm$ 5.14	
Exophytic lesions	28	19.43 $\pm$ 4.22	
Total	101	26.53 $\pm$ 4.15	
Medication and treatment			
Oral lichen planus	22	27.22 $\pm$ 5.12	2.585
RAS	32	26.42 $\pm$ 6.21	
Pemphigus	10	4.44 $\pm$ 28.12	
Leukoplakia	9	4.04 $\pm$ 20.12	
Exophytic lesions	28	4.15 $\pm$ 20.22	
Total	101	5.25 $\pm$ 24.32	
Social and emotional			
Oral lichen planus	22	4.12 $\pm$ 30.03	0.312
RAS	32	5.54 $\pm$ 30.14	
Pemphigus	10	5.15 $\pm$ 29.15	
Leukoplakia	9	5.14 $\pm$ 21.41	
Exophytic lesions	28	4.12 $\pm$ 20.54	
Total	101	5.10 $\pm$ 26.03	
Patient support			
Oral lichen planus	22	3.14 $\pm$ 11.54	0.194
RAS	32	3.25 $\pm$ 11.15	
Pemphigus	10	4.15 $\pm$ 12.47	
Leukoplakia	9	2.27 $\pm$ 14.54	
Exophytic lesions	28	3.15 $\pm$ 12.05	
Total	101	3.05 $\pm$ 12.35	
Total			
Oral lichen planus	22	15.50 $\pm$ 91.01	4.547
RAS	32	17.54 $\pm$ 92.55	
Pemphigus	10	18.60 $\pm$ 91.25	
Leukoplakia	9	17.16 $\pm$ 85.45	
Exophytic lesions	28	18.65 $\pm$ 89.22	
Total	101	17.57 $\pm$ 89.23	

RAS: Recurrent aphthous stomatitis; SD: Standard deviation

**Table 6.** Scores on the questionnaire subscales according to the type of the disease

		Dependent variable, P				
		Pain and functional limitation	Medication and treatment	Social and emotional	Patient support	Total
Oral lichen planus	RAS	> 0.999	0.325	0.328	> 0.999	0.358
	Pemphigus	0.075	0.812	0.245	> 0.999	0.125
	Leukoplakia	0.084	0.084	0.076	> 0.999	0.248
	Exophytic lesions	> 0.999	> 0.999	> 0.999	> 0.999	> 0.999
RAS	Oral lichen planus	> 0.999	0.325	0.328	> 0.999	0.358
	Pemphigus	0.015*	0.035*	0.012*	> 0.999	0.015*
	Leukoplakia	0.065	0.317	0.315	> 0.999	0.412
	Exophytic lesions	0.071	0.079	> 0.999	> 0.999	0.231
Pemphigus	Oral lichen planus	0.075	0.812	0.245	> 0.999	0.125
	Exophytic lesions	0.068	0.065	0.165	> 0.999	0.073
	Leukoplakia	0.076	0.317	0.425	> 0.999	0.189
	RAS	0.015*	0.035*	0.012*	> 0.999	0.015*
Leukoplakia	Oral lichen planus	0.084	0.084	0.076	> 0.999	0.248
	Exophytic lesions	0.085	0.086	0.068	> 0.999	0.215
	RAS	0.065	0.317	0.315	> 0.999	0.412
	Pemphigus	0.076	0.317	0.425	> 0.999	0.189
Exophytic lesions	Oral lichen planus	> 0.999	> 0.999	> 0.999	> 0.999	> 0.999
	Pemphigus	0.068	0.065	0.165	> 0.999	0.073
	RAS	0.071	0.079	> 0.999	> 0.999	0.231
	Leukoplakia	0.085	0.086	0.068	> 0.999	0.215

RAS: Recurrent aphthous stomatitis

\*Statistically significant (P &lt; 0.05)

## Discussion

This study addressed the impact of oral mucosal chronic diseases on the QOL. These diseases cause pain and limited function, have social, psychological, and pharmacological effects, and cause support problems. The study indicated that pain and limited function were mainly experienced by patients during their daily lives causing effects such as changes in diet and limitation of the consumption of certain beverages and foods that is consistent with the results of Ni Riordain et al.<sup>17</sup> and Rajan et al.<sup>20</sup>

Llewellyn and Warnakulasuriya investigated oral and dental diseases such as aphthous ulcers, lichen planus, oral candidiasis, burning and dryness of mouth, and temporomandibular disorders using Oral Health Impact Profile-14 (OHIP-14) and found that these can seriously affect oral health-related quality of life (OHRQOL).<sup>21</sup> Mumcu et al. examined the effect of a mouth illness and recurrent aphthous ulcers on QOL using OHIP-14 and indicated that patients with active mouth ulcers had a lower QOL

compared to patients without ulcers.<sup>16</sup> Hegarty et al. showed that oral lichen planus is painful and is associated with poor OHQOL.<sup>2</sup>

The present study revealed that the severity of pain, psychological status and function in patients with pemphigus and aphthous ulcers was affected and people with these problems had a lower life quality compared to patients with lesions of leukoplakia, exophytic lesions and lichen planus. This finding was consistent with the results of previously conducted studies.<sup>2,14,20,22</sup>

The literature shows that oral and dental problems can cause pain, discomfort and difficulty in eating, social relationships, and physical appearance. Accordingly, functional limitations and pain caused by these diseases should be rightfully assessed and appropriate treatments should be proposed to help patients to improve their life quality.<sup>23,24</sup>

In this study, women and those with older age reported poorer QOL which is consistent with the results of Rajan et al.<sup>20</sup> who reported that patients' QOL can be attributed to the

deterioration of social and emotional status. However, proper education and counseling regarding diseases of oral mucosa and reassuring the patients about the success of treatment and the availability of treatment can prevent the life quality in people with needy economic situation from dropping.

Delay in receiving the diagnosis experienced by patients was another thought-provoking issue. Visiting several doctors was reported as the most common cause of delay in diagnosis in this context. Studies have shown that patients with oral lesions face various problems among which delay in diagnosis and treatment can be considered as the most important one. Jovanovic et al.<sup>25</sup> conducted a research on the referral pattern of patients with oral mucosal lesions in 1992 in Netherlands and found that these patients' family doctors referred them to different medical specialists instead of a dentist. However, in most general medical courses, specialists are not precisely taught about the structure of the mouth, teeth and related diseases as an independent topic.

Haberland et al.<sup>26</sup> found that the average time between the appearance of primary symptoms and the time of examination by an oral disease specialist is about 15 months. Oral diseases are one of the professional disciplines of dentistry. Treatment of mucosal lesions is included in the practice of these specialists. Such lesions may belong to different topical lesions of oral mucosa or might be symptoms of systemic disease. Unfortunately, most doctors and even dentists are not aware of the range of ability, performance and medical equipment required for the specialty of oral diseases. This issue along with the lack of education on oral mucosa diseases in students of dentistry and lack of familiarity of different specialists with these diseases cause inappropriate and unnecessary diagnosis or treatment for most patients with mouth lesions.<sup>27</sup>

In addition, low awareness of clinical features and conditions of these chronic diseases is a concern. In the literature, the

dental information of doctors who are engaged in the area of primary care is noted to be scarce and improvements are offered.<sup>17,28,29</sup> A possible reason for delay in the diagnosis is the lack of regular contact of doctors and dentists with oral diseases specialists, as the result of which inappropriate referrals occur. Almost half of the patients in this study had at least once visited a doctor or a dentist, before referring to the oral diseases section. This is compatible with the studies of Ni Riordain et al.<sup>17</sup> and Miller et al.<sup>30</sup> The findings of Haberland et al.'s study showed that patients were examined by an average of 2.2 general practitioners before being visited by an oral diseases specialist.<sup>26</sup>

There is no doubt that the advancement of science on the oral cavity and soft tissue infections causes faster and more accurate referrals. Appropriate and timely referrals not only decrease delayed diagnosis, but also create more readiness to provide adequate services. Spending unnecessary time, especially during examinations, can lead to increased waiting time for patients who need medical services. Increases in financial cost and improper management for consulting are the outcomes of insufficient and unsuitable care for the patients. Advance knowledge of the medical community, especially in the field of oral diseases, and the performance and capabilities of specialists in this field are key factors affecting the improvement of the management of chronic oral mucosal diseases.<sup>17</sup>

## Conclusion

The present study indicated that chronic oral mucosal diseases affect patients' QOL. Therefore, it seems that oral disease specialists play a key role in the treatment of patients with chronic oral mucosal diseases, including disease management and symptomatic treatment, and in managing all issues affecting patients' living conditions.

## Conflict of Interests

Authors have no conflict of interest.

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## Comparison of transportation and centering ability using RECIPROC and iRace: A cone-beam computed tomography study

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** Root canal treatment, especially in curved and constricted root canals, can be very difficult and time consuming. Several investigations have compared the reciprocating and full sequence motions in terms of shaping ability. The purpose of the present study was to compare the root canal transportation and centering ability of RECIPROC and iRace using cone-beam computed tomography (CBCT).

**METHODS:** Thirty-two mesiobuccal (MB) root canals of maxillary first molars with curvature ranged 25-40 degrees were selected. Pre-instrumentation CBCT images were captured at 2, 4 and 6 mm distances from the root apex. Thirty samples were randomly divided into two groups (n = 15). After root canal preparation using either iRace or RECIPROC #25, post-instrumentation CBCT images were obtained at the same levels. Two specimens served as control group. Pre- and post-CBCT images were evaluated to measure root canal transportation and centering ability. Mann-Whitney and Friedman tests were used for statistical analysis.

**RESULTS:** There was no significant difference between the groups ( $P > 0.05$ ).

**CONCLUSION:** iRace and RECIPROC maintained original root canal geometry and may be safe to be used in curved root canals.

**KEYWORDS:** Cone-Beam Computed Tomography; Root Canal Preparation; Transportation

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Root canal treatment, especially in curved and constricted root canals of molar teeth, can be very difficult and time consuming.<sup>1</sup> Since stainless-steel instruments have a tendency to restore their original linear shape, they may result in canal transportation.<sup>2</sup> Introduction of Ni-Ti rotary instruments to endodontic therapy has resulted in more flexible files with the ability to maintain original root canal shape.<sup>3</sup> Race files (FKG, La Chaux-de-Fonds, Switzerland) consist of full rotary instruments with a triangular cross-section

and alternating cutting edges.<sup>4</sup> Several investigations have confirmed the ability of this system to properly clean and shape the curved root canals.<sup>5-7</sup> iRace is a recently introduced sequence with similar design features as Race consisting R1 (15.06), R2 (25.04) and R3 (30.04) and the manufacturer claimed that this sequence can be quick, safe and effective for preparation of curved root canals.<sup>8</sup>

Nowadays, reducing the number of instruments for root canal preparation has attracted more attention.<sup>9-15</sup>

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RECIPROC instruments (R25, R40 and R50; VDW GmbH, Munich, Germany) are made of M-wire, with regressive taper. They have S-shaped cross-section design and two effective cutting edges. The rationale of reciprocating movement is based on balanced-force technique.<sup>16</sup> The R25 is used at 10 cycles of reciprocating motion per second for preparation of small, curved canals.<sup>17</sup> So far, no investigation has been performed to compare the centering ability of iRace and RECIPROC. Therefore, the aim of the present study was to compare root canal transportation and centering ability of iRace and RECIPROC in mesiobuccal (MB) canals of maxillary first molars by CBCT.

### Methods

In this experimental study, thirty-two maxillary first molar teeth extracted for periodontal reasons were used. The inclusion criteria were: intact pulp chamber, fully formed MB roots, and MB root canal curvature ranging between 25-40 degrees according to the Schneider technique (1971). Exclusion criteria were sign of either presence of internal or external resorption and root canal calcification.

A #10 K-file (Maillefer/Dentsply, Ballaigues, Switzerland) was inserted in the MB canal until the tip was observed at the apical foramen and working length was established at 0.5 mm short of the measured length. The teeth with apical constriction wider than #15 K-file (as glide path), shorter than 21 mm and longer than 23 mm were excluded. Each tooth with the buccal root facing up was embedded in high-precision rubber-based impression material (Speedex, Coltene/Whaledent, Switzerland) for providing a mold. A #30 gutta-percha cone (Dia Dent, Korea) was placed along the MB root length as an indicator. Teeth with their impressions were mounted on some fiber platforms. Initial CBCT (NewTom VG, QR srl, Verona, Italy) images were conducted with the following settings: 0.3 mm voxel resolution at 110 kV and 10 mA, 12 s of

exposure time, matrix of 512 × 512 pixels, axial pitch 0.3 mm and axial thickness 0.4 mm. Axial cross sections with 0.16 mm thickness were obtained at 2, 4 and 6 mm far from the apex. The images were stored, analyzed and converted in to JPEG format with the software NNT (NewTom VG, QR srl, Verona, Italy) provided for the CBCT machine.

The specimens were randomly divided into two groups (n = 15) with similar mean root canal curvature and two samples were used as control.

#### Canal preparation

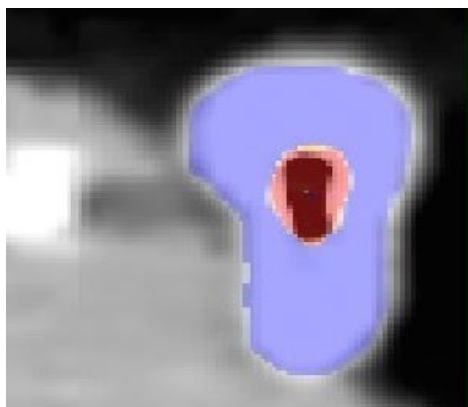
**Group A:** The canals in this group were prepared by iRace (FKG, La Chaux-de-Fonds, Switzerland) sequence for curved canals using VDW Silver RECIPROC motor (Sirona, Bensheim, Germany) set at full rotation, torque equal to 1.5 N/cm and speed set at 600 rpm. A #15.06 file was carried to the working length followed by #25.04.

**Group B:** The canals of this group were prepared with R25 RECIPROC file with a taper of 0.08 over the first 3mm. The file was gradually inserted to the working length according to the manufacturer instructions by a torque-controlled motor VDW, Silver RECIPROC motor (Sirona, Bensheim, Germany) set at reciprocating mode.

In both groups, the root canals were irrigated with 2 ml 5.25% NaOCl after each file using a 28-gauge needle (Dentsply Tulsa Dental, Tulsa, OK). After root canal preparation, rinsing was done with 2 ml 17% EDTA (Meta Biomed Co., Ltd., Mandaluyong, Korea) followed by normal saline and 5.25% NaOCl (each 2 ml), respectively then 5 ml normal saline served as final irrigation. An Endodontist (B.D) prepared all the canals and each file was discarded after using in three canals.

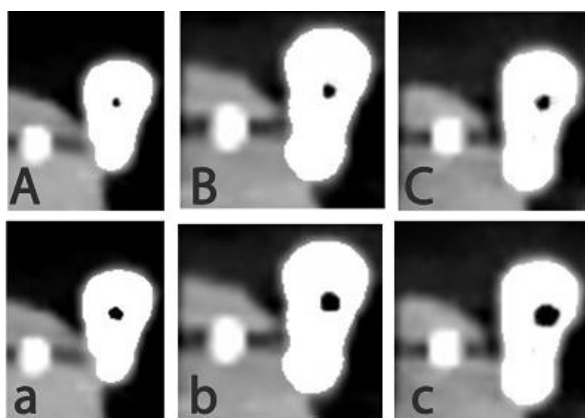
The specimens were then returned to their initial jigs and post-instrumentation CBCT images were captured in the same manner as pre-instrumentation images. No preparation was done for the two control samples. They served as controls for the accuracy of the imaging set up. The images were exported to

the Adobe Photoshop software (version 7.0, Adobe system Inc., San Joes, CA, USA). The Magic tool was selected. The initial canal image was colored dark red and the post-instrument one was colored pink. The outer borders of the MB root in pre- and post-images were superimposed, so that the outer borders coincided (Figure 1). Zoom was increased to 1200.<sup>2,18,19</sup>



**Figure 1.** Pre- and post-superimposed images at level of 6 mm from the apex in a RECIPROC sample

The shortest distance from the outer border of the root to the outer border of the root canal was measured on mesial and distal aspect of each pre-and post-instrumentation images at each level (2, 4 and 6 mm far from the apex) three times and the mean scores was recorded by a graduated dental student (Figure 2).



**Figure 2.** Pre-instrumentation (A, B and C) and post-instrumentation (a, b and c) images at 2, 4 and 6 mm distances from the apex, respectively in an iRace sample

Canal transportation was calculated according to the following formula:<sup>3</sup>

$$|(M_1 - M_2) - (D_1 - D_2)|$$

$M_1$  was the shortest distance from the mesial border of the root to the mesial border of the root canal before instrumentation.  $M_2$  was the same distance measured on the image of instrumented canal.  $D_1$  and  $D_2$  served for the same measurements on the distal aspect of the root canal. According to this formula the result equal to 0 indicated no transportation, otherwise indicated root canal transportation. The centering ability of the preparation systems was calculated based on the following formula:<sup>3</sup>

$$\frac{(M_1 - M_2)}{(D_1 - D_2)}$$

Perfect centering was gained when the ratio = 1, otherwise transportation was recorded. Since the distribution of dependent variable was not normal, to compare the differences between the two groups and between the groups, Mann-Whitney U and Friedman tests were used, respectively and the level of significance was set at  $P \leq 0.05$ . The findings were evaluated using SPSS software (version 22, IBM Corporation, Armonk, NY, USA).

## Results

The two control specimens showed exact superimposition of the root borders and canal border with no transportation.

iRace showed a lower transportation and a higher root canal centering ability compared to RECIPROC with no significant difference ( $P \geq 0.05$ ) (Tables 1 and 2).

**Table 1.** Root canal transportation regarding to the root canal level and rotary system

Level	iRace (mean $\pm$ SD)	RECIPROC (mean $\pm$ SD)	P
2 mm	0.03 $\pm$ 0.01	0.04 $\pm$ 0.03	0.653
4 mm	0.04 $\pm$ 0.03	0.06 $\pm$ 0.04	0.187
6 mm	0.04 $\pm$ 0.02	0.05 $\pm$ 0.03	0.217

Mann-Whitney U was used for pairwise comparisons  
SD: Standard deviation

Also there were no significant differences in transportation among different levels (i.e. 2 mm, 4 mm, 6 mm from the apex) ( $P \geq 0.05$ ).

**Table 2.** Centering ability regarding to the root canal level and rotary system

Level	iRace (mean $\pm$ SD)	RECIPROC (mean $\pm$ SD)	P
2 mm	0.52 $\pm$ 0.29	0.41 $\pm$ 0.35	0.325
4 mm	0.53 $\pm$ 0.25	0.49 $\pm$ 0.33	0.806
6 mm	0.49 $\pm$ 0.29	0.45 $\pm$ 0.26	0.775

Mann-Whitney U was used for pairwise comparisons  
SD: Standard deviation

### Discussion

The results of this study showed no significant difference between RECIPROC and iRace regarding either centering ability or transportation following root canal preparation. Several methods such as double exposure of conventional or digital periapical radiographs, CBCT or micro CT have been used to evaluate the centering ability and transportation of either different rotary instruments or root canal preparation techniques on original root canal curvature. CBCT is a useful device and has been extensively used for various aspects in endodontics such as diagnosis of root fractures<sup>2</sup> and the efficacy of different instrumentation systems on root canal centering ability and transportation.<sup>21-24</sup>

In the present study, for evaluating the centering ability and transportation of MB root canal of maxillary first molars using RECIPROC and iRace rotary files, CBCT method was used for providing the 3D images of pre- and post-instrumentation of the root canal without destroying the specimens.<sup>2,20,25-27</sup> In order to assess the effect of new endodontic preparation techniques and instruments, it is reasonable to use mature teeth, especially those with more complicated anatomy. The most MB root canals of maxillary molar teeth are curved and delicate, and most of the time their preparation is so challenging. Some previous investigations on centering ability and root canal transportation have also used curved root canals.<sup>2,3,5,7,28</sup> It has been shown that the

operator's level of experience had no influence on fracture or blockage of WaveOne reciprocating file,<sup>13,15</sup> however, in this study for improving internal reliability of the data, an endodontist (B.D) prepared all root canals.

In this study for apical matching of initial diameter of the samples and also for evaluation of the MB root canal curvature, a #15 K-file was introduced to the moderate to severe curved root canals as glide path. The manufacturer of RECIPROC has recommended creating a glide path with or without initial hand filing.<sup>29</sup> Nevertheless, it has been shown that glide path could help to reduce canal modification during reciprocating motion.<sup>30</sup> The usage of R25 RECIPROC instrument without a glide path for preparation of straight to moderate curved canals was recommended.<sup>31</sup>

Previous studies have attributed the ability of Race instruments on maintaining the original root canal morphology to the design of the active part of these files, with alternating cutting edges preventing the screw effect.<sup>5,7</sup> While, the ability of RECIPROC R25 to maintain the original root canal shape in this study might be the result of reciprocal motion that relieves stress on the instrument and prevents the screw effect as well.<sup>11</sup> Nevertheless, in this study, iRace showed a lower transportation and a higher root canal centering ability compared to RECIPROC with no significant difference. As Al-Gharrawi and Fadhil<sup>8</sup> have mentioned, it might be attributed to the greater taper of RECIPROC (0.08) compared to iRace (0.04) and smaller cross-sectional area and the resultant flexibility. On the other hand, the alternating cutting edges in iRace resulted in less screwing effect which had positive impact on shaping ability.<sup>32</sup> Also Hiran-us et al.<sup>33</sup> reported that the apical transportation was the least by iRace system.

In spite of different methods of evaluating centering ability and root canal transportation, the results of the present study regarding the RECIPROC was in

agreement with the findings of Burklein et al. who found no significant difference between RECIPROC, WaveOne, Mtwo and ProTaper.<sup>11</sup> Jain et al.<sup>34</sup> have stated that reciprocating movement can minimize torsional and flexural stresses, which results in less taper lock and minimum canal transportation.

### Conclusion

Based on the results of this study, iRace with the sequence of #15.06 and #25.04 and R25

RECIPROC, in spite of many design variables and taper differences, have similar centering ability and maintain root canal curvature. Both systems seem to be safe for preparation of curved root canals.

### Conflict of Interests

Authors have no conflict of interest.

### Acknowledgments

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## Dental caries status and its associated factors in pregnant women, Shiraz, Iran, 2014

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### Original Article

#### Abstract

**BACKGROUND AND AIM:** Dental caries is a common problem in pregnant women which has negative impacts on their quality of life. The aim of this study was to evaluate pregnant women's dental caries status and its associated risk factors in Shiraz, Iran, in 2014.

**METHODS:** In this cross-sectional study, we selected 423 pregnant women attending Shiraz governmental health centers for routine obstetric examinations by randomized cluster sampling. The women's dental caries status was assessed using decayed, missed, and filled tooth (DMFT) index. The women's demographic characteristics and their oral hygiene habits were evaluated using a valid and reliable questionnaire. The relationship between women's DMFT index and their demographic and oral hygiene characteristics was evaluated using Pearson correlation, analysis of variance, independent sample t-tests, and multiple linear regression models.

**RESULTS:** The mean DMFT index was  $5.8 \pm 3.6$ . We found lower scores of DMFT index in women who were younger ( $P < 0.001$ ), brushed their teeth more ( $P = 0.014$ ), and used home preventive measures such as mouthwash ( $P = 0.003$ ) and toothpick ( $P = 0.006$ ).

**CONCLUSION:** Dental caries status of the pregnant women was unacceptably lower than optimal. Interventions focusing on holding educational programs and taking office-based preventive measures for pregnant women or women who intend to be pregnant are recommended. The interventions are more necessary for older pregnant women and those who use fewer home preventive measures.

**KEYWORDS:** Dental Caries; Iran; Pregnancy

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Dental caries is caused by localized dissolution and destruction of calcified parts of the teeth.<sup>1,2</sup> It is the most prevalent infectious disease.<sup>3,4</sup> Its prevalence in adult population of developed countries is 40%-50%.<sup>5</sup> There are several indices for evaluating dental caries in a community; however, the most popular one is decayed missing filled teeth (DMFT) index.<sup>6</sup>

Dental caries is more prevalent among women than men. DMFT index in 15- to

24-year-old women has been reported twice higher than that of men in the same age.<sup>7</sup> One of the reasons for the high prevalence in women is the changes that occur during pregnancy. It is hypothesized that the risk of tooth decay in pregnancy could be increased because of changes in the saliva composition, repeated gastric reflux and vomiting. Furthermore, poor oral hygiene and changes in dietary habits like craving for carbohydrates during pregnancy can exacerbate the effect of such changes.<sup>8-10</sup>

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The prevalence of dental caries during pregnancy in different studies conducted in different countries has been reported differently. The prevalence was reported from 41% to 52% in the developed countries.<sup>11-13</sup> However, it was about 100% in two studies conducted in developing countries.<sup>14,15</sup> Furthermore, the mean score of DMFT index in pregnant women was reported 10 to 18.5 in developing countries<sup>14-16</sup> while it was 7.9 in a study done in Italy.<sup>13</sup> The reported prevalence of dental caries in pregnant women living in different parts of a country has also been different. For example, in India, the prevalence was described from 60% to 87%.<sup>17-19</sup> This is also the case in Iran. In Iran, the mean scores of DMFT index in Isfahan<sup>20</sup> and Mashhad,<sup>21</sup> were around 10 while the score was 6.2 and 5.4 in Ahvaz<sup>22</sup> and Arak,<sup>23</sup> respectively. However, to the best of our knowledge, no study has assessed the status of dental caries in pregnant women in Shiraz, a large city in the south of Iran.

Different studies have also reported different risk factors for dental caries in pregnant women. Socioeconomic status such as education level, employment during pregnancy, monthly family income and insurance coverage<sup>12,23,24</sup>, age<sup>19,20</sup>, gestational age,<sup>19</sup> number of previous pregnancies,<sup>20</sup> interval between pregnancies,<sup>20</sup> frequency of oral hygiene practice such as tooth brushing and applying fluoride toothpaste,<sup>24</sup> and knowledge about dental health care<sup>24</sup> were shown to be associated with dental caries in pregnant women.

Dental caries can lead to adverse consequences during pregnancy.<sup>19,20,23</sup> It often leads to painful and stressful situations negatively affecting the quality of life of pregnant women.<sup>25</sup> Moreover, because of pain, pregnant women may use analgesics and/or other medications with unpredictable risks for the health of fetus.<sup>26</sup> Therefore, reducing the prevalence of dental decay in pregnant women is of great importance. To hold interventional programs in this regard, the authorities require epidemiological data

indicating the current status. Although a few studies in this regard have been conducted in Iran, to the best of our knowledge, no research has evaluated the prevalence of dental decay and its associated factors in pregnant women in Shiraz. Because of a wide variance of the prevalence rate in different places, we were prompted to conduct this study.

## Methods

This cross-sectional study was done in Shiraz. The target population was pregnant women attending the governmental health centers affiliated to Shiraz University of Medical Sciences for routine obstetric examination from February to May 2014. Having considered  $\alpha = 0.05$ ,  $\delta = 3$ , and  $d = 0.3$ , the sample size was determined to be at least 387 to estimate mean DMFT indices. The participants were selected by randomized cluster sampling. To do the sampling, we wrote the name of all governmental health centers located in Shiraz ( $n = 88$ ) and selected 11 out of them by balloting. All women attending each selected center in a single day (totally 423 women) were requested to contribute in the study. The women who consented to contribute were included.

By using the World Health Organization (WHO) oral health questionnaire (version 2013) and considering the WHO criteria for DMFT index, we assessed the related indices of the pregnant women.<sup>27</sup> Two faculty members of the Department of Oral Medicine trained a senior dental student on how to measure the DMFT index. The student examined the women using a plane mouth mirror and WHO probe. Also, gauze or cotton rolls and a flashlight were used for field dryness and illumination. Dental examination was conducted in a systematic manner from one tooth to the adjacent one. The student recorded a tooth as decayed when he found a damaged enamel or a cavity or lesion on a tooth surface, or. A tooth was considered filled when it had permanent restorations. Also, the teeth extracted because of caries were recorded as missed. For the

purpose of diagnosing caries, radiography was not used because it was impossible to utilize the equipment in most field situations.<sup>27</sup> To evaluate intra-rater reliability, we conducted a pilot study on 20 women and the student examined the women twice two weeks apart. The intraclass correlation coefficient (ICC) between the calculated DMFT indices revealed a high agreement (ICC = 0.98,  $P < 0.001$ ).

To obtain data on the women's demographic and oral health status, we prepared a questionnaire and its content validity was confirmed by the faculty members of the department. The questionnaire consisted of two parts: demographic information (8 questions), and oral health status (4 questions). Reliability of the questionnaire was assessed using the above mentioned pilot study in which pregnant women were interviewed twice at an interval of two weeks to fill out the questionnaire. The agreement between the two measures was assessed using Kappa coefficient (Kappa = 0.625 and  $P = 0.005$  for frequency of tooth brushing, Kappa = 0.784 and  $P < 0.001$  for other home preventive measures, and Kappa = 0.732 and  $P = 0.001$  for dental visits).

The data were analyzed using SPSS software (version 18, SPSS Inc., Chicago, IL, USA) to determine the mean DMFT index. Independent sample t-test, analysis of variance (ANOVA, with Duncan post hoc test), and Pearson correlation test were used to evaluate the association between DMFT index and demographic and oral health factors. To control the confounding factors, we entered all demographic and oral health characteristics into a multiple linear regression model considering the DMFT index as the dependent variable. For all analyses, statistical significance was set as  $P < 0.05$ .

The Research Ethics Committee of Shiraz University of Medical Sciences approved the study protocol (Ethical code #ec-9375-7125). Informed consent was obtained from all participants. The DMFT index of the

pregnant women was determined without using any radiological procedures. The clinical examinations were performed for all women in the presence of a female health care worker. The name of the participants was not recorded in their questionnaires. Only the research team could have access to the data.

## Results

**Description of the participants:** Of the 423 pregnant women who were asked to participate in the study, 381 (90%) agreed to be interviewed. The women's age ranged from 16 to 41 years (median = 27 years) and their gestational age varied from 4 to 39 weeks (median = 27 weeks). Most of them did not have a university degree and were homemakers (Table 1).

**Oral health status of the studied pregnant women:** Of the studied women, 72.1% reported that they brush their teeth once or more per day. About half of them did not use any other preventive measures. Only 81 women (21.0%) had a prior dental visit for check-up (Table 1). Mean  $\pm$  standard deviation (SD) DMFT index was  $5.8 \pm 3.6$  (range: 0-18). The mean  $\pm$  SD decayed, missed, and filled teeth of the women were  $1.3 \pm 1.5$ ,  $2.7 \pm 2.3$ , and  $1.7 \pm 2.1$ , respectively.

**The association between the women's demographic characteristics and their dental caries:** There was a statistically significant association between the women's DMFT index and their age; the older the women, the higher the DMFT index ( $r = 0.378$ ,  $P < 0.001$ ). Furthermore, the mean DMFT index of the women with self-employed husbands was higher than that of those whose husband were employee ( $P = 0.042$ ) (Table 1).

**The association between the women's pregnancy status and their dental caries:** We did not find a significant association between women's gestational age and their DMFT index ( $r = 0.08$ ,  $P = 0.097$ ). However, we found a significant relationship between the women's DMFT index and the number of their pregnancies ( $P < 0.001$ ). Post hoc test



revealed a significant difference between the mean DMFT index of the women in their first and second pregnancies and that of the women in their third pregnancy or more ( $P < 0.001$ ) (Table 1).

**The association between the women's oral hygiene status and their dental caries:** To evaluate the effect of home preventive measures, we compared the mean DMFT index of the following 4 groups: the women who used dental floss, those who used tooth pick, those using mouth wash, and those who did not use any of these measures. A significant difference was shown among the 4 groups ( $P = 0.011$ ). Furthermore, post hoc test showed a significant difference between

DMFT index of the women who used mouth wash with that of those who did not use any of these measures, but it did not show a similar difference between the mean DMFT index of the women using dental floss or tooth pick and that of the women who did not. Mean DMFT index of the women who had a prior dental check-up was significantly lower than that of the women without such check-ups ( $P = 0.019$ ) (Table 1). However, we could not find a significant difference between the mean DMFT index of the women who had dental check-ups in different times, i.e. during the present pregnancy, during 6 months before pregnancy, and more than 6 months before pregnancy ( $P = 0.972$ ).

**Table 1.** Demographic characteristics and the factors affecting decayed, missed, filled tooth (DMFT) index of the pregnant women attending governmental health centers in Shiraz

Woman's characteristics (n = 381)	Values	DMFT (mean ± SD)	P
Demographic characteristics	Age (year) (mean ± SD)	28.10 ± 5.34	-
	Education [n (%)]		0.318**
	Without university education	295 (77.4)	5.86 ± 3.73
	With university education	86 (22.6)	5.42 ± 3.31
	Woman's occupational status [n (%)]		0.626**
	Homemaker	361 (94.8)	5.74 ± 3.66
	Employed	20 (5.2)	6.15 ± 3.23
	Husband's education [n (%)]		0.166**
	Without university education	260 (68.2)	5.93 ± 3.86
	With university education	121 (31.8)	5.41 ± 3.10
	Husband's occupational [n (%)]		0.042**
	Self-employed	286 (75.1)	5.96 ± 3.79
	Employee	95 (24.9)	5.17 ± 3.07
	Insurance status [n (%)]		0.126**
With insurance	340 (89.2)	5.66 ± 3.62	
Without insurance	41 (10.8)	6.58 ± 3.74	
Pregnancy status	Gestational age (month) (mean ± SD)	25.80 ± 8.50	-
	Pregnancies number [n (%)]		< 0.001*
	One	156 (40.9)	4.97 ± 3.50***
	Two	137 (36.0)	5.73 ± 3.47***
Oral hygiene status	Three or more	88 (23.1)	7.23 ± 3.72 <sup>#</sup>
	Tooth brushing frequency [n (%)]		0.084**
	Once or more per day	275 (72.1)	5.45 ± 3.40
	Less than once per day	106 (27.8)	6.10 ± 3.86
	Other preventive measure [n (%)]		0.011*
	None	176 (46.2)	6.20 ± 3.82***
	Dental floss	135 (35.4)	5.76 ± 3.48***
	Tooth pick	63 (16.5)	4.89 ± 3.31***
	Mouth wash	7 (1.8)	2.71 ± 2.14 <sup>#</sup>
	Dental check-up [n (%)]		0.019**
No	300 (78.7)	6.60 ± 4.12	
Yes	81 (21.3)	5.54 ± 3.47	
In present pregnancy [n (%)]			
< 6 month before pregnancy	25 (6.6)	-	
≥ 6 month before pregnancy	22 (5.8)	-	
	34 (8.9)	-	

SD: Standard Deviation; DMFT: Decayed, missed, filled tooth

\*One-way ANOVA, \*\*Independent sample t-test, \*\*\*<sup>#</sup>Different symbols show statistically significant differences

**Table 2.** Multiple linear regression model for the factors affecting decayed, missed, filled tooth (DMFT) index of the pregnant women attending governmental health centers in Shiraz

Independent variables (n = 381)	$\beta$	SE	P
Number of pregnancies (/three or more)			
One	-0.41	0.55	0.458
Two	-0.45	0.50	0.362
Woman's education level (/with university education)			
Without university education	0.09	0.52	0.865
Woman's occupational status (/employed)			
Housekeeper	-0.08	0.83	0.919
Husband's education level (/with university education)			
Without university education	-0.07	0.47	0.876
Husband's occupational status (/employee)			
Self-employed	0.57	0.49	0.244
Insurance status (/without insurance)			
With insurance	-0.80	0.58	0.171
Frequency of tooth brushing (/less than once daily)			
Once or more per day	-1.01	0.41	0.014
Other home preventive measure (/none)			
Dental floss	-0.32	0.40	0.419
Tooth pick	-1.38	0.49	0.006
Mouth wash	-3.92	1.30	0.003
Dental check-up (/no)			
Yes	0.64	0.43	0.137
Age (year)	0.23	0.04	< 0.001
Gestational age (week)	0.02	0.02	0.369

SE: Standard error

**Multiple linear regressions analysis:** No significant association was found between the women's DMFT index and their number of pregnancies, their husband's occupational status, and having dental check-ups. However, there was a significant relationship between the women's DMFT index and their age ( $P < 0.001$ ), frequency of tooth-brushing ( $P = 0.014$ ), and using tooth pick ( $P = 0.006$ ) and mouth wash ( $P = 0.003$ ). If the women brushed their teeth once or more per day, their DMFT index would decrease about 1.01. One year increase in the women's age led to 0.23 increases in their DMFT index. Using tooth pick and mouth wash as home preventive measures caused 1.38 and 3.92 decrease in the women's DMFT index, respectively (Table 2).

## Discussion

This study evaluated dental caries status and its associated factors in pregnant women in Shiraz in 2014. We found unacceptable oral hygiene habits and high dental caries in the pregnant women. There was a significant

association between the women's DMFT index and their use of home preventive measures.

### Oral health status of pregnant women:

Oral health habits of the pregnant women in our study were worse than those in other countries. In our study, 72.1% of the pregnant women versus 84.0% in Spain,<sup>28</sup> 86.2% in Lithuania,<sup>14</sup> 99.1% in Italy,<sup>13</sup> and 94.0% in Kuwait<sup>29</sup> reported daily tooth brushing. In addition, only half of the women in our study versus two-thirds of Kuwaiti pregnant women<sup>29</sup> had used other preventive measures. Considering poor oral hygiene in pregnant women, we recommend that dentists and oral health care providers should instruct pregnant women regarding their oral hygiene habits.

Only one-fifth of pregnant women in the present study had a prior dental check-up while more than half of the pregnant women in Spain had regular dental check-up.<sup>28</sup> To decrease the consequences of dental problems during pregnancy, the problems should be diagnosed and treated before pregnancy.

Therefore, women should be educated about the importance of regular dental visit before pregnancy. Furthermore, for better management of dental problems during pregnancy, prenatal care providers should encourage all pregnant women to visit a dentist and follow the dentists' recommendations.

#### *Dental caries status of pregnant women:*

In our study, the mean score of DMFT index in the pregnant women was 5.8. The score was lower than that of Iranian adults (35-44 years old) which was  $11.0 \pm 6.4$ <sup>30</sup> and higher than that of Iranian adolescents (14-18 years old) which was  $2.61 \pm 1.89$ .<sup>31</sup> Furthermore, other Iranian studies reported the scores in pregnant women ranging from 5.4<sup>23</sup> to 10.6.<sup>20</sup> Also, the scores ranging from 7.9 to 18 were shown in pregnant women of other countries.<sup>13-15</sup> Several factors were shown to be effective on the score in pregnant women such as dietary habits,<sup>1</sup> oral hygiene,<sup>28</sup> the use of fluoridated toothpastes,<sup>1</sup> level of fluoride in drinking water,<sup>32</sup> and access to oral health services.<sup>11</sup> The high scores of DMFT index in pregnant women highlight the urgent need for interventional programs to promote oral health in this population. Pregnant women and those who intend to be pregnant should be considered as a target group for oral health promotion programs and oral health services should be more accessible and affordable for them. Pregnant women should be educated about proper oral hygiene techniques and appropriate non-cariogenic diet. Furthermore, the fluoride level of drinking water should be optimal in all regions.

In our study, similar to researches conducted in other developing countries,<sup>9,18,19</sup> untreated dental caries constituted a major proportion of DMFT index scores; however, in developed countries, the filled teeth had the highest proportion.<sup>11,13</sup> This finding emphasizes the importance of free, or with a minimum charge, dental check-up before and during pregnancy. Furthermore, in our study, similar to the one from Lithuania, many missed teeth were found in the

pregnant women.<sup>14</sup> These findings can show the women's lack of awareness about the importance of their teeth and highlight the need for training on oral hygiene and consequences of tooth loss.

**Factors affecting pregnant women's dental caries:** Our results, similar to other studies done in Iran and other countries,<sup>9,11,14,19,20</sup> showed a significant positive correlation between the pregnant women's DMFT index and their age. This may be because of the cumulative effect of various risk factors in women's teeth during years. The results highlight the importance of interventional programs about oral hygiene habits for older pregnant women.<sup>33,34</sup>

Our study, similar to other studies<sup>23,24,28,35</sup> showed a significant association between the women's DMFT index and their oral hygiene habits such as frequency of tooth brushing and the use of other home preventive measures. Because preventive measures lower the environmental opportunities of microbial growth in the mouth, taking such measures leads to fewer dental caries. The high prevalence of dental caries in pregnant women highlights the importance of holding interventional programs to improve the women's oral hygiene habits. Pregnant women should be educated on the importance of oral hygiene and proper techniques of preventive measures.

In our study, univariate analysis showed higher scores of DMFT index in the pregnant women with more previous pregnancies. Another Iranian study<sup>20</sup> and the studies conducted in Hungary<sup>36</sup> and the US<sup>37</sup> also showed similar findings. The mentioned studies considered pregnancy as a risk factor for women's tooth decay.<sup>37</sup> Although pregnancy does not have any direct effect on the dental caries,<sup>8,20,24</sup> the high prevalence of dental caries in pregnant women may be because of the changes in the saliva composition, repeated gastric reflux, and vomiting.<sup>8</sup> However, in our study, multivariate analysis could not confirm the association.

In the current study, univariate analysis also

showed a significant relationship between the occupation of the women's husband, a good determinant of socioeconomic status of family, and the women's DMFT index. Low socioeconomic status was reported as a risk factor for pregnant women's dental caries in other studies, as well.<sup>12,20,23</sup> The finding might be because of more pregnancies, poor dietary habits, and oral hygiene in the women of low socioeconomic families. Thus, after controlling the confounding factors, using multivariate analysis, there was not a significant relationship between the women's DMFT index and determinants of socioeconomic status.

This study had some limitations. First of all, it was a cross-sectional study and all limitations of this type of study are possibly present. Furthermore, because some pregnant women in Shiraz attended private health centers for routine obstetric examinations, our selected participants attending governmental health centers in Shiraz might not be a true representative of the general population. Also, an important risk factor of dental caries in pregnancy, excess usage of carbohydrates, was not evaluated in this study. For better evaluation of the risk factors of dental caries in pregnant women, a prospective cohort study in all pregnant women is recommended.

### Conclusion

We found unacceptably poor oral hygiene and high dental caries in the studied pregnant women. This may show the

inadequacy of the current programs for prevention of pregnant women's dental caries. To establish new interventional programs, authorities should consider the pregnant women as a target group for oral health promotion programs and oral health services should be provided for them with a more accessible and affordable manner. Women in childbearing age, especially pregnant women and those who intend to be pregnant, should be encouraged to have regular dental visits. Furthermore, oral health education programs are necessary for these women. They should be educated on the importance of oral hygiene in pregnancy and the proper techniques of home preventive measures such as tooth brushing and mouth washing. We recommend the educational programs to be held especially for older pregnant women and those who use fewer home preventive measures.

### Conflict of Interests

Authors have no conflict of interest.

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