Elsevier Editorial System(tm) for American Journal of Orthodontics & Dentofacial Orthopedics
Manuscript Draft

Manuscript Number:

Title: Study Investigating the Pain Experience with Round and Rectangular Cross-Sectional Heat-Activated Nickel-Titanium Initial Archwires

Article Type: Original Article

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Abstract: Introduction: Pain control has always been of great importance for orthodontists. I-Arch (SIA ORTHODONTICS, Rome, Italy), inspired by the historical Ribbon Arch technique, is one of the brands of new thermoelastic archwires that promises torque control and simultaneously offer light leveling forces due to its special dimension (0.016"x0.014"). Per our literature review, no former study compares rectangular NiTi Ribbon arch and round heat-activated NiTi wires in terms of pain perception. The initial hypothesis was that rectangular heat-activated NiTi(HANT) wires cause more pain/discomfort compared with round heat-activated NiTi wires.
Material and methods: 21 patients with similar amount of crowding were randomly divided into two groups. The treatment of the first group was initiated with 0.016" round HANT wires, and 0.016"x0.014" rectangular levelling archwires were used for the second group. Subjects were given the "Horizontal Visual Analogue Scale (VAS)" to fill out during the first 10 days following each visit for the first three months (VAS1, VAS2, VAS3). Pain sensations were recorded four times a day.
Results: Statistically significant difference was found in pain experience for VAS1 and VAS2 between the groups. The mean VAS1 score in Group B indicates higher pain than the mean VAS1 score in Group A. Similarly, the mean VAS2 score in Group B was found to be higher than that of Group A. There was no significant correlation between gender and VAS scores for both groups.
Conclusion: The initial hypothesis has been rejected. The rectangular 0.016"x0.014" HANT wires cause less pain compared with 0.016" round HANT wires.

COVER LETTER FOR SUBMISSION OF MANUSCRIPT

To American Journal of Orthodontics&Dentofacial Orthopedics

Dear Editor-in-Chief,

I am enclosing herewith a manuscript entitled "Study Investigating the Pain Experience with Round and Rectangular Cross-Sectional Heat-Activated Nickel-Titanium Initial Archwires" for publication in American Journal of Orthodontics&Dentofacial Orthopedics for possible evaluation. With the submission of this manuscript I would like to undertake that the contents of this manuscript have not been copyrighted or published previously, the contents of this manuscript are not now under consideration for publication elsewhere and I have no financial interests.

I look forward to hearing from you at your earliest convenience.

Sincerely yours, Dr. Berza SEN YILMAZ.

Study Investigating the Pain Experience with Round and Rectangular Cross-Sectional Heat-Activated Nickel-Titanium Initial Archwires

Type of manuscript: Original article.

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Highlights

- I-Arch *is* a new rectangular thermoelastic levelling archwire.
- The Ribbon Arch technique inspires the I-Arch system.
- The I-Arch system promises torque control from the leveling stage.
- Pain perception with 0.016” and 0.016”x0.014” archwires has been investigated.
- 0.016”x0.014” HANT wires cause less pain compared with 0.016” round HANT wires.

Study Investigating the Pain Experience with Round and Rectangular Cross-Sectional Heat-Activated Nickel-Titanium Initial Archwires

ABSTRACT

Introduction: Pain control has always been of great importance for orthodontists. I-Arch (*SIA ORTHODONTICS®, Rome, Italy)*, inspired by the historical Ribbon Arch technique, *is* one of the brands of new thermoelastic archwires that promises torque control and simultaneously offer light leveling forces due to its special dimension (0.016”x0.014”). Per our literature review, no former study compares rectangular NiTi Ribbon arch and round heat-activated NiTi wires in terms of pain perception. The initial hypothesis was that rectangular heat-activated NiTi(HANT) wires cause more pain/discomfort compared with round heat-activated NiTi wires.

Material and methods: 21 patients with similar amount of crowding were randomly divided into two groups. The treatment of the first group was initiated with 0.016” round HANT wires, and 0.016”x0.014” rectangular levelling archwires were used for the second group. Subjects were given the “Horizontal Visual Analogue Scale (VAS)” to fill out during the first 10 days following each visit for the first three months (VAS1, VAS2, VAS3). Pain sensations were recorded four times a day.

Results: Statistically significant difference was found in pain experience for VAS1 and VAS2 between the groups. The mean VAS1 score in Group B indicates higher pain than the mean VAS1 score in Group A. Similarly, the mean VAS2 score in Group B was found to be higher than that of Group A. There was no significant correlation between gender and VAS scores for both groups.

Conclusion: The initial hypothesis has been rejected. The rectangular 0.016”x0.014” HANT wires cause less pain compared with 0.016” round HANT wires.

Introduction

The percentage of patients reporting discomfort and/or pain during the initial stages of orthodontic treatment ranges from 80% to 91% (1-3). It has been reported that about 8% up to 30% of patients discontinue orthodontic treatment because of the pain perceived in the beginning of their treatment (1, 4). Moreover, this negative experience may affect patient compliance, which is a crucial factor for orthodontic treatment success (5, 6). Thus, pain control during orthodontic treatment has always been of great importance for clinicians.

Light forces are recommended throughout this type of treatment; however, different kinds of appliances deliver forces and moments that are not usually quantitatively predictable. These forces lead to changes in the periodontal ligament and stimulate the acute inflammatory process, which results in a subjective pain response. In other words, orthodontic treatment causes an inflammatory response in the periodontium and dental pulp, which stimulates the release of different biochemical mediators (1, 7). More precisely, orthodontic pain is correlated with variation in blood perfusion and the rise of substance P, histamine, serotonin, enkephalin, dopamine, glycine, glutamate gamma-amino butyric acid, prostaglandin E (PGE), cytokines, and leukotriens (8-12). Many factors other than biological ones have been assumed to be related to the perception of pain during orthodontic treatment, such as the intensity and duration of the applied forces, age and gender, degree of the initial crowding, structure of the wires, and patient’s psychology (13).

The key component in minimizing discomfort and pain during the initial stage of treatment is appropriate archwire selection (14). It is recommended to administer light forces in the initial stage of treatment to decrease the amount of discomfort and pain experienced (15). Additionally, most authors have recommended intermittent forces to achieve the desired tooth movement without any damage to the tooth and its surrounding tissues (16, 17). Considering these facts, we can conclude that an ideal archwire should be able to move teeth with optimum light forces, minimizing patient discomfort, tissue hyalinization, and root resorption.

Progress in wire technology has resulted in the preponderant clinical usage of nickel titanium (NiTi). In addition to NiTi, other alloys have been developed with shape-memory characteristics, e.g., superelastic or thermoelastic archwires. The superelasticity and shape memory result from changes that occur in the atomic lattice of the alloy from the austenitic phase to the martensitic phase, which are induced by stress (18).

Thermoelastic archwires are martensitic-active alloys in which the transition between the martensite and austenite phases occurs in the range of the mouth temperature (19). At predetermined temperature ranges, the thermoelastic wires are active, and below the transition temperature, the archwires are soft and inactive (20).

More effective thermoelastic orthodontic archwires are manufactured by setting the memory properties at human body temperature ranges and by making the force plateau compatible with optimal biologic tooth movement (18, 21). At similar deflections, thermoelastic archwires deliver a lower level of force and longer force plateaus than superelastic archwires do (22). As a consequence, it is assumed that thermoelastic archwires could cause less initial orthodontic pain compared with conventional superelastic archwires.

I-Arch (*SIA ORTHODONTICS®, Rome, Italy)* is one of the brands of new thermoelastic archwires that promises the gentle forces required especially in the initial phase of treatment. The historical Ribbon Arch technique inspired the system. The Ribbon Arch technique was very popular in the decade between its publication in 1916 and the introduction of the Edgewise appliance in 1927 (23). It eventually lost its appeal, however, its advantages provided the mechanical basis for Atkinson’s Universal and Begg Lightwire appliances (23, 24). The slot of the Ribbon Arch bracket opened vertically, with its largest dimension in that direction, and the arches had the greatest flexibility in the horizontal plane. This provided clinicians with a gentle wire that provided the degree of control once found only in full-size edgewise archwires. The I-Arch is said to furnish control and simultaneously offer light leveling forces, which patients could easily tolerate due to its special rectangular shape and dimensions. The first wire of the system is a rectangular (0.016”x0.014”) thermoelastic NiTi wire allowing immediate torque delivery. The three-dimensional control of the tooth movement early in treatment provides axial control and prevents round tripping, through alignment and leveling with round wires. The wire system claims to reduce the total treatment time by enabling the clinician to switch to thicker wires more quickly, causing no additional patient discomfort and offering torque control with the first leveling wires. The I-Arch approach has an archwire sequence of: 0.016”x0.014” NiTi Thermal activated, 0.018”x0.014” NiTi Superelastic, and finally, 0.016”x0.016” Beta Titanium wires. Besides the I-Arch, only one thermal NiTi Ribbon arch is available on the market with a 0.018”x 0.014” dimension, produced by ClassOne Orthodontics (Lubbock, TX, USA). Another alternative includes the 0.018”x0.014” and 0.02175”x0.016” superelastic NiTi and stainless steel arches provided by Highland Metal (San Jose, CA, USA). The I-Arch first wire is unique in shape and dimension.

According to our literature review, no former study compares the rectangular NiTi Ribbon arch and round heat-activated NiTi wires in terms of pain perception. We aimed to compare the effects of round and rectangular heat-activated NiTi wires on orthodontic pain over a period of three months. Our hypothesis was that rectangular heat-activated NiTi wires cause more pain/discomfort compared with round heat-activated NiTi wires.

Materials and Methods

This study was approved and followed by the Ethical Committee of [redacted]

The objective of this study was explained individually, and written approval was obtained. Minor patients were included in this study with the approval of their parents.

Inclusion criteria for patients' selection

- Volunteer patients with permanent dentition
- Treatment plan requiring no additional appliances (e.g., transpalatal arch, lingual arch, expansion screw, etc.)
- Patients having no missing tooth and no indication of extraction
- No tooth-size anomalies
- Moderate crowding (4-5mm)
- No systemic condition that could contraindicate orthodontic treatment

Exclusion criteria for patients' selection

- Patient with missing teeth and indication of tooth extraction
- Slight or severe crowding (less than 3mm, more than 6mm)
- The presence of systemic conditions contraindicating orthodontic treatment
- Presence of impacted tooth
- Patients with mixed dentition

Exclusion criteria from the study

- Patients missing their appointments

- Patients having many broken brackets during treatment
- Patients from whom pain perception data could not be obtained

The study comprised 21 patients, who were randomly divided into two groups. Upper and lower brackets were bonded at the same appointment (*SIA ORTHODONTICS®, Rome, Italy*, Roth prescription, 0.018-inch slot, Hexagon line). The treatment of the first group was initiated with 0.016-inch round heat-activated wires (*SIA ORTHODONTICS®, Rome, Italy*, ORTHO II shape), and 0.016” x 0.014” rectangular wires were used for the second group (*SIA ORTHODONTICS®, Rome, Italy*, ORTHO II shape). To standardize the ligation method, elastomeric modules were used with complete engagement.

The pain level was assessed using a pain questionnaire with “Horizontal Visual Analogue Scale (VAS).”

Subjects were given the VAS to fill out during the first 10 days following each visit for the first three months (VAS1, VAS2, VAS3). Pain sensations were recorded four times a day: at 8:00 am, 12:00 am, 4:00 pm, and 8:00 pm. The patients were given oral instructions about marking the points showing their levels of pain. The horizontal VAS was divided into a 10-cm length. The number “0” indicated no pain, and “10” indicated unendurable pain. Nonprescription analgesics were not prohibited during the treatment. However, the patients were asked to precisely indicate the usage of pain killers in the questionnaire.

Statistical analysis

Data were analyzed with IBM SPSS V21. The normality was tested with the Shapiro-Wilk method. Repeated measures variance analysis (r-ANOVA) and an independent samples t-test were used for the analysis of the normally distributed data. Non-normally distributed data was evaluated with the Mann-Whitney U test. Comparisons between categorical data were carried out by means of the chi-square test. The results are presented as arithmetic mean $\pm$ standard deviation, median (min-max), frequency, and percentage. The level of statistical significance was determined to be $p<.05$.

Results

The 21 subjects (7 males, 14 females) agreed to participate in the study by completing their pain diaries for the 10 days following the first three appointments. One subject from Group B failed to return the pain questionnaire and was excluded from the study. Group B (*round wire*) comprised three males and seven females with a mean age of 23.8 years (± 6.1). Group A (*rectangular wire)* consisted of four males and six females with a mean age of 17.4 years (± 3.2). The mean age of Group B was found to be higher than that of Group A (Table I)

The two groups were comparable in terms of crowding. The arch discrepancies in Group B ranged from -8 to 0 (min – max) with a median of -5 for the mandible, and -5 to -1 with a median of -3.5 for the maxilla. The arch discrepancies for Group A ranged from -7 to 8 (min – max) with a median of -3.3 for the mandible, and -10 to 2 with a median of -2.6 for the maxilla. The gender distribution of the two groups was similar (40% male in Group A versus 33.3% in Group B) (Table I)

A statistically significant difference was found in pain experience for VAS1 and VAS2 between the groups. The mean VAS1 score in Group B (5.59) indicates higher pain than the mean VAS1 score in Group A (2.01). Similarly, the mean VAS2 score in Group B (3.02) was found to be higher than that of Group A (1.23) (Table II).

Repeated measure analysis showed a statistically significant difference between VAS1 and VAS2, and VAS1 and VAS3. Whereas, no significant difference was found between VAS2 and VAS3.

There was no significant correlation between gender and VAS scores for both groups.

The difference between the first and the third mean VAS scores of the patients was analyzed between the groups. A higher mean difference indicates a greater decrease of pain for the related group. The differences of the VAS scores present variety in groups A and B ($p<0,001$). A greater decrease was found in Group B (Table III).

Discussion

Nitinol, the first nickel-titanium archwire, was introduced in 1971 by Unitek/3M (25). The first-generation nickel-titanium was followed by the second-generation superelastic Chinese NiTi marketed as “NiTi” by Ormco/ Sybron; the third-generation Japanese NiTi marketed as “Sentalloy” by GAC International; and finally, the fourth-generation one in the early 1990s, thermally activated nickel-titanium wires (26).

In the literature, many studies investigate the mechanical characteristics of different types of Niti wires, and heat-activated versions appear to generate lighter forces over greater deflection plateaus (27, 28). The thermally activated NiTi, also called Copper-NiTi, wires are resistant to permanent deformation and exhibit excellent spring-back characteristics (29).

The pain perceived during orthodontic treatment develops because of ischemic areas in the PDL (30, 31). It is stated that the heavier a force is, the larger the ischemic area, thus intensifying the pain sensation (30). Thermoelastic archwires seem to exhibit reduced levels of force; thus, it is hypothesized and reported that they could cause less initial orthodontic pain compared with conventional superelastic archwires (22). However, besides the numerous research studies that focus on mechanical properties, only a few research studies focus on the pain perception with thermal NiTi wires.

In a randomized controlled clinical trial by Jones and Chan, the nature, prevalence, intensity, and duration of pain related to the use of a superelastic archwire and a multi-stranded steel archwire were compared, and it was found that the prevalence, intensity, and duration of pain were similar after the insertion of the two types of wire. They also reported that the pain response was not related to the dental arch, crowding, sex, or social class (32). On the other hand, in a study by Cioffi et al., the pain perception was compared following the first archwire placement in patients with heat-activated thermal NiTi and superelastic NiTi wires. It is reported that patients starting with heat-activated thermal NiTi archwires had significantly lower VAS scores than did subjects with superelastic archwires (18). Recently, Abdelrahman et al. investigated the three different NiTi wires (*conventional, superelastic, and thermoelastic)* in terms of pain intensity during the initial aligning stage of orthodontic fixed-appliance therapy. They found no significant difference among the three types of NiTi archwires (33).

In the present study, VAS was used to evaluate the pain intensity because it is a precise, convenient, and reliable method (34, 35). VAS is the most commonly used method for the evaluation of pain during orthodontic treatment (32, 36). All of the patients followed the instructions of clinicians and completed the pain diaries expect for one patient, who was excluded from the study. The VAS paper used in our study was similar to the one that Cioffi et al. used in a former study (18).

In our study, to standardize the archwire alloy and to avoid the differences that might occur due to the choice of material, we preferred to compare two heat-activated thermal NiTi wires with those with different cross-sectional shapes. Although some studies compare differences in the pain sensation between heat-activated thermal NiTi and other wires, no study investigates the different cross-sectional shapes of heat-activated NiTi wires. Additionally, no former study investigates the Ribbon Arch–inspired I-Arch (*SIA ORTHODONTICS®, Rome, Italy)* system's wires.

The analysis of the VAS scores revealed that a significant difference exists in the pain experienced between the groups; Group B (*round* heat-activated thermal NiTi*)* presented higher pain scores for VAS1 and VAS2 compared to Group A (*rectangular* heat-activated thermal NiTi*).* As the amount of crowding was similar between the groups and the bracket system was standardized, this difference might be explained by the fact that the cross-sectional shape of the archwires is different. The 0.016"x0.014" arch does not fully fill the slot, and the thin 0.014" side is facing the slot's upper and lower walls, whereas the thicker 0.016" side is facing the slot's base. On the other hand, the round arch with a 0.016" diameter exerts the same force toward the upper, lower, and base-side slot's walls (Figure 1).

We found no significant correlation between gender and VAS scores for both groups. These findings are in harmony with former studies that similarly reported that pain response was not related to sex (14, 32). On the other hand, previous studies have reported that female patients chose significantly higher pain ratings (37, 38). The relatively small sample size of the groups could have led to insignificant differences related to gender.

It has been reported that age has an effect on orthodontic pain (39). Per our findings, more pain was found in Group B, which could be explained with the higher age mean compared to Group A (17.4 ± 3.2 versus 23.8 ± 6.1).

The difference between the first and the third mean VAS scores of the patients were analyzed between the groups. The analysis showed a greater decrease in pain in Group B. This finding might be related to the fact that the mean VAS score is lower in Group B. In the present study, the distribution of the pain score indicated a significant difference between the groups between the VAS1-VAS2 and VAS1-VAS3 experienced. This result indicates that pain experience decreased with time, which could be logically understood with the achievement of levelling and alignment.

Participants were not restricted to take any over-the-counter analgesics for pain control. They were instructed to complete the VAS scale before taking the medication to minimize the effect of the medication. It is possible that analgesic consumption could have led to bias in pain assessment. However, it is unethical to ask the participant not to take medication or to control the timing or frequency of analgesic consumption. In our study, two different patients reported using a single analgesic pill each for menstrual pain control.

Conclusion

In conclusion, the initial hypothesis has been rejected. The present study comparing the effects of round and rectangular heat-activated NiTi wires on orthodontic pain over a period of three months demonstrated that 0.016”x0.014” heat-activated NiTi wires cause less pain compared with 0.016” round heat-activated NiTi wires. Therefore the 0.016”x0.014” rectangular heat-activated NiTi archwire can be used during the initial stage of the treatment. However, the I-Arch effectiveness on controlling torque from the beginning, and its benefits on shortening the treatment time remain be investigated in a further study.

Acknowledgement: I would like to express my very great appreciation to my PHD student [redacted] for her valuable efforts during the development of this research work. Her willingness to give her time so generously has been very much appreciated.

Tables and Figures

Table I: Age, gender distribution and crowding amount for Groups A and B

Table II: Mean VAS scores for Groups A and B.

Table III: The difference between the first and the third mean VAS scores.

Figure 1: Schematic representation of the two-different cross-sectional archwires in the bracket. a) 0.016” heat-activated NiTi b) 0.016”x0.014” heat-activated NiTi.

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Figure 1
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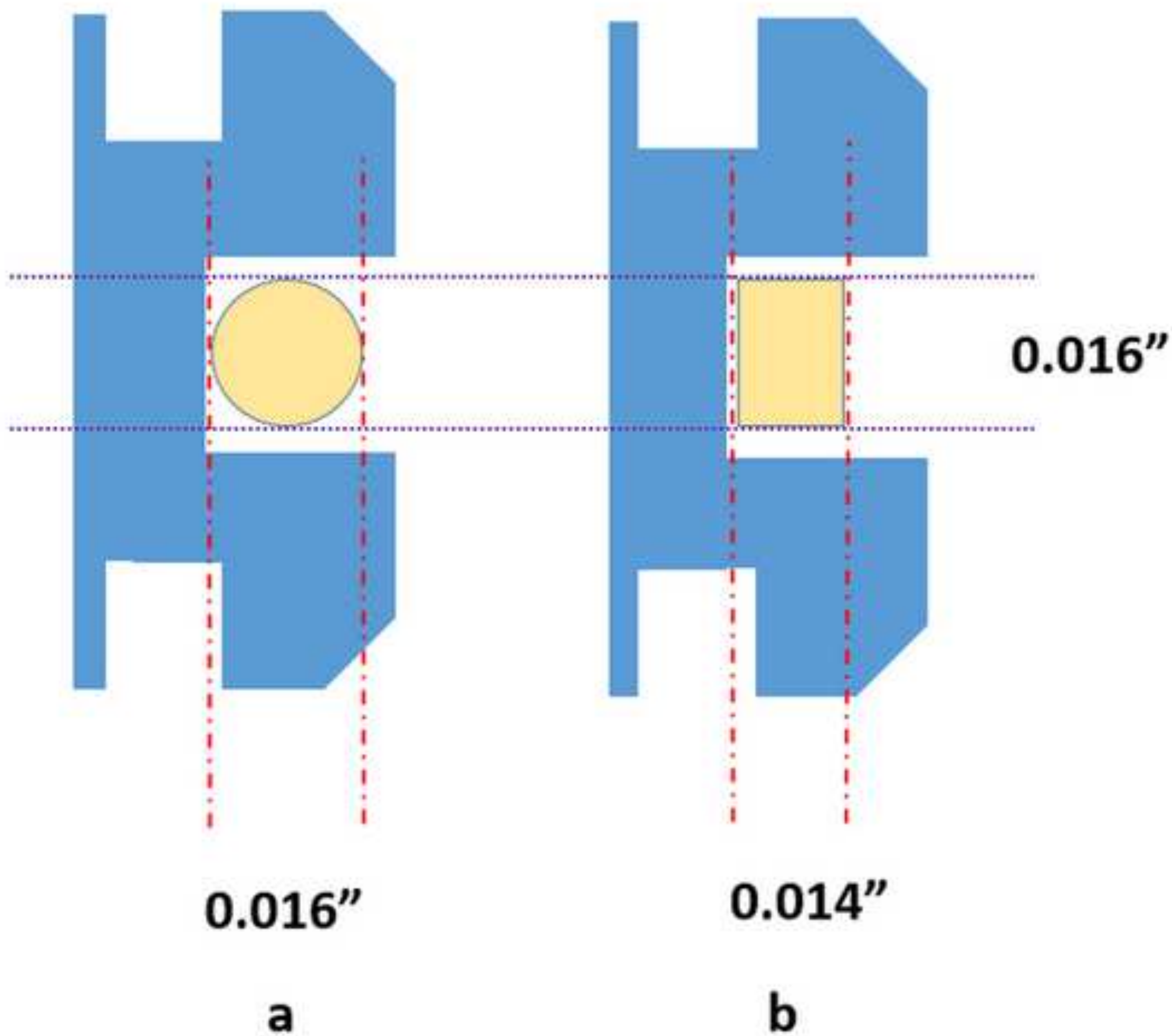

Table I

Table I: Age, gender distribution and crowding amount for Groups A and B.

	A	B	p value
Age	17,4 ± 3,2	23,8 ± 6,1	**0,015**
Gender (male) n (%)	4 (40,0)	3 (33,3)	0,764
Lower crowding in mm [*median* (min-max)]	-3,3 (-7 – 8)	-5,5 (-8 – 0)	0,086
Upper crowding in mm [*median* (min-max)]	-2,6 (-10 – 2)	-3,5 (-5 - -1)	0,253

Table II

Table II: Mean VAS scores for Groups A and B.

Group		Mean	Std. Deviation	p value
VAS1	B	5,59	2,051	
	A	2,01	1,481	**0,001**
VAS2	B	3,02	1,725	
	A	1,23	0,944	**0,020**
VAS3	B	0,96	0,599	
	A	1,42	1,812	0,538

Table III

Table III: The difference between the first and the third mean VAS scores.

	Mean	Std. Deviation	p değeri
B	4,2	2,0	<0,001
A	0,5	0,9	

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