Original Article

CHANGES IN GINGIVAL HEALTH WITH DIFFERENT ORAL HYGIENE PROTOCOLS IN ADULT PATIENTS WITH FIXED ORTHODONTIC APPLIANCE: A RANDOMIZED CLINICAL TRIAL

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Abstract

Aim: This study aimed to evaluate the impact of three distinct oral hygiene protocols on the gingival health of adult patients undergoing treatment with fixed orthodontic appliances

Materials and methods: A total of 27 participants who met the eligibility requirements were randomly assigned to three distinct groups, i.e., Group I (conventional soft toothbrushing using fluoridated toothpaste), Group II (Conventional soft toothbrushing in addition to interdental brushes) and Group III (Conventional soft toothbrushing in addition to interdental brushes and chlorhexidine mouthwash). Gingival index (GI) was determined by gingival color and bleeding on probing with score 0-3. Score 0, when gingiva has natural coral pink color, 1 indicates mild inflammation, 2 indicates moderate inflammation and 3 indicates severe inflammation. The baseline data of the gingival index were recorded on the day of bonding (T0) and one month later (T1). Comparison of gingival index percentage change between the three groups were calculated.

Results: T1 *vs.* T0: The three various oral hygiene protocols exhibited no significant changes, either within the groups or across different groups.

Conclusion: There is no privilege for using either interdental brushes only or combined with chlorhexidine mouthwash over the conventional manual toothbrushing regarding the gingival health in patients with fixed orthodontic appliance.

Keywords: Gingiva, Orthodontic, Oral hygiene

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Introduction

Over many years, the risk of developing dental caries, white spot lesions, periodontitis and gingivitis as result of fixed orthodontic treatment, has increased. A microbial balance among more than 300 different bacterial species exist in the oral microbiota. This balance might be interrupted by the introduction of fixed orthodontic appliances inside the oral cavity (Marcotte and Lavoie, 1998). Chemical alteration of oral environment starts by pre-bonding enamel surface etching treatment that provides favorable environment for adhesion and proliferation of number of different microbial species (Mulimani and Popowics, 2022). Fixed orthodontic treatment is associated with several prevalent clinical side effects, including: (1) enamel demineralization caused by the accumulation of bacterial plaque. (2) The development of caries in the vicinity of bonded fixed braces, which manifests as white spot lesions. (3) Gingival inflammation, which affects approximately 90% of young adult patients (Kim et al., 2012). It was found that oral micribiome showed many complex changes during first 2-6 months of fixed orthodontic treatment (Reichardt et al., 2019, Singla et al., 2022). Accordingly, predetermination of high-risk orthodontic patients should be done early since the first week (Papageorgiou et al., 2018).

The configuration of fixed orthodontic appliances including fixed brackets, wires, ligatures, elastomeric chains and other attachments provided shelters for cariogenic bacteria to colonize and settle with other microbial species forming thick adhesive biofilm around brackets. These thicker, multi-bacterial stranded, long-standing bacterial biofilms were more stable and harder to be removed by routine oral hygiene protocols (Reichardt et al., 2019, Ristic et al., 2007, Alexander, 1991). These bacterial deposits resulted in changes represented clinically by increased plaque, gingival indices and tendency for bleeding on probing (Papageorgiou et al., 2018, Reichardt et al., 2019, Ristic et al., 2007, Singla et al., 2022). However, some studies reported that these periodontal indices were raised temporarily after fixed orthodontic appliance bonding and returned back to normal levels or decreased after few months of treatment due to reestablishment of host-microorganism balance (Ristic et al., 2007, Singla et al., 2022). On the other hand, some other studies reported that changes in the bacterial counts appeared only after 6 months of orthodontic appliances insertion and that only physiologic changes followed the start of orthodontic treatment as increased salivary flow rate, buffer capacity and salivary pH, to maintain oral health and provide anti-cariogenic oral environment. This was justified by the increased patients' compliance and motivation that resulted in good oral hygiene maintenance during the first 6 months of treatment. (Singla et al., 2022, Guo et al., 2017)

The protocols for maintaining oral hygiene in orthodontic patients encompass the use of standard tooth brushing with fluoridated toothpaste, which can be enhanced by the incorporation of interdental brushes and mouth rinses. Quaranta et al. (2018),Rao et al. (2018) found that the combined use of interdental brushing with conventional manual toothbrushing provided better plaque control and gingival condition compared to using manual toothbrushes alone. Moreover, chlorhexidine mouthwash is the most potent chemical agent that is why it is the most commonly used antiseptic mouthwash.

Mahjoub et al. (2023) in their cross sectional study about the oral hygiene practice in orthodontic patients found that the majority of patients (>90%) brushed their teeth twice per day and about half of them used soft toothbrushes. Also, the majority of patients were using interdental brushes (88%) and only 47% used mouthwash and 20% used dental floss. In contrast to these findings, other studies (Aljohani and Alsaggaf, 2020, Baheti and Toshniwal, 2015, Han et al., 2016) reported lesser percentages for patients using interdental brushes (23-68%) and mouthwashes (25-30%). The contradictory results regarding the adherence to oral hygiene protocols among orthodontic patients remain inconclusive, and to date, there is no established evidence-based oral hygiene protocol specifically recommended for these patients.

Consequently, our study seeks to identify an effective oral hygiene protocol that preserves and ensures the integrity of patients' gingival health throughout fixed orthodontic treatment by evaluating the effectiveness of three distinct oral hygiene measures in reducing the gingival index

Materials and methods

The CONSORT 2010 (Pandis et al., 2015) (explanation and elaboration guidelines for randomized controlled trials) was followed in this clinical trial. A medical history questionnaire was taken for every patient. Gingival tissues were examined for any gingivitis, periodontitis, recession or lesions. Patients selection and examination were done according to inclusion and exclusion criteria as follow:

Inclusion Criteria:

- 1. Adult patients, both male and female, within the age range of 18 to 30 years were eligible.
- 2. Participants should demonstrate good to fair oral hygiene, characterized by healthy, non-inflamed gums and the absence of dental caries at the time of enrollment.
- 3. Complete permanent dentition was required, excluding third molars.
- 4. Mild to moderate crowding of teeth was permissible.
- Participants were required to abstain from using any mouth rinses for at least one month prior to the study's initiation and should not exhibit any sensitivity to mouthwash products.

Exclusion Criteria:

- 1. The existence of any systemic or infectious diseases.
- 2. A record of antibiotic or hormonal treatment administered within the six months preceding orthodontic intervention.
- 3. History of smoking.
- 4. A record of professional dental scaling performed within three days before gingival assessment.
- The presence of significant untreated dental conditions, including untreated carious lesions at the baseline assessment.

Trial design:

The current study is a randomized, parallel, single-blinded, comparative design with allocation ratio of 1:1:1.

ClinicalTrials.gov registration number: NCT05016713

Study Settings:

- Source of patients: outpatients of Orthodontic department clinic, Faculty of Dentistry, Cairo University, Cairo, Egypt.
- Time: 2021 the study continued for 2 years. All patients had their orthodontic treatment completed in clinic of Orthodontic department, Faculty of Dentistry, Cairo University.

Intervention:

A. Patient Screening and Preparation:

Patients were examined and their chief complain were taken in consideration for setting treatment objectives. A meticulously structured treatment plan was recorded in the diagnostic sheets. Thorough documentation of the patients was conducted, encompassing full intra-oral photographs, study models for both the maxilla and mandible, and panoramic and lateral cephalometric radiographs. A scaling session was done 2 weeks before bonding. The patients were instructed for oral hygiene measures and not to use any kind of mouthwash for 1 month pre-bonding.

B. Bonding:

Brackets were bonded indirectly for upper and lower arches using bracket prescription American Orthodontics MBT 0.022-inch and bondable tubes on molars **Figure (1)**. 37% phosphoric acid etch (Meta-etch) was employed for the treatment of the enamel surface prior to bonding, while Grenglo composite served as the adhesive for the attachment of brackets. Standardized American orthodontics o-ties were utilized for all participants. During the initial month of treatment, a 0.014-inch NiTi wire was used for alignment and initial leveling. The 3 followed oral hygiene protocols:

they were asked to use them for at least 5 times



Figure (1): Indirect bonding technique

After proper randomization process, each patient was assigned to one of the following groups:

A. Group I (Fluoride toothpaste with conventional toothbrush)

Conventional soft toothbrushes (Oral-B soft) were used with fluoride containing toothpaste (Signal Toothpaste) only. Patients were advised to utilize the Modified Bass technique for brushing their teeth, where toothbrush bristles were positioned at an angle 45° to the long axes of the teeth cervically then occlusally with slight rolling in back and forth direction **Figure (2).** Brushing was to be done for a minimum of 3 minutes, 5 times daily. All patients had this brushing technique well explained and elaborated both verbally and visually.

B. Group II (Conventional manual toothbrushing in addition to interdental brushes)

Interdental brushes (Dr. Smith shape 4M, tapered 1.2mm) were used with conventional soft toothbrushes with the fluoride based toothpaste (Signal Toothpaste). Verbal and visual demonstration about the technique of using interdental brushes were done for patients and

per day in back and forth motion over the fixed brackets. Patients were instructed to wash the brushes after their use with water and leave them to dry in clean place.

C. Group III (Conventional manual toothbrushing in addition to interdental brushes and chlorhexidine mouthwash)

Besides using conventional toothbrush interdental toothbrush. chlorhexidine mouthwash was added to the oral hygiene protocol in this group. Following the instructions provided by the manufacturer, patients were advised to use the mouthwash subsequent to brushing their teeth. The protocol specified the application of 5 mL of 0.125% CHX for 60 seconds during both morning and evening routines, with a stipulation that no food or beverages be ingested for a minimum of 30 minutes after using the mouthwash. Patients were supplied with the mouthwash in pre-graded containers and were instructed to return these containers, to evaluate their adherence based on the volume of liquid remaining. To limit the CHX side effects, patients were asked to use the mouthwash on the second and fourth week only. Moreover, they were instructed to stop using the mouthwash immediately if they showed any signs of hypersensitivity.







Figure (2): Modified Bass brushing technique

C. Patient adherence:

The motivation of patients was driven by both chair-side motivation and active reminders. The chair-side method highlighted the adverse effects of poor oral hygiene, fostering a feeling of concern among patients regarding the importance of following the prescribed protocols. Active reminder motivation by using app-based text messages that patients preferred, allowed for patients' compliance to their oral hygiene

Gingival index assessment

According to Silness and Löe (1964), gingival index (GI) was determined by gingival color and bleeding on probing with score 0-3. Score 0, when gingiva has natural coral pink color without any signs of edema or inflammation, a score of 1 signifies mild inflammation, characterized by minor alterations in gingival color accompanied by slight edema and the absence of bleeding upon probing. A score of 2 denotes moderate inflammation, where the gingiva exhibits redness, edema, and bleeding during probing. A score of 3 reflects severe inflammation, indicated by pronounced redness, significant swelling, edema, and spontaneous bleeding of the gingiva. The comparison of gingival index percentage change between the three groups were calculated as follows:

 $(T1\ score - T0\ score) / T0\ score \times 100$

Sample size:

After sample size calculation, 9 subjects were allocated in each group, resulting in a total sample size of 27 subjects in the current study.

Randomization:

The study comprised two intervention groups: one group utilized conventional manual toothbrushing in conjunction with interdental brushes, while the other group employed conventional manual toothbrushing along with

interdental brushes and chlorhexidine mouthwash. Additionally, there was comparative group that practiced conventional manual toothbrushing with fluoridated toothpaste only. All subjects consented to participate in the study. Randomization was executed with a 1:1:1 allocation ratio, utilizing computer-generated random numbers to sequence the three groups. Blinding of the outcome assessor was not feasible, as the principal operator was responsible for both prescribing the designated oral hygiene protocol and evaluating periodontal indices at T0 and T1.

Statistical analysis:

The numerical data were assessed for normality by examining the data distribution and applying normality tests, Kolmogorov-Smirnov and Shapiro-Wilk tests. The analysis revealed that the age data followed a normal (parametric) distribution, whereas the GI scores exhibited a non-normal (non-parametric) distribution. The data were expressed in terms of median, range, mean, and standard deviation (SD) values. For parametric data, a one-way ANOVA test was employed to assess the differences in mean age across the three groups. In the case of nonparametric data, the Kruskal-Wallis test, followed by Dunn's post hoc multiple comparison test, was utilized to evaluate the differences among the three groups. The Wilcoxon signed-rank test was applied to examine the changes within each group. Qualitative data were reported as frequencies and percentages. To compare gender distributions among the three groups, Fisher's Exact test was conducted. The significance threshold was established at $P \le 0.05$. Statistical analyses were carried out using IBM SPSS Statistics for Windows, Version 23.0, from IBM Corp., Armonk, NY.

Results

Only twenty-seven participants (n=27) continued the study **Figure (3)**.

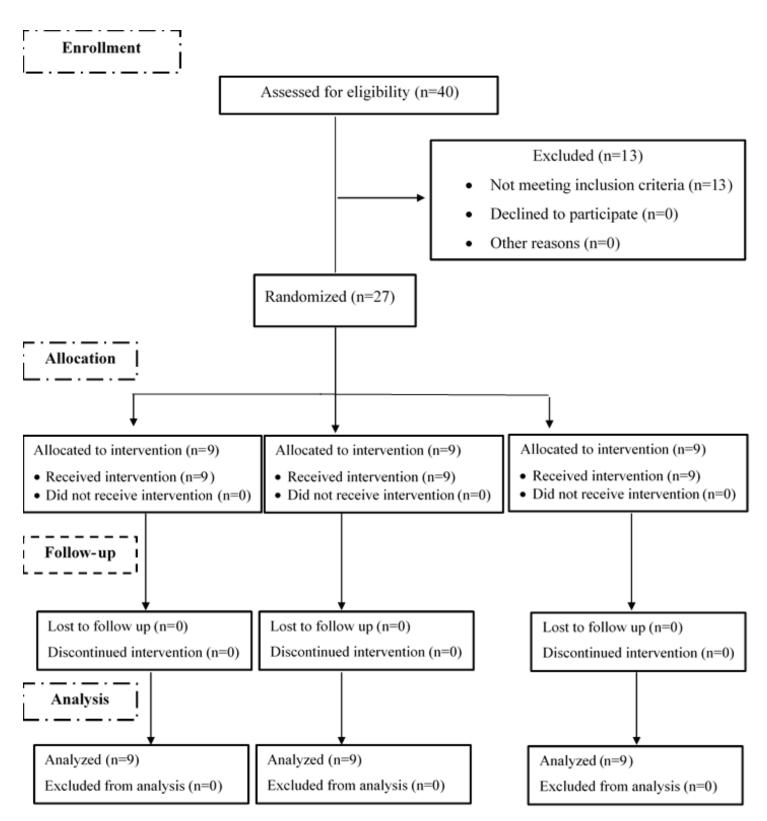


Figure (3): Patients flow chart

The analysis revealed that there was no statistically significant difference in the mean age values across the three groups. Additionally, the gender distributions among the three groups did not show any statistically significant differences. **Table (I)**.

Table (I): Descriptive statistics, percentages and results of one-way ANOVA test and Fisher's Exact test for comparison between base line characteristics in the three groups

	Group I (n = 9)	Group II (n = 9)	Group III (n = 9)	P-value
Age (Years)				
Mean (SD)	22.1 (3.7)	19.9 (2.5)	19.6 (1.1)	0.102
Gender [n (%)]				
Male	2 (22.2)	1 (11.1)	1 (11.1)	1
Female	7 (77.8)	8 (88.9)	8 (88.9)	

^{*:} Significant at $P \le 0.05$

Changes by time within each group:

As regards Group I, Group II as well as Group III; there was no statistically significant

changes in GI scores at T1 (P-value = 1, Effect size = 0), (P-value = 0.180, Effect size = 1) and (P-value = 0.157, Effect size = 1.069), respectively (**Table (II)**, **Figure (4)**).

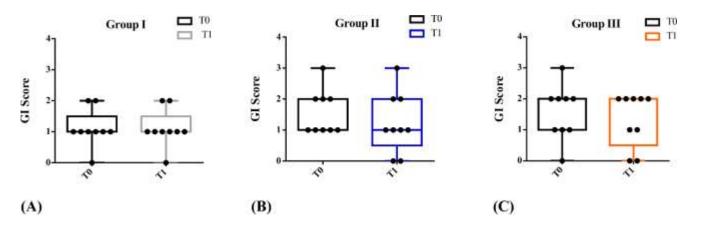


Figure (4): Box plot representing median and range values for GI scores in the three groups

Table (II): Descriptive statistics and results of Wilcoxon signed-rank test for the changes in GI scores within each group

	Group I		Group II		Group III	
Time	(n =9)		(n =9)		(n =9)	
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)
T0	1 (0-2)	1.11 (0.6)	1 (1-3)	1.56 (0.73)	2 (0-3)	1.56 (0.88)
T1	1 (0-2)	1.11 (0.6)	1 (0-3)	1.22 (0.97)	2 (0-2)	1.33 (0.87)
P-value	1		0.180		0.157	
Effect size(d)	0		1		1.069	

^{*:} Significant at $P \le 0.05$

Comparison between groups

For GI; there was no statistically significant difference between percentage changes in the three groups (P-value = 0.985, Effect size = 0.037, **Table (III)**, **Figure (5)**).

Also, Dunn's post hoc multiple comparison test showed no significant GI percentage change between any two groups **Table (IV).** This was represented clinically by lack of any significant improvements regarding gingival inflammation and bleeding on probing.

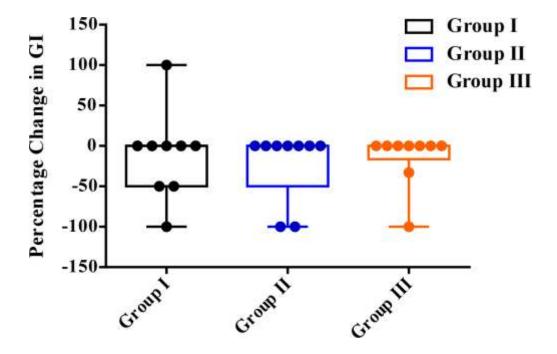


Figure (5): Box plot representing median and range values for percentage changes in GI scores in the three groups

Table (III): Descriptive statistics and results of Kruskal-Wallis test for comparison between percentage changes in GI in the three groups

	Group I		Group II		Group III			Effect
Inde	(n =9)		(n =9)		(n =9)		siz —— P-value (Ei	
X	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	. I -value	squar ed)
GI	0 (-100- 100) ^A	0 (66.1)	0 (-100- 0) ^A	-22.2 (44.1)	0 (-100- 0) ^A	-14.8 (33.8)	0.985	0.037

^{*:} Significant at $P \le 0.05$, Different superscripts in the same row indicate statistically significant difference between groups

Table (IV): Dunn's post hoc multiple comparison test for assessing the percentage changes in GI in the three groups

Dunn's multiple comparisons test	Mean rank diff.	Significant	<i>P</i> -value
Group I vs. Group II	0.1667	No	> 0.9999
Group I vs. Group III	-0.333	No	> 0.9999
Group II vs. Group III	-0.50	No	> 0.9999

Discussion

The lack of having definite and efficient oral hygiene protocol that can be followed in orthodontic patients to limit fixed appliances drawbacks is still challenging, besides having great variability in prescribed protocols by orthodontists. In a study about oral hygiene protocols done by **Mahjoub et al. (2023)**, the results were conflicting and inconclusive.

Participants were screened in accordance with the criteria established by **Ko-Adams et al.** (2020) and **Jing et al.** (2019) where male and female patients aged 18 to 30 years with complete permanent dentition were recruited, as this age group is typically more aware of following the prescribed oral hygiene routines. Exclusion criteria encompassed any factors that could potentially affect gingival health, including the use of mouthwashes within one month prior to the study. Furthermore, participants were required to exhibit good to fair oral hygiene, which was indicated by the presence of healthy, non-inflamed gingiva and the absence of carious

lesions. Exclusion criteria were the presence of any systemic or infectious disease or the presence of any carious lesion that might affect the oral microbiota. In addition to, presence of history of smoking, antibiotic or hormonal therapy within the past 6 months of recruitment, history of scaling within the past 3 days before treatment to provide enough time for biofilm development and maturation (Ko-Adams et al., 2020, Jing et al., 2019).

Based on ADA recommendations, the soft bristles toothbrushes were used as **Zanatta et al.** (2011) found that, the soft toothbrushes showed lesser risk of developing gingival abrasion than the medium toothbrushes while the medium toothbrushes removed more plaque. Moreover, **Kawsar et al.** (2018) in their study found that using soft toothbrushes compared to medium toothbrushes in orthodontic patients resulted in significant reduced gingival bleeding index and accrodingly they recommeded to use soft toothbrushes in orthodontic patients.

Based on Worthington et al. (2019) findings, using interdental brushes had significant reduced orthodontic patients' gingival indices and allowed for better oral hygiene.

Moreover, the effectivness of added use of CHX mouthwashes and interdental brushes in reducing the gingival index in fixed orthodontic patients were evaluated. The concentration 0.125% CHX mouthwash was used instead of 0.2% due to the commercial availability of only 0.125% concentration in the Egyptian market and as studies done by Hussain et al. (2023), Karamani et al. (2022), Zanela et al. (2002) found that both CHX concentrations (0.125% and 0.2%) had the same effect in reducing gingival inflammation, limiting amount of plaque accumulation and reducing pocket depths. Moreover, studies done by Dehghani et al. (2015) and Al-Sayagh et al. (2013) showed that using 0.12% chlorhexidine mouthwash had lesser side-effects and lesser teeth staining than 0.2% CHX. All participants were informed to alternatively use the CHX mouthwash on the second and fourth week to minimize the undesired drawbacks of CHX continual use.

To promote patient adherence effectively, chair-side motivation must concentrate on the detrimental impacts of insufficient oral hygiene, creating a feeling of jeopardy for patients who do not follow the prescribed instructions.

Changes in the gingival index in the conventional manual toothbrushes group (Group I) were insignificant before bonding and one month later with insignificant percentage changes. These findings were different than those found by **Kumar et al. (2023)** who found that the manual toothbrushing only group showed increased gingival index.

Changes in interdental brushing group (Group II) were also insignificant at T0 and T1. The percentage changes were insignificant when compared with the two other groups. These findings were in accordance with those findings stated by Worthington et al. (2019), Quaranta et al. (2018), Graziani et al. (2018), Rao et al. (2018), Bock et al. (2010), Slot et al. (2008) in their Cochrane review which stated that the additional use of interdental brushes provided no added significant effect on reducing gingivitis compared to using regular toothbrushes alone. On

the other hand, our findings were in disagreement with those found by Kotsakis et al. (2018), Bock et al. (2010) who stated that there were significant large reductions in gingival index on using interdental brushes. These reported findings about gingival index changes diminishes the effectiveness of interdental brushes regular use in orthodontic patients, the thing that were questionable by Goh (2007) in their Cochrane systematic review who stated that the amount of toothbrushes' bristles wear had increased significantly when used by orthodontic patients which accordingly increased the economic burden of oral hygiene products for orthodontic patients by at least three folds.

In CHX group (Group III), there were no significant changes neither within the same group nor between the three groups. These findings were in accordance with those stated by **Hussain et al.** (2023), **Ren et al.** (2023), **Karamani et al.** (2022), **Shilpa et al.** (2019) where they all came to conclusion that chlorhexidine mouthwashes had insignificant effect on gingival index.

Conclusion

Regarding changes in gingival index in fixed orthodontic patients, still there is no privilege for one of the three used oral hygiene protocols over the other as the differences were insignificant. Limitations in this study:

- 1. The one-month follow-up period may not provide adequate time to evaluate the complete impact of the oral hygiene protocols that have been adopted.
- 2. Patient-based trials; despite the implementation of various strategies in this trial to enhance patient adherence, including active reminders through SMS and WhatsApp text messages, the level of adherence to the prescribed protocols was inadequate, particularly during the Covid-19 pandemic.

RECOMMENDATIONS

In the light of limitations in this study, it is recommended for future studies to apply this study on longer term follow up period with subsequent intervals up to 12 months.

Conflict of interest: No conflict of interest.

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commercial, or not-for-profit sectors.

Ethics: This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo university on: 30/03/2021, approval number: 8-3-21.

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