Systematic Review and Meta-Analysis

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Assessment of the periodontal health status in patients undergoing orthodontic treatment with fixed appliances and Invisalign system

A meta-analysis

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Abstract

Background: At present, many scholars have studied the periodontal health status of patients undergoing orthodontic treatment with fixed appliances and invisalign. However, those results are inconsistent. Therefore, we conducted this meta-analysis, and then provide reference for clinical treatment.

Methods: Most databases, such as the Cochrane Library, EMBASE, PubMed, Medline, Chinese Biomedical Literature Database, CNKI, and Wan Fang Data were retrieved for related articles from the establishment of the database to October 2017. Meanwhile, we also searched the references of the related literatures manually, in order to increase the included literatures. Two researchers screened the related literatures according to the inclusion criteria and exclusion criteria. Stata 12.0 software was used for data analysis, and results are estimated by odds ratio (OR) and 95% confidence interval (CI).

Results: Finally, 7 articles, including 368 patients, were included into our meta-analysis. Meta-analysis results showed that there was no statistically significant difference of gingival index (GI) and sulcus probing depth (SPD) status between the invisalign group and the control group, including at 1, 3, and 6 months (all $P > .05$). When compared with the control group, the invisalign group presented a lower plaque index (PLI) and sulcus bleeding index (SBI) status at 1 month (OR = −0.53, 95% CI: −0.89 to −0.18; OR = −0.44, 95% CI: −0.70 to −0.19, respectively), 3 months (OR = −0.69, 95% CI: −1.12 to −0.27; OR = −0.49, 95% CI: −0.93 to −0.05, respectively), and 6 months (OR = −0.91, 95% CI: −1.47 to −0.35; OR = −0.40, 95% CI: −0.63 to −0.07, respectively). Subgroup analysis showed that the SPD status was lower in the invisalign group at 6 months when measured the teeth using Ramfjord index (OR = −0.74, 95% CI: −1.35 to −0.12). However, there was no statistically significant difference between the 2 groups when using other measure methods (OR = 0.12, 95% CI: −0.26 to 0.17).

Conclusion: Our meta-analysis suggests that comparing with the traditional fixed appliances, patients treated with invisalign have a better periodontal health. However, more studies are needed to confirm this conclusion in the future.

Abbreviations: 95% CI = 95% confidence interval, GI = gingival index, NOS = Newcastle-Ottawa Scale, OR = odds ratio, PLI = plaque index, RCT = randomized controlled trial, SBI = sulcus bleeding index, SPD = sulcus probing depth.

Keywords: fixed appliances, invisalign, meta-analysis., orthodontic, periodontal health status

1. Introduction

At present, with the development of medical technology and the improvement of people's living standard, people pay more and more attention to the appearance of their periodontal health status. Up to now, fixed orthodontic treatment is still the best choice for the various types of malocclusions.[1] Traditional metal stents are often recommended for patients with severe occlusion or corrective problems. Although the efficacy of the traditional braces has been recognized all over the world, it still has some disadvantages. For example, wearing a traditional braces will make people feel uncomfortable, and it is difficult to conventional cleaning. Patients must carefully brush each bracket and floss around the wires to remove all traces of plaque, in order to reduce the risk of demineralization during this treatment.[2] In addition, Yáñez-Vico et al[3] found that regular adjustments can be uncomfortable and inconvenient, which will seriously hampers proper oral hygiene, creates numerous plaque retention sites and then potentially leading to develop white spot lesions, caries, and periodontitis. Some previous studies have found that treating with fixed orthodontic appliances will stimulate the growth of a subgingival plaque, thus leading to some adverse effects, and then increase the discomfort of those patient.[4–6] Therefore, using an alternative removable orthodontic appliances may allow those patients to maintain an adequate oral hygiene, and then reduce the risk for negative dental and periodontal complications.[6–8]

The Invisalign system (Align Technology, Santa Clara, CA), a new generation of removable, clear semi elastic polyurethane

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aligners, was first introduced into orthodontics in 1999.[9] It based on a polymer composed by a chain of organic units joined with urethane links and are made from a thin, transparent plastic that fits over the buccal, lingual/palatal, and occlusal surfaces on the teeth, which was formerly a computer designed[10] and could gradually move the teeth into an ideal position.[9] It is not permanently bonded to teeth the way traditional braces, and can be easily removed for cleaning. In addition, Bräscher et al[2] performed a study including 72 patients, and they pointed out that brushing and flossing can be performed as usual and without any complicated procedures in patients who treated with the Invisalign system for a mean of 6 months.

Indeed, invisalign aligners can just be switched at home for a more convenient adjustment experience. It may be an option for most patients with mild to moderate bite or alignment problem. At present, many scholars believe that the invisalign aligners are more beneficial to maintain the periodontal health than the traditional fixed appliances. However, the Invisalign system usually requires those patients to spend a minimum of 20 hours per day to wear the aligners, and remove it only at eating, drinking, tooth brushing, or flossing.[10] Because the surfaces of the teeth are fitted over, it is possible to cause periodontal damage due to improper cleaning of the oral cavity and the unsmooth edge of the appliances.

In recent years, a large number of studies[11–17] about the periodontal health status in patients undergoing orthodontic treatment with fixed appliances and invisalign had been carried out. Clinical parameters, such as a plaque index (PLI), probing depth and bleeding on probing, was assessed in those studies. However, there are still some controversies in these studies. Huang and Li[14] found that invisalign can affect oral hygiene, and it still could influence periodontal tissue health in the short term, but invisalign still has some advantages over fixed appliances. In contrast, Levrini et al[16] pointed out that patients treated with the Invisalign system have a better periodontal health in the short term, compared to patients treated with fixed orthodontic appliances. Since this clinical problem is still in dispute, we hypothesis that patients treated with the Invisalign system may be superior to patients treated with fixed orthodontic appliances, and then conduct this meta-analysis to confirm this hypothesis.

2. Methods

2.1. Literature search and screening

A large number of databases were retrieved from the establishment of the database to October 2017, including the Cochrane Library, EMBASE, PubMed, Medline, Chinese Biomedical Literature Database, CNKI, and Wan Fang Data. Furthermore, we also performed a manual searching by retrieving the reference lists from relevant studies and contacted authors to obtain information about ongoing or nonpublished studies. If the necessary articles to be analyzed were still unavailable, then this article was excluded from this study. The search strategy of this meta-analysis was performed according to medical subject heading terms (Mesh) and nonmesh terms, and the mesh and nonmesh terms are as follows: "(Orthodontic) and (Extrusion, Orthodontic) and (Orthodontic Extrusions) and "Index for Need of Orthodontic Treatment" and "Index of Orthodontic Treatment Needs" and (Forced Eruption) and (Eruption, Forced) and (Forced Eruptions) and (Tooth Extrusion) and (Extrusion, Tooth) and (Tooth Extrusions)" and "(Orthodontic Appliances)" and "(Appliance, Orthodontic) and (Appliances, Orthodontic) and (Orthodontic Appliance)" and "(Orthodontic Appliances, Removable) and (Appliance, Removable Orthodontic) and (Appliances, Removable Orthodontic) and (Orthodontic Appliance, Removable) and (Removable Orthodontic Appliance) and (Removable Orthodontic Appliances)." This meta-analysis only included articles published in journal with Chinese or English due to language restrictions. Because this analyses was based on previously published studies, so there was no require for ethical approval and patient consent.

2.2. Inclusion criteria

Randomized controlled trial (RCT) or prospective cohort study which compared the periodontal health status in patients undergoing orthodontic treatment with fixed appliances or invisalign. Patients were diagnosed as malocclusions, and treated with fixed appliances or Invisalign system. Types of interventions: fixed orthodontic appliances or invisalign aligners.

2.3. Exclusion criteria

Nonprospective cohort study and non-RCT trial. Review articles. Nonpreclinical studies, such as rats, mice, pig, or dog. Data are not available or data cannot be used for this meta-analysis. The data in the original literature is not available, and is still unavailable after contact with the author, then this article was excluded from this meta-analysis.

2.4. Observation index

Gingival index (GI), PLI, sulcus probing depth (SPD), and sulcus bleeding index (SBI). Outcomes at T1 (1 month), T2 (3 months), and T3 (6 months) of the parameters mentioned above were evaluated in this meta-analysis.

2.5. Data collection and analysis

By scanning the titles and abstracts of potential studies retrieved from the database searches, 2 authors (HL and HT) performed the selection process independently to determine whether those articles were potentially eligible for inclusion criteria in this meta-analysis. When meet with any disagreements, it was resolved through the third review author (NK).

2.6. Quality assessments

We pilot tested The Newcastle-Ottawa Scale (NOS) and developed decision rules to accompany existing guidance for the NOS. The main contents are as follows: *Selection*: (1) is the case definition adequate? (2) Representativeness of the cases; (3) Selection of controls; (4) Definition of controls. A maximum of 1 star can be allotted in this category. *Comparability*: Comparability of cases and controls on the basis of the design or analysis. A maximum of 2 stars can be allotted in this category. *Exposure*: (1) Ascertainment of exposure; (2) Same method of ascertainment for cases and controls; (3) Nonresponse rate. A maximum of 2 stars can be allotted in item (1), and a maximum of 1 star can be allotted in item (2) and (3). *Outcomes*: (1) Assessment of outcome; (2) Was follow-up long enough for outcomes to occur; (3) Adequacy of follow-up of cohorts. A maximum of 2 stars can be allotted in item (1) and (3) a maximum of 1 star can be allotted in item (2). Studies that achieved 7 or more stars on the modified NOS were considered high quality. All studies were assessed using the NOS independently by 2 reviewers (HL and HT). Discrepancies were resolved through discussion to produce consensus assessments for each study (Table 1). It is known from the previous results, the full score of NOS was 9 stars, and a high-quality study was defined as a study with 7 or more stars. From the

Table 1

Assessment of methodological quality of included studies.

	Selection				Comparability	Exposure			Outcomes			
Refs.	Adequate definition of cases	Representativeness of the cases	Selection of controls	Definition of controls	Control for important factor	Ascertainment of exposure	Same method of ascertainment for cases and controls	Nonresponse rate	Assessment of outcome	Was follow-up long enough for outcomes to occur	Adequacy of follow up of cohorts	Scores
Zhou and Wang[11]	☆	☆	—	☆	☆	☆	☆	—	☆	—	—	7
Zhou[12]	☆	☆	☆	☆	☆	—	☆	—	☆	—	—	7
Li et al[13]	☆	☆	☆	☆	☆	—	☆	☆	☆	—	—	8
Huang and Li[14]	☆	☆	☆	☆	☆	—	☆	—	☆	—	—	7
Chu et al[15]	☆	☆	☆	—	☆	☆	—	☆	☆	—	—	7
Levrini et al[16]	☆	☆	☆	☆	☆	☆	—	☆	☆	—	—	8
Zhou and Guo[17]	☆	☆	☆	☆	☆	☆	☆	—	☆	—	—	8

description of Table 1, the NOS of each literature included in this meta-analysis is 7 or more stars. Therefore, the literatures included in this study are of high quality.

2.7. Data extraction and management

The following information was extracted and recorded independently by 2 review authors (HT and TZ) by using prepiloted data extraction forms: the primary author's name, year of publication, author nationality, patient recruitment time, malocclusion types of the included patients, study design, sample size of the included studies, the average age of the patient, outcome measures for each literature and measurement time of each literature. A third review author (NK) resolved any disagreements.

2.8. Statistical analysis

Stata 12.0 software was used to pool and analyze results from the individual studies. Heterogeneity test: if $P > .1$, $I^2 < 50\%$ indicating that the included studies have homogeneity, we intends to use fixed effect model to analyze the data; and if $P < .1$, $I^2 \geq 50\%$, it shows that the heterogeneity of the included studies is large, and the random effects model is used to analyze the data. If $P < .1$ is unable to determine the source of heterogeneity, descriptive analysis was used to analyze the data. After the output of the combined odds ratios (OR) and 95% confidence interval (CI), using Z test for data analysis, test level: $\alpha = 0.05$. *Bias analysis*: funnel plot was used to estimate the bias in the literature. *Sensitivity analysis*: when the heterogeneity of the study was large, the sensitivity analysis was conducted to explore the sources of heterogeneity.

3. Results

3.1. Study selection and characteristics

The primary search yielded a total of 178 studies, of which 30 records were duplicates. After a primary screening of the titles and abstracts, 96 records were excluded. By reviewing full-text articles, we excluded 15 articles. Thirty-seven full-text studies were accessed, and 30 studies were excluded according to the exclusion criteria and inclusion criteria. Finally, 7 eligible studies involving 368 patients were enrolled in this meta-analysis. Among those patients, 183 patients in the invisalign group and 185 patients in the control group. The flow diagram of study selection is shown in Fig. 1. The basic information of each included literature is shown in Table 2.

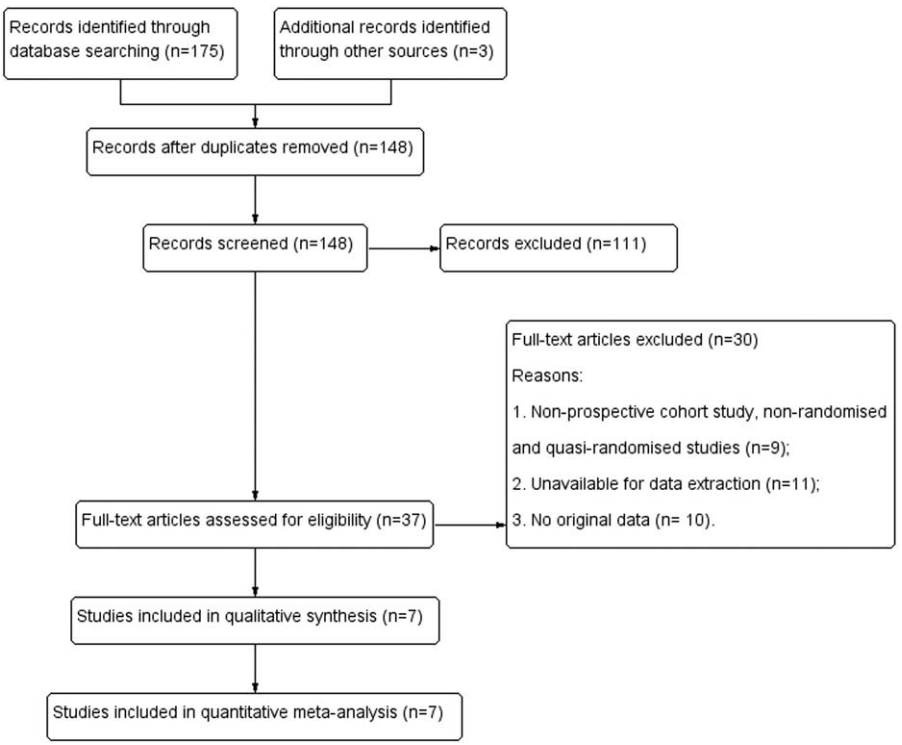

Figure 1. Flow diagram of the study selection process and specific reasons for exclusion in the meta-analysis.

Table 2

Characteristics of the eligible studies in this meta-analysis.

Refs.	Female/ male	Country	Recruitment time	Malocclusion types	Study design	Sample number	Average age, y			Outcome measures	Time measures
						I	C	I	C		
Zhou and Wang[11] 2014	47/33	China	2010–2012	Class I	Prospective cohort study	40	40	28.4	24.6	GI, PLI, SPD	T3
Zhou[12]	40/20	China	2011–2013	Mild malocclusion	Prospective cohort study	30	30	22.4	23.6	GI, PLI, SPD, SBI	T1, T2, T3
Li et al[13]	30/16	China	2010–2013	Class I	Prospective cohort study	26	20	27.4	28.3	PLI, SPD, SBI	T1, T2, T3
Huang and Li[14]	29/11	China	—	Mild and moderate malocclusion	Prospective cohort study	20	20	18~34	18~34	GI, PLI, SBI	T1, T2, T3
Chu et al[15]	17/13	China	2012–2014	Nonextraction treatment types	Prospective cohort study	15	15	16~35	16~35	GI, PLI, SPD	T3
Levrini et al[16]	44/23	Italy	—	Class I	Prospective cohort study	32	35	24.3	24.3	SPD, SBI	T1, T2
Zhou and Guo[17]	35/10	China	2010–2012	Mild malocclusion	Prospective cohort study	20	25	25.1	26.3	GI, PLI, SPD, SBI	T1, T2, T3

C = the control group, GI = gingival index, I = the invisalign group, PLI = plaque index, SBI = sulcus bleeding index, SPD = sulcus probing depth, T1 = 1 month, T2 = 3 months, T3 = 6 months.

3.2. The status of GI

Meta-analysis (random effect's model) results showed that there was no significant difference of GI between the invisalign group and the control group, including at 1 month (OR = −0.24, 95% CI: −0.57 to 0.09), 3 months (OR = −0.23, 95% CI: −0.56 to 0.10), and 6 months (OR = −0.78, 95% CI: −1.05 to −0.52). There was a large heterogeneity of GI index at T3 (I^2 = 89.7%), as shown in Fig. 2. The significant heterogeneity may be explained by the fact that a larger trial conducted by Q. Zhou used a different measure method. After excluding the study conducted by Q. Zhou, the heterogeneity obviously decreased (OR = −0.39, 95% CI: −0.85 to 0.06, I^2 = 54.6%), as shown in Fig. 3.

3.3. The status of PLI

Patients who treated with invisalign has a significantly lower status of PLI, including at 1 month (OR = −0.53, 95% CI: −0.89 to −0.18), 3 months (OR = −0.69, 95% CI: −1.12 to −0.27), and 6 months (OR = −0.91, 95% CI: −1.47 to −0.35), as shown in Fig. 4.

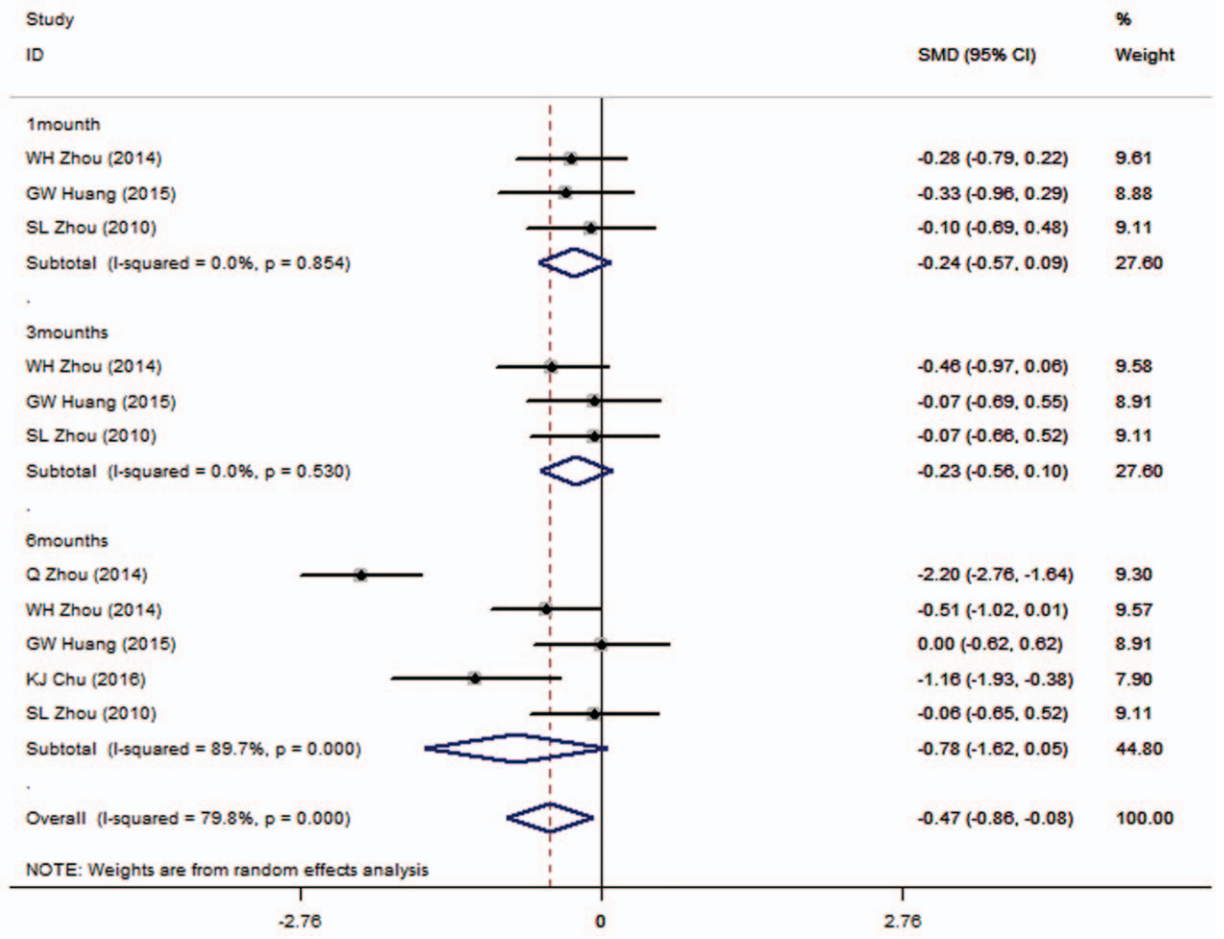

Figure 2. The status of GI index at 1, 3, and 6 months between the invisalign group and the fixed appliances group.

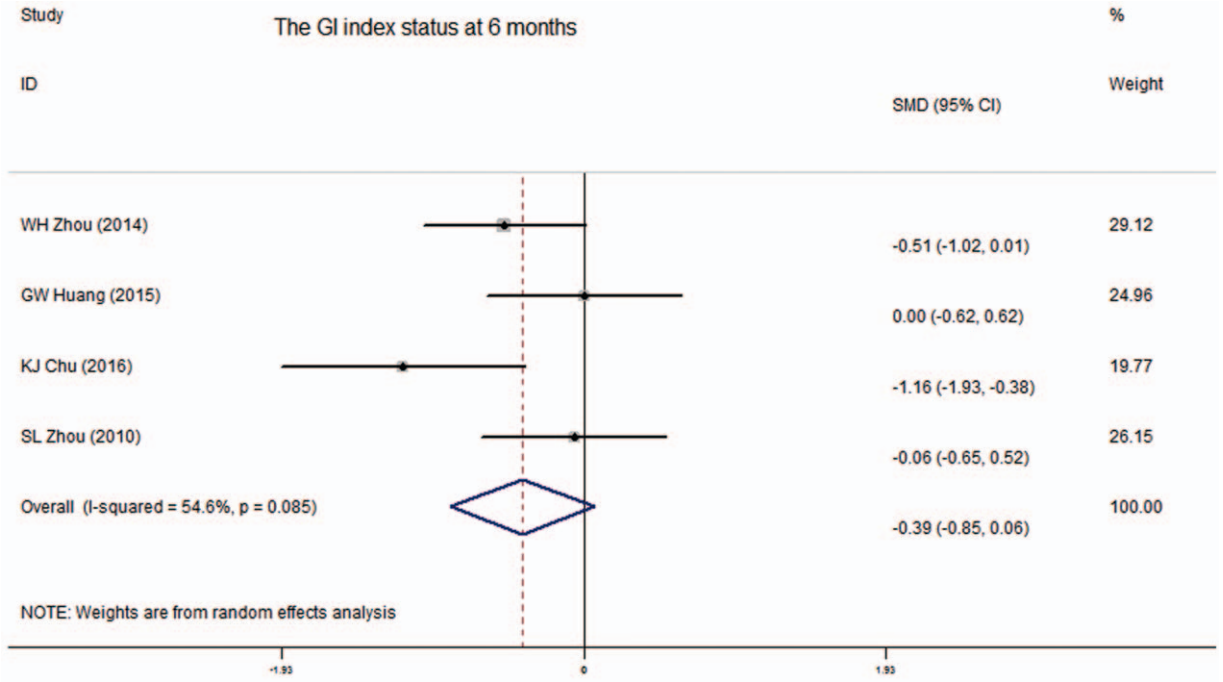

Figure 3. The status of GI index at 6 months between the invisalign group and the fixed appliances group after excluding a large heterogeneity study.

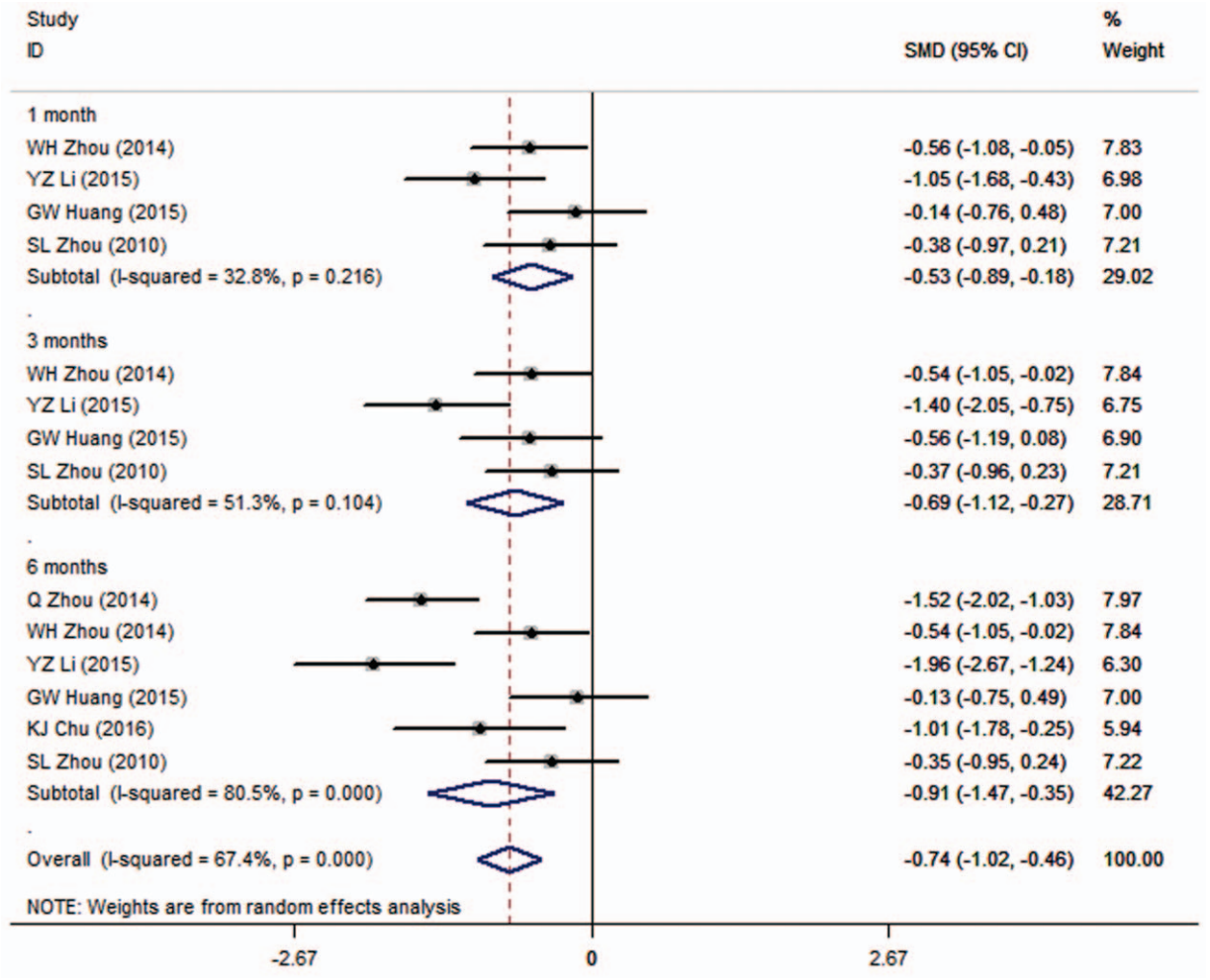

Figure 4. The status of PLI index at 1, 3, and 6 months between the invisalign group and the fixed appliances group.

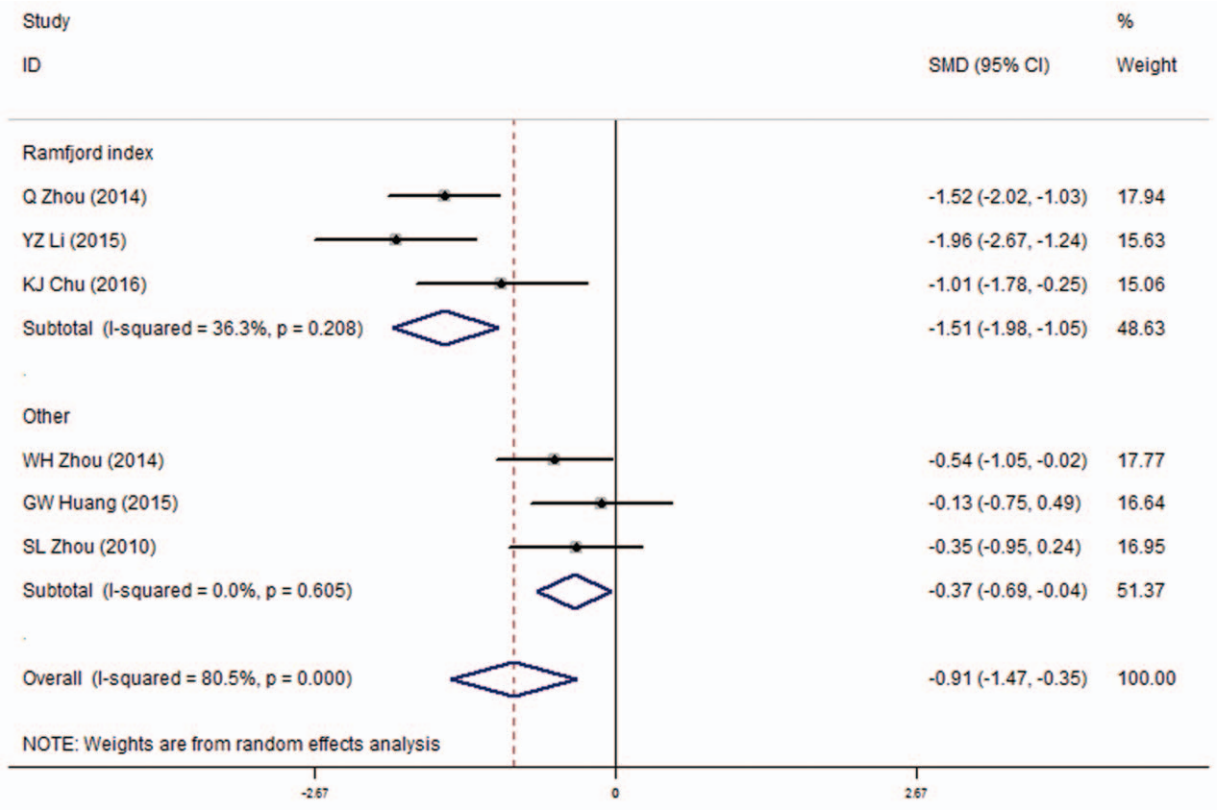

Figure 5. Subgroup of status of PLI index at 6 months between the invisalign group and the fixed appliances group.

3.4. Subgroup analysis

Because different tooth regions of the included studies of PLI at 6 months were measured, 3 studies measured the teeth by using Ramfjord index (the teeth was 16, 21, 24, 36, 41, 44) and the others were not. Thus, those studies were divided into the Ramfjord index group and the non Ramfjord index group, and then a subgroup analysis was conducted. Subgroup analysis showed that for the Ramfjord index group (OR = −1.51, 95% CI: −1.9 to −1.05) and non Ramfjord index group (OR = −0.37, 95% CI: −0.69 to −0.04, $P = 0.030$), invisalign aligners show a significant lower level of PLI in the 2 groups, as shown in Fig. 5.

3.5. The status of SPD

There was no significant difference of SPD between the invisalign group and the control group, including at 1 month (OR = −0.39, 95% CI: −0.98 to 0.21), 3 months (OR = −0.36, 95% CI: −1.00 to 0.27), and 6 months (OR = −0.38, 95% CI: −0.93 to 0.17), as shown in Fig. 6.

3.6. Subgroup analysis

In addition, studies that include the SPD index status at 6 months were divided into the Ramfjord index group and the non-Ramfjord index group, and then a subgroup analysis was conducted. Subgroup analysis showed that the Ramfjord index group show a significant lower level of SPD (OR = −0.74, 95% CI: −1.35 to −0.12), and the non Ramfjord index group show a difference level of SPD (OR = 0.12, 95% CI: −0.26 to 0.51), as shown in Fig. 7.

3.7. The status of SBI

Patients who treated with Invisalign system has a significantly lower status of SBI, including at 1 month (OR = −0.44, 95% CI: −0.70 to −0.19), 3 months (OR = −0.49, 95% CI: −0.93 to −0.05), and 6 months (OR = −0.40, 95% CI: −0.73 to −0.07), as shown in Fig. 8.

4. Discussion

The invisalign is a new orthodontic technique in the late 1990s,[10] compared with current traditional orthodontic techniques depending on brackets and wires for orthodontic tooth movements. It is characterized with the advantages of more aesthetic, comfortable, simple and high-efficient and predictable. As for their effects on the periodontal, Ristic et al[18] pointed out that the GI index increased gradually at 4 weeks and 3 months after wearing the fixed appliance, and it reach the highest value in 6 months. At the same time, some scholars have shown that after wearing a fixed appliance 5 to 6 months, the development of gingivitis can reach its peak. Since then, gingivitis has generally been maintained at this level during treatment. So we mainly studied the periodontal condition in the first 6 months. The results of our study show that compared with traditional fixed orthodontic treatment, invisalign presented a significantly lower status of SBI and PLI index over the course of treatment ($P < .05$). However, we found there was no statistically significant difference of GI and SPD index status between the invisalign group and the control group throughout the treatment time ($P > .05$). The results of this meta-analysis showed that the invisalign aligners are more conducive to the maintenance of periodontal health.

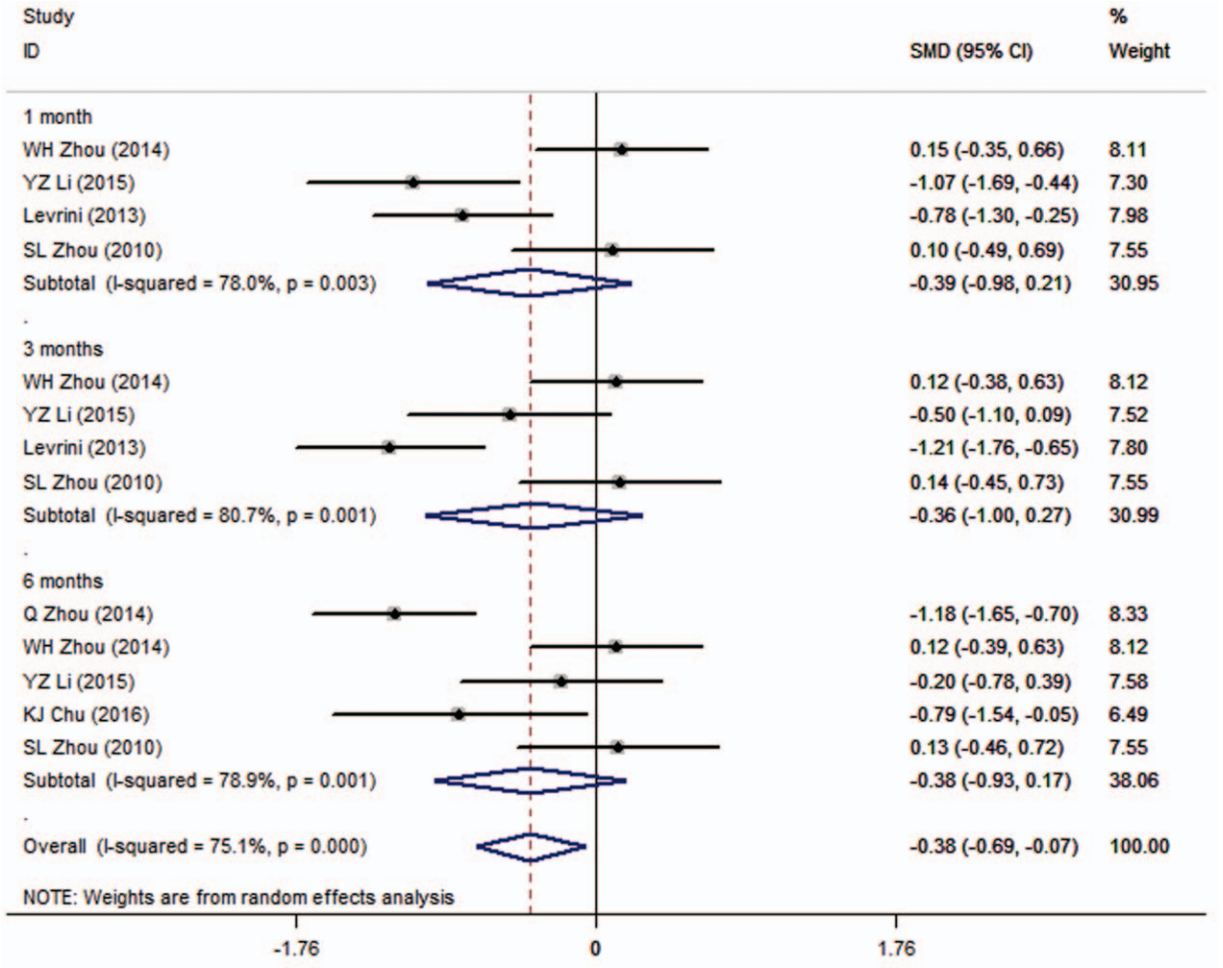

Figure 6. The status of SPD index at 1, 3, and 6 months between the invisalign group and the fixed appliances group.

The possible reasons could mainly be explained as follow: patients treated with Invisalign system can clean the appliance out of the mouth, and remove the appliance when brushing, which is beneficial for patients to clean up the teeth; invisalign allow patients to use dental floss, which is conducive to maintain oral hygiene; invisalign covering a large part of the crown and can control the force measures. So that the teeth move closer to the overall movement, which can prevent supragingival plaque from migrating to subgingival tissue to destroy the periodontal tissue.

Mumghamba et al[19] conducted an experiment and found that periodontal assessment using Ramfjord teeth may be a useful alternative to full-mouth measurements in epidemiological studies. Our results are in agreement with previous studies. Subgroup analysis in our meta-analysis also showed that different measurement methods showed an indifference of both groups of GI status at 6 months, but the result in different outcomes of SPD index status at 6 months, the Ramfjord index group show a significant lower level of SPD ($P < .05$) and the non-Ramfjord index group show a difference level of SPD ($P > .05$). Due to the limited number of samples, we did not conduct the subgroup of another stage.

The effect of orthodontic appliances on periodontal health has been evaluated in many studies. Miethke and Vogt[9] reported that the PLI scores of patients treated with fixed appliances were significantly higher than those of patients treated with clear aligners at baseline and at 3 different evaluation time points. However, they found no statistically significant differences in probing depth between patients treated with fixed appliances and those treated with clear aligners. Abbate et al[20] by researching 50 teenagers aged 10 to 18 orthodontic condition's years with similar initial orthodontic, and they found that adolescents who wore invisalign aligners presented a higher indices of periodontal health than their peers treated with fixed attachments after the same duration of orthodontic treatment. They findings seem to contradict to the result of Alstad and Zachrisson,[21] who found that no statistically significant difference was observed in the mean plaque score or gingival condition. Despite the widespread use of fixed and Invisalign system, there is still an absence of evidence to determine the effect on both types of appliances on the periodontal. Bollen et al[22] and Van et al[23] by conducting a systematic review and a review of the literature, and they pointed out that orthodontic treatment itself does not increase the incidence of periodontal pathologies. However, some scholars found oral hygiene procedures have a great impact on the periodontal status of orthodontic patients.[24]

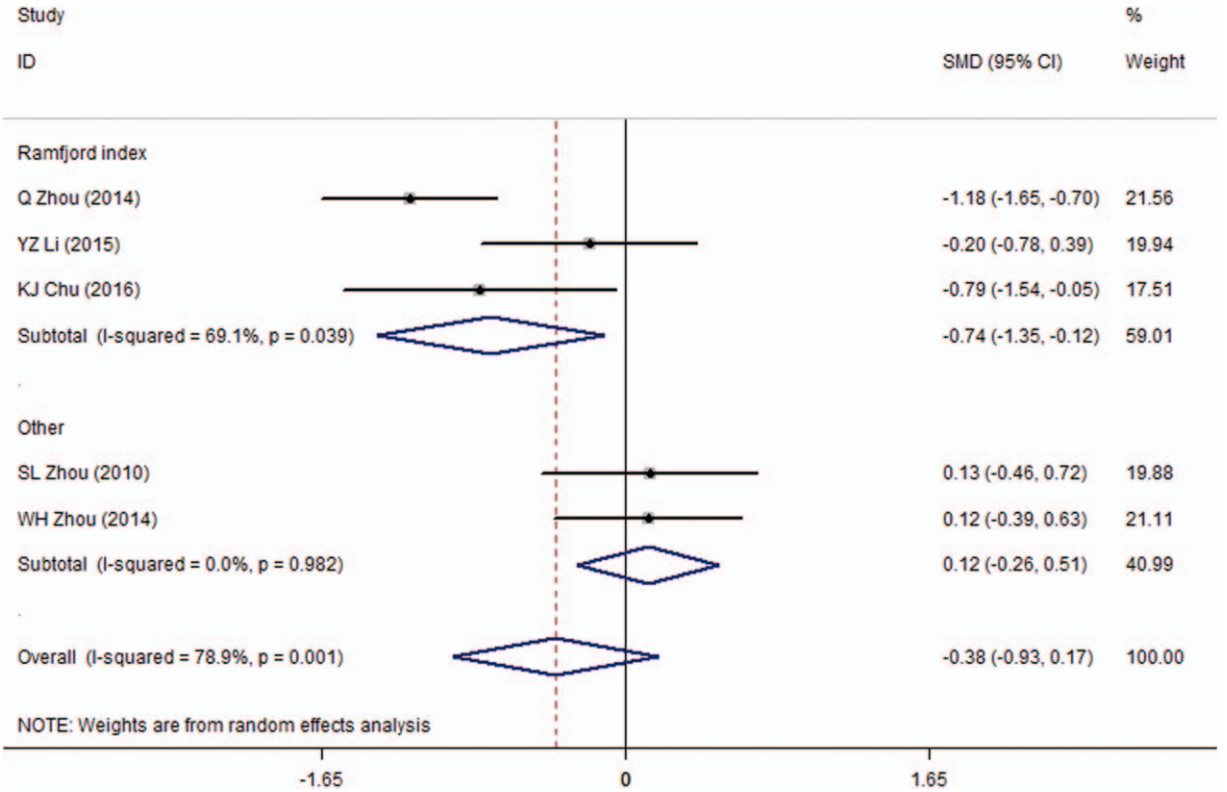

Figure 7. Subgroup of status of SPD index at 6 months between the invisalign group and the fixed appliances group.

At present, it is a phenomenon that cannot be ignored that the incidence of periodontitis increases with age, and more and more adult patients are actively seeking orthodontic treatment.[25] Accordingly, the number of patients with periodontitis selected for orthodontic treatment is more than before.[26] Orthodontic treatment is sometimes considered to be a predisposing factor for periodontal disease, because orthodontic appliances may prevent complete oral hygiene procedures and cause bacterial aggregation. However, some scholars believe that orthodontic treatment can be used as a causative factor for periodontal disease. The explanation for this viewpoint is that orthodontic devices may prevent complete oral hygiene procedures and cause an increase in bacterial aggregation.[18,27–31] Some clinical and experimental studies have shown that when inflammation is not completely controlled, orthodontic treatment may also cause inflammatory response even in patients with good oral hygiene, thereby accelerating the development of periodontal damage and resulting in attachment loss.[32,33] A number of previous studies have also shown that the fixed appliance is easy to promote the accumulation of dental plaque, resulting in gingival swelling, gingival bleeding and other inflammatory manifestations.[34–36] At present, there are a wide variety of studies comparing different orthodontic methods with Invisalign systems, and the results of those study all agree that Invisalign systems is superior to other treatments. Because Invisalign systems can significantly reduce the accumulation of dental plaque, thus improving oral hygiene.[36–38] From a clinical perspective, the treatment of clear aligner is a safer method for periodontal tissues respect to fixed appliance treatment techniques.[39] The explanation may be that invisalign aligners promotes the normalization of oral hygiene, and then reducing the amount of plaque retentive surfaces. Taking into account the results of those observations, the invisalign aligners can be used in orthodontic treatment for patients with poor periodontal health. However, strong evidence is still needed to support this hypothesis.

The limitations of our meta-analysis include the following aspects: The included studies are mainly coming from China and Italy, lacking of relative researches from other countries. Index measurement of the position and the number of teeth is uniform. Some articles measured the full mouth teeth, and some articles only measured some specific teeth, even some articles did not describe the specific measure methods, which may lead to a certain bias in implementation. In addition, there is no unity of malocclusion types, which may increase the presence of confounding factor. The articles included in our meta-analysis were prospective cohort study, lacking of RCTs, bias will be inevitable appear. We compare the periodontal health status of both appliances during the treatment and obtain this conclusion that patients treated with invisalign have a better periodontal health. As a result of the number of literature included in this meta-analysis and other reasons (such as race, nationality, and measuring method), more studies are still needed to confirm this result.

5. Conclusion

Our meta-analysis indicate that compared with the traditional fixed appliances, patients treated with invisalign have a better periodontal health. However, due to the limitations of the quality and quantity of the articles, this conclusion still needs to be confirmed by more RCTs.

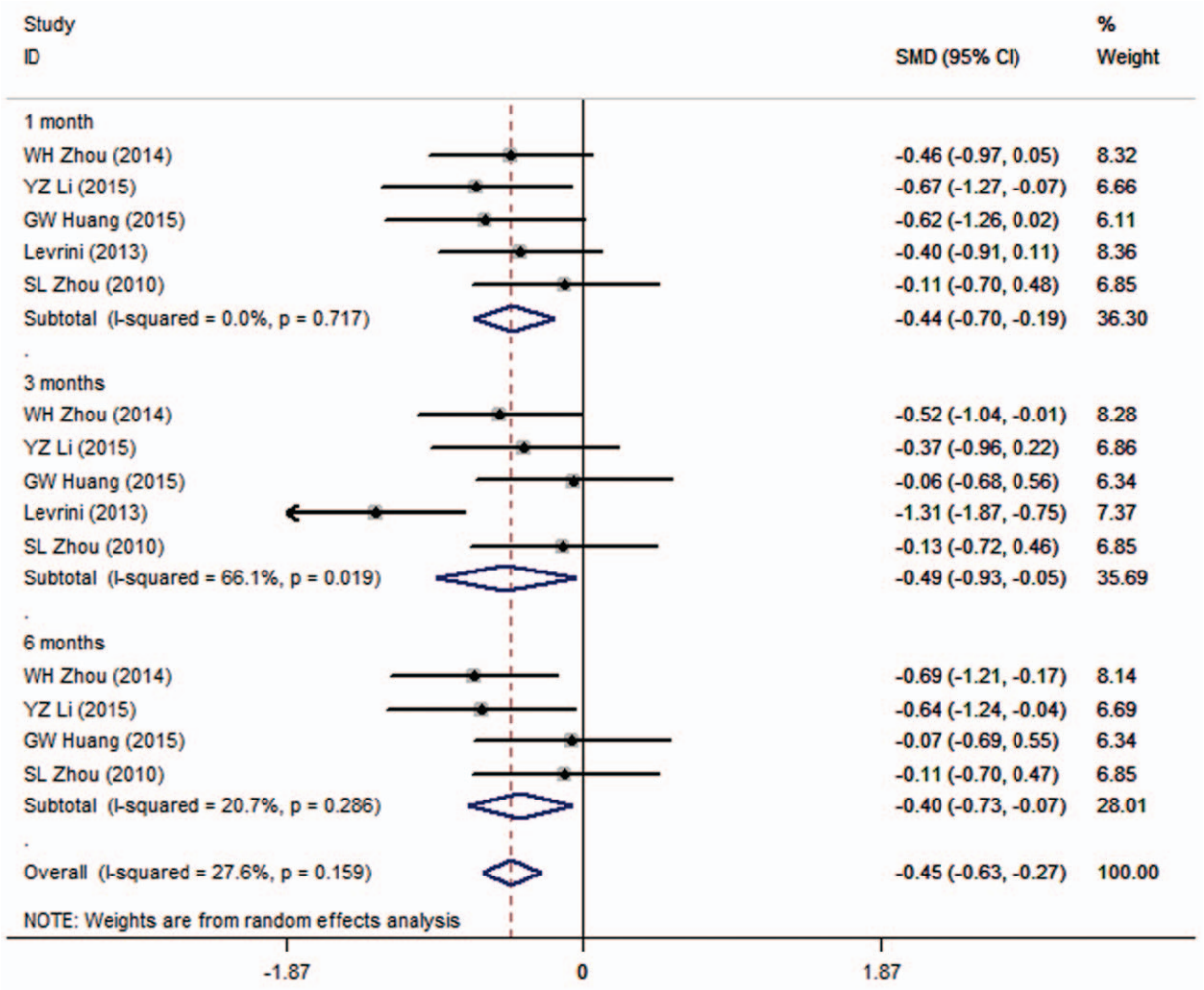

Figure 8. The status of SBI index at 1, 3, and 6 months between the invisalign group and the fixed appliances group.

Author contributions

All authors' responsibilities were as follows: HL designed the subject and revised the article, HT and TZ developed inclusion and exclusion criteria, developed and performed the search strategy, HL and NK conducted the statistical analysis and wrote the article. HL and NK screened relevant literature, made decisions according to inclusion and exclusion criteria. All authors participated in the interpretation of data and reviewed the manuscript.

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Visualization: T. Zhou.
Writing – original draft: T. Zhou.
Writing – review & editing: T. Zhou.

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