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Clinical Study Protocol

A Single-center, Open-label, Randomized Controlled Clinical Trial to Evaluate the Efficacy and Safety of the Indirect Bonding Technique

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Although accurate bracket placement is essential for orthodontic treatment, many practitioners apply brackets indiscriminately with direct or indirect bonding techniques. Nonetheless, there have been few prospective clinical comparisons of the 2 techniques. We will therefore conduct a single-center, randomized control trial in 100 patients aged ≥ 12 years and diagnosed with malocclusion. All patients will receive orthodontic treatment using brackets with direct or indirect bonding techniques. The primary endpoints will be the total treatment time, occlusal index, discomfort at bonding, and oral hygiene after bonding. This study will clarify whether indirect bonding can improve the efficiency of orthodontic treatment.

Key words: indirect bonding, comprehensive evaluation, bracket

Dental brackets are the most common appliances used in fixed orthodontic treatment to align and straighten permanent teeth and help to position them with regard to a patient's malocclusion, while also working to improve dental health. Accurate bracket placement is essential for effective and efficient fixed orthodontic treatment that realizes the full potential of brackets. However, many practitioners apply brackets indiscriminately, making the finishing stage of comprehensive orthodontic treatment more difficult and time-consuming, in addition to increasing the risk of unpredictable reaction of tooth movement [1].

At present, there are 2 techniques for the placement of orthodontic brackets on the tooth surface. The first is called the direct technique, where the brackets are directly placed on the enamel surface by the operator, as initially described by Newman in 1965 [2]. The second method of bracket placement is the indirect bonding technique, which was first described by Silverman *et al.* in 1972 [3]. This is a two-stage procedure: the first stage is carried out in the laboratory, where the brackets are located and attached to a plaster model of the patient's teeth, and in the second stage the brackets in their positions are transferred by means of a tray to the patient's mouth, where they are attached to the etched enamel surface of the teeth [4].

In the orthodontic literature, the advantages and disadvantages of the direct and indirect bonding techniques have been discussed by many investigators [5-8]. Briefly, direct bonding is a fuss-free way of placing the brackets on the tooth surface, and the bond strength may be better because the bracket bases fit

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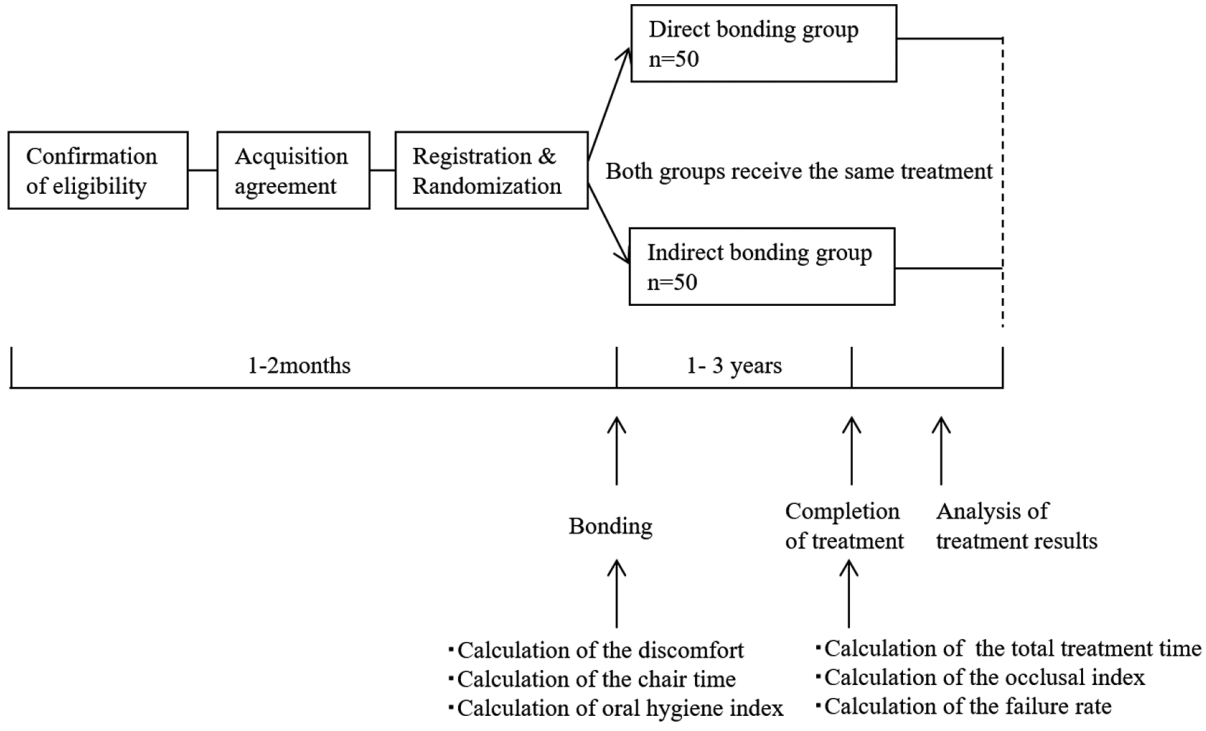

Fig. 1 Overview of the study flow

closer to the tooth surfaces [9]. However, direct bonding is believed to take longer and to be more stressful for the orthodontist than indirect bonding [5,8]. In contrast, in terms of the accuracy of bracket placement, many reports indicated that indirect bonding is superior because it is easier to place brackets on models (better vision and unlimited working time) than on teeth *in vivo* [3,5,8]. Improving bracket placement accuracy could reduce the need for subsequent repositioning and even shorten the treatment time [1]. However, indirect bonding is more technique-sensitive and requires more laboratory procedures and time than direct bonding [10]. Additionally, several cross-sectional and retrospective studies have shown a high failure rate of indirectly placed brackets during the treatment period [9,11].

There have been few prospective investigations comparing the direct and indirect techniques by means of comprehensive and detailed clinical evaluation, with consideration of the impact from all line items. The aim of the proposed study is thus to evaluate the efficacy and safety of the indirect bonding technique. We will conduct a single-center, open-label, parallel, prospective randomized control trial (UMIN registration number of 000022182). Fig. 1 overviews the design of the study, which is currently in the initial stage of subject recruitment.

Endpoints

We will perform a detailed comparison of the indirect and direct bonding techniques. The primary outcome parameters are "Total treatment time (months)," "Occlusal index (Peer Assessment Rating index [12]) between pre- and post-treatment (scores)," "Discomfort at bonding (VAS scores)," and "Oral hygiene (PCR: plaque control record [13]) after bonding (%)." The secondary outcome measures are "Chair time (min)" and "Failure (bracket detachment from a tooth) rate (%: the number of detached brackets/the number of bonded brackets x100)." The null hypothesis is that the efficacy and safety of indirect bonding do not differ markedly from those of the direct bonding technique.

Eligibility Criteria

All of the patients who meet the main inclusion and exclusion criteria will be invited for screening. The

Table 1 Eligibility Criteria

Incrusion criteria
To be eligible for this study, patients must fulfill all of the following criteria: 1. Patients with malocclusion 2. Outpatients visiting the Department of Orthodntics, Okayama University Hospital 3. Patients who are older than 12 years of age with all permanent teeth 4. Underage patients with a consent of their parents, a person with parental authority, spouse, adult brother or sister, grandparent, relative, or guardian
Exclusion criteria
Patients fulfilling any of the following criteria are ineligible for this study: 1. Patients without mailooclusion 2. Patients with amelogenesis imperfecta or enamel hypoplasia 3. Patients with vomiting reflex 4. Patients with primary teeth 5. Patients with jaw deformity or syndrome 6. Patients to be treated by minor tooth movement 7. Patients with poor oral hygiene (PCR > 20%) 8. Patients who will not be able to continue the treatment until completion of the full treatment protocol 9. Inappropriate patients judged by the principle investigator or the member of this study

main inclusion and exclusion criteria are listed in Table 1. Witten informed consent must be obtained by an investigator from the patient before any screening or inclusion procedures. Patients who do not agree to participate will not be enrolled. This study will be conducted in compliance with the principles of the Declaration of Helsinki, and the protocol has been approved by the institutional review board of Okayama University Hospital (approval number: d10001).

Treatment Methods

Sample size calculation. The sample size was determined using the results from a previous retrospective study that compared the difference in treatment times between direct bonding techniques ($N = 11$; total treatment time: 22.91 ± 4.35 months) and indirect bonding techniques ($N = 35$; total treatment time: 14.23 ± 5.02 months) [14], using Power and Sample Size Calculation software (version 3.1.2; Department of Biostatics, Vanderbilt University, TN, USA). The calculation was based on the number of subjects required for a two-sample *t*-test. In consideration of the occurrence of dropout, the target sample size was calculated to be 50 subjects per group based on a significance level of 0.05, a power of 80%, and a standard deviation of 5 points in both groups.

Intervention. Following confirmation of the eligibility of patients as mentioned above, patients will be randomized to receive treatment with either the conventional direct bonding technique or the indirect bonding technique. At the first stage of treatment, in the direct bonding group, all of the brackets will be directly placed on the enamel surface by the operator. In the indirect bonding group, all of the brackets will first be located and attached to a plaster model of the patient's teeth in the laboratory, and then the pre-positioned brackets will be transferred in a tray to the patient's mouth, where they will be attached to the etched enamel surface of the teeth. All participating orthodontists are full-time employees of the Department of Orthodontics, Okayama University Hospital and have already been preliminarily reviewed for their knowledge of basic orthodontia and techniques of the direct and indirect bonding techniques.

Follow-up. All of the enrolled patients will be followed up for 1 to 3 years after bonding. At bonding of brackets, we will calculate the chair time (min) for each bonding procedure. Within a month after bonding, we will distribute a questionnaire to the patients prompting them to describe their level of discomfort during the bonding procedure using a 100-point visual analog scale (VAS). In addition, the oral hygiene index (%) will be calculated by a dental hygienist. After the treatment, the total treatment time (months), the occlusal index (scores) between pre- and

post-treatment, and the failure rate (%) will be calculated.

Randomization. After confirming the fulfillment of the eligibility criteria, the enrolled patients will be randomized to either the direct bonding technique arm or the indirect bonding technique arm of the study. The leader of the project (HK), who will remain blinded to all clinical data, will make the allocation using a prepared random number list.

Statistical Consideration

The primary endpoints (treatment time, the occlusal index between pre- and post-treatment, the discomfort at bonding, and the oral hygiene after bonding) will be compared by a two-sample *t*-test. The secondary outcomes (the chair time and the failure rate) will also be compared by a two-sample *t*-test. A probability of less than 0.05 will be considered to indicate statistical significance. All of the statistical analyses will be performed using JMP statistical analysis software (SAS Institute Inc., Cary, NC, USA).

Discussion

The present study was designed to prospectively evaluate the relative efficacy and safety of the direct and indirect bonding techniques in fixed orthodontic treatment from a comprehensive perspective. Although many authors have discussed the comparative advantages of the direct and indirect bonding techniques for orthodontic brackets, neither method has been shown to have a clear advantage across the board. In addition, most of these investigations were cross-sectional or retrospective in nature. In our study, therefore, to obtain more insight into factors related to the efficacy and safety of bracket bonding in orthodontic treatment, the effects of determinants will also be explored.

We expect that this study will provide valuable information for choosing an appropriate bracket bonding technique for particular types of malocclusion, and thereby will help to realize better and more cost-effective outcomes in orthodontic treatment.

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