Comparative assessment of treatment efficacy and adverse effects during nonextraction orthodontic treatment of Class I malocclusion patients with direct and indirect bonding: A parallel randomized clinical trial

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Introduction: The objective of this 2-arm parallel trial was to compare the effects of direct and indirect bonding techniques on the orthodontic treatment process and outcomes. **Methods:** Thirty patients were randomly assigned to undergo bonding of brackets indirectly (group A, n = 15) or directly (group B, n = 15). Eligibility criteria included permanent dentition with bilateral Angle Class I molar and canine relationships, no previous orthodontic treatment, no skeletal discrepancy, and mild or moderate crowding. The main outcome was the orthodontic treatment results assessed using the American Board of Orthodontics Objective Grading System; the secondary outcomes were times taken to perform the laboratory and clinical steps, total treatment duration, plaque accumulation, formation of white spot lesions, bond failures, and need for additional archwire bending and bracket repositioning. The randomization sequence was created using an online randomization software. The patients were allocated with a 1:1 ratio using a block size of 4. The sequence generator was contacted by phone for group assignment after a patient was enrolled for allocation concealment. Blinding was implemented during the dental cast and radiographic evaluations, data entry, and data analysis. Patients were evaluated before treatment, and 1, 2, and 6 months after the start of treatment, and at the end of treatment. **Results:** All patients completed the study and were analyzed. There were no dropouts. Marginal ridge (median difference, −1.000; 95% confidence interval [CI], −2.99 to −0.001; $P = 0.03$) and total Objective Grading System scores (median difference, −3.999; 95% CI, −6.000 to −0.005; $P = 0.03$) were significantly higher in group B than in group A; other Objective Grading System categories did not differ significantly between the groups. The clinical time was significantly longer in group B than in group A (mean difference, −26.51; 95% CI, −29.57 to −23.46; $P < 0.001$), and the total time was significantly longer in group A than in group B (mean difference, 19.03; 95% CI, 15.32 to 22.74; $P < 0.001$). There were no significant between-group differences in treatment duration, plaque accumulation, formation of white spot lesions, bond failure, or need for additional archwire bending or bracket repositioning. No harms were encountered. **Conclusions:** Indirect bonding was significantly faster than direct bonding in the clinical stage and yielded better marginal ridge and total scores. Both techniques showed similar rates of plaque accumulation, formation of white spot lesions, bond failure, and additional archwire bending and bracket repositioning. **Registration:** The trial was not registered. **Protocol:** The protocol was not published before trial commencement. (Am J Orthod Dentofacial Orthop 2018;154:26-34)

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Direct bonding is the method most commonly used for attaching orthodontic appliances to teeth in clinical practice.[1] However, use of indirect bonding has increased in recent years.[1,2] The indirect bonding technique is a 2-stage procedure that was introduced by Silverman et al[3] in 1972. The laboratory stage involves positioning and attachment of brackets on dental plaster models and preparation of transfer trays. These brackets are then

transferred and bonded to the patient's teeth in the clinical stage. Increased accuracy in bracket positioning and reduced clinical chair time have been suggested as the most important advantages of this technique.[3-5]

Over the years, several in-vitro and in-vivo studies have compared direct and indirect bonding techniques with respect to bond strength,[6-9] bond failure,[9-15] accuracy of bracket placement,[11,16-18] accumulation of plaque,[10,19] formation of white spot lesions,[19] treatment time,[13] and time taken to complete the laboratory and clinical steps.[11,14] In general, these studies have shown no differences between the 2 methods in terms of bond strength,[6-8] bracket failure rate,[11-15] treatment time,[13] or effect on periodontal tissues.[10]

Although accuracy in bracket positioning is an important reason that clinicians choose indirect over direct bonding,[6,11,20,21] laboratory and clinical studies comparing these techniques have yielded contradictory results.[11,16-18] Although some investigators have found only small differences in bracket placement errors between the 2 methods,[11] others have shown that indirect bonding significantly reduces absolute torque error and rotation deviation, which can make it easier for the orthodontist to correct transverse discrepancy, disclusion with antagonist teeth, and irregularities in interproximal contact points.[18] However, whether these differences would result in better overall orthodontic treatment outcomes is not clear.

Knowledge of the clinical variables that are affected by these different bonding techniques during orthodontic treatment might help clinicians when choosing the best method for bracket bonding.

Specific objectives or hypotheses

The aims of this study were to evaluate the effects of direct and indirect bonding techniques on the orthodontic treatment process and to compare the orthodontic treatment outcomes achieved using these 2 bonding methods. Our hypotheses were the following: (1) orthodontic treatment outcomes do not differ in patients treated using direct bonding and indirect bonding techniques; (2) there is no difference between the 2 bonding methods in terms of total treatment time, accumulation of plaque, formation of white spot lesions, bond failure rates, need for additional archwire bending and bracket repositioning; and (3) the chair-side time needed for indirect bonding of brackets is shorter than the time needed for direct bonding.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This was a single-center, 2-arm parallel randomized clinical trial with a 1:1 allocation ratio. No changes were made to the protocol after trial commencement.

Participants, eligibility criteria, and settings

Initially, 47 patients who had been referred to a tertiary clinic in Ankara, Turkey for orthodontic treatment between January and June 2015 were assessed for eligibility by the senior clinician (B.S.A.). The inclusion criteria were as follows: (1) complete permanent dentition, including second molars with bilateral Angle Class I molar and canine relationships; (2) no previous orthodontic treatment; (3) no skeletal discrepancy; and (4) mild or moderate crowding. The exclusion criteria were (1) morphologic or numeric dental anomalies or enamel defects, (2) severe crowding or bimaxillary protrusion that would require tooth extraction, (3) cigarette smoking, (4) chronic use of medication, (5) systemic disease potentially affecting the study outcome, and (6) poor oral hygiene. The study was carried out in accordance with the tenets of the Declaration of Helsinki, and its protocol was approved by the scientific ethical committee at Hacettepe University, Ankara, Turkey (approval number 07-15/KA-15041). Informed consent was obtained from all patients or a parent.

Interventions

The patients were randomly allocated to 1 of 2 treatment groups: indirect bonding and (2) direct bonding. In the direct bonding group, the teeth were etched with 37% phosphoric acid gel (blue etchant gel with benzalkonium chloride; Reliance Orthodontic Products, Itasca, Ill) for 30 seconds, rinsed, dried with oil-free compressed air for 10 seconds. After drying the enamel surface, the primer (Transbond MIP Moisture Insensitive Primer; 3M Unitek, St Paul, Minn) was applied with a small brush and spread with oil-free compressed air. The brackets were then bonded using Transbond Plus Color Change Adhesive (3M Unitek) and polymerized for 40 seconds per bracket with a light-emitting diode curing light (Starlight S; Mectron, Carasco, Italy) (Fig 1).

In the indirect bonding group, maxillary and mandibular arch impressions were taken with heavy-bodied alginate (Alginoplast MIP; Heraeus Kulzer, Hanau, Germany), and dental models were cast with hard dental stone. After the dental models dried, vertical and horizontal bracket-positioning guidelines were drawn. A separating agent (Isodent Gypsum Separating Fluid;