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Expectations, acceptance, and preferences regarding microimplant treatment in orthodontic patients: A randomized controlled trial

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Introduction: In this study, we evaluated the pain and discomfort experienced by orthodontic patients by comparing how they rated pain associated with had microimplant placement, tooth extraction, and gingival tissue removal in preparation for implant placement. **Methods:** Fifty-six microimplants were placed in 28 consecutive orthodontic patients for anchorage reinforcement in the maxilla for en-masse retraction. For all patients, extractions of maxillary, or maxillary and mandibular, premolars had been planned. The recruited patients were randomized into 2 groups according to the timing of the extractions. In group A, at least 1 extraction was performed during the evaluation period; the extractions in group B were after the evaluations. Furthermore, all patients had 2 different surgical procedures for placement. On 1 side, the gingival tissue was removed before placement. On the contralateral side, the implant was placed transgingivally. Each patient's perception of pain and discomfort was evaluated by a questionnaire before, immediately after, and 1 week after the intervention. **Results:** The discomfort experienced during the extractions was described as very painful by 50% of the patients. It was significantly greater than during tissue removal and microimplant placement ($P < 0.05$). Microimplant placement produced no pain in 30% of the patients and was described as the least painful procedure ($P < 0.05$). Transgingival microimplant placement was significantly preferred by all patients ($P < 0.05$). **Conclusions:** Microimplant surgery seems to be a well-accepted treatment option in orthodontic patients, with significantly lower pain levels than for tooth extractions. Furthermore, transgingival placement is clearly favored by patients who do not need tissue removed before placement. (Am J Orthod Dentofacial Orthop 2010;138:250.e1-250.e10)

The use of microimplants for anchorage purposes is a daily orthodontic routine. They have proven to be efficient and valuable for controlling anchorage and preventing unwanted side effects such as reciprocal tooth movement when maximum anchorage is required.[1] Before the use of implants, orthodontists controlled unwanted tooth movement by choosing the appropriate appliance or technique for the patient's clinical goals. The treatment objective is dictated by the concepts of ideal occlusion and function. The patient can in general influence the treatment only by cooperation and compliance.

The level of compliance is significantly affected by the patient's experience of discomfort or pain. Pain has previously been defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage.[2] Pain and discomfort are frequently experienced during orthodontic treatment,[3] including separation, initial archwire placement, adjustment or change, and debonding.[4-8] It has also been reported that every tenth orthodontic patient fails to complete treatment because of the pain experienced during care.[2] This also occurs when so-called noncompliance appliances are used.

To address this, it is necessary to consider other techniques including orthodontic microimplants. To date, few data are available with regard to pain associated with microimplants.[9-11] To understand patient compliance and acceptance, it is not sufficient to only analyze treatment effectiveness, but the extent to which patients can or are willing to tolerate pain during the proposed treatment option must also be determined.[10]

Rating scales are widely accepted and validated tools that are reliable for assessing patients' discomfort

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Table I. The patients were randomized into groups A and B, and the subgroups were determined by placement technique: soft-tissue punch (ia) vs transgingival placement (ib)

A Extraction before placement		*B Extraction after placement*	
ia	*ib*	*ia*	*ib*
Soft-tissue punch, left side	Transgingival placement, right side	Soft-tissue punch, left side	Transgingival placement, right side

In every patient, a soft-tissue punch (Fig 2) was used on the left side, with transgingival placement on the right.

or pain during treatment. They can be continuous (visual analog scale [VAS]), discrete (numerical rating scale [NRS]), or verbal (VRS).[12-16] All 3 pain-rating scales are valid, reliable, and appropriate for use in clinical practice.[17] Because differences in the VAS score seem to be clinically significant only in the 20% range,[18,19] a discrete 5-category NRS was chosen for this study.

Previous studies concentrated on comparing pain and discomfort associated with microimplant treatment with other potentially painful procedures including extractions,[10] other interventions,[9] or various anchorage devices.[11,20] The aim of this study was to compare the pain associated with microimplant placement and various dental procedures routinely accompanying placement. The procedures were microimplant placement, soft-tissue preparation by punch excision, and tooth extractions. Even though these techniques are common in orthodontic practices, the comparative pain associated with them has not been investigated to establish to what extent these techniques are tolerated by patients or how they will be ranked in a comparison.[21]

MATERIAL AND METHODS

Twenty-eight consecutive orthodontic patients fulfilling the inclusion criteria were recruited (mean age,14.94 ± .95 years; 14 girls, 14 boys) for this study. The inclusion criteria were that they were in the permanent dentition, were less than 18 years of age, had an orthodontic treatment need that included a treatment plan involving maxillary or maxillary and mandibular premolar extractions, needed en-masse retraction to reduce an excessive overjet, and had maximum anchorage requirements. The sample was taken from patients referred for orthodontic assessment in a private specialist (M.B.) practice.

Information about the treatment and the study was given orally and in writing to all patients and their parents. Also, written consent was obtained from all selected patients and their parents. The patients were randomized and stratified by sex into 2 groups. Group A comprised 7 boys and 7 girls; group B also had 7 boys and 7 girls. In group A, at least 1 extraction was performed before placement of the microimplant. In group B, all extractions were performed after placement of the microimplant (Table I).

All microimplants were placed into the interradicular area of the maxillary second premolar and first molar in both maxillary quadrants. For all patients, the Tomas

Fig 1. The Tomas punch (photo courtesy of Dentaurum, Ispringen, Germany).

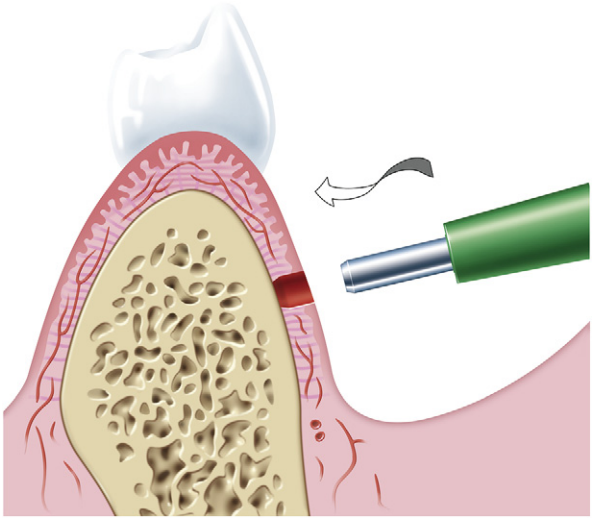

Fig 2. A soft-tissue punch was used on the left side (photo courtesy of Dentaurum, Ispringen, Germany).

Prior to treatment

1. What are your expectations regarding the treatment?

ok 0 I II III IV great discomfort

Immediately after treatment

2. Which side was more uncomfortable?

left 0 I equal III IV right

3. How would you describe the gingiva removal?

ok 0 I II III IV great discomfort

4. How would you describe the pin placement?

ok 0 I II III IV great discomfort

5. How would you describe the extraction?

ok 0 I II III IV great discomfort

6. What was more uncomfortable?

extraction 0 I equal III IV placement

7. How would you describe the feeling on the left during the procedure?

pain 0 I equal III IV pressure

8. How would you describe the feeling on the right during the procedure?

pain 0 I equal III IV pressure

9. How would you describe the complete procedure on the left?

no pain 0 I II III IV great pain

10. How would you describe the complete procedure on the right?

no pain 0 I II III IV great pain

11. Was the procedure as expected?

definetely 0 I II III IV totally different

One Day after treatment

12. Which side was more uncomfortable?

left 0 I equal III IV right

Fig 3. The questionnaire used for the evaluations.

pin (length, 8.0 mm; diameter, 1.6 mm; Dentaurum, Ispringen, Germany) was used.

Two placement techniques were used for each patient (Table I) in a split-mouth design. On the left side, the Tomas punch (diameter, 2.0 mm; Dentaurum) was used for gingival tissue removal in the placement area (Figs 1 and 2). On the right hand side, the microimplant was transgingivally placed.

Tooth extraction and microimplant placement were performed on consecutive days by different operators. The teeth were extracted by each patient's local dentist, and all microimplants were placed by 1 orthodontist trained in implant placement.

For anesthesia, a superficial injection was directly applied in the placement area by using 0.2 mL Scandonest (3% mepivacaine hydrochloride; Septodent, Niederkassel, Germany).

The quadrant for the first placement was randomly chosen to prevent bias because of the patient's anxiety. Also, the patient was not informed which technique was used for which side.

During the interview, the term *microimplant* was replaced by *pin* to reduce anxiety in the patients. Before treatment, all patients were asked about their expectations. Immediately after the microimplant placement, they were asked about pain and discomfort during the

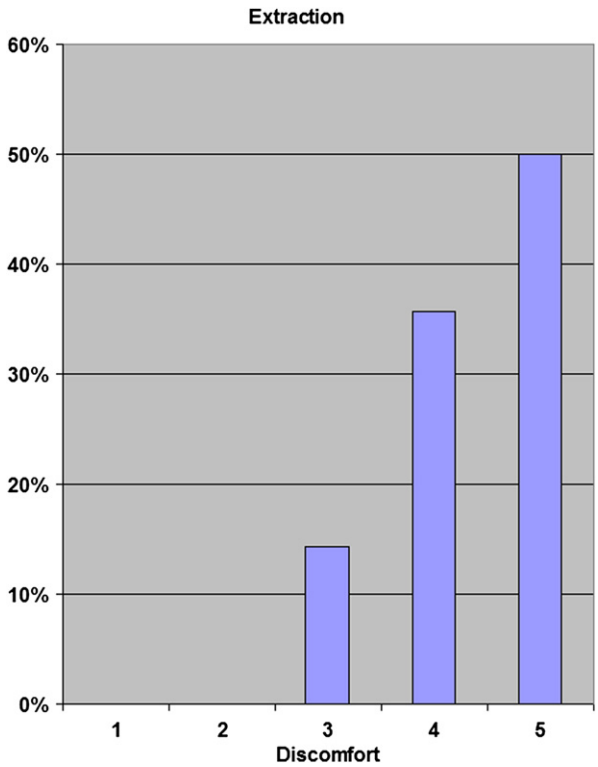

Fig 4. The overall pain values for the procedure involving premolar extractions (question 5).

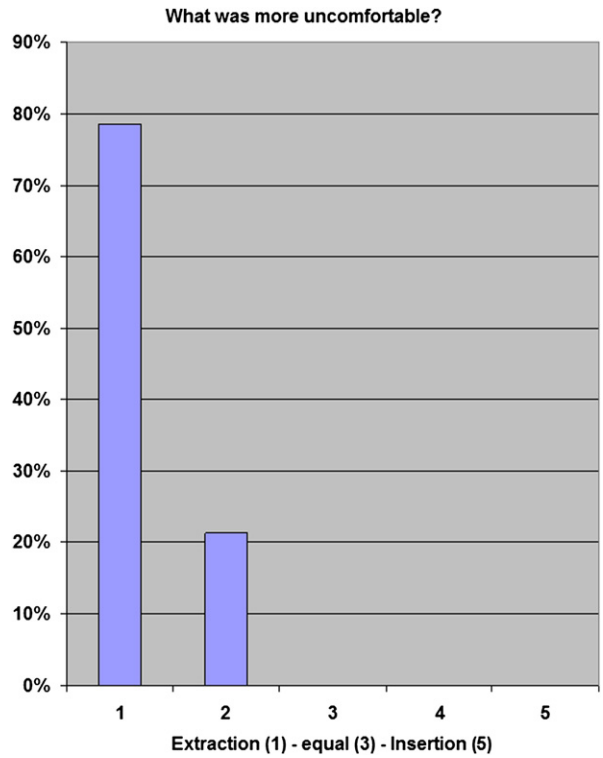

Fig 5. Comparison of tooth extraction and microimplant placement (question 6). Patients experienced more discomfort during extractions (*1* and *2*) than during the microimplant placement. No patient described the placement as more painful (*4* and *5*) or equal to the extractions (*3*).

procedure and to what extent their expectations had been fulfilled. One day after treatment, the preferences in gingival tissue removal and transgingival placement were evaluated. A standardized questionnaire containing 12 items was used for the evaluation (Fig 3). The interviewer was neither involved in nor informed about the clinical procedure to prevent bias.

Statistical analysis

Differences between the groups were tested with the nonparametric Kruskal-Wallis and Mann-Whitney tests for pain and discomfort. The chi-square test was used to determine differences between the procedures. To compare the pain levels of extraction, soft-tissue punch, and transgingival placement, the Wilcoxon test was used.

Differences at $P < 0.05$ were considered statistically significant.

RESULTS

All 28 patients completed the questionnaire, for a response rate of 100%.

The expectations ranked from mild pain to great pain, but, after treatment, most patients described the experience as less painful than expected.

The highest pain values were reached during the extractions, with 50% of the patients describing great discomfort (Fig 4). All patients stated that extractions were more uncomfortable than microimplant placement (Fig 5).

There were no statistically significant differences between groups A and B in the comparison of the pain levels of gingival tissue removal and microimplant placement. No differences were observed between extractions before or after placement of the implants.

The soft-tissue punch caused significantly higher discomfort levels compared with transgingival placement ($P = 0.002$; Fig 6). Also, the feeling of the soft-tissue punch side (left) was significantly more often described as painful, but the feeling on the right (transgingival placement) was described as pressure rather than pain ($P = 0.036$; Fig 7).

This led to a significant preference for the transgingival procedure ($P = 0.002$; Fig 8).

When the 3 interventions were compared, extractions caused the greatest discomfort, followed by the

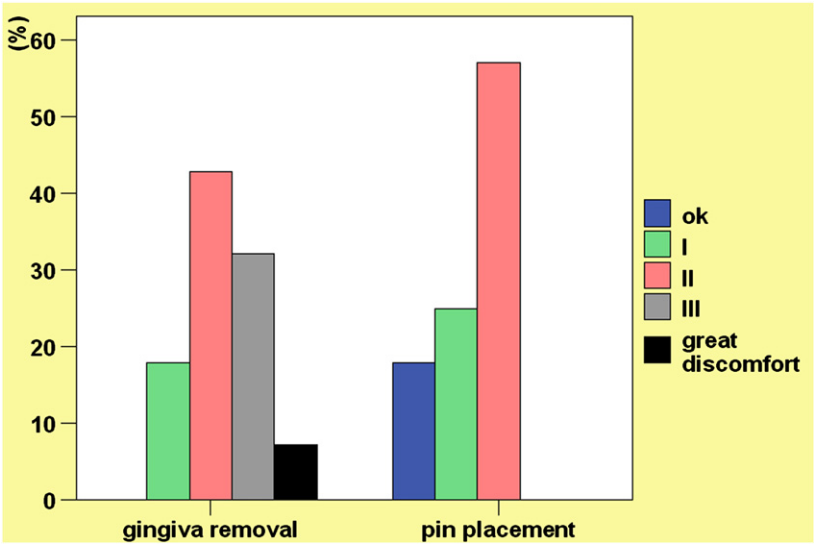

Fig 6. Patients' discomfort with the soft-tissue punch and transgingival placement.

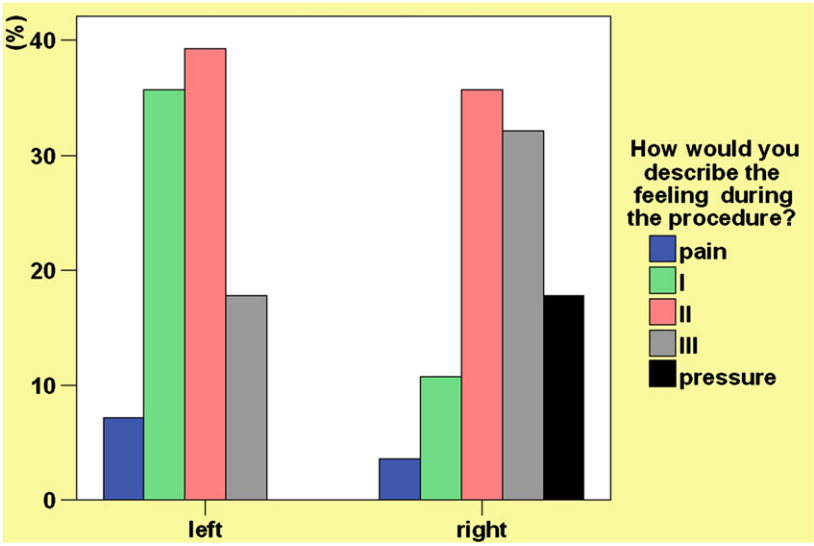

Fig 7. During transgingival placement, pressure rather than pain caused the discomfort in contrast to the soft-tissue punch, which was described as painful.

soft-tissue punch. Transgingival placement produced the least discomfort. These results were also statistically significant (Table II; Fig 9).

The overall preferred side evaluated 1 day after the treatment was the right side (Fig 10).

There was no significant difference between the sexes in this study.

There was no significant difference in pain perception between the patients older than the median of 14.85 years compared with the younger patients.

DISCUSSION

This study was designed to investigate microimplant treatment from the patient's point of view.

Microimplants are widely accepted as useful tools in orthodontic care. Ample evidence shows the broad range of indications for microimplants.[21-27] Much of this research was concerned with biomechanical issues such as increasing primary stability and preventing failure.[28] Interestingly, only a few studies

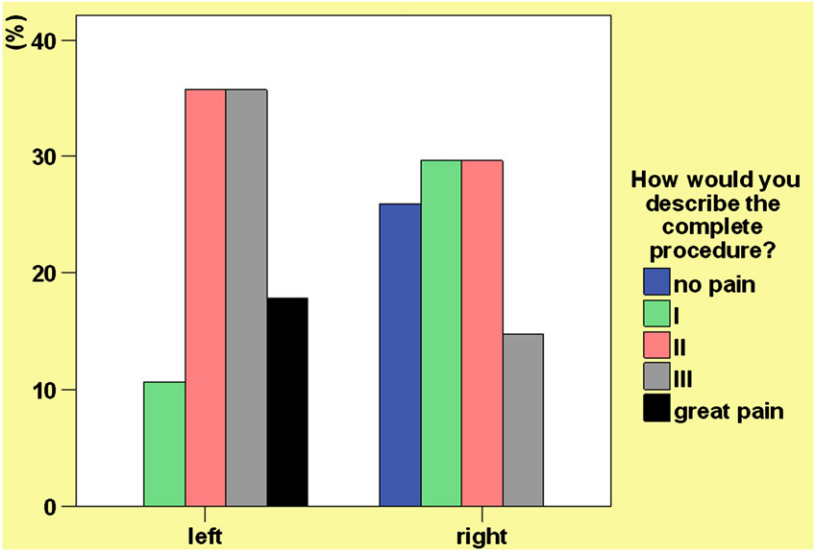

Fig 8. Pain values of the soft-tissue punch (*left*) compared with transgingival placement (*right*).

Table II. Comparison of the 3 interventions (the results were statistically significant)

	3. How would you describe the gingiva removal?	*4. How would you describe the pin placement?*	*5. How would you describe the extraction?*
Valid (n)	28	28	14
Missing (n)	0	0	14
Mean	2.29	1.39	3.36
Median	2.00	2.00	3.50
SD	0.85	0.79	0.75
Minimum	1	0	2
Maximum	4	2	4
	4. How would you describe the pin placement? 3. How would you describe the gingiva removal?	*5. How would you describe the extraction? 3. How would you describe the gingiva removal?*	*5. How would you describe the extraction? 4. How would you describe the pin placement?*
Asymptotic significance (2-sided)	0.001	0.003	0.002

were found evaluating the preferences of the patients undergoing this treatment.[9,10,29]

Pain and discomfort are not rare during orthodontic treatment[2] and can mean that every tenth patient drops out because of the pain.[30] A previous study demonstrated that the injection was more painful than the actual surgical procedure.[31] Pain and discomfort are subjective and much influenced by factors such as the patient's anxiety level,[3,32] which is most often based on a history of previous extractions.[33] Expectations regarding treatment often seem to be worse than the actual experience.[34] Especially in children, self-report measures assessing pain have been underused.[35] To address this, it was decided to evaluate expectations and discomfort levels for treatment procedures that are routinely performed with microimplant treatment. Relevant and comparable procedures were tooth extraction, gingival-tissue preparation, and the placement itself; these were chosen as the basis for the evaluation.

The results showed that the highest pain levels were reached during tooth extractions: 50% of the patients described great pain. The soft-tissue punch was less painful, and the least discomfort was noticed during microimplant placement. This agrees with the study of Sandler et al,[36] who described the acceptance of midpalatal implants as unproblematic. Another study showed that surgical placement of a palatally placed onplant and premolar extractions caused the same pain intensity.[10] This might show that temporary, nonosseointegrated microimplants are advantageous because of their simple implementation into the orthodontist's repertoire. They also appear to be acceptable to patients because of the less-invasive surgical procedures required for placement.

Methodologically, patients could benefit even more by having the microimplant placed and the premolar extracted in 1 session by the referring dentist or an oral surgeon. But because of the importance of correct positioning and the orthodontist's biomechanical

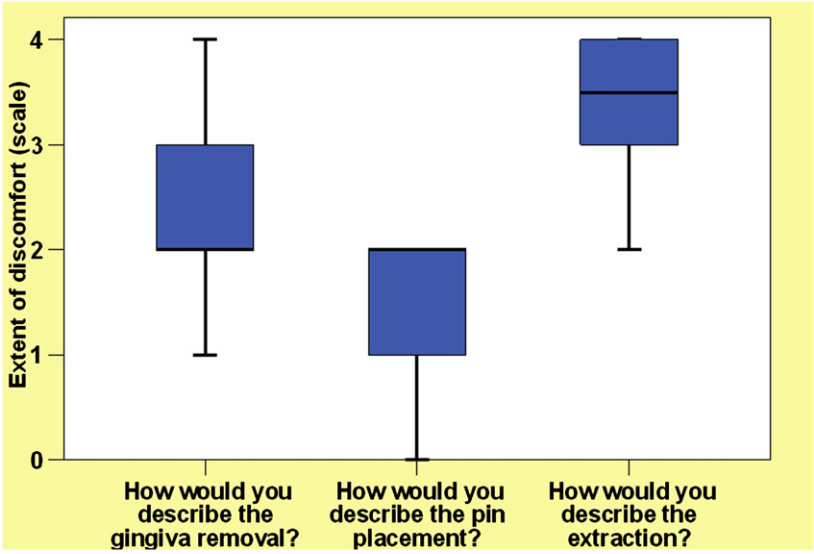

Fig 9. Comparison of discomfort levels of all 3 interventions.

considerations, the microimplant was placed by an experienced orthodontist. Nevertheless, further studies are needed to determine whether patients' acceptance is improved when extraction and microimplant placement are performed in the same session.

The sequence of the interventions might also have an impact on the pain experienced. Laboratory studies found lower pain reports when pain proceeds from high to low rather than from low to high.[37] This expected distortion of the results was not observed in this study. Average and maximum pain values for microimplant placement did not differ significantly when the tooth extraction was performed before or after placement, or the microimplant was placed transgingivally or after the tissue punch.

Another aim of this study was to compare the transgingival placement of a microimplant with the soft-tissue-punch technique for gingival-tissue preparation.

Two basic methods for gingival preparation in implant treatment have been described in the literature: flap surgery and the punch technique. These techniques were designed to reduce the risk of peri-implantitis,[38] and to create[39] or preserve[40] the papilla between the teeth and prosthetic implants. The punch technique was also identified as a less-invasive method.[40] Only a few studies were concerned with soft-tissue preparation techniques. In one of these, the authors learned that there was no significant difference in the success rates of miniscrews with or without flap surgery.[29] Moreover, less pain and discomfort were experienced after treatment when the microimplants were placed transgingivally. Also, anecdotal reports explain the possible benefits of a soft-tissue punch for orthodontic microimplants, but no scientific evidence was found in the literature.

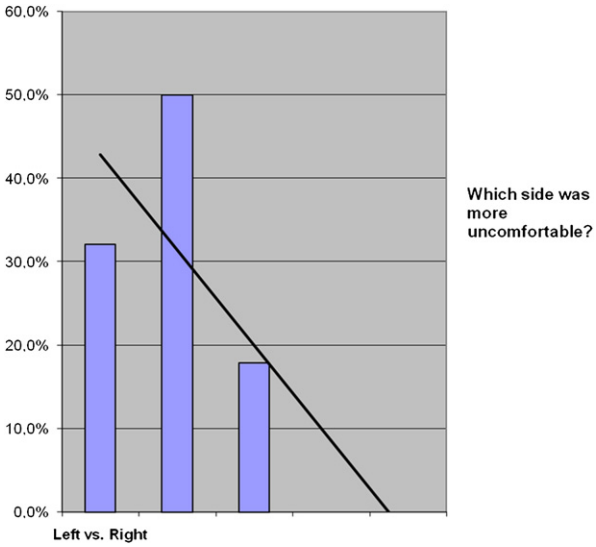

Fig 10. The overall discomfort of the left and right sides 1 day after treatment (question 12) shows that most patients experienced discomfort from the soft-tissue punch (*left*), but none had pain during transgingival placement (*right*).

The results of this study show that the soft-tissue punch is experienced as more painful than microimplant placement but also as less painful than a premolar extraction; this was statistically significant ($P < 0.003$). The transgingival placement and the soft-tissue punch caused comparable discomfort levels during the surgical

procedures. The feeling of discomfort was described as pain in the punch group but pressure rather than pain in the transgingival placement group.

The evaluation 1 day after the surgical intervention showed a statistically significant preference for the transgingival procedure. This might have been caused by the slightly larger wound area and the resulting pain and swelling from the soft-tissue punch.

These findings indicate that the soft-tissue punch does not seem to be necessary from the patients'point of view. From the clinicians' point of view, further studies are needed to evaluate the impact of the soft-tissue punch on the success rate of microimplants.

For the comparison of the soft-tissue punch and transgingival placement, the split-mouth concept was used. This is a frequent and established technique that can be applied when comparing 2 clinical interventions.[41] It is cost-effective and allows evaluation in a relatively small number of patients, although steps must be taken to prevent bias; blinding is necessary.[41] To minimize bias in this study, the quadrant for the first placement was randomly chosen. The patients were also not informed which technique was used for which side. Nevertheless, the patients could readily presume, immediately after the intervention, which procedure had been performed on which side. This was due to comparing a 3-step intervention (injection, soft-tissue punch, placement) with a 2-step intervention (injection, placement). The interviewer did not take part in the surgical procedure and was not influenced by the patients' reactions during the intervention.

The patients' ages at the time of intervention did not influence the results significantly. No differences were observed when comparing the pain and discomfort values of patients under the median age of 14.85 years with the older patients. We expected higher pain values in the younger patients because they usually have less experience with pain management and coping strategies.[42] This effect might become more pronounced when evaluating pain in younger children.

The best known way to evaluate acute pain is to analyze the intensity and discomfort of the experience by using a VAS.[10] There is considerable evidence in the literature that this scale is reliable.[12-15] Other methods are categorical scales such as the VRS[16] and the NRS,[17] which are also valid, reliable, and appropriate for use in clinical practice.

A main difficulty when using a VAS methodology is finding a clinically significant difference in the scores. This has been addressed in previous studies. They concluded that a significant interval tends to be in the 10% to 20% range.[18,19] This led to the assumption that an equidistant 5-category scale would be appropriate for this study. The VRS is mostly used to evaluate the quality of pain, whereas the NRS is preferred when measuring pain intensity, but no gold standard has yet been established.[16] The NRS seems to be superior to the VRS when used in children because the suggested answers might not reflect the children's vocabulary appropriately, causing misunderstanding and distortion of the results.[43] Therefore, the NRS with 2 verbal endpoints was chosen (no pain, great pain).

To prevent selection bias, consecutive patients fulfilling the inclusion criteria were recruited for this study and randomized. Furthermore, the age distribution of our patient sample was similar to that in other studies of patients undergoing fixed appliance treatment.[7,44-47]

The distribution of the sexes was the same in all groups, and no effect was observed.

Nevertheless, the number of 28 patients enrolled in this study seems to be relatively small, and the results should be interpreted with caution. However, nonparametric evaluation was used to support the numbers in this study. To support these findings further, it might be beneficial to increase the number of participants in future studies.

CONCLUSIONS

1. The highest pain values were reported for premolar extractions. Somewhat lower levels of pain were reported for the soft-tissue punch. The lowest pain levels were reported for microimplant placement ($P = 0.003$).
2. Transgingival placement was generally reported to be felt as pressure rather than pain, whereas the feeling of the soft-tissue punch was more often described as pain.
3. There was a statistically significant difference in the patients' perception regarding the placement technique. Transgingival placement was clearly favored by the patients ($P = 0.002$).

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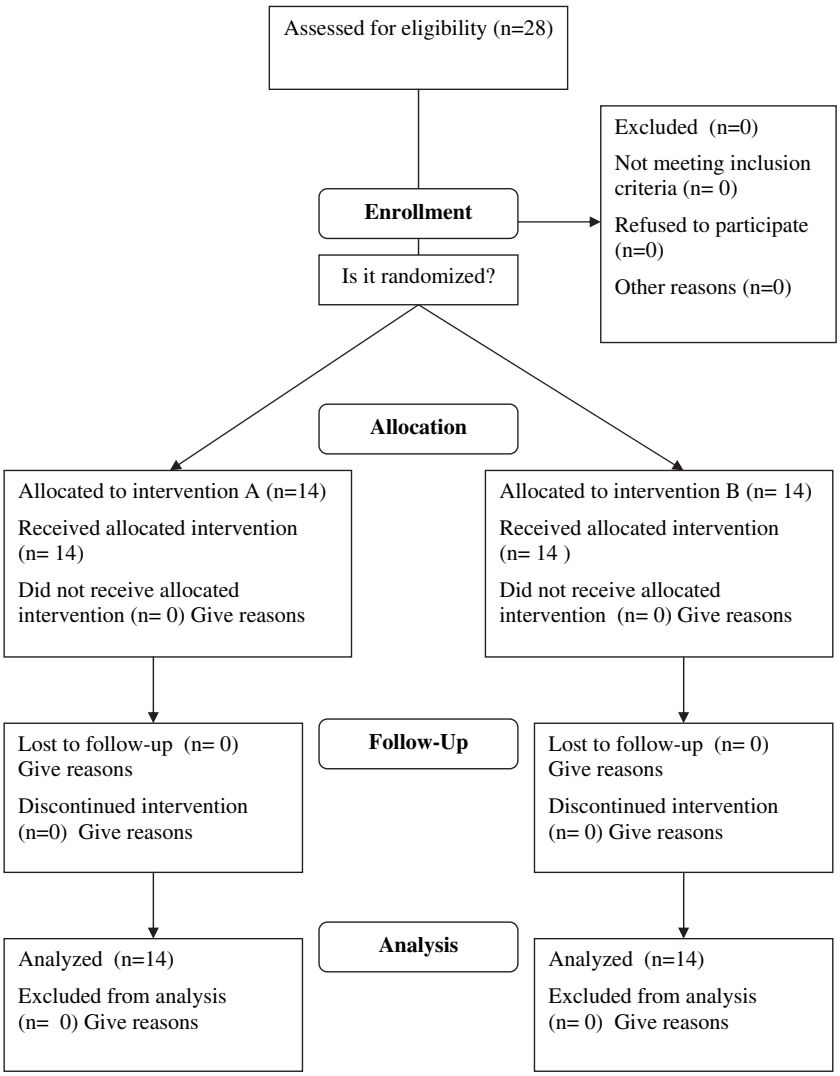
APPENDIX. CONSORT FLOW CHART