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The effect of mini-implant design on peri-implantitis and pain level after insertion in orthodontic treatment: A prospective clinical study

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Abstract

Background. Orthodontic mini-implants provide skeletal anchorage for tooth movement. There are two designs of mini-implants, tapered and cylindrical, which exhibit different clinical characteristics, including possible micro-damage to cortical bone. Complications such as peri-implantitis and pain after mini-implant placement are common. The aim of this study was to evaluate the effect of mini-implant design on peri-implantitis and post-insertion pain level.

Methods. A total of 152 tapered and cylindrical mini-implants were randomly inserted into 76 patients (17 male, 59 female) who were over 16 years of age. Peri-implantitis was assessed using signs of inflammation around mini-implant head. Pain levels of injection, during and immediately after insertion up to one week after implantation, were registered using an 11-point horizontal visual analogue scale (VAS). Data were analyzed using chi-squared and Mann-Whitney U tests.

Results. Peri-implantitis was observed in 7% of mini-implants. There was no significant difference between tapered and cylindrical mini-implants in the number of peri-implantitis cases ($P > 0.05$). Post-insertion pain increased for 6 hours after insertion, and then decreased gradually. None of the patients reported pain a week after mini-implant insertion. There was no significant difference in pain levels of the two groups at all time intervals ($P > 0.05$). Maximum post-insertion pain (6 hours after implantation: 2.52 ± 2.66) was significantly higher than injection pain (1.38 ± 1.71) ($P < 0.001$).

Conclusion. It was concluded that mini-implant design had no significant effect on peri-implantitis and post-insertion pain level.

Key words: **Mini-implant design, peri-implantitis, pain level, injection.**

Introduction

Resistance to unwanted tooth movement is an important prerequisite for orthodontic treatment.[1] Mini-implants have gained in popularity for their successful role in providing skeletal anchorage for tooth movement.[2] Furthermore, The use of mini-implants is simple with low cost, and minimal need for patient compliance.[3] Factors associating with

clinical success of dental implants may not be the same for orthodontic mini-implants due to shape and diameter, anatomic region for implantation, loading time, patient age with regard to bone density, etc.[4] In addition, osseointegration is not necessary for orthodontic mini-implants due to temporary usage.[5] Various types of orthodontic mini-implants are available.[3] There are two main designs of mini-implants according to the shape of the threading part: cylindrical and taper. Many studies have shown that the amount of insertion and removal torque, initial stability, clinical failure rate, and micro-damage to the cortical bone during insertion are different between the two designs. However, no clear evidence is available in this respect.[6-10] Although clinical features and adverse effects of dental implants (e.g. peri-implantitis and pain) have been investigated extensively, lack of sufficient evidence still exists for orthodontic mini-implants.[4] Inflammation around the head of orthodontic mini-implants usually occurs as a result of placement through non-keratinized gingiva or close to the mucogingival junction.[11] This increases the risk of clinical failure.[12] Additionally, using coil spring, chain, and ligature wire along with poor plaque control or patient manipulation have been attributed to peri-implantitis.[11]

Another complication is post-insertion pain. It is known that less surgical invasion leads to less swelling and pain.[5] Although the procedure of mini-implant placement is considered minimally invasive, a potentially painful moment for the patient has been introduced to routine orthodontic treatment.[13,14] It is generally agreed that most of the patients do not feel pain during and after mini-implant placement and general satisfaction has been observed.[15] However, along with the subjectivity of pain, other factors including mini-implant type, anatomic place, local anesthesia, and pre- or postoperative medications can potentially affect the pain level.[13] Numerous studies have evaluated pain and discomfort following mini-implant insertion.[13-16] However, overall conclusions are difficult to draw due to various confounding factors.[13]

With regard to the characteristics of tapered and cylindrical mini-implants and possible differences in micro-damage to the cortical bone, the aim of the present study was to evaluate the effect of mini-implant design on peri-implantitis and pain level under and after insertion and compare the experience of pain and discomfort after insertion of mini-implants and local anesthesia injection as a reference procedure in adult patients.

Methods

Subjects

A total of 76 patients (18 male and 58 female) with an age range of 16-34 years were included in this single-blind, randomized, single-centered study after informed consent was obtained. The inclusion criteria consisted of adults in need of fixed orthodontic treatment, with treatment plan consisting of extraction of the maxillary first premolars, and absolute anchorage for en-masse anterior retraction.

Mini-implant insertion

Seventy-six patients, after meeting inclusion criteria, were randomly divided into two groups and 152 tapered and cylindrical mini-implants were placed by one orthodontist according to the following protocol:
-Buccal infiltration of 0.2 mL per site of 2% lidocaine hydrochloride + 1:100000 units of norepinephrine with a 25-gauge needle.
-Insertion of two mini-implants (cylindrical or tapered, 11 mm in length and 1.6 mm in diameter) (General Implant Company) (Figure 1) buccally and interdentally between the second premolar and the first molar of both sides of maxilla, after a ten-minute pause for appropriate anesthesia.
-Immediate loading of mini-implants as direct anchorage with 200-g closed-coil springs (Biom, China).

The patients were unaware of the study groups but the clinician inevitably was aware of mini-implant design during insertion. The patients were instructed in plaque control around the head of mini-implant along with routine plaque control activities. They were asked to complete questionnaires of pain one week after mini-implant placement.

General inflammation signs, including swelling,

Figure 1. Cylindrical (right) and tapered (left) mini-implants.

gingival enlargement, redness and bleeding on probing around the head of mini-implants, were assessed 4 and 8 weeks after implantation. The clinician put "yes" for the presence of inflammation and "no" for clinically healthy soft tissue. The outcome of pain was evaluated by measuring pain levels with a visual analog scale at 7 time intervals: injection pain, during and immediately after insertion, 6 hours, 24 hours, 48 hours and a week after insertion. The participants registered pain levels by placing a mark along an eleven-point horizontal visual analog scale (VAS) according to the time table. Analgesic consumption (type, dosage, intervals) were self-reported.

Statistical analysis

Data were analyzed with SPSS 20. Inflammation around tapered and cylindrical mini-implants was compared using chi-squared test. For analysis of the data related to pain levels a parametric or non-parametric test was to be chosen according to the results of normality test. In this study $P < 0.05$ was considered statistically significant.

Results

There were 10 cases (6.8%) of peri-implantitis (in 4 tapered and in 8 cylindrical mini-implants) in the first 8 weeks after insertion. There was no statistically significant difference in inflammation between the two groups (df = 1, P = 0.355).

At the questionnaire delivery session three patients were excluded from the study (1 lost the questionnaire; 2 provided incomplete information). Table 1 presents the valid data of 146 mini-implants of 16 male and 57 female subjects with an age range of 16.20–35.66 years (19.42 ± 6.15 years [mean ± SD]).

The distribution of data was not normal. Thus, pain levels between the two groups were compared using Mann-Whitney U test. There were no statistically significant differences in pain levels between the two groups during the insertion (P = 0.34), immediately after insertion (P = 0.34), and 6 hours (P = 0.76), 24 hours (P = 0.69) and 48 hours (P = 0.26) after insertion. All the subjects reported no pain a week after insertion; therefore, the median difference between the two groups was not significant (P = 1.00) (Table 2).

Table 1. Mean values of pain levels of all samples (n=146)

Pain level	Min	Max	Mean ± SD
Injection	0	6	1.38 ± 1.71
During insertion	0	6	0.66 ± 1.40
Immediately after	0	6	0.36 ± 1.20
6 hours	0	10	2.52 ± 2.66
24 hours	0	8	0.92 ± 1.91
48 hours	0	5	0.64 ± 1.33
1 week	0	0	0.00 ± 0.00

Min: minimum, Max: maximum, SD: standard deviation

There was a significant difference between injection pain and the maximum pain following mini-implant insertion (after 6 hours). The patients reported higher levels of pain 6 hours after implantation (P < 0.001) (Figure 2).

Eleven patients (15%) reported that they had taken analgesics in the first six hours after implantation and 16 patients (22%) reported no post-insertion pain.

Discussion

Several complications associated with orthodontic mini-implants have been reported in the literature.[11] Inflammation of soft tissues around the head of mini-implant is common and may lead to loss of clinical stability.[5-11] The main action to prevent peri-implantitis is mini-implant insertion through firm attached gingiva.[2,15] Other factors related to inflammation are root contact during insertion, orthodontic auxiliaries attachment and oral hygiene.[11,18] Despite the great effect, there is lack of information about exact features and duration of peri-implantitis around mini-implants.[2,3] Furthermore, criteria used for inflammation are not clearly defined.[2-5,17] Park et al[4] reported that peri-implantitis was associated with decreased clinical success rate. Another study reported that failure rate was 30% higher in mini-implants with peri-implantitis.[19] In this study less

Table 2. Pain levels in two groups of the study at different time points

Pain	Cylindrical (n=72)		Taper (n=74)		P	U
	Min-Max	Mean ± SD	Min-Max	Mean ± SD		
Injection	0-5	1.61 ± 1.31	0-6	1.36±1.82	0.57	2801.00
During insertion	0-6	0.73±1.49	0-5	0.58±1.30	0.34	2856.00
Immediately after	0-6	0.41± 1.24	0-5	0.31±1.15	0.34	2769.00
6 hours	0-8	2.49 ±2.4 6	0-10	2.56±2.87	0.76	2740.00
24 hours	0-7	0.93 ± 1.82	0-8	0.92±2.01	0.69	2744.00
48 hours	0-5	0.73 ±1.3 2	0-5	0.57±1.35	0.26	2877.00
1 week	0-0	0.00±0.00	0-0	0.00±0.00	1.00	2664.00

(Min: minimum pain level, Max: maximum pain level, SD: standard deviation)
*P < 0.05 was statistically significant.

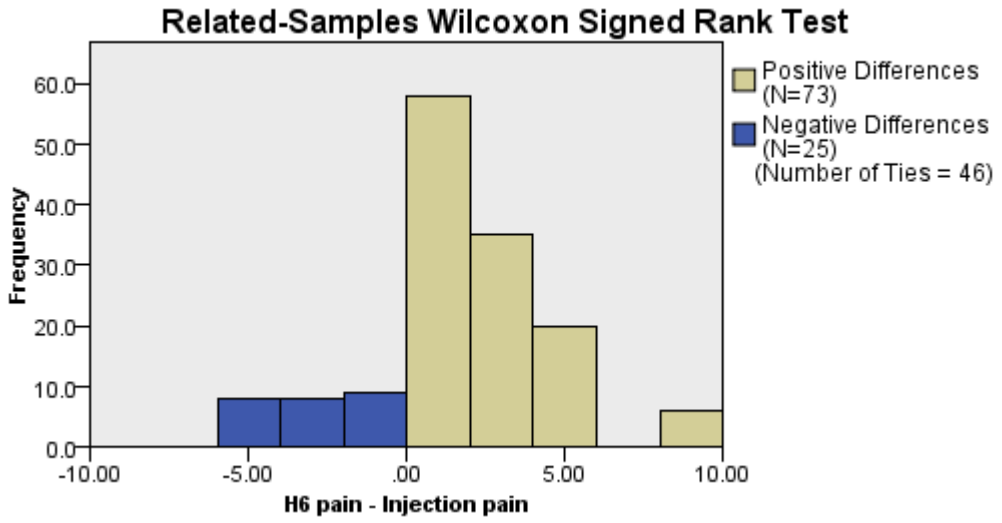

Figure 2. Comparison of pain levels during injection and 6 hours after implantation.

than 10% of the samples manifested inflammation signs. In addition, inflammation prevalence in cylindrical and tapered mini-implants were compared and there was no significant difference between the two groups ($P > 0.05$). To the best of our knowledge there was no previous investigation in this respect. We assessed inflammation for two months after placement. However, it seems that longer follow-ups are needed for more valid information.

Pain level increased up to 6 hours after insertion and then decreased in the following days. No patient reported pain and discomfort on implantation site after 1 week. Some studies have also shown no report of pain a week after mini-implant insertion.[13-15,17] In this study there was no statistically significant difference between the pain levels of the two groups at all the time intervals. It seems that mini-implant design has no effect on pain and discomfort. To the best of our knowledge it was the first investigation on the effect of mini-implant design on pain levels after insertion. A positive point of this study was assessment of injection pain as a reference procedure, which was used in some previous studies.[13,17] Pain of mini-implant insertion (after 6 hours) was significantly higher than injection pain ($P < 0.001$). Patients participating in this study were all over 16 years old, which was another positive aspect of the present study. Perception of pain is said to change with age due to central nervous system tracts.[15] The maximum pain level at 6 hours after insertion suggests that it is necessary to reassure the patients and drug administration of analgesics at this time interval as 15% of patients in this study took pain killers during this period.

Further studies are required to investigate the effect of mini-implant design on bone remodeling, healing and micro-damage to the cortical bone relative to various clinical features of mini-implants in orthodontic treatment.

Conclusion

- Mini-implant design had no significant effect on peri-implantitis and post-insertion pain levels.
- Maximum pain level occurred 6 hours after implantation.
- Injection pain was less than mini-implant insertion pain.

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