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Original

A prospective study of factors associated with orthodontic mini-implant survival

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Abstract: **The orthodontic mini-implant (MI) is a widely used anchorage device in orthodontic treatment. This prospective study analyzed MI survival and factors associated with MI survival in 139 patients (114 females and 25 males; average age, 25.7 years; age range, 12-56 years) who had received orthodontic treatment with MIs. Survival analysis and Kaplan-Meier curves were used to identify clinical variables associated with MI survival. For the 254 MIs investigated, the overall success rate was 85.8%, and the 1-year cumulative survival rate was 81.6%. MI survival was significantly associated with patient age and MI size. Notably, MI survival was significantly longer in patients aged 20-30 years than in older patients. The Cox proportional-hazards model revealed a 5% increase in failure risk for every 1-year increase in age among participants older than 30 years. Additionally, MI failure risk was inversely associated with MI length. MIs are generally reliable anchorage devices for orthodontic treatment but should be used with caution in older patients, due to the higher rate of failure in that population. Another important factor in MI survival is implant size. Future studies should attempt to clarify associations between MI survival and clinical variables.**
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Keywords: orthodontic mini-implant; survival rate; success rate; Kaplan-Meier survival analysis.

Introduction

Orthodontic anchorage is defined as the nature and degree of resistance to displacement offered by an anatomic unit. Anchorage systems used in conventional orthodontic treatments are classified as extraoral or intraoral devices. For extraoral devices, anchorage is provided by a headgear or facial mask connected to the teeth. For intraoral devices, anchorage is provided by a transpalatal arch or lingual holding arch. However, these anchorage systems have many disadvantages, including anchorage loss, the need for high patient compliance, and esthetic limitations.

A recent development is temporary anchorage devices (TADs), which are anchored to the alveolar bone and provide direct or indirect anchorage with good stability. The advantages of TADs, as compared with conventional anchorage devices, include easier manipulation, simpler treatment mechanics, shorter total treatment time, and greater patient comfort during orthodontic treatment (1). Additionally, treatment outcome does not depend on patient compliance, and anchorage loss is not a concern. Commonly used TADs include mini-implants (MIs) and miniplates.

However, TADs have several drawbacks. Infection of surrounding soft tissues can cause inflammation that leads to poor osteointegration and loss of primary stability. Good oral hygiene is therefore essential for maintaining TAD stability, since infection usually results from poor oral hygiene. Because of their good biocom-

Table 1 Characteristics of participants

Characteristic	Number (%)
Sex (male/female)	25/114
Age (years) (mean ± SD)	25.7 ± 7.5
Type of malocclusion	
Class I	59 (42.4)
Class II	53 (38.1)
Class III	27 (19.4)
Facial divergence	
High	63 (45.3)
Average	63 (45.3)
Low	13 (9.4)
Operator	
A	66 (47.5)
B	40 (28.8)
C	33 (23.7)
Total	139 (100)

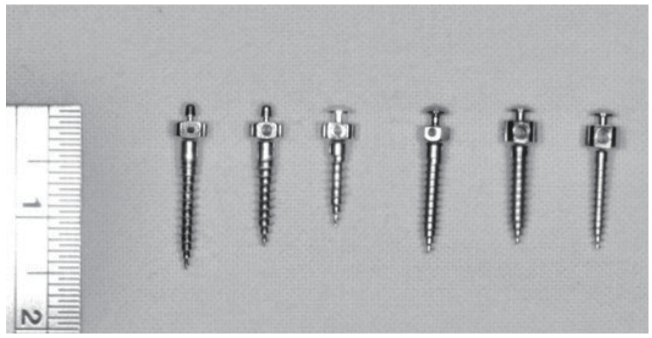

Fig. 1 Mini-implants used in this study (from left to right: stainless steel 2 × 12 mm, 2 × 10 mm, and 2 × 8 mm; Ti-alloy 2 × 11 mm, 2 × 9 mm, and 1.5 × 9 mm).

patibility and good osteointegration with bone tissue, Ti-alloy MIs are useful when anatomic structures such as tooth roots, blood vessels, or nerves must be avoided (2). Another advantage of Ti-alloy MIs is that their stability increases as resistance to orthodontic force increases. As compared with stainless steel MIs, Ti-alloy MIs have higher corrosion resistance (3). However, the disadvantages of Ti-alloy MIs include lower mechanical strength and the need to drill a pilot hole for placements in very dense cortical bone (3). According to Deguchi et al. (2), osteointegration between Ti-alloy MIs and alveolar bone requires at least 3 weeks. While the primary advantage of pure titanium is its excellent osteointegration (2), titanium MIs are very brittle, which limits their penetrability. As compared with pure titanium and titanium alloy MIs, stainless steel MIs have better penetration and do not require a pilot hole (3). Another advantage of stainless steel MIs is their ease of placement.

MI success and the factors associated with MI success have been thoroughly studied in recent years. Reported success rates for MIs vary widely, from 52 to 100% (4). Although most clinicians and researchers agree that MIs are effective, the success rates for stainless steel MIs are rarely reported. Therefore, this prospective study evaluated MI survival rates and factors associated with MI stability. In addition, MI survival rate and factors associated with MI survival were compared between stainless steel MIs and Ti-alloy MIs.

Materials and Methods

Patients

Table 1 shows the characteristics of the 139 study participants (114 females and 25 males; average age, 25.7 ± 7.5 years; age range, 12-56 years). All patients were treated with fixed orthodontic appliances and MIs (titanium alloy MIs, Ancer, Huang-Liang Biomedical Technology, Kaohsiung, Taiwan; stainless steel MIs, Bio-Ray, Syntec Scientific Corp., Taipei, Taiwan) from October 2012 through August 2014. Habitual smokers and patients with osteoporosis or other bone diseases were excluded. Before the study was begun, written informed consent was obtained from the patients. The consent procedure and treatment protocol was approved by the institutional review board of Kaohsiung Medical University Hospital (KMUH-IRB-20120288).

Surgical procedure

The MI placements were performed as follows. Extraoral and intraoral aseptic procedures were followed by local anesthesia and MI placement. MI size was selected according to the clinical requirements of each patient (5). Normal saline solution (0.9%) was used to irrigate the area surrounding the MI site. Analgesics were prescribed for pain control. MI failure was defined as an MI that required removal due to loosening, pain, infection, or pathologic changes in surrounding soft tissues.

Patient- and implant-related characteristics

The variables investigated were divided into patient-related and implant-related characteristics. Patient-related characteristics included age (<20 years, 20-30 years, or >30 years, i.e., adolescent, young adult, or older adult, respectively), sex, occlusion type (Class I, Class II, or Class III according to Angle's classification of malocclusion), and facial divergence (high, low, or average: SN-MP >32°, <21°, or 21° to 32°, respectively, in males, and >35°, <24°, or 24° to 35°, respectively, in females). Implant-related characteristics included MI size (2 × 12 mm, 2 × 11 mm, 2 × 10 mm, 2 × 9 mm, 2 × 8 mm, or 1.5 × 9 mm, as shown in Fig. 1; MI size was selected

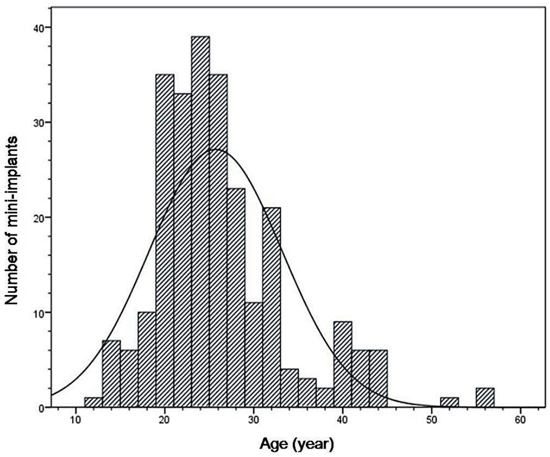

Fig. 2 Histogram of patient age distribution for the 254 mini-implants.

Table 2 Patient-related characteristics for mini-implants

Patient-related characteristic	Number (%)
Sex	
Male	45 (17.7)
Female	209 (82.3)
Age (years)	
<20	36 (14.2)
20-30	159 (62.6)
>30	59 (23.2)
Type of occlusion	
Class I	117 (46.1)
Class II	89 (35.0)
Class III	48 (18.9)
Facial divergence	
High	113 (44.5)
Average	118 (46.5)
Low	23 (8.9)
Operator	
A	129 (50.8)
B	72 (28.3)
C	53 (20.9)
Total	254 (100)

Table 3 Implant-related characteristics of mini-implants

Implant-related characteristic	Number (%)
Materials	
Stainless steel	151 (59.4)
Ti-alloy	103 (40.6)
Jaw	
Maxilla	213 (83.9)
Mandible	41 (16.1)
Position	
Anterior	18 (7.1)
Posterior	236 (92.9)
Site	
Left	103 (40.6)
Right	101 (39.8)
Purpose	
Retraction	152 (61.8)
Protraction	8 (2.8)
Intrusion	52 (19.7)
Upright	26 (10.2)
Reinforced anchorages	10 (3.1)
BAMP	6 (2.4)
Size, mm	
2 × 12	58 (22.8)
2 × 10	63 (24.8)
2 × 8	28 (11.0)
2 × 11	73 (28.7)
2 × 9	17 (6.7)
1.5 × 9	15 (5.9)
Mode of force application	
Elastomeric chain	244 (96.1)
Ligature wire	4 (1.6)
Inter-arch elastics	6 (2.4)
Healing time	
Early loading (≤3 weeks)	176 (69.3)
Late loading (>3 weeks)	78 (30.7)
Total	254 (100)

according to the bone available at the insertion site) (5), insertion site (maxilla or mandible; right or left; anterior incisor and canine regions or posterior premolar and molar regions), implant material (stainless steel or Ti-alloy), mode of force application (elastomeric chain, interarch elastic, or ligature wire), implant purpose (retraction, protraction, intrusion, uprighting, anchorage reinforcement, or bone-anchored maxillary protraction), healing time (≤3 weeks or >3 weeks), and operator (A, Y.C.T.; B, C.Y.P.; C, S.T.C.).

Statistical analysis

First, descriptive statistics were used to calculate the overall success rate for MIs. Kaplan-Meier survival analyses with log-rank tests were used to evaluate and compare patient- and implant-related characteristics. The effects of age on survival were further assessed by a Cox proportional-hazards model (hazard ratio or risk ratio = e^{β} or $\exp(\beta)$). Statistical analysis was performed using SPSS software for Windows (version 20, SPSS Corp., Chicago, IL, USA). In all tests, $P < 0.05$ was considered to indicate statistical significance (confidence interval, 95%).

Results

Figure 2 shows the distribution of the 254 MIs in relation to patient age. Tables 2 and 3 show the patient- and implant-related characteristics of the MIs, respectively. The overall MI success rate was 85.8% (218 of 254 MIs), and the cumulative 1-year survival rate was 81.6%.

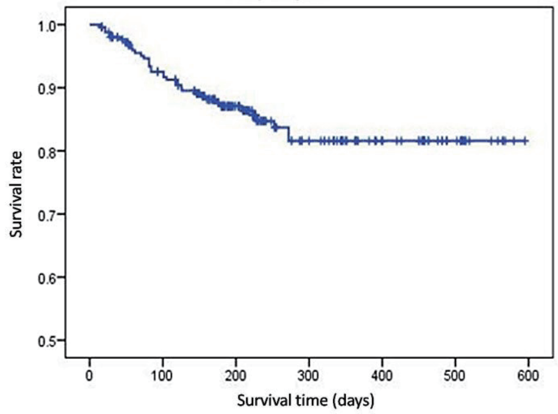

Fig. 3 Kaplan-Meier curve for mini-implant survival.

Table 4 Results of analysis of patient-related characteristics associated with mini-implant survival

Patient-related characteristics	Failure/total implants (*n*)	1-year cumulative survival rate (%)	Significance (*P* value)	aHR (95% CI)
Sex			0.853	
Male	6/45	81.0		1
Female	30/209	83.8		1.015 (0.413-2.492)
Age (years)			0.011	
<20	4/36	88.2		1
20-30*	17/159	84.5		0.976 (0.328-2.903)
>30*	15/59	69.6		2.603 (0.863-7.850)
Type of occlusion			0.111	
Class I	18/117	80.1		1
Class II	8/89	85.7		0.497 (0.214-1.152)
Class III	10/48	76.5		1.345 (0.617-2.932)
Facial divergence			0.488	
Low	5/23	76.7		1
Average	18/118	81.5		0.697 (0.255-1.905)
High	13/113	83.1		0.596 (0.207-1.702)
Operator			0.156	
A	16/129	87.0		1
B	14/72	58.8		2.040 (0.978-4.254)
C	6/53	78.3		1.561 (0.592-4.114)
Total	36/254	81.6		

aHR: adjusted hazard ratio; CI: confidence interval. *$P < 0.05$ for age 20-30 years vs. age >30 years; log-rank test.

Figure 3 shows the Kaplan-Meier curve for MI survival. Tables 4 and 5 show the patient- and implant-related characteristics associated with mini-implant survival, respectively. Age and MI size had the greatest effects on MI survival. MI survival was significantly longer in younger patients than in older patients ($P = 0.011$). The log-rank test showed a significantly higher survival rate in the age group 20-30 years than in the age group >30 years ($P < 0.05$). The Cox proportional-hazards model showed that the HR for MI failure risk was 1.05 for a 1-year increase in age among patients older than 30 years ($HR = e^{\beta} = e^{0.049} = 1.05$; $P = 0.008$). Figure 4 shows the Kaplan-Meier curves for MI survival, by age group. Notably, the survival rate was significantly higher in patients with long MIs than in those with short MIs ($P = 0.004$; Table 5).

Discussion

After the introduction of MIs to orthodontic practice, several studies investigated MI success rates and factors associated with MI failure (1,5-10). However, previous studies did not consistently define these outcomes, which complicate subsequent follow-up studies of MI success and failure rates. Thus, for various reasons, researchers may be unable to continuously follow the status of an MI. One solution is survival analysis, which is used to investigate the relationship between a specific medical therapy and survival rate. This study used survival analysis to investigate MI survival and defined an MI failure as MI removal due to loosening, inflammation, or patho-

Table 5 Results of analysis of implant-related characteristics associated with mini-implant survival

Implant-related characteristics	Failure/total implants (*n*)	1-year cumulative survival rate (%)	Significance (*P*-value)	aHR (95% CI)
Material			0.437	
Stainless steel	20/151	55.7		1
Ti alloy	16/103	84.2		0.758 (0.377-1.528)
Jaw			0.956	
Maxilla	30/213	81.1		1
Mandible	17/159	85.1		0.912 (0.376-2.209)
Position			0.736	
Anterior	3/18	73.6		1
Posterior	33/236	82.0		0.748 (0.229-2.444)
Site[†]			0.815	
Left	13/103	85.0		1
Right	13/101	80.7		1.137 (0.527-2.456)
Purpose			0.300	
Retraction	20/157	82.4		1
Protraction	1/7	85.7		1.095 (0.147-8.185)
Intrusion	11/50	70.8		1.786 (0.832-3.831)
Upright	3/26	86.7		0.917 (0.268-3.131)
Others	1/14	93.3		0.495 (0.066-3.702)
Size, mm			0.004	
2 × 12; 2 × 11; 2 × 10[‡]	22/194	83.4		1
2 × 9; 2 × 8[‡]	10/46	75.0		2.622 (1.250-5.498)
1.5 × 9	4/14	73.3		2.205 (0.948-2.858)
Mode of force application			0.533	
Elastomeric chain	34/244	81.6		1
Inter-arch elastics	1/6	83.3		0.979 (0.133-7.183)
Ligature wire	1/4	50.0		2.953 (0.402-21.673)
Healing time			0.511	
Early loading (≤3 weeks)	22/176	81.9		1
Late loading (>3 weeks)	14/78	79.8		1.314 (0.678-2.654)
Total	36/254	81.6		

aHR: adjusted hazard ratio; CI: confidence interval. [†]Mini-implants at anterior nasal spine, para-median palate, and mandibular interdental area could not be classified in this category and were thus excluded from classification. ‡$P < 0.05$ for implant size of 2 × 12/2 × 11/2 × 10 mm vs. 2 × 8/2 × 9 mm; log-rank test.

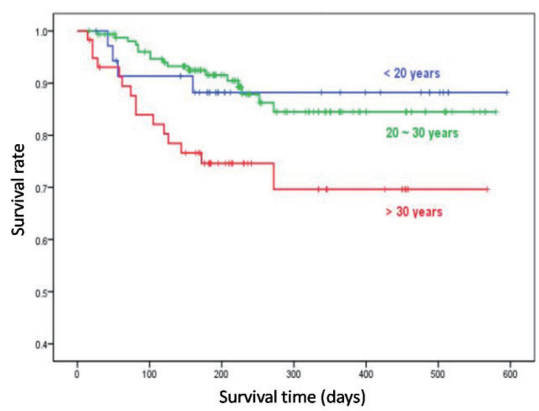

Fig. 4 Kaplan-Meier curves for mini-implant survival, by age group.

logic change in surrounding soft tissue. Censored data included data for an MI that remained stable throughout the observation period or was removed after completion of treatment. This study did not predict MI outcomes after the observation period, i.e., we did not determine whether MIs succeeded or failed after removal upon completion of treatment and did not determine whether MIs failed if they were not removed. Survival analysis was used to determine MI survival rate, and the log-rank test was used to identify factors associated with survival rate, as indicated by the relationship between the survival curve and the investigated variable.

The overall success rate was 85.8%, which is within the range of previous studies, including that of Chen et al. (1), who reported an overall success rate of 85.2% in a retrospective study of three different skeletal anchorage systems, including miniplates, MIs, and microscrews. Other studies reported a higher success rate for miniplates than for MIs (1,8,11). Wu et al. (12) evaluated 414 MIs, including stainless steel and Ti-alloy MIs, and reported a success rate of 89.9%, which is higher than that in the present study. However, although the MI materials were similar, the surgical procedures differed. According to Chen et al. (5), drilling a pilot hole substantially increases the MI success rate. Additionally, mechanical strength is lower for pure titanium and Ti-alloy MIs than for stainless steel MIs (13). Drilling into the alveolar bone usually blunts the tip of the MI, which increases the risk of MI breakage. No pilot holes were drilled for the present MIs, which may explain the difference in success rates between studies (12).

A prosthodontic dental implant increases the density of the alveolar bone, thus increasing the implant success rate. As compared with prosthodontic implants, orthodontic MIs are smaller and require less healing time. The effect of age on MI success rate is controversial. Some studies reported a higher MI failure rate in younger patients (1,14). Chen et al. (1) reported that MI stability primarily depends on the mechanical lock between the alveolar bone and the MI. Therefore, cortical bone density and thickness are important factors in the success of an MI. Additionally, because bone turnover rate and density decrease with age, the MI failure rate is likely to increase with age. Nevertheless, some studies found that MI success rates do not vary by age (5,8,12,15,16). In the present study, the MI failure risk increased by 5% for every 1-year increase in age among patients older than 30 years. The exponent of the coefficient for age indicates that a 20-year increase in age is associated with a 2.66-fold increase in the risk of MI failure (($e^{\beta*n} = e^{0.049*20} = (1.05)^{20} = 2.66$). The risk ratio is a multiplicative effect. Aging alters the distribution of organic and non-organic constituents in bone. MI implantation can be regard as a form of alveolar bone trauma, and the healing of bone traumas or fractures is slower in older patients than in younger patients. If healing is insufficient, the stability and success rate of MIs decrease. Additionally, 82% of the present participants were female. Sex-stratified analysis of the association between MI survival rate and age showed that MI survival significantly differed between older females and older males ($P = 0.030$).

Current standard clinical practice calls for the use of stainless steel or pure titanium bone screws for internal fixation in orthopedic surgery and oral/maxillofacial surgery. Ti alloy (Ti_6Al_4V) is used for dental implants because it has greater stiffness than pure titanium but comparable biocompatibility. In clinical practice, both stainless steel and Ti alloy are considered acceptable for MIs. The survival and success of an MI depends on whether a good mechanical lock is obtained between the MI and the alveolar bone.

In 2012 Pan et al. (17) used a resonance frequency detection device (Implomates; BioTech One, Inc., Taipei, Taiwan) to measure the resonance frequencies of MIs inserted into artificial bone blocks. Primary stability was then compared among MIs of varying sizes, compositions, and insertion depths. With respect to stability, insertion depth was more important than MI composition. The present study similarly showed that MI success rate and survival did not significantly differ in relation to implant material. Some clinicians have used Ti-alloy MIs to achieve osteointegration with alveolar bone tissue. One study found that at least 3 weeks of healing time was needed to achieve sufficient osteointegration to resist orthodontic force (2). Therefore, the present study classified the participants by healing time into an early loading group (≤3 weeks) and late loading group (>3 weeks). Healing time was also assessed in relation to implant material. In the early loading group, success rates did not significantly ($P = 0.065$) differ between stainless steel MIs (86.3%; 113/131) and Ti-alloy MIs (91.1%; 41/45). In the late loading group, the success rate did not significantly differ ($P = 0.664$) between stainless steel MIs (90.0%; 18/20) and Ti-alloy MIs (79.3%; 46/58). In other words, the MI material did not affect MI success rate, regardless of healing time.

Further comparisons of MIs (diameter, 2 mm) showed that survival rate significantly ($P = 0.004$) differed between long MIs (length, 10-12 mm) and short MIs (length, 8-9 mm). MI failure risk was inversely associated with MI length. Insertion depth is greater for longer MIs, and, as was previously noted (17), insertion depth is positively associated with primary stability. However, other studies reported that MI length was not significantly associated with MI success rate (5,6,8), and some studies (12,18) found that MI diameter was associated with MI success rate. For example, use of large-diameter (1.4-1.5 mm) interradicular MIs might increase the risk of surface damage to the adjacent root, which would decrease primary stability.

Several studies reported that oral hygiene is an important factor in MI success and survival (4,9,15,16). However, oral hygiene was not assessed in this study for two reasons. First, all patients were educated in oral

health maintenance and were followed up to determine the status of their MIs. Second, for all MIs removed due to failure, the cause of failure was excessive mobility with inflammation of surrounding soft tissue. Because it was not possible to distinguish between failures caused by excessive mobility and failures caused by inflammation, oral hygiene was not considered.

In conclusion, although the use of MIs for anchorage is a recent trend in clinical orthodontic treatment, factors associated with MI survival and success have not been clearly identified. Therefore, this prospective study evaluated survival in 254 MIs. The 1-year survival rate was 81.6%, and the overall success rate was 85.8%. Kaplan-Meier survival analysis revealed that the most important factor in MI outcome is patient age, which was positively associated with MI failure risk. Another important factor was MI length. MI survival and success were not significantly associated with other variables, including sex, facial divergence, malocclusion type, operator, MI site, MI purpose, MI size, mode of force application, or healing time.

An earlier version of this work was recognized as the outstanding research poster presentation at the 6th World Implant Orthodontic Conference, in Anaheim, CA, USA, October 4, 2014.

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Conflicts of interest

None declared.

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