Original Article

A novel auxiliary device enhances the miniscrew stability under immediate heavy loading simulating orthopedic treatment

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ABSTRACT

Objectives: To evaluate miniscrew stability and perform a histomorphometric analysis of the bone around the miniscrew under a load corresponding to orthopedic force.

Materials and Methods: Thirty-two miniscrews were implanted into eight rabbit tibias. Auxiliary group rabbits received auxiliary devices with miniscrews (n = 8, 28 days; n = 8, 56 days), and those in the nonauxiliary control group received miniscrews without auxiliary devices (n = 8, 28 days; n = 8, 56 days). Elastics were placed between miniscrews to apply a load of 5 N. Miniscrew stability was evaluated using a Periotest. Bone-to-implant contact (BIC) and spike implantation depth were measured histomorphologically.

Results: Periotest values in the auxiliary group were significantly lower than those in the nonauxiliary group at all time periods. There was no significant difference in BIC between the auxiliary and nonauxiliary groups at 28 or 56 days postimplantation. The implantation spike depth in the auxiliary group was significantly greater at 56 days compared to that at 28 days. Newly formed bone was observed around the spike of the auxiliary device at 56 days.

Conclusions: The results suggest that the use of miniscrews in conjunction with auxiliary devices provides stable skeletal anchorage, which may be useful in orthopedic treatments. (*Angle Orthod.* 0000;00:000–000.)

KEY WORDS: Miniscrew; Stability; Animal study; Temporary anchorage device; Orthopedic force; Immediate loading

INTRODUCTION

Clinical studies[1–3] have reported orthopedic treatment using skeletal anchorage, including miniscrews or miniplates anchored directly to the bone, with forces of 3–6 N. Compared to conventional treatment methods using teeth as anchorage, skeletal anchorage may provide superior clinical results, such as reduced treatment times and minimization of unnecessary dental changes.[1,2]

Miniscrews are less invasive than miniplates but have a higher failure rate (17%) and lower retention force threshold in orthopedic treatment.[1,4] Conversely, miniplates have a failure rate of 0–8.6%, but their

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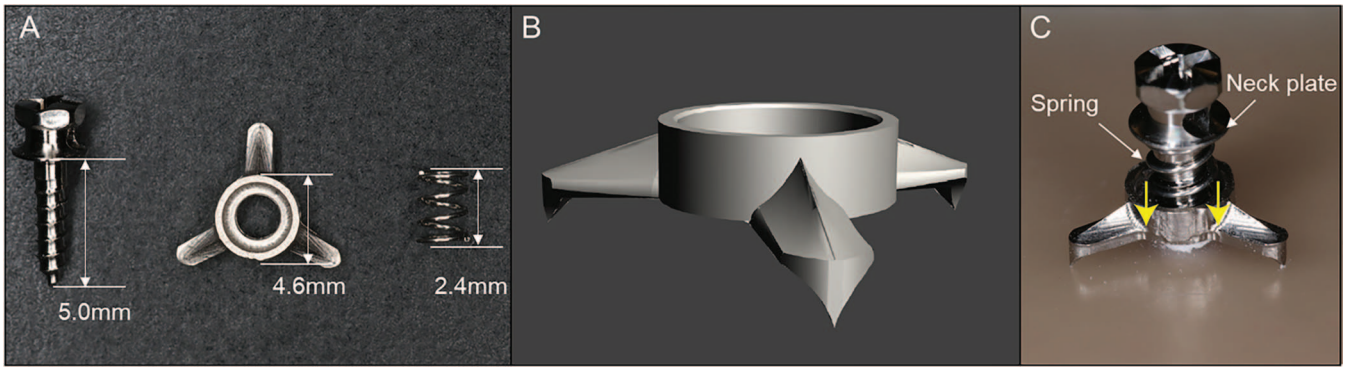

Figure 1. (A) Miniscrew implanted into bone with auxiliary device and spring. (B) Auxiliary skeletal anchorage device used in this study. (C) Spring is compressed by 1.4 mm, transmitting a compression force of 1.6 N to the auxiliary device (yellow arrows).

placement requires flap surgery with high infection risk.[3,5] Thus, novel skeletal anchorage that is less invasive and more stable under heavy loads is needed. Several studies[6–9] reported the development of skeletal anchorage with superior features using a combination of miniscrews and auxiliary devices. One[6] demonstrated that auxiliary device use increased miniscrew mechanical retention force by three to five times compared to nonuse. In an in vivo study,[7] miniscrews with auxiliary devices that received no external force improved mechanical retention by an approximately twofold measure at 4 and 8 weeks. Computed tomography images revealed that the auxiliary device tip was embedded in the cortical bone. Using finite element analysis, and not through in vivo experiments, another study[8] reported that the application of "washers" (similar to those used in the previous studies[6,7]) may reduce stress on the surrounding bone and decrease miniscrew displacement. Kim et al.[9] used a similar device for intermaxillary fixation and applied a 150 g load. They reported that the device was stable during the trial period under orthodontic force, without harmful effects on the periodontal tissues. No study has ever investigated both stability of a miniscrew with an auxiliary device and the histological response of the bone surrounding the miniscrew with the auxiliary device simultaneously under heavy loading.

Therefore, the aim of this study was to validate the clinical applicability of an auxiliary device during orthopedic treatment by evaluating miniscrew stability along with a histomorphometric analysis of the bone around the miniscrew subjected to heavy force loads.

MATERIALS AND METHODS

Novel Auxiliary Device

Conventional miniscrews with 1.3-mm diameter and 5.0-mm length (Dual-Top; Jeil Medical, Seoul, Korea); auxiliary skeletal anchorage devices with a 4.6-mm outer diameter, 3.2-mm inner diameter, and 1.8-mm height (Kono Seisakusyo Corp, Chiba, Japan; raw material, Ti6Al4V; ASTM F136-96, PCT International Publication No. WO 2014/088116 A1); and springs with 2.4-mm length (Kono Seisakusyo Corp, Chiba, Japan; raw material, CoCrNi) were used (Figure 1A,B). The spike-like structure of the auxiliary device was in contact with the bone surface. During implantation, the auxiliary device was pressed on the bone and fixed by the reinforcing pressure of the spring compressed between the neck plate and auxiliary device (Figure 1C).

Protocol

The experimental protocol was approved by the institutional experimentation committee of Kagoshima University (No. D20014). Eight adult male Japanese white rabbits (3.5–4.0 kg) were used as experimental models; adequate measures were taken to minimize pain or discomfort, and "The Animal Research: Reporting of In Vivo Experiments" guidelines were followed. Thirty-two miniscrews were implanted into eight rabbit tibias. Rabbits were randomly divided into two groups: auxiliary group rabbits received auxiliary devices with miniscrews ($n = 8$, 28 days; $n = 8$, 56 days); nonauxiliary control group rabbits received miniscrews without the auxiliary device ($n = 8$, 28 days; $n = 8$, 56 days). All experimental animals were injected intramuscularly with three types of mixed anesthesia: medetomidine 0.5 mg/kg, midazolam 2.0 mg/kg, and butorphanol 0.5 mg/kg. Anesthesia was maintained with 2% sevoflurane. Local anesthesia with lidocaine containing 1/80,000 epinephrine was applied to each implantation site. A pilot hole was drilled with a 1.0-mm–diameter spiral drill using an electric drill with physiological saline solution irrigation. With a driver machine (Orthonia; Jeil Medical), two miniscrews were implanted 7 mm apart on each side.

All miniscrews were placed such that the distance from the cortical bone surface to the head, as measured by a digital caliper (Mitutoyo, Kanagawa, Japan), was 3.5 mm. In the auxiliary device group, a

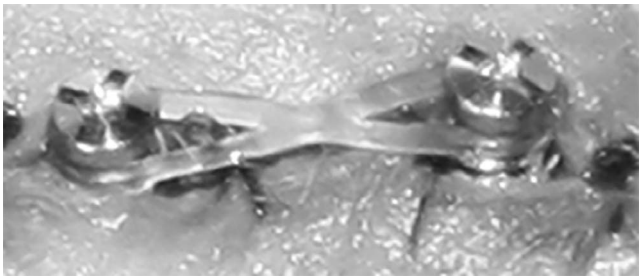

Figure 2. Miniscrews in rabbit tibia with load applied.

spring was interposed between the neck plate and auxiliary device, with the spike tips facing each other. The sutures were placed with the miniscrew head exposed on the skin in both groups, and the auxiliary device was covered by skin using a suture needle and nylon suture (Akiyama Mfg, Tokyo, Japan). Elastics were placed between the miniscrews to apply a load and were replaced weekly (Figure 2). Because a load of 3–6 N is often used in orthopedic treatment,[1–3] the load was set at 5 N using a tension gauge (YDM Co, Tokyo, Japan). At 28 or 56 days postimplantation, the animals were euthanized with sodium pentobarbital (80–100 mg/kg) through the ear vein (Figure 3).

Stability Measurement

Miniscrew stability tests were performed using a Periotest (Siemens AG, Bensheim, Germany), which measures specimen mobility by electromagnetically driven percussion and an electronically controlled rod fitted to the instrument. During the measurements, miniscrew heads were separated from the tapping rod by 1 mm and percussed from three directions (Figure 4). Measurements were repeated three times for each direction; the average values were used as representative values. Measurements were taken at the time of implantation and after 28 and 56 days for the 28-day and 56-day models, respectively.

Histomorphometric Analysis

After euthanasia, the tibia was immediately removed and fixed in 4% formaldehyde solution, dehydrated in a series of graded ethanol solutions, and, subsequently, embedded into resin (Rigolac; Oken, Tokyo, Japan). The resin blocks were cut with a diamond band cutting system (BS-300CP, EXAKT Advanced Technologies GmbH, Norderstedt, Germany) parallel to the miniscrew long axis and traction direction. The cut blocks were polished with water-resistant paper until the spike tip appeared on the surface and specimens were then attached to acrylic plates with adhesive paste on the polished surface. Specimens were thinly sliced and polished to approximately 100 μm using waterproof paper. Thirty-two histological slides were double-

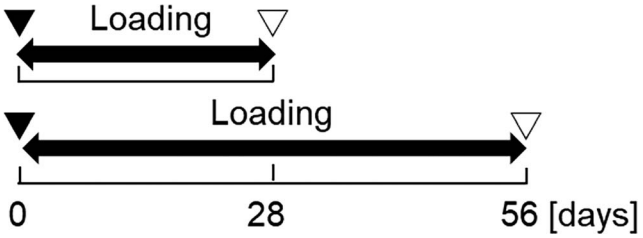

Figure 3. Experimental schedule. The auxiliary and nonauxiliary groups consisted of 28-day (n = 8) and 56-day loading models (n = 8). ▼: implantation and stability measurement. ▽: sacrifice and stability measurement.

stained with fuchsin and methylene blue and observed under an optical microscope (XC10; Olympus, Tokyo, Japan).[10] The bone tissue around the miniscrew was evaluated for the following:

1. Bone-to-implant contact (BIC%): bone contact length at cortical bone/miniscrew surface length at cortical bone × 100 (Figure 5A,C).[11,12] BIC indicates osseointegration of the miniscrew and bone tissue.
2. Implantation spike depth (mm): length from spike apices to bone surface (Figure 5A,B).[7] Implantation spike depth was measured as a factor of miniscrew stability.[8]

If the tip of the spike was broken off during specimen preparation, a virtual spike line was drawn and measured. Specimens with severely chipped-off spikes during cutting were not measured for implantation depth.

Statistical Analysis

The effects of auxiliary devices (with vs without) and days (0, 28, 56) on Periotest values (PTVs) were evaluated using the nparLD and Brunner-Langer nonparametric analyses. The relative treatment effect was interpreted as follows: values below and above .5 indicated decreases and increases in the outcome variable, respectively; P values $< .05$ were considered statistically significant.[13,14] PTVs were analyzed statistically using R software, version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria). The Wilcoxon signed rank test was used to compare BICs between the auxiliary and nonauxiliary groups for the 28- and 56-day loading groups and the spike implantation depth in the auxiliary group at 28 and 56 days. Histomorphometric data were statistically analyzed using SPSS version 25 (IBM Corp, Armonk, NY).

RESULTS

Stability Measurement

The highest median PTV was 2.22 in the nonauxiliary group at 0 days and the lowest was −3.41 in the auxiliary group at 56 days (Table 1). Using the

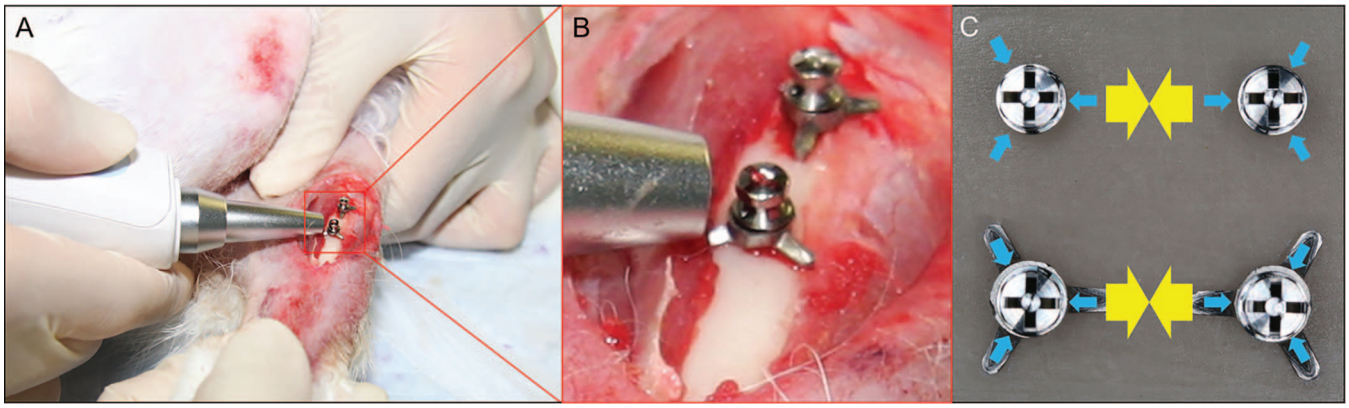

Figure 4. (A, B) Periotest experimental setup. (C) Each miniscrew underwent Periotest measurements from three directions (blue arrows). Yellow arrows indicate the loading direction.

Brunner-Langer nonparametric analysis, significant differences were observed between groups (with vs without auxiliary device; $P < .001$) and among days (0 vs 28 vs 56 days; $P < .001$) (Table 2; Figure 6). The interaction between the effects of the auxiliary device and days was not significant.

Histomorphometric Analysis

There were no significant differences in BICs between the auxiliary and nonauxiliary groups at both 28 and 56 days (Table 3; Figure 7). The median implantation spike depth in the auxiliary group was 0.09 mm at 28 days and 0.64 mm at 56 days. Median implantation spike depth was significantly greater in the 56-day group. At 56 days, both newly formed bone and bone deformation were observed around the spikes. At 28 days, only bone deformation was observed (Figure 8A,B).

DISCUSSION

There was a statistically significant main effect of the auxiliary device on miniscrew stability. To improve miniscrew stability, the contact area of the miniscrew and the cortical bone must be increased.[15,16] Another group developed a new structure called a "washer," similar to that used in the current auxiliary device.[8] Through finite element analysis, the "washer" could decrease the maximum stress on the bone adjacent to the mini-implant to reduce the possibility of bone fatigue failure and subsequent bone resorption. It was considered that the "washer" and current auxiliary device contributed equally to improve miniscrew stability. Increasing the contact area by increasing the screw diameter and length is effective in improving miniscrew stability. However, it increases the root proximity and contact risk, and possibly the miniscrew failure risk.[17,18] Additionally, miniscrew stability is improved when it is embedded in a site of thick cortical bone, although the implantation site is restricted.[19] A combination of miniscrews and auxiliary devices can increase miniscrew stability without changing its design, suggesting the possibility of using miniscrews in various locations.

There was no significant difference in osseointegration between the auxiliary and nonauxiliary groups at 28 days and 56 days postimplantation. Therefore, no significant effect of the auxiliary devices on osseointegration was observed in the study period. BIC is a crucial factor associated with miniscrew stability.[20] However, it was assumed that BIC had no effect on improving miniscrew stability in the auxiliary group in the present study.

There were significant main effects of days on miniscrew stability. The stability of the auxiliary group improved from 0 to 56 days, even under immediate corresponding orthopedic force loads. The stability of the nonauxiliary group also improved from 0 to 28 days. Previously, animal experiments were conducted using a similar device without loading; however, no change in retention force was observed over time in either group.[7] Miniscrew stability reportedly improves when orthodontic force is applied to the miniscrew.[21] Increased semaphorin 3A (regulates peri-implant bone cell production), bone morphogenetic protein, and type I and III collagen were observed when loading was applied, which may be attributed to active bone remodeling around the miniscrew under a load.[22,23] Loading may have contributed to improving miniscrew stability in this study. The effects of the auxiliary device and days did not interact significantly in affecting miniscrew stability. Each influenced miniscrew stability independently, and the presence or absence of auxiliary devices did not affect the biological responses, which changed over time (eg, healing of trauma from miniscrew placement or bone remodeling around loaded miniscrew). In other words, the auxiliary device

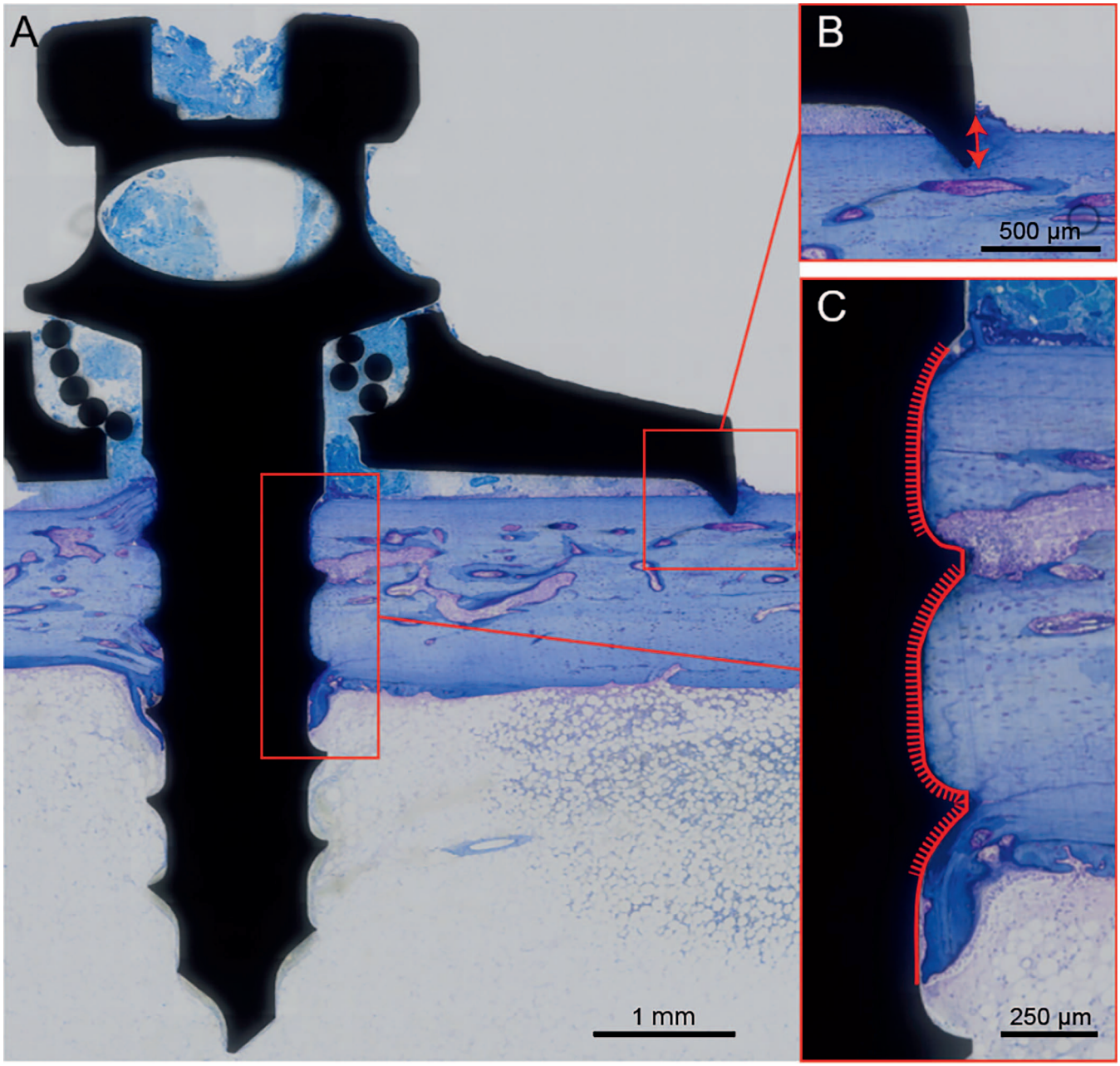

Figure 5. Histomorphometric analysis. (A) Miniscrew with the auxiliary device. (B) The double-headed red arrow indicates the embedded spike depth. (C) The red line indicates the miniscrew surface length at the cortical bone, and the dashed line indicates the length of the cortical bone-to-implant contact.

Table 1. Comparison of Periotest Values Between the Auxiliary and Nonauxiliary Groups at 0, 28, and 56 Days After Implantation[a]

	Periotest Value	
Time After Implantation, d	Auxiliary Group Median (IQR)	Nonauxiliary Group Median (IQR)
0	−0.33 (−1.68, 0.52)	2.22 (0.81, 3.16)
28	−1.81 (−2.89, −1.10)	0.96 (−0.91, 1.45)
56	−3.41 (−4.55, −2.88)	0.38 (0.08, 0.63)

[a] IQR indicates interquartile range.

Table 2. Analysis of Variance of the Factorial Model of Interactions With and Without the Auxiliary Device at 28 and 56 Days[a]

	Statistic	df	*P*-Value
Auxiliary device	93.19	1.00	<.001
Days	18.71	1.44	<.001
Auxiliary device: Days	0.70	1.44	.45

[a] Brunner-Langer nonparametric analysis. df indicates degrees of freedom.

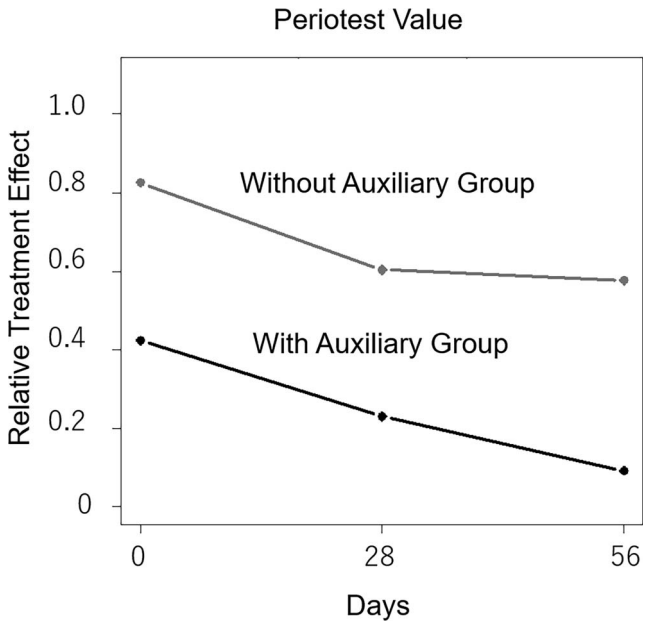

Figure 6. Estimates of the relative treatment effect for the Periotest value of miniscrews with and without the auxiliary device at 0, 28, and 56 days after implantation.

had no effect on remodeling activation or healing acceleration.

Greater implantation spike depth was observed around the spike of the auxiliary device at 56 days than at 28 days. Previously, it was unclear whether the spikes entered the bone or the bone formed around the spikes.[6,7] Newly formed bone and bone deformation were observed around the spike at 56 days. Animal studies[24,25] have suggested that newly formed bone along the lateral surface of titanium implants and on implants placed in bone may contribute to improved stability. Here, it was assumed that the newly formed bone around the spike of the auxiliary device was firmly fixed to enhance stability from 28 to 56 days. It has also been reported[8] that increasing the embedded spike depth may help reduce stress on the miniscrew. However, as mentioned above, the effects of the auxiliary device and days did not interact significantly to affect miniscrew stability. Hence, the improved implantation spike depth at 56 days did not seem to contribute to improving miniscrew stability.

Table 3. Comparison of the Bone-to-Implant Contact (BIC%) Between the Auxiliary and Nonauxiliary Groups at 28 and 56 Days After Implantation[a]

	BIC(%)		
Time After Implantation, d	Auxiliary Group Median (IQR)	Nonauxiliary Group Median (IQR)	*P*-Value
28	73.73 (61.84, 80.39)	63.63 (54.21, 74.24)	.401
56	71.93 (54.55, 83.77)	51.02 (43.23, 63.00)	.069

[a] Wilcoxon signed rank test. IQR indicates interquartile range.

Limitations

The auxiliary device is intended for use in adolescent patients; hence, in principle, it may have been

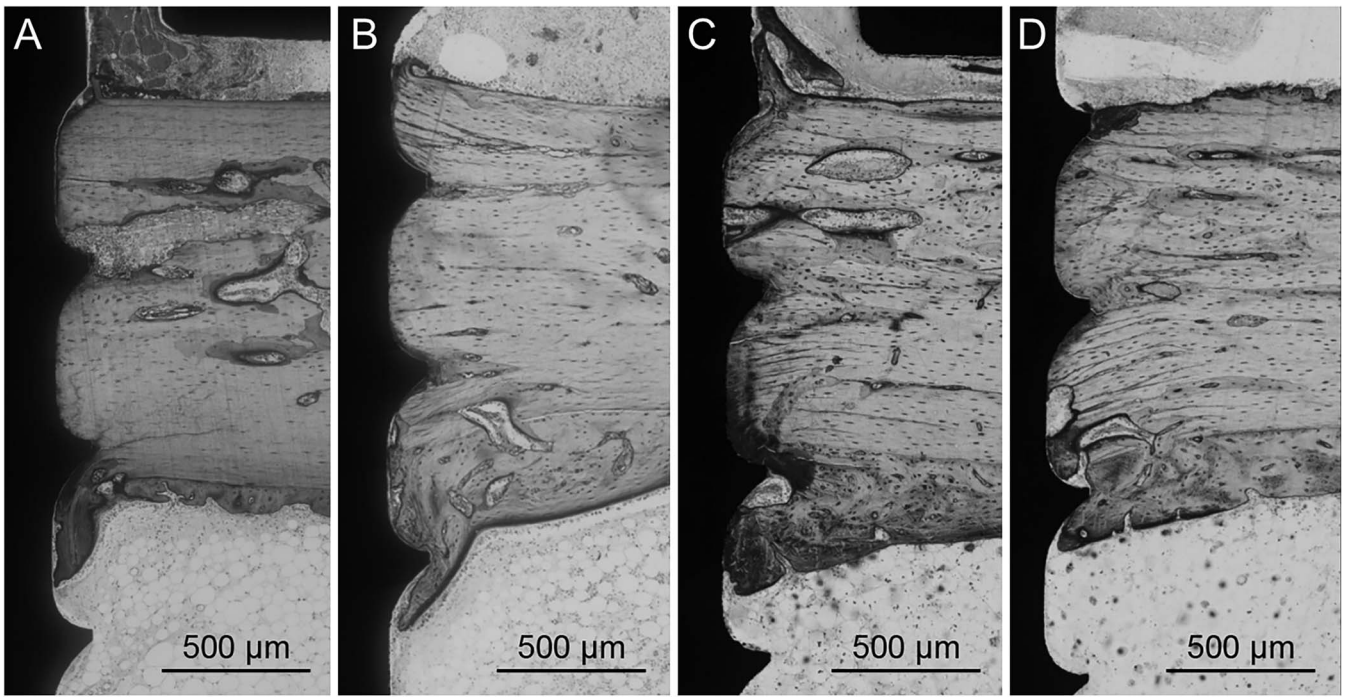

Figure 7. Representative images of bone-to-implant contact assessment. (A) Auxiliary group: 28 days; (B) Nonauxiliary group: 28 days; (C) Auxiliary group: 56 days; (D) Nonauxiliary group: 56 days.

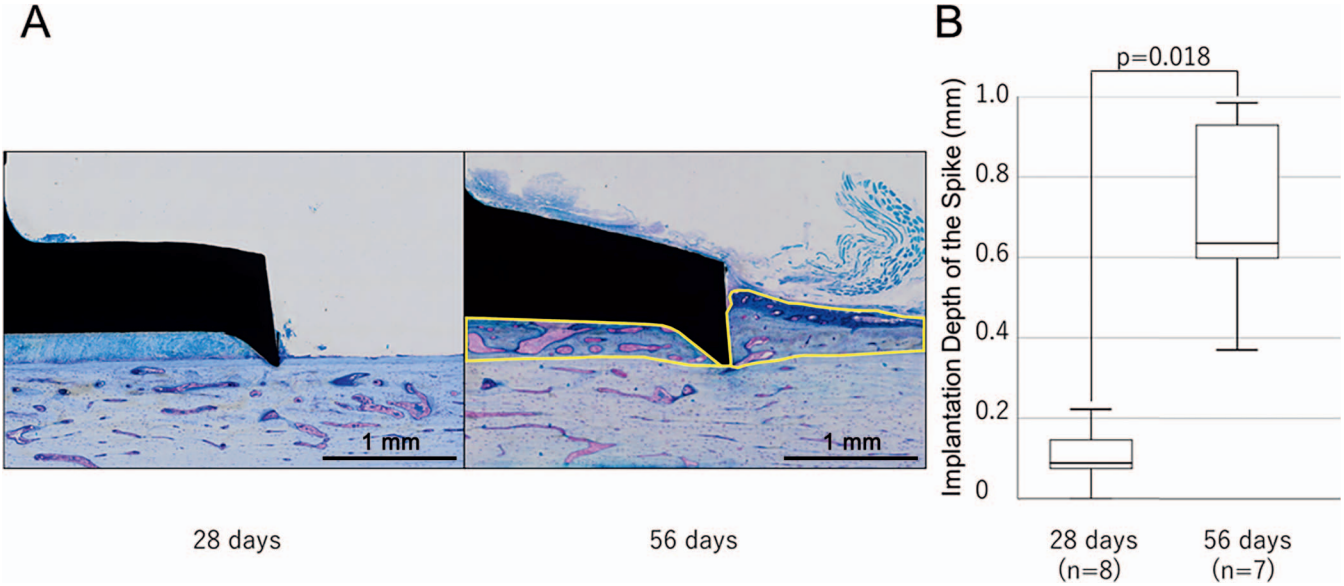

Figure 8. (A) Representative images of implantation spike depth. Area surrounded by the yellow line indicates newly formed bone. (B) Implantation spike depth was significantly increased at 56 days.

appropriate to have used experimental animals that were immature. On the other hand, if immature rabbits were used, it would have been difficult to distinguish whether the stability and histological changes were due to the interventions or due to growth of the rabbit. For this reason, mature rabbits were used in this study. The experimental results should be applied with caution to clinical situations. In clinical practice, it is assumed that this auxiliary device is implanted on the gingiva. To improve reproducibility, the skin was incised to harmonize the miniscrew implanting angle and the direction of the auxiliary device. Further experiments without incisions are needed to confirm the safety and usefulness of these devices by evaluating histological responses and soft and hard tissue changes in animal jawbones, such as those of beagles and pigs. In this study, the elastics were dry because of their exposure on the skin. Thus, their force degradation was considered acceptable.[26] However, if a constant 5 N load is applied, the results may vary slightly. Additionally, owing to the rapid turnover rate in rabbits and long-term use of miniscrews in orthopedic treatment, experiments must be performed over different study durations.

CONCLUSIONS

- In rabbit tibias, the auxiliary device contributed to improving miniscrew stability under an immediate 5 N load.
- Miniscrew use in conjunction with auxiliary devices is a stable and less-invasive form of skeletal anchorage and may be useful in orthopedic treatment.

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