

Examination of A Novel Designed Device Used for Dental Implants Stability Detection – An Animal Study

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Abstract

Natural frequency (NF) technology was used to design a dental implant stability detector. Both in vivo and in vitro experiments were performed to test the possibility of using such device for detecting the status of implants. The natural frequency increasing ratio (NFIR), defined as the percentage changes between the measured NF value at each testing time-point and its initial testing value, was used as a parameter to assess implant stability. In in vitro tests, changes in stability of the root form of the dental implant were simulated by clamping the implant with a clamping stand. When the clamping torque was increased from 2 to 10 N-cm, the NFIRs obtained from the traditional hammer-impacting method and from the current designed device showed no significant differences ($p = 0.053$). When the implants placed in a dog's mandible were measured using the NF device, there was a continuous increase in NFIR for the first 8 weeks. The mean NFIR value at the first week was 0.13 ± 0.048 ; the NFIR significantly increased to 0.408 ± 0.076 ($p < 0.05$) by week 8. Thereafter, the measurements maintained at a plateau. When comparing the NFIR curve obtained from in vivo tests to the histological images, a strong correlation between the two data sets was found. In conclusion, the idea of using the present NF device for detecting the degree of bone healing during the osseointegration process seems feasible.

Keywords: Natural frequency, Dental implant, Device, Histology, Stability

Introduction

Although development and research regarding root form dental implants have advanced to the mature stage, there are not many devices or methods available at present for the accurate detection of implant stability after placement.

Observation of resected tissue along the implant interface is considered the best method for detecting bone integration [1-2]. However, during the resection process, it is hard to immobilize the dental implant and bone, thus, rendering observations and evaluations more difficult to make. Moreover, this method is invasive, and therefore, not suitable for clinical evaluation. In 1987, Johansson and Albrektsson utilized removal torque values to investigate the mechanical properties of dental implant-bone interfaces. They discovered that the torque needed for removal became greater as time increased

[3]. This suggests that the removal torque value is related to the contact area along the interface. As the contact area becomes bigger, it necessitates a corresponding increase in the removal torque value [4,5]. However, this method is also a destructive technology. In addition, the removal torque value is frequently affected by the precision of the measuring device and manmade errors. Goheen *et al.* used a manually controlled method and achieved a result with a variance as high as 48% [6].

The percussion method is a non-invasive method of detecting dental implant stability. Because sensitivity to sound varies with each individual, this is considered a subjective method of assessment. Recently, a tooth mobility detecting device, named Periotest[®] (Siemens AG, Bensheim, Germany), was used to monitor the mobility of dental implants [7-9]. Although some reports claimed that correlation was found between the Periotest value (PTV) and the boundary tissue condition of an implant [10,11], Caulier *et al.* found that the PTV value was easily affected by many factors [12]. Thus, the use of the Periotest for assessing the bone-implant integration

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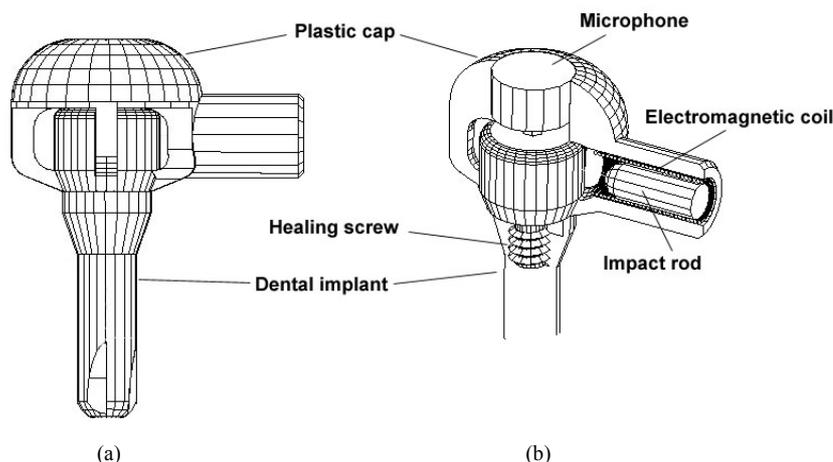


Figure 1. Diagrams of the natural frequency (NF) detector used in this study. (a) The device was directly mounted onto the healing abutment. (b) Sagittal section of the device. An electromagnetic driving actuator and a non-contacting microphone were incorporated in it.

process is still restricted. Elias *et al.* directly struck the dental implant using an impulse force hammer [13]. The boundary condition was then analyzed based on its force-time curve. This type of stability detection device is considerably too large for use in *in vivo* experiments.

The use of natural frequency (NF) values for detecting the degree of bone healing with orthopedic treatment has been studied by many scholars. However, due to problems with the soft tissue covering, the clinical use of such techniques is still unavailable [14]. Recently, there have been several dental research reports concerning this topic. Their results showed that the principle of NF can be used to monitor the process of osseointegration after dental implant placement [15-17]. Recently, a commercially available NF detecting device (OSSTELL, Integration Diagnostics, Göteborgsvängen, Sweden) was introduced for dental implant status monitoring. The basic principle adopted by this device is the harmonic response method. For clinical application, an L-shaped sensor is connected to the free end of the fixed implant. The L-shaped converter is triggered to vibrate by means of sinusoidal waves with frequencies of 5 to 15 kHz. The first NF value obtained is used to analyze implant stability [18]. The impulse force triggering method is another type of NF analysis. After a series of both *in vivo* and *in vitro* experiments, the impulse force method proved to be useful in detecting dental implant stability [19-21].

In this study, the capability of the experimental NF device to detect dental implant stability was tested using the concept of the impulse force method. This device was designed to be compact and easily installed and disassembled, with the trigger and signal collecting components contained in the device. To validate the experimental NF device for determining implant stability, a series of *in vivo* and *in vitro* tests was performed.

Materials and Methods

A cup-shaped detecting device was designed to house the

trigger and signal receptor devices, as shown in Fig. 1. The device was directly mounted on the healing abutment without an additional screw (Fig. 1a). To trigger the dental implant into vibration, an impact rod is driven by electromagnetic coils using low DC voltage. As shown in Fig. 1b, the device consists of two sections of electromagnetic coils as the driving feedback of the demagnetized iron impact head. When the impulse current passes through the first section of the coil, the generated electromagnetic field attracts the iron impact head and drives it to strike against the healing abutment. The impact force is 0.18 N, which was determined by pressure-sensitive film (Prescale Pressure Series, Fuji Photo Film, Tokyo, Japan). The other end of the coil generates an electromagnetic field that functions in the opposite direction, which drives the impact head back, causing the impact head to return to its original position. When the impact head strikes the test implant, the vibration signal of the implant is collected via a piezoelectric microphone and is transferred to a spectrum analyzer (Implomates, Biotech One Inc., Taipei, Taiwan; with a resolution of 50 Hz). The specific natural frequency of the tested implant is determined by means of the relatively highest point with a peak value of vibration amplitude. This device was used throughout the research.

After the components were completed, a standard monotonous pitchfork ($f = 600$ Hz) was measured using the experimental NF device. Before measuring, the standard pitchfork mounted on a test device was firmly fixed at its hand-held end by a clamping stand. The accuracy of the device was tested by comparing the results obtained from a conventional hammer-impacting device (PCB system, PCB Piezotronics, Buffalo, NY, USA) conducted in our previous studies [19-21]. To test the performance of the NF device, *in vitro* experiments for detecting various levels of boundary stiffness were performed. Before the experiments, a test implant (POI 32-08F, Kyocera, Tokyo, Japan) with a healing abutment on it was clamped directly onto a clamping stand (Fig. 2a). According to our previous report, the dynamic characteristics of an implant with various levels of boundary

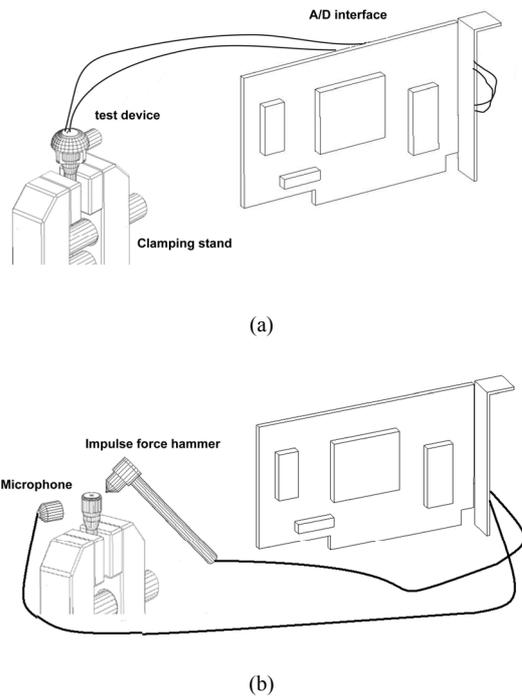


Figure 2. Equipment and methods of operation for dental implant detection. (a) The natural frequency (NF) experimental device designed in this study and (b) impulse force hammer test.

stiffness can be obtained by measuring the NF value of an implant clamped with different torque values.¹⁹ Therefore, in this study, to simulate the various degrees of implant stability, the clamping torque applied on the dental implant was increased from 2 to 10 N-cm, in increments of 2 N-cm. The clamping strength was controlled by a quantifiable torque wrench. Since the clamping strength is correlated to the torque value applied to the clamping stand, the applied torque value was used as an indicator to present the boundary strength of test implants. The greater the clamping torque, the greater the degree of implant stability and vice versa. Furthermore, results obtained with the experimental NF device were compared to those obtained with the conventional hammer-impacting method (Fig. 2b). According to our previous finite element simulation, the first three vibrational mode shapes of an implant-bone block system are bending, torsion, and elongation, respectively [20]. In addition, when an implant is firmly attached by the surrounding tissue, only the first NF value of the implant is lower than 20 kHz which is the limitation of the microphone sensor used in this study. Therefore, only the first NF values of the tested implants were analyzed and discussed in this study.

In animal experiments, six healthy adult beagles (weighing 9-12 kg) were used as test subjects. At 3 months prior to implantation, under general anesthesia (intravenous injection of ketamine at a dose of 0.5 mg/kg of body weight, followed by an intramuscular injection of pentobarbital at a

dose of 25 mg/kg of body weight), the second mandibular premolar and the first mandibular molar were bilaterally removed. Prior to dental implant surgery, the animals were anesthetized as described above. The buccal mucoperiosteum was incised horizontally, and the alveolar crest was exposed. The preparation sites in the extraction sockets were drilled using the standard procedure given by the dental implant manufacturer. The test implants were placed into the prepared holes until the collar margin reached the boundary of the cortical bone. After implant placement, the flaps were then repositioned and sutured. The entire surgical procedure was performed under profuse cooling with a cold normal saline solution. After surgery, the animals were fed a soft diet (Pep dog food, Quaker Oats, Peterborough, Ontario, Canada) for the first 2 weeks, and were given long-acting penicillin (Penlong XL, Rogar STB, London, Ontario, Canada) at appropriate intervals during this period. In total, 24 implants were placed in the six dogs.

Immediately after the implants were placed, the NF values of the implants were measured. The cap-shaped device (Fig. 1) designed for this study was used for the measurements. Although impact direction does not affect the NF values of test implants, the test devices were mounted on the implant samples along the buccal-lingual direction to fit the limited space of the implantation site. The measurements were performed at 1, 3, 4, 8, 12, and 16 weeks after the implantation surgery. To avoid implant failure caused by uncontrolled forces, the traditional hammer-impacting method was not used in our animal experiments. The natural frequency increasing ratio (NFIR) of each implant was defined and calculated as the percentage changes between the measured NF value at each test time-point and its initial test value. All test samples were subjected to five continuous experimental tests, and the results were reported as the mean and standard deviation of NFIRs calculated from the experimental values. The averages are given for values of the four implants in each animal regardless of where they were placed. One-way analysis of variance was used to confirm the statistical differences of test parameters.

At each testing period, after the NF value was obtained, one of the dogs was sacrificed for histomorphometric evaluation. The specimen was collected using the method described by Deporter et al. [22]. Briefly, the animals were killed under general anesthesia by bilateral carotid perfusion with a solution of 37% formalin and 99% methanol in distilled water (1:1.5 v/v) following an intravenous injection of heparin to prevent intravascular clotting. Segments of the bone containing the implants were resected, and placed in a fixative solution consisting of 10% formalin. After demineralization [23], the blocks were sectioned into 2-mm slices through the long axis of the implants with a diamond-edged saw. The specimens were then dehydrated in ascending concentrations of alcohol up to 100%, and embedded in paraffin wax. The embedded blocks were sliced into 10- μ m sections using an ultramicrotome (Bright 5040, Bright Instrument, Cambs, England). For histological examination, specimens were stained with hematoxylin-eosin as described by Xiang et al. [24]. A light microscope (CH2, Nikon, Tokyo, Japan) equipped

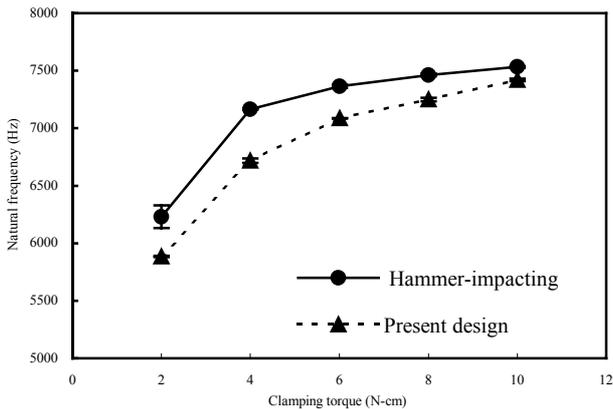


Figure 3. Frequency response spectrum with various clamping torques using (a) an impulse force hammer and (b) the natural frequency (NF) experimental device designed in this study. The data are presented as the mean±SD.

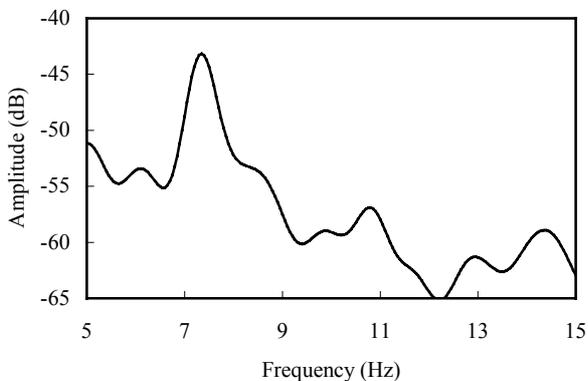


Figure 4. A typical example of a power spectrum plot with an NF value of 7.3 kHz. The location of the NF value of test implant was judged by mean of the relatively highest point with a peak value of vibration amplitude.

with a digital camera (COOLPIX 950, Nikon) was used for digitizing the histological images. To standardize the image, only the third thread portion of each implant was used for image analysis. The design of the experimental work has been approved by the Laboratory Animal Research Committee of Taipei Medical University.

Results

When the 600-Hz monotonous pitchfork was measured, mean NF values of 599.8 ± 0.5 and 588.4 ± 0.5 Hz were obtained using the conventional hammer-impacting method and the experimental NF device, respectively. In the simulated bone-healing experiment, when the clamping torque was altered, the mean NF values detected by these two methods were concentrated between 5800 and 7600 Hz. As shown in Fig. 3, both curves displayed greater NF values as the clamping torque was increased. Additionally, both arrived at the plateau stage when the clamping torque reached 6 N-cm. However, a higher mean NF value was obtained when the conventional hammer-impacting was used. The NFIRs of the

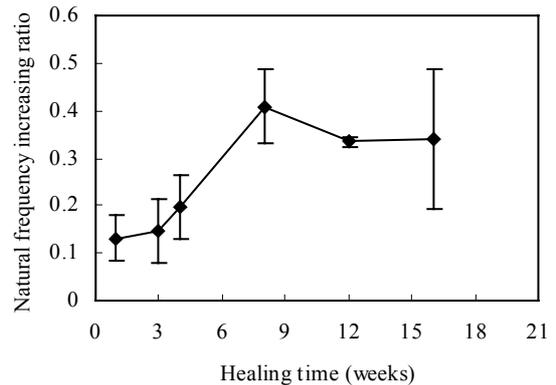


Figure 5. Healing curve plot of NFIR values obtained from tested implants in experimental dogs with the proposed device. The data are presented as the mean±SD.

implant at the plateau measured using the impulse force hammer and the test NF device were 0.182 ± 0.018 and 0.204 ± 0.011 , respectively. Statistical evaluation (Student *t*-test) showed no significant differences between the two values ($p = 0.053$).

All animals remained in excellent health throughout the course of the experiment. Because two implants failed at an early stage (each one in dogs D and E), only 22 implants were tested throughout the experiments. Figure 4 demonstrates a typical example of a power spectrum plot with an NF value of 7.3 kHz. The location of the NF value of the tested implant is judged by means of the relatively highest point with the peak value of the vibration amplitude. Table 1 lists the measured NF values of tested samples. The initial NF values of tested samples were varied due to individual differences. Therefore, NFIR was used as a parameter of implant stability for the following *in vivo* tests. Figure 5 shows that a significant increase in NFIR occurred at 8 weeks after surgery. The mean NFIR value at week 1 was 0.13 ± 0.048 , increasing to 0.408 ± 0.076 at week 8 after surgery ($p < 0.05$). Thereafter, measurements reached a plateau. At 12 and 16 weeks, the NFIRs of the sample implants were 0.334 ± 0.010 and 0.341 ± 0.017 , respectively. Statistical analysis showed no significant differences in NFIR values from 8 to 16 weeks ($p = 0.639$).

Histologically, at week 1 after implantation, loose fibrous connective tissue and inflammatory cells were seen in the threaded implant site, and clotted blood was found at the margins of the implant site (Fig. 6a). After 3 weeks, dense fibrous connective tissue was seen within the threaded implant site (Fig. 6b). Four weeks after implantation, there was marked new bone formation at the margins of the implantation bed (Fig. 6c). Afterward, there was direct bone apposition to the surface of the implant at 8 weeks of healing (Fig. 6d). From 12 to 16 weeks, the histomorphologic images showed no differences when compared to images at 8 weeks.

Discussion

OSSTELL is the first commercial NF device. The method introduced by the device has been proven to be useful in

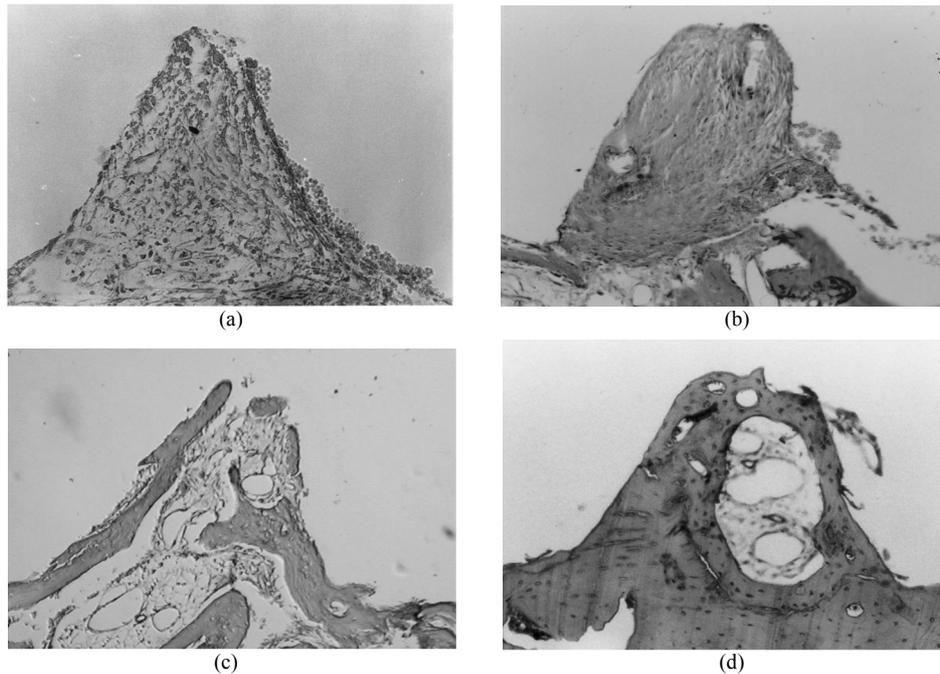


Figure 6. A series of histological photomicrographs within the threaded implant site at 1 (a), 3 (b), 4 (c), and 8 (d) weeks after implantation. Loose and dense fibrous connective tissue and inflammatory cells are seen in the first and third weeks, respectively. Marked new bone formation at the margin is seen at 4 weeks of healing. At week 8, direct bone can be seen in the pictures.

Table 1. Lists of NF and NFIR values of each tested implant placed in experimental animals.

	Animal A			Animal B			Animal C			Animal D			Animal E			Animal F		
	0 week	1 week	NFIR	0 week	3 week	NFIR	0 week	4 week	NFIR	0 week	8 week	NFIR	0 week	12 week	NFIR	0 week	16 week	NFIR
R1*	5825.9	6911.4	0.186	5643.0	7030.9	0.246	6733.2	8714.1	0.294	- [#]	-	-	-	-	-	3935.9	4953.1	0.258
L1	6125.4	7078.7	0.155	8020.4	8913.9	0.112	7207.0	8569.1	0.189	5980.0	8764.1	0.466	7023.3	9400.5	0.338	3935.9	5020.1	0.275
R2	6060.5	6629.2	0.094	8235.9	9313.4	0.131	7581.1	8713.5	0.149	4324.5	6220.3	0.438	6854.7	9200.2	0.342	5347.7	6791.5	0.270
L2	6275.1	6816.5	0.086	8654.3	9538.1	0.102	7855.7	9088.7	0.157	6823.5	9021.3	0.322	7303.5	9663.2	0.323	4772.8	7450.9	0.561
Mean	6071.7	6858.9	0.130	7638.4	8699.1	0.148	7344.2	8771.4	0.197	5709.3	8001.9	0.409	7060.5	9421.3	0.334	4498.1	6053.9	0.341
SD	186.9	187.6	0.048	1356.0	1141.7	0.067	486.4	222.3	0.067	1271.3	1548.3	0.076	226.7	232.2	0.010	690.3	1261.8	0.147

* R, L denotes right and left side, respectively. 1 and 2 denote the second mandibular premolar and the first mandibular molar, respectively.

[#] Denotes implant failure at an early stage.

implant stability detection.²⁵ However, the transducer used in the OSSTELL system needs to screw into the test implant with a torque value of 10 N-cm, which accounts for almost half of the amount used to place an implant, reducing the merit of such a device when applying in to early-stage assessment. The transducer used in this study was designed as a mounting device. There is no additional torque needed when the transducer is installed or removed. In addition, a shorter design makes our device more convenient for use in the posterior zone where most dental implants are located.

Computer-aided design (CAD) was used to fabricate the stability detector component. Its structural size is minute and the entire component, including the plastic cap, coil, impact head, and microphone, weighs only 1.2 g. However, the dental

implants used in this study weighed 0.6 g. The weight ratio of the detector to the dental implant is 2:1. Therefore, the signals collected included the mass effect of the detector. This is why the NF values detected by the present design were lower than those of the hammer-impacting method (Fig. 3). The smaller design of this device creates another limitation of this system. Because the internal space of the device is limited, the impact force response was not recorded in the current design. Therefore, the frequency response function (FRF) is not taken into account by the system. This may result in a human error of reading when identifying the peak location corresponding to the first NF value.

In Fig. 3, NF values obtained from both the test NF device and traditional hammer-impacting method reached a

plateau when the clamping torque exceeded 6 N-cm. That is, under this constraint, the implants were thoroughly fixed in position. Furthermore, although the NF values detected by the test NF device were lower than the results detected by the conventional hammer-impacting method, the data obtained from the two methods showed no differences in NFIR values before they reached a plateau (Fig. 5). Because the initial NF value is personalized, the NFIR value is more suitable for monitoring changes in dental implant stability.

Histomorphometry is often used for calculating the ratio of the surface area of the contact between the dental implant and the bone in a resected tissue to assess the condition of bone integration. Researchers discovered that the surface area of contact between the dental implant and the bone increases with time [4,5]. Although histomorphometry is considered invasive and is not clinically appropriate, it is an appropriate means to validate the application of the newly designed NF device.

When comparing NFIR curves obtained from the test NF device to the corresponding histological images, strong correlations were found. In Fig. 5, the slope of the NFIR curve prior to 3 weeks after surgery is much smaller than for the period between 3 and 8 weeks. Histologically, this is because the main tissue within the threaded implant site was fibrous connective tissue prior to 3 weeks after surgery. Obvious new bone at the margin of the implantation bed formed between 3 and 8 weeks postoperatively (Fig. 6). Previous animal studies also found that the osseointegration process is slow during the first 2 weeks after implantation. This is due to inflammation, i.e., initial resorption occurring at the implant site [26]. Previous clinical findings indicated that initial resorption periods are 1, 1.5, and 2 weeks for rabbits, canines, and humans, respectively [27]. Our NFIR results are consistent with those findings as well.

In conclusion, although the *in vivo* data were limited due to a small sample size, our results show that healed implants demonstrated higher NFIR values than not-yet healed ones ($p < 0.01$). Based on the results, the idea of using the present NF device for detecting the degree of bone healing during the osseointegration process seems feasible. The greatest advantage of this device is its ease of handling and manipulation. Therefore, the device designed and used in this study is substantially valuable for future advanced experiments. Furthermore, the feasibility of its future clinical use is significant.

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