




Communication

Effect of the Magnetic Field Generated by a New NeFeB Cover Screw on Bone Healing around Endosseous Implants: A Case Series Report from Dental Practice

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Abstract: This study aimed to investigate the effect of static magnetic field (SMF) generated by innovative cover screws made of NeFeB on early bone healing around dental implants. The study was carried out on humans in a private dental practice. Eight 3i implants (Biomet, Palm Beach, FL, USA) were placed in the posterior mandible at 3.6 and 3.7. The control implants were closed with a conventional screw (G1), while the test implants were closed with a Supercharged[®] screw (G2). Both groups were compared for stability at 0, 7, 14, 21, 50, and 90 days using a resonant frequency analyzer with Ostell Mentor (Osstell AB, Gothenburg, Sweden). After 50 days, the Supercharged[®] cover screw was removed. A significant increase in implant stability quotient (ISQ), corresponding to a lower degree of bone resorption, was observed in G2 throughout the follow-up period ($p < 0.05$), while an initial ISQ decrease was observed until day 21 in G1. In conclusion, the effect of SMF seems to be in the early stages of osseointegration and increases the stability of dental implants.

Keywords: endosseous implants; static magnetic field; osseointegration; resonance frequency analyzer



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1. Introduction

The use of magnetic fields in medicine, specifically pulsed magnetic fields (PEMF) generated by electric current, has been approved by the FDA for the treatment of bone fractures since 1979 [1]. Later, the effects of static magnetic fields (SMF) were also studied to evaluate their effects in orthopedics. Many studies have shown that the use of magnetic fields in orthopedics and oral implantology can be highly beneficial for healing bone fractures and osseointegration in terms of bone-to-implant contact (BIC) of dental implants [2–4].

In 2017, we investigated the proliferation rate and gene expression of osteoblast-like MG63 cells at 24, 48, and 72 h after SMF stimulation generated by a small, custom-made, helical neodymium–iron–boron (NeFeB) magnet placed inside the cavity of a dental implant [5]. As a result, we found that applying an SMF to osteoblast-like cells slightly decreased the cell proliferation rate, while it increased the expression of those genes that correlate with differentiation and mineralization. In gene expression profiling, we found that in the samples with implants with magnetic Sc (test group) compared with those with Sc made of titanium (control group), the expression of the following genes was increased: (1) CSF-3 (colony-stimulating factor 3), IGF-1 (insulin-like growth factor 1) by 2.2-fold after 24 h of exposure; (2) COL10A1 by 2.5-fold; (3) TGF- β 1 by 2.5-fold; (4) VEGF-A by 1.9-fold; (5) PDGF-A (platelet-derived growth factor alfa polypeptide) increased 2.3-fold; (6) BMP-2 increased 3.3-fold; (7) AMELY (amelogenin y-linked) increased 2.5-fold after 72 h of exposure. These results represent the first clinically operational technique for dental implants demonstrating the ability of SMF to promote osteogenesis in vitro.

In another study aimed to investigate BIC and newly formed bone volume around dental implants placed in the tibia of New Zealand rabbits after SMF stimulation generated by a small, custom-made Sc-shaped neodymium–iron–boron magnet placed in the inner cavity of the dental implants, Bambini et al. demonstrated the significant role of SMF field generated around the dental implants in improving bone healing in the animal model [6]. This proved for the first time the ability of SMF to promote osteogenesis in vivo and proposed a ready-to-use clinical technique for dental implants. Until the introduction of the possibility of replacing titanium Sc with NeFeB Sc, which is coated with titanium by PVD (physical vapor deposition), it was not possible to use static magnetic field SMF in dentistry in a way that is accessible to every dentist. As far as we know, this is the first study to investigate the role of SFM on implant stability and success in humans.

The objective of this case series report was to investigate the effects of SMF on implant stability by RFA (resonance frequency analysis), implant success, and surrounding soft tissue health over a 90-day observation period. The null hypothesis was that the magnetic screw would not affect implant stability.

2. Materials and Methods

2.1. Study Design

A case series report was conducted on a sample of five patients with partial or complete edentulism who had elected to receive dental implants for fixed prosthetic rehabilitation. All patients included in the present study were treated in an Italian private practice by an experienced surgeon between June and December 2018. The study was conducted following good clinical practice guidelines and the recommendations of the ethical principles of the Declaration of Helsinki of the World Medical Association for Medical Research Involving Human Subjects. Verbal and written informed consent was obtained from all patients regarding the procedure and enrollment in the study.

All patients required at least two Osseotite Tapered Certain 3i dental implants (Biomet, Palm Beach, FL, USA) with a diameter of 3.25 mm and a length of 8.5 mm in areas 3.6 and 3.7. After implant placement, one implant was restored with Titan Sc (control, G1) and the other with the magnetic Supercharged® Cover Screw MED 31216 (publication number: WO/2010/119092) (test, G2). At 7-, 14-, 21-, 50-, and 90-day follow-ups, resonance frequency analysis (RFA) was performed using Ostell Mentor (Osstell AB, Gothenburg, Sweden) to investigate the stability of the tests and controls [7].

2.2. Admission Criteria

Patients were included according to the following criteria: (1) age ≥ 18 years; (2) edentulous patients who required dental implants because of a completely or partially edentulous jaw. Patients were excluded if they had untreated periodontitis, active infection, or severe inflammation in the areas planned for implant placement or if they required any type of bone augmentation in the area of implant placement. Patients were also excluded if they had uncontrolled diabetes mellitus, were being treated for metabolic bone disease, had received therapeutic radiation to the cervical-head region within the previous 12 months, or were being or had been treated with intravenous bisphosphonates, and were pregnant or lactating women.

2.3. Study Protocol

2.3.1. Visit 1—Baseline (Pre-Surgical Assessment)

During the initial visit, a clinical assessment of the patient was performed. Demographic, medical, and dental data were collected. Radiographs of the existing dentition were obtained. CBCTs were performed to assess patients' suitability in terms of bone volume for implant placement [8]. Areas suitable for implant placement at crestal levels of elements 3.6 and 3.7 and without bone regeneration procedures were selected for the study to avoid differences in the predictability of clinical outcomes.

2.3.2. Visit 2—Site Evaluation Implant Placement

Osseotite Tapered Certain 3i implants (Biomet, Palm Beach, FL, USA) were placed using the techniques described in the 3i Surgical Manual to prepare for osteotomy in areas 3.6 and 3.7. At least 1 mm of the coronal portion of the implants remained supra-crestal. Supercharged[®] Sc in NeFeB with titanium PVD coating (Figure 1a) was used, producing an SMF of 0.6 mT in one of the two implants at 2 mm from the implant surface. Magnetic field measurements were performed in vitro by inserting a cover screw into an Osseotite Tapered Certain 3i implant (Biomet, Palm Beach, FL, USA) identical to the implant used in the present study (3.25 mm in diameter, 8.5 mm in length) and taking measurements at 1 mm with an instrument. The flux density measurements related to the magnetic field were performed by a customized Gaussmeter with a Hall probe (Allegro Microsystem Inc., Worcester, MA, USA). The magnetic field decreases with the square of the distance. In G1 (control), conventional titanium 3i Sc was used, while in G2 (test), Supercharged[®] Sc remained on the implants. The flaps were sutured without tension. At the end of the surgical procedure, a panoramic or periapical radiograph was taken (Figure 1b).

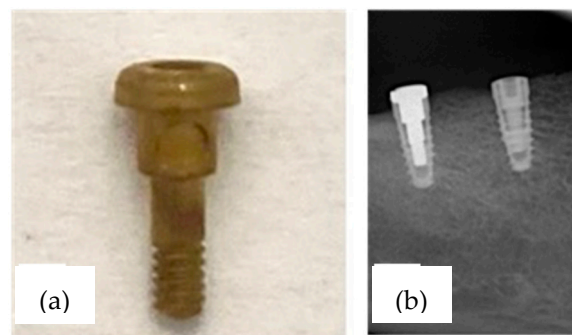


Figure 1. (a) Supercharged[®] Sc in NeFeB coated in titanium PVD used in the test group; (b) Radiographic evaluation of the inserted implants at the end of the surgical procedure.

During the healing process, the patient was not fitted with removable prostheses. Amoxicillin plus clavulanic acid 2 g 1 h before implantation and 2 g/day for five days were prescribed [9,10].

2.3.3. Follow-Up Visit 3, 4, 5, 6, and 7—Implant Stability Quotient (ISQ) Measurements

After implant placement, regular examinations were performed at 7 (T7), 14 (T14), 21 (T21), 50 (T50), and 90 (T90) days. Osstell Mentor (Osstell AB, Gothenburg, Sweden) was used to measure the ISQ values of both groups.

2.4. Resonance Frequency Analysis

The stability of each implant was evaluated by RFA with the Osstell Mentor (Osstell AB, Gothenburg, Sweden) using ISQ values, following the manufacturer's instructions.

RFAs were performed at 0 days (immediately after implant placement) (T0), T7, T14, T21, T50, and T90. The Supercharged[®] Sc was removed on day 50. At the time of measurements, both the titanium and the Supercharged[®] Sc were removed, and a suture was reapplied for each implant.

2.5. Statistical Analysis

Given the study design (case series report), the sample size was not determined beforehand. The final data set was longitudinal, with repeated measures for ISQ in two different groups. ISQ descriptive statistics are reported as mean and standard deviation after checking for normality through the Shapiro–Wilk test. To account for the specific longitudinal composition of the data set, the data were examined using a mixed model in which the group was treated as fixed effects, whereas participants were used as a random effect. Pairwise comparisons of marginal linear predictions were used to assess the change

in outcomes between- and intra-group was considered. Statistical analyses were performed using Stata17 (StataCorp., College Station, TX, USA).

3. Results

Analysis of the overall trend in ISQ changes revealed a continued increase in ISQ from baseline T0 to the 90th day, while for the control group, the same analysis showed an initial decrease in ISQ and a subsequent increase starting from the 14th day (Figure 2). On the 14th day, the ISQ resulted statistically higher in G2 (64.40 ± 3.85) than in G1 (58.40 ± 3.58) (effect size: 1.61, $p = 0.010$). This significant trend continued until the 21st day (G1: 61.20 ± 3.63 , G2: 67.60 ± 2.97 , effect size: 1.93, $p = 0.006$) and after 50 days from the implant placement (G1: 65.20 ± 3.35 , G2: 71.20 ± 1.79 , effect size: 2.23, $p = 0.010$). In G2, a series of statistically significant differences emerged in the comparisons between T0 and the subsequent follow-up; specifically, ISQ resulted significantly higher than baseline (62.60 ± 4.34) on the 14th day (64.40 ± 3.85 , $p = 0.049$), on the 21st day (67.60 ± 2.97 , $p < 0.001$), on the 50th day (71.20 ± 1.79 , $p < 0.001$), and on the 90th day (72.40 ± 1.52 , $p < 0.001$).

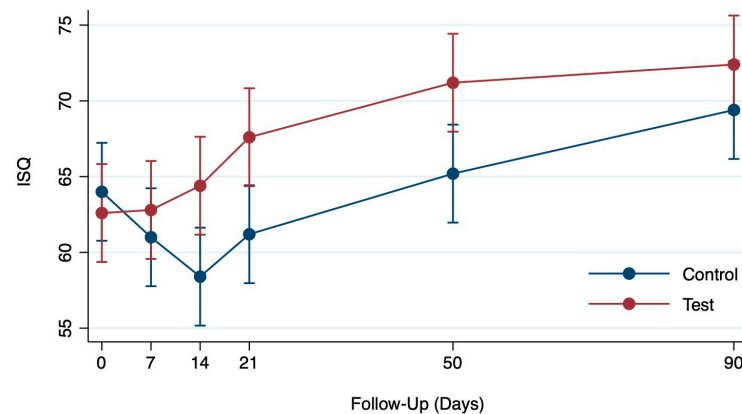


Figure 2. ISQ mean values and standard deviation (vertical bars) of the control (G1) and the test (G2) group. Measurements were recorded during the follow-up visits at different time points: T0 (immediately after the implant placement), T7 (7th day after implant placement), T14 (14th day after implant placement), T21 (21st day after implant placement), T50 (50th day after implant placement), and T90 (90th day after implant placement).

During the follow-up visits, the soft tissues around the implants of both groups (G1 and G2) were healthy. None of the patients experienced inflammation or discomfort.

4. Discussion

Implant stability can be divided into primary and secondary stability. The first is a mechanical type of bond determined by factors related to both implant characteristics (macroscopic, surface morphology) and implant site (type of preparation, bone quality) [11]. Secondary stability, on the other hand, is a biological type of bond determined by the formation of new bone and bone remodeling in contact with the implant surface [12]. During the osseointegration process, primary stability gradually decreases, while secondary stability increases [13]. These changes, which occur at the bone–implant interface, can be detected by RFA using ISQ values [14].

Several studies have investigated the correlation between ISQ values and implant outcome (survival rate), but with inconsistent results. Sjöström et al. found a significant correlation between poor primary stability, measured with RFA, and implant failure [15]. In contrast, Huwiler et al. did not attribute any predictive value to RFA findings for implant failure [16]. In a prospective study conducted on a sample of 1500 patients and 4000 implants, aimed to investigate the role of primary stability as a predictive factor for implant outcome, Rodrigo et al. showed that ISQ values (primary stability) measured at the time of implant placement was not predictive of implant outcome (no implant failed

when $ISQ \leq 60$). In contrast, ISQ values measured after the healing period of 2–4 months (secondary stability) showed a statistically significant correlation with implant outcome: no implant failed with an $ISQ \geq 60$, while 19% of implants failed with an $ISQ < 60$, suggesting a different degree of osseointegration, with a lack of bone–implant contact in implants with lower ISQ values [17].

The present study was the first human study in which NeFeB Supercharged® Sc was prepared specifically for implants to evaluate its effect on bone healing and stability. The null hypothesis was rejected. Overall, at the end of the follow-up, all implants in both the test and control groups were in place and functioning, with no signs of inflammation of the surrounding soft tissue. Even though the observation period was short (90 days), there was no early implant failure. Probably, the reason for this is that the factors blamed for early implant failure (such as smoking habits, occlusal overloading, etc.) were avoided [18,19]. In the control group, ISQ values decreased from T0 to T21, only to increase during the remaining observation period. These findings can be the result of the expression of the osseointegration process, which is characterized by the progressive lack of primary stability and the increase in secondary stability. In contrast, in the test group, ISQ values increased progressively, reaching from the 14th day a statistically significant difference ($p < 0.05$) compared to T0. Comparing the data of the test group with those of the control group, differences can be seen at T14, T21, and T50. At T90, there were no statistical differences in ISQ between the two groups. The results of the present study appear to be consistent with those reported in the literature, reflecting the fact that SMFs have a beneficial effect in the early stages of the osseointegration process. Several studies have investigated the positive effects of SMF on the osseointegration process of implants [20–23]. Siadat et al. reported an increase in ISQ scores and a decrease in peri-implant bone loss in the SMF group compared to the control group in the first months of healing [24]. Gujjalapudi et al. showed an increase in ISQ values in implants treated with SMF during the 90-day observation period, whereas in the control group, ISQ values decreased in the first 30 days and increased up to 90 days [25].

The mechanism by which the effect of SMF on the osseointegration process occurs is not well understood, although some studies have attempted to clarify it [26]. The in vitro study by Yamamoto et al. showed that SMF stimulates bone growth by promoting the differentiation and/or activation of osteoblasts [27], which is also claimed by Chiu et al. [28]. Bone formation around implants seems to be accelerated under the influence of SMF compared to control [29,30]. Kim et al. found that SMF did not affect the adsorption of fibronectin on the titanium surface but promoted cell adhesion and proliferation [31]. Additionally, the in vivo study by Xu et al. suggests that the use of SMF may promote angiogenesis [32]. The effects of SMF seem to be most evident in the early stages of the osseointegration process of dental implants [33]. The use of Supercharged® Sc offers a unique advantage, as Sc are temporary devices used in the early stages of healing. Additionally, the improved stability of the implant allows a reduction in the time required for fixed prosthetic rehabilitation. It can be assumed that regenerative procedures can also benefit from SMF [34–37]. The major limitation of this study is represented by the small sample size. However, it should be noted that this is the first study conducted on humans.

5. Conclusions

The present human case series study shows the potential use of SMF prepared with Supercharged® Sc in oral implantology. The effect of SMF seems to come into play in the early stages of osseointegration and to increase the stability of dental implants. This allows a reduction in the time required for fixed prosthetic rehabilitation, given that SMF could be used to accelerate the osteointegration of implants. Further studies with a larger number of patients will be needed to better understand the potential use of SMF in implants.

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