# Resonance Frequency Analysis Assessment of Implants Placed with a Simultaneous or a Delayed Approach in Grafted and Nongrafted Sinus Sites: A 12-Month Clinical Study

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#### ABSTRACT

*Background:* Implant stability is one of the key factors for a successful osseointegration. At present, several techniques are available to regenerate bone tissue, but it is not clear whether implants placed in grafted bone are as stable as implants in native bone over time.

*Purpose:* The aim of the present study was to compare, by means of resonance frequency analysis (RFA), the stability of implants placed in sinus-grafted and -nongrafted sites during 12-month follow-up.

*Methods:* Twenty-five patients received a total of 38 implants. Nineteen implants were placed in maxillary native bone (group A) and 19 implants following maxillary sinus floor augmentation using anorganic bovine bone and autogenous bone (group B) in a 50:50 ratio. Group B was divided into groups B1 and B2 depending on the timing of implant insertion, that is, B1 simultaneously and B2 6 months after sinus lift. The implants were inserted according to a two-stage procedure. RFA values were collected at baseline, 6 and 12 months after implant placement.

*Results:* Between the tested groups, no statistically significant difference was found in RFA values of implants placed in sinus-grafted and -nongrafted sites after the surgery as well as at 6 and 12 months, while a significant difference was recorded in group B1 (p = .0297) when RFA values were compared over time.

Conclusions: The results of the present study suggest that regenerated bone can offer good stability for dental implants.

**KEY WORDS:** bone regeneration, dental implants, implant stability, maxillary sinus augmentation, resonance frequency analysis (RFA)

### INTRODUCTION

The sinus floor augmentation technique is, nowadays, a common procedure to increase the bone volume, thus allowing the placement of osseointegrated dental

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implants in patients with an atrophic posterior maxilla.<sup>1,2</sup> Bone grafting material selection is one of the crucial factors that affects the final outcome.<sup>3</sup>

In literature, autologous bone is still considered the gold standard<sup>4</sup>; however, several different allografts or mixtures of autologous bone and allografts<sup>5</sup> were also proposed. Allografts are generally used due to the limitations of autologous bone, such as insufficient quantity, or the need of a secondary surgical procedure in an extraoral or intraoral donor site.<sup>6</sup> Anorganic bovine bone (ABB) is a biocompatible material that presents structure and physical properties similar to human cancellous bone, it may represent an excellent grafting material for maxillary sinus augmentation.<sup>8</sup>

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In grafted sites, where the risk of failure seems to be higher,<sup>9</sup> a method to assess the implant stability is required. The analysis of implants' resonance frequency analysis (RFA) values can be an option as it provides a measure of the stiffness of bone implant bond.<sup>10</sup> Further methods to evaluate implant stability, such as reverse torque, were mainly investigated in the past. However, at present, it is generally accepted that RFA can be successfully used in experimental studies and clinical practice with reliable outcomes,<sup>11,12</sup> because it is a valuable tool to monitor implant stability changes over time.13-15 The RFA technique analyzes the first resonance frequency of a small transducer that is fixed to a dental implant fixture or abutment and depends upon three different factors: the design of the transducer, the stiffness of the dental implant fixture and its bond with the surrounding bone, and the total length above the marginal bone level.<sup>16</sup> RFA values are represented by a quantitative unit called the implant stability quotient (ISQ), on a scale from 1 to 100, and are measured with the Osstell® (Integration Diagnostics AB, Gothenburg, Sweden); an increased ISQ value indicates increased stability.17

By comparing RFA values of the same implant system, at different time points, it is possible to monitor the stiffness of the dental implant bone bond at any stage of the rehabilitative treatment.<sup>18</sup> Although it has been shown that regenerated bone is able to offer good long-term survival rate to implants,<sup>19,20</sup> at present, very little information is available about the stability of dental implants placed in grafted bone and in native bone.<sup>21</sup>

The aim of the present study was to compare, by means of RFA, the stability of implants placed in sinusgrafted and -nongrafted sites at implant insertion and after 6- and 12-month follow-up.

## **MATERIALS AND METHODS**

#### Study Design

In the period between March 2009 and February 2012, 25 consecutive healthy patients (11 male and 14 female, aged from 35 to 70, mean age 59), who needed an implant rehabilitation, were included for the present study (Table 1). Patients affected by bruxism, alcoholism, smoking more than 20 cigarettes per day, taking medicaments interfering with regular healing process, patients with poor oral hygiene, pregnant women, and

| TABLE 1 Patients' Age and Gender |      |        |       |  |  |
|----------------------------------|------|--------|-------|--|--|
| Age,* Year                       | Male | Female | Total |  |  |
| 30-40                            | 0    | 1      | 1     |  |  |
| 40-50                            | 0    | 1      | 1     |  |  |
| 50-60                            | 5    | 5      | 10    |  |  |
| 60-70                            | 5    | 7      | 12    |  |  |
| 70-80                            | 1    | 0      | 1     |  |  |
| Total                            | 11   | 14     | 25    |  |  |

\*Mean age 59 years, range 35-70 years.

patients affected by serious systemic diseases were excluded from this study. Computed axial tomography scans and orthopantomography were performed before surgery for the examination of each clinical case. Intraoral preoperative calibrated X-rays were performed to classify patients in different groups. In 12 patients, 19 implants were inserted in native bone (group A, control). Patients included in the control group showed sufficient height so that the implant did not encroach on nasal structures and had enough bone beyond the apex to guarantee primary implant stability. In 13 patients, 19 implants were placed following a maxillary sinus floor augmentation (group B, test). Group B was then divided into two groups depending on the residual bone height and, consequently, on the timing of implant insertion: in group B1, nine implants were inserted simultaneously to the sinus floor augmentation, due to a residual bone height of 3 mm; in group B2, 10 implants were inserted 6 months after the regenerative procedure, because a residual bone height less than 3 mm was present. Patients selected for the test group showed an edentulous area in the posterior maxilla corresponding to a Cawood and Howell's Class V.22

Informed written consent was obtained from the patients, and the protocol of the study was approved by the Ethics Committee of the University of Chieti-Pescara, Chieti, Italy. After a detailed oral and physical examination, patients were scheduled for sinus lift procedures and implant insertion. Preoperatively, they were extensively informed concerning the surgical procedures and they were asked for their full cooperation during treatment.

In all the 25 patients, 38 Neoss ProActive implants (Neoss Ltd, Windsor House, Cornwall Road, Harrogate, North Yorkshire, UK) were inserted in the posterior maxilla (Figure 1).

12 10 No. of Implants 8 6 4 2 0 9 11 13 11 13 11 13 9 11 13 11 Length 3,5 4 4,5 5 5,5 **D**iameters

Figure 1 Graphic distribution of 38 Neoss ProActive implants placed in 25 patients.

#### Surgical Technique

All the patients underwent oral hygiene prior to surgery. Antimicrobial prophylaxis was obtained with 875 mg amoxicillin + 125 mg of clavulanic acid twice/day for 5 days, starting 12 hours before surgery. Patients' mouths were rinsed with a chlorhexidine digluconate solution 0.2% for 2 minutes.

The surgical procedure for maxillary sinus floor augmentation was executed with a crestal incision and two vertical releasing incisions. A full-thickness mucoperiosteal flap was elevated. The maxillary sinus was opened from the vestibular side with a diamond round burr (1.6 mm diameter). Irrigation was performed with a sterile saline solution. The bone window was reversed into the sinus cavity. After the sinus opening, the Schneider's membrane was elevated. The sinuses were filled with a mixture of ABB (Bio-Oss, Geistlich Pharma AG, Wolhusen) and autologous bone in a 50:50 ratio, being careful that the material was in contact with the sinus medial bone wall. Autologous bone was taken with a disposable scraper (Safescraper Curve Twist C.G.M. s.p.a. divisione medicale Meta, Reggio Emilia, Italy) from areas surrounding the sinus vestibular opening, in the posterior maxilla (intraoral donor site). It consisted of cortical and spongious bone, belonging to class D3 of Misch classification.<sup>23</sup> The bone quality was clinically assessed by the surgeon (S.DiL.) from the resistance to drilling.24

Implants were inserted following the manufacturer's instructions in a two-stage procedure. No countersink drills were used. The last drill used to prepare implant sites had a diameter 0.6 mm smaller than the diameter of the fixtures placed, while for implant diameters 3.5 mm, a 3-mm drill was used (Table 2). Local anesthesia was induced by infiltration with articaine epinephrine 1:100,000.

A postsurgical analgesic therapy was obtained with Ketoprofen in granules for oral solution (OKI, Dompé S.p.A., Via Campo di Pile, L'Aquila, Italy); a packet contains Ketoprofen lysine salt 80 mg corresponding to

| TABLE 2 Baseline Characteristics of the Implants<br>and Bone Quality |                 |                          |                             |  |
|--|-----------------|--------------------------|-----------------------------|--|
| Groups   | Bone<br>quality | Implant<br>diameter (mm) | Last drill<br>diameter (mm) |  |
|  | D2              | 2.5                      | 2                           |  |
| A  | D3              | 3,5<br>3,5               | 3                           |  |
|  | D3              | 5,5                      | 3.4                         |  |
|  | D3              | 4                        | 3.4                         |  |
|  | D3              | 4                        | 3.4                         |  |
|  | D2              | 4                        | 3,4                         |  |
|  | D4              | 4,5                      | 3,9                         |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D4              | 5,5                      | 4,9                         |  |
| B1   | D4              | 3,5                      | 3                           |  |
|  | D4              | 4,5                      | 3,9                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
| B2   | D3              | 3,5                      | 3                           |  |
|  | D3              | 4,5                      | 3,9                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D4              | 5                        | 4,4                         |  |
|  | D3              | 5                        | 4,4                         |  |



Distribution of 38 implants by diameters and lengths

50 mg of Ketoprofen. The dosage is one packet (80 mg) every 12 hours for 4 days after food. The oral hygiene was controlled with chlorhexidine 0.2% for 15 days. Oral hygiene instructions were also provided. Vicryl sutures (Ethicon, Inc., a Johnson & Johnson Company, Somerville, NJ, USA) were performed with a 5/0 wire and a FS-2 needle. Sutures were removed 15 days after surgery. All the implants were loaded 6 months after insertion.

### **RFA** Collection

The mean RFA values were collected on the day of the surgery (RFA<sup>0</sup>) and 6 (RFA<sup>6</sup>) and 12 (RFA<sup>12</sup>) months after the insertion of dental implants using the ISQ scale developed by Osstell (Integration Diagnostics AB).

#### Statistical Analysis

RFA values were statistically compared between groups at different time points (0, 6, and 12 months) by means of Kruskal–Wallis Test, for independent samples, while ISQ values within the same group over time were compared using Friedman with posttest, for paired samples. Differences were accepted as p < 0.05, and data are presented as means ± standard errors.

## RESULTS

No adverse situations occurred after a 12-month healing period and the implant survival rate was 100%. All the implants were clinically osseointegrated and mobility was not present.

The RFA values found for group A were  $70.26 \pm 2.42$  at baseline,  $72.66 \pm 1.55$  after 6 months,

and  $73.92 \pm 1.28$  after 12 months; values for group B1 were  $68.31 \pm 3.27$  at baseline,  $77.28 \pm 1.68$  after 6 months, and  $77.61 \pm 0.84$  after 12 months; values for group B2 were  $69.94 \pm 4.05$  at baseline,  $75.8 \pm 2.14$  after 6 months, and  $75.31 \pm 1.59$  after 12 months.

After 6 months, in all the groups, an increase of RFA mean values was recorded. After 12 months, group A and group B1 showed an increase of the values, while for group B2, a not statistically significant decrease of ISQ values was registered between 6 and 12 months.

Differences were not statistically significant for RFA<sup>0</sup> (p = .741), RFA<sup>6</sup> (p = .269), and RFA<sup>12</sup> mean values (p = .2729) between the three groups examined (Figure 2).

Regarding the evaluation of ISQ values within each group, no statistically significant differences were found for groups A (p = .3892) and B2 (p = .3553), while statistically significant differences were recorded in group B1 (p = .0297) when B1<sup>0</sup>, B1<sup>6</sup>, and B1<sup>12</sup> RFA mean values were compared.

### DISCUSSION

The RFA technique has been proven sensitive in monitoring changes in implant stability during the healing time.<sup>25</sup> In a prospective study, Hallman and colleagues<sup>26</sup> placed 108 dental implants 6 months after a sinus floor augmentation with a 20:80 mixture of ABB and autologous bone. The mean RFA values, recorded after 3 years of loading, were  $66.4 \pm 4.1$ , with no significant difference between implants in grafted and residual bone,



**Figure 2** Evolution of ISQ values (mean values ± standard errors) in groups A, B1, and B2 at baseline, after 6 months, and after 12 months.

indicating a good middle-term stability for dental implants inserted in grafted bone. Similarly, Degidi and colleagues<sup>27</sup> followed for 12 months 80 implants placed in sinuses augmented with a 50:50 mixture of ABB and autologous bone 6 months before the implant insertion time and in nongrafted areas. ISQ values, recorded using an Osstell Device, were, for implants placed in grafted sites,  $66.0 \pm 7.7$  after 6 months and  $70.0 \pm 5.9$ after 12 months. Regarding implants inserted in nongrafted sites, RFA values were  $61.5 \pm 10.5$  after 6 months and  $66.7 \pm 4.5$  after 12 months. Likewise, they demonstrated the long-term stability of implants placed in sites grafted with ABB. In addition, Degidi and colleagues<sup>27</sup> showed a statistically significant difference of long-term ISQ values between implants placed in grafted and nongrafted sites. This was explained by the authors with the presence in the control group of fresh postextractive sites. Indeed, Vanden Bogaerde and colleagues<sup>28</sup> demonstrated that implant inserted in fresh postextractive sites could show a wide range of RFA measurements. In the current study, the evaluation of RFA values, recorded according to the procedure described by Sennerby and Meredith,<sup>10</sup> placed in grafted and nongrafted sinus sites was investigated during a 12-month healing period. The data obtained were in agreement with the previous studies that showed a good stability after 6 and 12 months from implant insertion surgery in sinus-lifted sites. Indeed, regarding RFA values, no statistical differences were found when comparing implants placed in non-regenerated and regenerated sites, indicating the regenerated bone could offer a stability as good as native bone after a 12-month observation period.<sup>25,28</sup>

The increase of RFA values after 12 months was present in all the sites and it could be explained by the maturation of the bone tissue after implant insertion. In addition, the highest RFA values, shown by implants placed in sinus-grafted sites, might be explained by the fact that regenerated sites always maintain the cortical native bone.<sup>29</sup> Regarding the comparison between group B1 and B2, the present study suggested that there were no significant differences between the two groups, even though in group B1 a statistically significant increase of ISQ values was registered over time. Rasmusson and colleagues reported that RFA values significantly increased when a delayed implant placement was compared with a simultaneous approach, suggesting that with the delayed technique, an improvement of osseous integration can be detected over time.<sup>30</sup> This is not in agreement with the data of the current study. The significant increase of ISQ values in implants placed simultaneously to sinus floor augmentation (group B1) might be explained by the presence of a minimum of 3 mm of residual crestal bone height recommended in order to achieve sufficient initial implant stability.<sup>31,32</sup> In addition, in experimental animal trials, simultaneous implant placement during sinus lift also yields a sufficient degree of implant stability, showing a significant association of alveolar bone height and implant stability, at the time of implant placement and at 6-month follow-up.<sup>33</sup>

In 2011, Cricchio and colleagues<sup>11</sup> investigated the long-term stability of implants placed in a void space created by the elevation of the maxillary sinus membrane without combining any graft material. In that study, they recorded RFA values over time. The ISQ values were  $67.4 \pm 6.1$  at placement,  $66.4 \pm 5.2$  after 6 months, and  $66.6 \pm 3.6$  after 12 months. While RFA at baseline are similar to values recorded in the present paper, ISQ values at 6 and 12 months are lower than those recorded in group B1 and B2 of the present study. Indeed, while, in the present study, RFA values grow from RFA<sup>0</sup> to RFA<sup>12</sup>, Cricchio and colleagues recorded a decrease of value from baseline to 12 months. In addition, with the technique presented, it is possible to rehabilitate only patients in which it is possible to achieve adequate primary stability. While using bone graft materials, it is possible to regenerate bone and insert dental implants after the regenerative surgery, even if the remaining bone does not guarantee an adequate primary stability.

Finally, RFA technique might also be a clinical tool for identifying implants at risk of failure at the time of placement.<sup>15</sup> Concerning the failures, it is interesting to note that during the study, all the implants were stable, showing on average high primary stability. Scarano and colleagues<sup>34</sup> showed a statistically significant association between an ISQ <40 and irretrievably failed implants, while Rabel and colleagues<sup>35</sup> pointed out that values under 50 ISQ should be seen as critical. This is in agreement with the current findings, which showed a correlation between ISQ values and implant survival rate; in particular, all the implants evaluated presented ISQ values >50 during 12-month follow-up and the survival rate was 100%.

#### CONCLUSION

RFA measurement is a valid support to investigate dental implant stability over time because it is an easy, noninvasive, reproducible method. Dental implants placed in grafted or nongrafted sites were monitored for 12 months and, within the limitation of the present study, it can be concluded that regenerated sites can guarantee good stability 6 and 12 months following implant insertion time.

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