

# A Prospective Study of 3 Weeks' Loading of Chemically Modified Titanium Implants in the Maxillary Molar Region: 1-year Results

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**Purpose:** Recent research has demonstrated that modification of implant surface chemistry can influence osseointegration events, leading to increased bone-to-implant contact at earlier times. Clinical studies have been initiated to investigate the potential of modified surfaces to reduce the needed healing period between surgery and prosthesis insertion. The purpose of this prospective clinical study was to evaluate the clinical outcome after 3 weeks of loading single implants with hydrophilic surfaces in the maxillary molar areas. **Materials and Methods:** This prospective two-center clinical trial consecutively included healthy patients who needed an implant in the maxillary molar areas. Drilling was limited to the minimum, most of the site preparation was produced with osteotomes, and screw tapping was never performed. Abutment connection was carried out at 15 Ncm, at 21 ( $\pm$  2) days after surgery, and provisional restorations were fabricated in occlusion. Further abutment tightening at 35 Ncm was performed after 4 to 6 additional weeks, for the definitive restoration. **Results:** Thirty-five patients were treated. No major adverse events were registered during and/or after surgery. Primary stability was always achieved. At abutment connection, six of the 35 patients reported minor pain, and placement of provisional restorations was postponed for 4 additional weeks. Clinical and radiographic measures were taken at baseline (abutment connection) and at the 1-year follow-up appointment. No patients dropped out, and no implant losses were registered during the first 12 months of observation. No significant differences between baseline and the 1-year examination were recorded for any outcome measure. **Conclusions:** These results suggest that, by means of the surgical and restorative technique presented, surface-modified hydrophilic implants are suitable for loading at 3 weeks in maxillary molar areas. INT J ORAL MAXILLOFAC IMPLANTS 2009;24:65–72

**Key words:** dental implants, early loading, healing time, osseointegration, osteotome technique, posterior maxilla

The importance of the surface characteristics of dental implants in contributing to bone anchorage has been clear for a long time, and various surface treatments have been studied in the hopes of achieving faster bone integration. In the last few years, various researchers have demonstrated that implants with sandblasted and acid-etched surfaces can be loaded at earlier times, thus reducing the

period between surgery and restoration.<sup>1–2</sup> Moreover, recent prospective studies demonstrated that these implants can achieve and maintain successful tissue integration, with high predictability, for at least 5 years.<sup>3–6</sup> Norton and Gamble suggested that placement of implants in poor-quality bone should be avoided since failure is more likely.<sup>7</sup> Szmukler-Moncler et al proposed that shorter healing periods should be applied to implants placed in bone types 1 and 2 since, under the commonly used placement protocol, implant prognosis is significantly affected by bone quality.<sup>8</sup> Rocuzzo and Wilson demonstrated that sandblasted and acid-etched implants are suitable for loading at 6 weeks, even in the region of the maxillary second and third molars, where bone density is typically low.<sup>9</sup>

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Many investigations have been conducted to improve the surface characteristics to increase bone-to-implant contact at earlier times. Buser et al evaluated bone apposition to a modified sandblasted/acid-etched surface, as compared with a standard sandblasted/acid-etched surface, during early stages of bone regeneration, in miniature pigs.<sup>10</sup> Test and control implants had the same topography, but their surface chemistry differed. Test surfaces were conditioned in an isotonic sodium chloride solution following acid etching and stored in a liquid environment (sodium chloride) to avoid contamination with molecules from the atmosphere. Therefore, test implants showed greater hydrophilic properties. Test implants demonstrated a significantly greater mean percentage of bone-to-implant contact compared to controls after 2 and 4 weeks of healing. It was concluded that the modified sandblasted/acid-etched surface promoted enhanced bone apposition during early stages of bone regeneration. Schwarz et al<sup>11,12</sup> recently showed similar results and also demonstrated highly osteoconductive properties of the modified sandblasted/acid-etched surface in a dehiscence-type defect model in dogs.

More recently, Ferguson et al performed, in a split-mouth experimental design, implant removal torque testing to assess the biomechanical properties of the bone-implant interface.<sup>13</sup> The authors concluded that a chemically modified sandblasted and acid-etched surface achieved better bone anchorage during the early stages of bone healing than the standard sandblasted and acid-etched surface. Oates et al recently compared the early changes in stability of modified sandblasted/acid-etched implants to those of controls, suggesting the possibility, for the former, of shortening the clinical loading protocols.<sup>14</sup>

Regarding early loading in the partially dentate maxilla, the Third ITI Consensus Conference recommended the use of implants characterized by rough surfaces and allowed to heal for at least 6 weeks in type 1, 2, or 3 bone only.<sup>15</sup> Currently, however, interest in early and immediate loading is growing, and a reduction of time between surgery and prosthetic restoration in low-density bone would be beneficial for both patients and clinicians, if the risk of failure can be reduced. Changes in loading protocols are not uncommon in implant dentistry, although there is still a widespread tendency to embrace novel developments without documented advantages deriving from rigorous testing. Careful investigation of such protocols is necessary.

The aim of this prospective study is to assess whether chemically modified titanium implants are suitable for early loading 3 weeks after surgery in maxillary molar areas and to monitor the peri-

implant conditions over time. This report focuses on surgical feasibility, early aspects of implant stability, and postsurgical transmucosal healing. Clinical and radiographic results after 1 year are also presented.

## MATERIALS AND METHODS

### Patient Selection

Healthy nonsmoking patients, with no systemic contraindications to implant placement, were consecutively selected from those seeking implant rehabilitation between November 1, 2005, and October 31, 2006, in two private practices. The patients agreed to participate in this prospective study and gave their informed consent, in accordance with the Helsinki Declaration on human experimentation. All patients presented with one or more edentulous areas in the posterior maxilla corresponding to the position of one of the molars, to be replaced with single- or multiple-unit fixed partial dentures. Only one implant per patient was included in the study. If treatment comprised two or more implants, only the most distal implant was included. In patients with two contralateral implants in the same position, the implant was chosen by means of a coin toss.

Edentulous areas were required to have 3 months of healing following tooth extraction, with no previous bone grafting and/or sinus lift. The areas to be treated had good occlusal relationships and did not present any of the following local exclusion criteria:

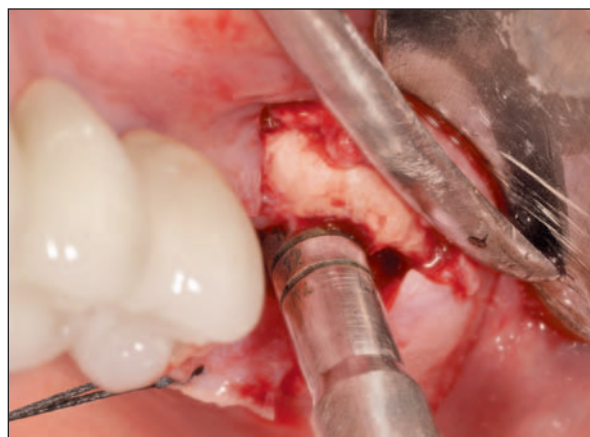
- Inflammation, including untreated periodontitis at the residual dentition
- Mucosal diseases such as erosive lichen planus
- History of local radiation therapy
- Presence of oral lesions (such as ulceration or malignancy)
- Severe bruxing or clenching habits

Following selection, all patients were instructed in oral hygiene until they reached a clinically acceptable level. Full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) were recorded as the percentage of surfaces (four per tooth) that revealed the presence of plaque and of bleeding on probing.<sup>16,17</sup> At the end of the initial therapy, before commencing the surgical procedures, all patients had controlled their periodontal conditions (FMPS < 20% and FMBS < 20%).

Radiographic evaluations were performed to assess the dimensions of the alveolar process. A minimum of 10 mm in apicocoronal height and 6 mm in buccolingual width was necessary to be included in



**Fig 1** Incision of the thick mucosa in the maxillary molar area.



**Fig 2** Site preparation with osteotome.

this study. Patients who required ridge expansion osteotomy and/or sinus floor elevation were excluded from the present protocol. Moreover, the investigators decided that patients in whom it was not possible to obtain implant primary stability should be excluded after surgery.

### Surgical Procedure

The research was conducted in two private offices by two periodontists with more than 15 years of implant experience. Before study initiation, the authors met to review the protocol and to standardize case selection and surgical procedures.

After local anesthesia was achieved, a midcrestal incision was made from the distal aspect of the last tooth in the maxilla to the tuberosity. Oblique releasing incisions were made and full-thickness flaps were elevated to expose the bone. The flaps were elevated on the palatal and buccal aspects of the alveolar ridge, and sutures were used for retraction. If the mucosa was too thick (ie, more than 3 mm) a modification was introduced to remove excessive soft tissue so as to avoid the creation of a deep pocket around the implants (Fig 1). Initial drilling was limited to a 2.0-mm round bur at 680 rpm to facilitate the use of osteotomes in the sites. The osteotomy sites were prepared using Straumann osteotomes for sinus floor elevation (Institut Straumann, Basel, Switzerland) according to a previously described technique.<sup>9</sup> Instruments of increasing diameters were gently tapped with a mallet to compress bone apicolaterally (Fig 2). Further drilling was performed only when very strong resistance to the osteotome was found. Screw taps were not used. Solid-screw nonsubmerged chemically modified titanium implants (SLActive, Institut Straumann) were placed

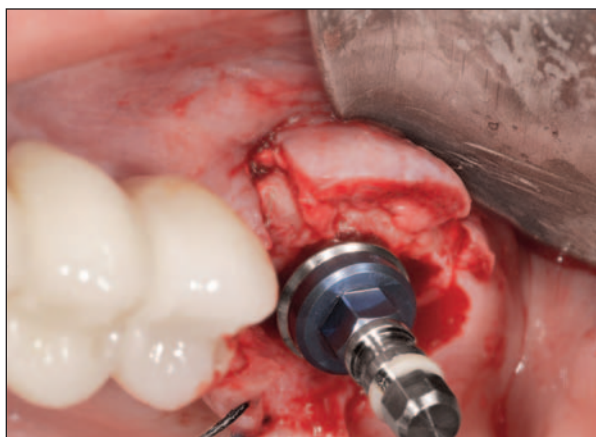
according to the manufacturer's instructions. All implants were inserted manually in a self-tapping fashion with the border of the rough surface approximating the alveolar bone crest and the machined neck portion left in the transmucosal area (Fig 3). Healing screws were placed on the implants and the flaps were sutured. If necessary, further excision of soft tissue was performed to allow close adaptation of the wound margins to the implant shoulder without submerging it (Fig 4). The number, position, and type of implants to be placed in each patient were determined after a thorough diagnosis of the anticipated needs for the planned prosthesis and the presence of any anatomic limitations.<sup>18</sup>

### Postsurgical Care

Patients were instructed to take 1 g of amoxicillin and clavulanic acid twice a day for 6 days, starting at least 1 hour prior to surgery, and nonsteroidal analgesics as needed. Immediately after surgery, the patients applied ice packs at the treated area, and it was recommended that these be kept in place for at least 4 hours. Patients were advised to discontinue tooth brushing and to avoid trauma at the site of surgery for 3 weeks. They were also instructed to use 0.2% chlorhexidine digluconate rinse for 1 minute 3 times a day for the same period of time. Patients were seen after 7 days to monitor healing and to remove sutures.

### Prosthetic Reconstruction

Abutment connection was carried out at 15 Ncm 21 ( $\pm 2$ ) days postsurgery by means of a ratchet and torque control device (Figs 5 and 6). Solid abutments for cemented restorations were selected according to the amount of available maxillomandibular space,



**Fig 3** Implant positioning with primary stability.



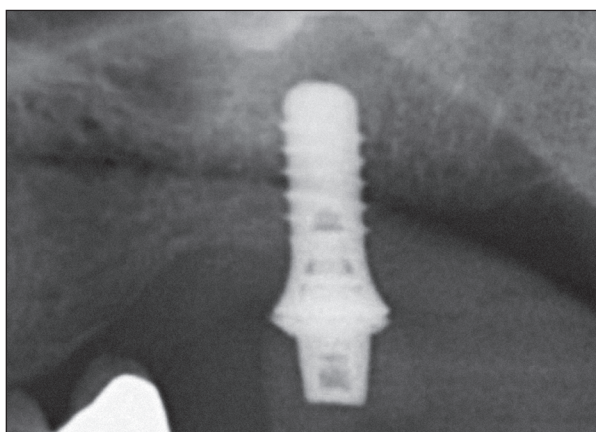
**Fig 4** Suture after removal of excessive soft tissue distal to the implant.



**Fig 5** Soft tissue healing at 3 weeks postoperative.



**Fig 6** Abutment connection at 15 Ncm.



**Fig 7** Radiograph of the implant after loading with provisional crown.

and provisional restorations were fabricated immediately. The provisional restoration was made in occlusion with the opposing dentition, with occlusal contacts distributed in centric occlusion or maximum intercuspation (Fig 7). Four to 6 weeks later, the abutments were tightened to 35 Ncm to proceed with the definitive restorations. Impressions were made, with impression caps and positioning cylinders, to transfer the positions of the implants to the master model. A variety of porcelain-fused-to-gold crowns and fixed partial dentures were fabricated and cemented; none were splinted to natural teeth.

**Clinical Assessments**

Probing depth (PD) according to Fiorellini and Weber<sup>19</sup> was evaluated at the mesial, distal, buccal, and palatal aspects of each implant by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, IL) at baseline (ie, abutment connection) and 12 months postoperatively. Figures were



**Table 1** Data on Patients, Implants, and Complications

| Patient no. | Age  | Sex | Implant type       | Surface area (mm <sup>2</sup> ) | Molar area | Abutment (d)* | Implant stability |
|-------------|------|-----|--------------------|---------------------------------|------------|---------------|-------------------|
| 1           | 43   | F   | SP RN, 4.1 × 10 mm | 132                             | L first    | 20            | No                |
| 2           | 46   | F   | SP WN, 4.8 × 10 mm | 162                             | R first    | 24            |                   |
| 3           | 55   | M   | SP WN, 4.8 × 12 mm | 197                             | R second   | 21            |                   |
| 4           | 47   | F   | SP RN, 4.8 × 10 mm | 161                             | R first    | 21            |                   |
| 5           | 44   | F   | SP WN, 4.8 × 12 mm | 197                             | R first    | 21            |                   |
| 6           | 70   | F   | S WN, 4.8 × 10 mm  | 165                             | L second   | 21            |                   |
| 7           | 58   | F   | S RN, 4.1 × 12 mm  | 165                             | L second   | 21            |                   |
| 8           | 60   | F   | S RN, 4.1 × 10 mm  | 135                             | R third    | 21            |                   |
| 9           | 52   | F   | S WN, 4.8 × 10 mm  | 165                             | L third    | 21            |                   |
| 10          | 66   | F   | S WN, 4.8 × 10 mm  | 165                             | L second   | 22            | No                |
| 11          | 50   | F   | SP RN, 4.1 × 10 mm | 132                             | R second   | 23            |                   |
| 12          | 67   | F   | S WN, 4.8 × 10 mm  | 165                             | L second   | 23            | No                |
| 13          | 48   | M   | S WN, 4.8 × 10 mm  | 165                             | L third    | 21            |                   |
| 14          | 52   | F   | S WN, 4.8 × 10 mm  | 165                             | R third    | 21            |                   |
| 15          | 64   | F   | S WN, 4.8 × 10 mm  | 165                             | R second   | 22            |                   |
| 16          | 67   | M   | S WN, 4.8 × 10 mm  | 165                             | R third    | 21            |                   |
| 17          | 42   | F   | S WN, 4.8 × 10 mm  | 165                             | R second   | 21            |                   |
| 18          | 48   | F   | S WN, 4.8 × 10 mm  | 165                             | L second   | 21            |                   |
| 19          | 46   | F   | S WN, 4.8 × 10 mm  | 165                             | L second   | 21            | No                |
| 20          | 73   | F   | TE RN, 4.1 × 10 mm | 158                             | R first    | 19            |                   |
| 21          | 45   | F   | TE RN, 4.1 × 10 mm | 158                             | R second   | 20            | No                |
| 22          | 52   | F   | SP WN, 4.8 × 10 mm | 162                             | L second   | 22            |                   |
| 23          | 38   | F   | SP WN, 4.8 × 10 mm | 162                             | L first    | 21            |                   |
| 24          | 43   | F   | SP WN, 4.8 × 10 mm | 162                             | L first    | 22            |                   |
| 25          | 58   | F   | SP WN, 4.8 × 10 mm | 162                             | R first    | 22            |                   |
| 26          | 53   | M   | SP WN, 4.8 × 10 mm | 162                             | R second   | 20            |                   |
| 27          | 61   | F   | SP WN, 4.8 × 10 mm | 162                             | L first    | 22            | No                |
| 28          | 47   | F   | SP WN, 4.8 × 12 mm | 197                             | R second   | 22            |                   |
| 29          | 63   | M   | SP WN, 4.8 × 10 mm | 162                             | L second   | 21            |                   |
| 30          | 57   | M   | SP WN, 4.8 × 10 mm | 162                             | R first    | 20            |                   |
| 31          | 68   | F   | SP RN, 4.8 × 10 mm | 161                             | R first    | 22            |                   |
| 32          | 61   | M   | SP WN, 4.8 × 12 mm | 197                             | R second   | 21            |                   |
| 33          | 46   | F   | SP WN, 4.8 × 10 mm | 162                             | L first    | 22            |                   |
| 34          | 65   | F   | SP WN, 4.8 × 12 mm | 197                             | R second   | 20            |                   |
| 35          | 68   | F   | SP WN, 4.8 × 12 mm | 197                             | R second   | 23            |                   |
| Mean        | 54.9 |     |                    |                                 |            | 21.3          |                   |

S = standard; SP = standard plus; TE = tapered effect; WN = wide neck; RN = regular neck.

\*No. of days after surgery before abutment connection.

rounded off to the nearest millimeter. At the same time and sites, the presence of dental plaque (PI) and of bleeding on probing (BOP) was recorded.<sup>20</sup> Standardized periapical radiographs were taken at baseline (ie, abutment connection) and 1 year post-surgery according to the technique previously described by Roccozzo et al.<sup>6</sup>

### Statistical Analysis

Statistical analysis was performed using the Wilcoxon signed-rank test and the paired-sample *t* test to assess the significance of the differences between the clinical (PD) and the radiographic data (bone loss). Differences in PI and BOP were tested using the chi-square test. A *P* value < .05 was considered to be statistically significant.

## RESULTS

Thirty-five patients (seven men and 28 women, mean age 54.9 years) were treated. In all patients, surgery and healing proceeded without complications and with minimal postoperative discomfort. Implant primary stability was achieved in all cases.

During abutment connection, six of the 35 implants rotated slightly, patients reported slight pain, and connection was not completed. Plastic protective caps were placed, with provisional cement, for an additional healing time of 3 to 4 weeks. After the additional healing period, the abutments were retightened at the time of prosthetic reconstruction, as described. No patient dropouts were registered during the first 12 months of observation.

**Table 2 Clinical Parameters Around the 35 Loaded Implants at Baseline and 1 Year After Placement**

|     | Baseline     | 12-month follow-up | Statistical difference |
|-----|--------------|--------------------|------------------------|
| PI  | 14 %         | 17 %               | NS                     |
| BOP | 16 %         | 18 %               | NS                     |
| PD  | 3.5 (0.9) mm | 3.4 (1.0) mm       | NS                     |
| BL  |              | 0.22 (0.35) mm     |                        |

PI = Plaque Index (presence of dental plaque); BOP = presence of bleeding on probing; PD = mean probing depth (SD); BL = bone loss; NS = not significant

Data on patients, implant types, recipient sites, and complications encountered at abutment connection are reported in Table 1.

The clinical data obtained at baseline and the 1-year follow-up are listed in Table 2. The six implants that rotated at time of abutment connection were thoroughly checked. Patients' subjective experience concerning prosthetic function presented no difference between these and all the other implants throughout the initial 12-month period of examination.

## DISCUSSION

In a recent systematic review Esposito et al<sup>21</sup> found some evidence, from trials in subjects with healthy mandibles, that outcomes were similar with immediate or early loading with dentures (in 6 weeks) and the traditional protocol of waiting several months. However, more research was considered necessary "to be sure that immediate or early loading is safe and effective, in upper and lower jaws, and for whom."

The aim of the present study was to verify whether chemically modified titanium implants could be successfully loaded after 3 weeks in maxillary molar areas using a bone-condensing implant site preparation technique. Implant placement in the posterior maxilla is often complicated by a deficiency in bone quality. With the osteotomes, it was possible to compact bone and to improve the probability of initial implant stability. This is in accordance with a recent systematic review<sup>21</sup> that concluded that a high degree of primary stability at implant insertion is a key prerequisite for a successful early loading procedure. Nevertheless, no scientific data are currently available regarding the influence of bone condensing on bone biology. Stavropoulos et al<sup>22</sup> conducted an animal study in which the preparation of the implant site by means of osteotomes had a

deleterious effect on osseointegration. The disagreement between the results of the present study and those of a similar study by Nkenke et al<sup>23</sup> is difficult to explain. Further histomorphometric studies are necessary to fully understand bone healing in compacted sites before any firm conclusion can be reached. On the other hand, extrapolation of information from animal studies to human clinical realities should always be done with caution.

Because of the surgical technique employed, it was not possible to precisely assess the percentage of sites that had lower bone density (class 4 according to Lekholm and Zarb<sup>24</sup>). The possibility of a reliable clinical evaluation to differentiate among the various types of bone in practice has recently been questioned.<sup>25</sup> Moreover, in a recent publication Sullivan et al suggested the use of implants with a chemically enhanced surface in areas of poor-quality bone (types 3 and 4).<sup>26</sup>

The success rate for implant placement in the posterior maxilla has been reported to be lower when compared to that of other areas of the mouth.<sup>27-31</sup> Nonetheless, it must be noted that all published results were achieved with implants placed according to standard drilling protocols. Nocini and associates<sup>32</sup> presented a case of implant placement in the maxillary tuberosity with modified osteotomes. However, in that case report, the waiting time between surgery and loading was not specified.

In the present study, all implants were self-tapped. By avoiding the use of drills, and using a bone-condensing technique with osteotomes, it was possible to achieve sufficient implant stability, which was considered necessary for early loading. However, it is not possible to know whether the bone-condensing preparation or the improved surface characteristics of the implants (or both) contributed to the positive outcome. After the positive preliminary results of this study, a randomized controlled trial to assess which variable most strongly influences the results is desirable.

A prospective double-blind study to evaluate the outcome of two similar implants that differ by only one variable of interest (surface characteristics) will soon be started. In this manner, as results from future measurements become available, it will be possible to estimate the relative impact of this variable on the success rate.<sup>33</sup>

In a previous similar protocol, if primary stability was not achieved with a 4.1-mm-diameter implant, the implant was immediately removed and replaced with a 4.8-mm-diameter version.<sup>9</sup> It must be noted, however, that this never happened in the present case series, thanks to the experience of the operators and to the configuration of the osteotomes, which have a

curvature that enables access to the most posterior areas, even in patients with limited mouth opening.

Confusion is still present among clinicians and researchers about what constitutes early loading. A recent consensus statement defined early loading as a restoration that is in contact with the opposing dentition and placed at least 48 hours after implant placement but not later than 3 months afterward.<sup>15</sup> It is obvious that the time frame is very flexible, and more consensus is necessary to craft terminology that more accurately reflects quickly changing clinical protocols.

Recently Vanden Bogaerde et al presented the results of a multicenter study on oxidized titanium implants used for early function in the maxilla and the posterior mandible.<sup>34</sup> Although provisional prostheses were placed within 9 days and no later than 16 days after implant placement—ie, a shorter period of time than that used in the present study—it must be noted that all implants were splinted and no implants were placed in the positions of the maxillary second and third molars, where bone density is usually the lowest.

Although it has been demonstrated that bone-to-implant interfacial strength is influenced by surface area, in previous studies, implants have been loaded according to similar protocols regardless of length and diameter.<sup>13,14,31</sup> It is interesting to note that the present investigation was limited to implants that presented a surface area greater than 130 mm<sup>2</sup> (Table 1). Unlike other studies, in which a higher failure rate was found for short implants in the posterior region of the maxilla,<sup>29,33</sup> all 10-mm implants showed clinical success in this preliminary evaluation. Further studies are necessary to establish more precise loading protocols according to the type of implants employed.<sup>35</sup>

It remains to be seen whether 8-mm-long and/or 3.3-mm-diameter implants could be included in a similar study protocol. In addition, the possibility of abutment connection at 35 Ncm after 3 to 4 weeks for the posterior maxilla is currently unknown. However, the feasibility of abutment connection at 15 Ncm, for provisional restoration only, is confirmed by these results. In this early report, however, it was not possible to assess the impact of implant rotation on both hard and soft tissue outcomes. These results will be incorporated into 3- and 5-year follow-up reports. Nevertheless, it must be noted that a similar problem was first encountered with conventional sandblasted/acid-etched surfaces and abutment connection at 6 weeks. A recent publication confirmed that if limited rotation is properly handled, it should have no detrimental effect on the clinical outcome for at least 5 years.<sup>6</sup>

## CONCLUSIONS

The results of this clinical investigation suggest that successful functional loading of chemically modified titanium implants is possible at 3 weeks in the maxillary molar region using the protocol described. This procedure, therefore, represents an important step toward faster healing and increased treatment predictability, especially in cases with time-critical protocols. With these positive preliminary results, randomized controlled clinical trials should be encouraged to confirm the hypothesis that a hydrophilic surface may encourage faster osseointegration and reduce the failure rate in the early healing phase. More years of observation are necessary to verify whether osseointegration can be maintained over a long period of time.<sup>1,6</sup>

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