Prospective multicentre study

Evaluation of the implant stability quotient for early-loaded implants with a new hydrophilic surface

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Clinical protocols originally suggested a three- to six-month healing period before implant loading [1]. Today, clinical research is focusing on shorter and less invasive procedures. Different placement and loading protocols are currently used to shorten treatment times and decrease the number of surgical interventions, enabling clinicians to choose between a one-stage (non-submerged) and a two-stage (submerged) approach. It has been suggested that the two-stage approach is not a prerequisite for osseointegration [2].

Primary stability depends mainly on the macro- and micro-design of the implant [3–5]. Nevertheless, in the last decade there has been an ongoing effort to improve the interface between bone and implant in order to accelerate and enhance the osseointegration of dental implants, providing novel and practical perspectives for further advancement in implant therapy [6]. These efforts have concentrated on improving this interface chemically (by incorporating inorganic phases on or within the titanium oxide layer) or physically (by increasing the level of roughness) [7]. These techniques may apply additive or subtractive concepts. Long-term studies have shown that additive surfaces are associated with a higher incidence of complications [8]; hence, subtractive surfaces have become more popular with clinicians.

Shorter healing period was introduced in many experimental and clinical studies using sandblasted and acid-etched (SLA) surfaces [9–11]. Modification of the original implant surfaces can result in earlier and increased bone-to-implant contact, thus reducing the healing period between surgery and restoration even in patients with poorly controlled type 2 diabetes mellitus [12].

The present prospective multicentre study was aimed to evaluate early implant failure, complications and ISQ values of one-stage Hiossen ETIII NH implants (Hiossen Inc., Fairless Hills, PA, USA) with the new hydrophilic surface, loaded four weeks after placement. This trial was reported according to the STROBE statement.

Materials and methods

This investigation was designed as multicentre single-cohort prospective study conducted according to the principles embodied in the 2008 Helsinki Declaration. Surgical and prosthetic procedures were performed at two centres in Korea and Italy by the authors, two expert clinicians, between September 2017 and April 2018. All participants were enrolled and treated in the study in consecutive order after being informed about the nature of the study and providing their written consent.

Any healthy patients, aged 18 years or older, who required at least one implant to be restored with a fixed implant-supported restoration using the early-loading protocol, with bleeding and plaque indices throughout the mouth no higher than 25 per cent , with a bone supply sufficient to allow the placement of implants at least 10 mm in length and with a bone width of at least 6 mm for the placement of a regular-platform Hiossen ETIII NH implants (Hiossen Inc.) were included in the study.

The exclusion criteria were: adverse medical conditions (such as stroke, recent cardiac infarction, severe bleeding disorder, uncontrolled diabetes or cancer); ››

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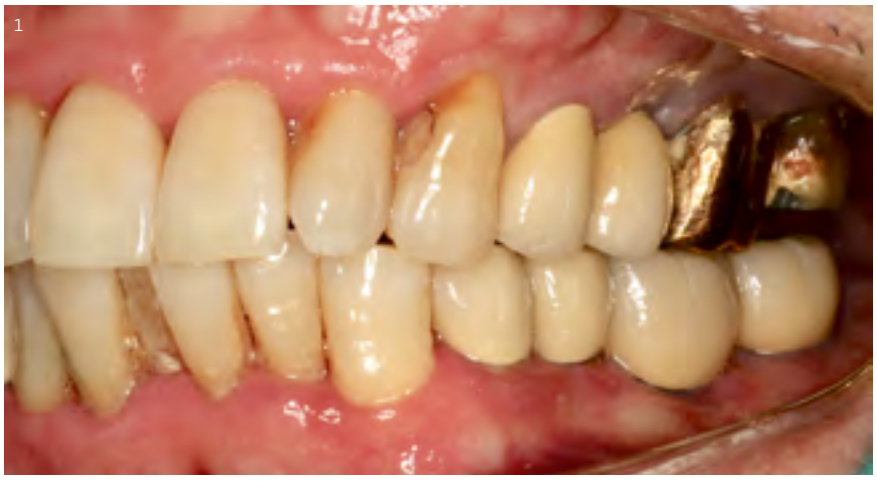
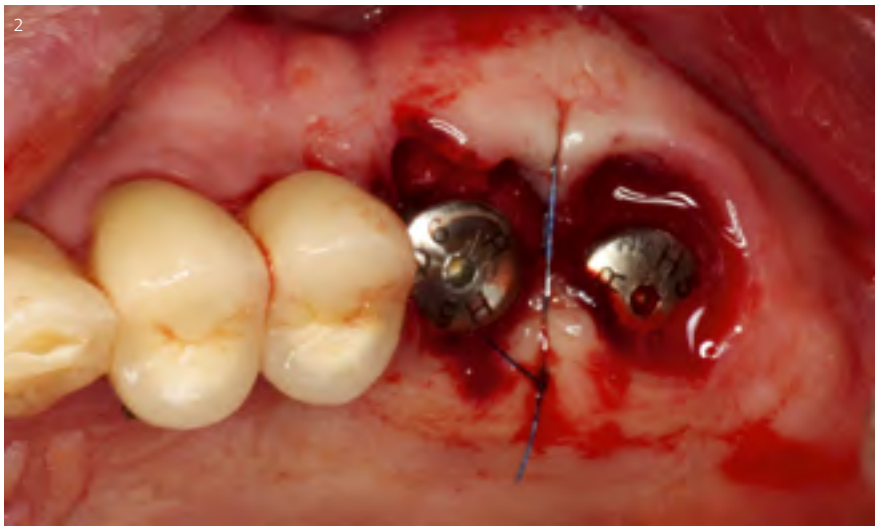
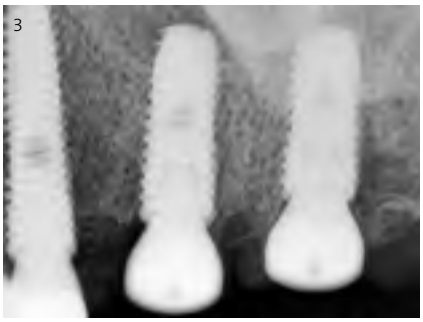






1 I Pre-clinical situation: lateral view.
2 I Implant placement using a one-stage approach.
3 I Periapical radiograph at the time of implant placement.

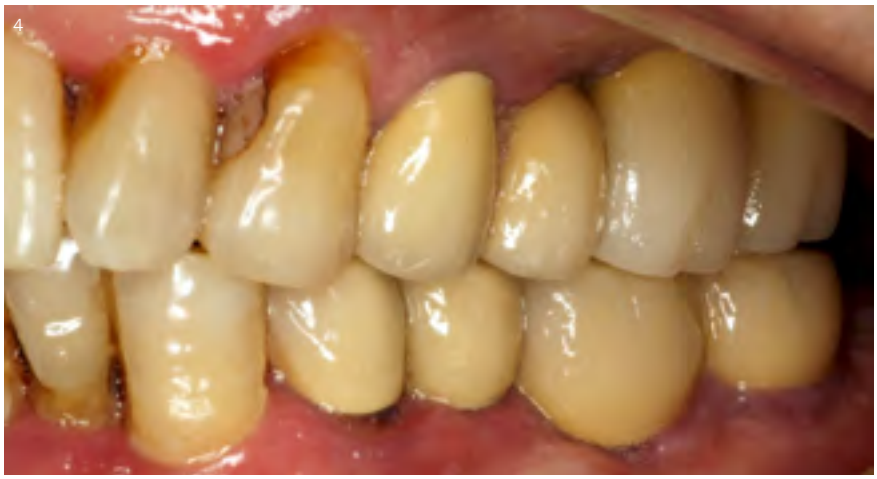
psychiatric therapy; pregnancy or nursing; smoking (more than ten cigarettes per day); insertion torque < 35 Ncm; untreated periodontitis; acute and chronic infections of the adjacent tissues or natural dentition; radiotherapy of the oral and maxillofacial region within the last five years; absence of teeth in the opposing jaw; severe clenching or bruxism; severe maxillomandibular skeletal discrepancy; poor oral hygiene.

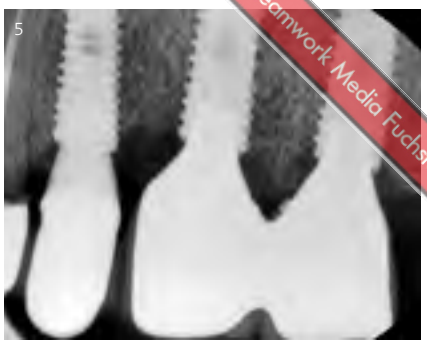
Patients were informed about the clinical procedures, the materials to be used, the benefits, potential risks and complications, as well as any follow-up evaluations required for the clinical study. Patients had to sign the informed consent before being included in the study.

Surgical and prosthetic protocol

A single dose of antibiotic (2 g of amoxicillin and clavulanic acid, or 600 mg of clindamycin if patients were allergic to penicillin) was administered prophylactically one hour prior to surgery. Patients rinsed with 0.2 % chlorhexidine for one minute. Local anaesthesia was induced by using a 4 % articaine solution with epinephrine 1: 100 000 (Ubistesin; 3M Italia, Milan, Italy).

Implants were placed at the planned anatomic sites by using a flapless or a miniflap approach. Implant sites were prepared according to the drilling protocol recommended by the manufacturer. Sandblasted and acid-etched surface implants (SA) with a newly developed bioabsorbable apatite nanocoating (Hiossen Inc.) were placed according to a one-stage protocol after implant site preparation (Figs. 1 to 3). After implant placement, a smart peg (Type 47, code 100478; Osstell, Goteborg, Sweden) was connected to the implants, and the implant stability quotient (ISQ) was measured and recorded using the Osstell Mentor device (Osstell, Goteborg, Sweden) at the time of implant placement and every week up to four weeks after implant placement. Post-surgical analgesic treatment was performed with 600 mg of ibuprofen, administered twice a day for two days after the surgery and continuing if required. A provisional restoration was delivered four weeks after implant placement (initial loading). To avoid any static and dynamic contacts, all implants received a “non-occluding” temporary restoration. To reduce the flexibility of the acrylic resin, the multiple implant-supported temporary restorations were metal-reinforced. Patients were instructed to stick to a soft diet during the first eight weeks. Sutures, if present, were removed eight days after implant placement.





4 I Delivery of the definitive crowns.
5 I Periapical radiograph at the time of definitive loading.

Three months after implant placement, the definitive restorations were delivered (Fig. 4). Periapical radiographs were taken with a customized holder at the time of implant placement, on initial loading and then at yearly intervals (Fig. 5).

Outcome parameters were implant survival rates, any biological or mechanical complications, ISQ values. The implant success rates and ISQ values were evaluated by an independent assessor. Complications were evaluated and resolved by the same operators.

- An implant was considered a failure if it presented with mobility, assessed after the osseointegration period by tapping or rocking the implant head with the metallic handles of two instruments, progressive marginal bone loss or infection, or any mechanical complications rendering the implant unusable, although still mechanically stable in the bone.
- Complications: Any biological complications (pain, swelling, suppuration, etc.) or mechanical complications (screw loosening, fracture of the framework or the veneering material, etc.) that occurred during the follow-up period.
- Implant stability quotient (ISQ) values were recorded each week up to four weeks after implant placement using resonance-frequency analysis (Osstell Mentor device; Osstell), according to a previously published study [12].

Statistical analysis

Patient data were entered in an Excel spreadsheet (Microsoft; Redmond, Washington, USA) that reflected the parameters in the patient records. The data were exported to SPSS software for Mac OS X (version 22.0; SPSS, Chicago, IL, USA) for the statistical analysis. Descriptive analysis was performed for numeric parameters using means and standard deviations (95 % confidence interval, CI). Comparison during follow-up was made by paired t-tests to detect any changes during osseointegration. Complications and failures were compared using *Fisher*'s exact test. All statistical comparisons were two-tailed and conducted at the 0.05 level of significance. The patient was used as the statistical unit of analysis.

Results

A total of 36 Hiossen ETIII NH implants were placed in 29 patients (24 female, 5 male; mean age: 53.9 years). All patients were treated according to the study protocol; no patient dropped out. No implants failed, and no complications occurred. There were 10 maxillary implants in 9 patients and 26 mandibular implants in 20 patients.

At implant placement, the ISQ value was 78.3 ± 6.6 (95 % CI: 77.8–82.2). Throughout the osseointegration period, the mean ISQ value improved with no stability drop. At the end of the study period, four weeks after implant placement, the mean ISQ value was 81.4 ± 5.3 (95 % CI: 80.8–84.2). The difference was statistically significant (p = 0.0000). In the maxilla, the mean ISQ value improved from 75.1 ± 6.2 (95 % CI: 71.1–78.9) at implant placement to 78.4 ± 5.3 (95 % CI: 74.0–80.5) four weeks later (p = 0.0000). In the mandible, the mean ISQ value improved from 79.5 ± 6.6 (95 % CI: 78.5–83.5) at implant placement to 82.6 ± 4.8 (95 % CI: 81.6–85.4) four weeks later (p = 0.0000). All data are reported in Table 1 and Figure 6 on the following page.

Discussion

This multicentre prospective study was conducted with the aim to evaluate changes in the implant stability quotient during osseointegration for early-loaded Hiossen ETIII NH implants with a new hydrophilic surface.

To the best of our knowledge, there were no published randomized controlled trials at the time of writing, evaluating the performance of this newly developed hydrophilic surface. Looking at the "grey" literature, the same authors reported that, although statistically significant differences were not encountered, high ISQ values were found for Hiossen ETIII NH implants compared to the SA surface, as they avoid the drop in ISQ during the remodelling phase [13]. In fact, at two weeks after implant placement, two implants with SA surface showed discontinuous measurements, versus none for the Hiossen ETIII NH

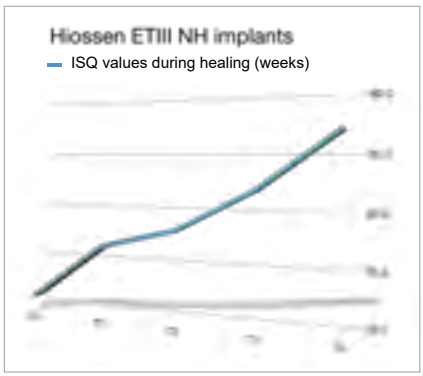
ISQ values during the study period						
	Implant placement	Week 1	Week 2	Week 3	Week 4	P-value (implant placement and week 4)
Maxilla	75.1 ± 6.2 [71.1–78.9]	76.2 ± 5.6 [71.8–78.9]	76.9 ± 4.8 [72.8–78.7]	77.1 ± 5.1 [73.1–79.4]	78.4 ± 5.3 [74.0–80.5]	0.0000
Mandible	79.5 ± 6.4 [78.5–83.5]	80.5 ± 6.3 [79.8–84.7]	80.7 ± 6.4 [80.3–85.2]	81.7 ± 5.2 [81.0–85.0]	82.6 ± 4.8 [81.6–85.4]	0.0000
Total	78.3 ± 6.6 [77.8–82.2]	79.3 ± 6.3 [79.9–84.1]	79.7 ± 6.2 [80.0–84.0]	80.4 ± 5.5 [81.2–84.8]	81.4 ± 5.3 [80.8–84.2]	0.0000

Table 1 I ISQ values during the study period.

group [14]. There are possible benefits in cases of immediate loading, poor bone quality, smoking, immuno-suppression, or controlled type 2 diabetes.

It is well known that roughness improves implant osseointegration, and several implant types are sandblasted and acid-etched to increase their surface and alter its texture [15]. Nevertheless, surfaces coated with hydroxyapatite (HA) were reported to have a higher incidence of complications [8], even if the evidence for implant surface characteristics as an indicator for the peri-implantitis risk is very limited [20]. Commonly, implant surface roughness is divided into macro-, micro- and nanoroughness. Typically, these different types of roughness are related to distinct effects during wound healing and osseointegration [18]. Nanostructures have been created on titanium using different approaches, such as oxidative nanopatterning by acid-etching in mixtures of sulphuric acid and hydrogen peroxide, by exposing titanium samples to a synthetic air flow, electrochemically by anodic oxidation, by processing samples after acid-etching under protective gas and storing them in saline, by plasma etching or by physical vapour deposition techniques [19].

Nanoroughness plays an important role in the adsorption of proteins, the adhesion of osteoblastic cells and thus the rate of osseointegration [21]. In fact, deposition by dipcoating a titanium substrate with a nanocomposite ($HA\text{-}ZrO_2\text{-}Al_2O_3$) showed the greatest adhesion strength compared to the HA coatings [22]. Furthermore,



6 I Graph showing the ISQ values during the first four weeks of healing. No stability drop was experienced.

Schwarz et al. showed that angiogenesis was enhanced on hydrophilic surfaces during the early stages of osseointegration [23].

Fast vascularization seems to be beneficial for bone formation because osteogenic cells have been observed to arise from pericytes adjacent to small blood vessels [14, 25].

In the present study, the implants with the hydrophilic surface seemed to avoid the drop in ISQ during the remodelling phase. The Hiossen ETIII NH offered the same clinical performance as sandblasted, acid-etched (SLA) surfaces. The bioabsorbable nanoapatite and hydrophilic coating improved osseointegration and decreased the healing period by over 30 per cent. The new hydrophilic surface improved wettability, significantly increasing blood adhesion. During the remodelling phase, the nanoapatite coating was absorbed and newly formed bone is integrated into the SLA surface.

The main limitation of the present study was that no a-priori sample size calculation was performed; the limited power of the analysis due to the small number of participants could have hidden some differences between groups. This can only be resolved by conducting more similar trials with larger sample sizes based on the present preliminary result.

Conclusions

The results of the present research demonstrated that Hiossen ETIII NH implants with a new surface can be restored after four weeks of healing with highly predictable success rates, as they seem to avoid the ISQ drop during the remodelling phase. High ISQ values were found in both maxilla and mandible. Further randomized controlled trials with larger sample sizes and longer follow-ups are needed to confirm this preliminary result.

Conflict of interest statement: Hiossen Inc. donated the implants. However, the data belong to the authors alone; at no time did the company attempt to influence the conduct of the trial or the publication of its results.

The references are available at www.teamwork-media.de/literatur

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