Commentary on "Scalloped Dental Implants: A Retrospective Analysis of Radiographic and Clinical Outcomes of 17 NobelPerfect™ Implants in 6 Patients"

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Improving the esthetic outcome of implant restorations in the partially edentulous patient has been a driving force in the dental implant field. To achieve this, changes have been made during the past decade to the hardware and software of implant therapy. Alterations in the timing of implant placement, implant surfaces, and abutment designs, as well as the introduction of procedures to improve site development, have one common goal: to improve implant survival[1] and esthetic outcome (quality of survival).[2]

One of these changes was the introduction of the NobelPerfect™ (Nobel Biocare AB, Göteborg, Sweden) implant.[3] The implant is characterized by interproximal scalloped hard and soft tissue apposition areas, designed to either maintain interproximal bone or to serve as a scaffold for graft maintenance in cases in which interproximal bone has undergone resorption and a three-dimensional reconstruction of the hard tissues is necessary. The ultimate goal of the scalloped implant design is to minimize bone remodeling around implants, thus improving the quality of survival by maintaining three-dimensional osseous and soft tissue contours.

The Nowzari and colleagues article retrospectively examines the radiographic and clinical outcome of 17 NobelPerfect™ implants placed in six patients.[4] First, I want to congratulate the authors for their efforts to contribute to the knowledge base in implant dentistry. Their hard work is exemplified by their efforts to provide the best possible outcome for their patients, often necessitating multiple surgical procedures.

The problems with the scientific validity of the results can be categorized and described as follows:

Study Design

This article presents six case reports for patients treated with the NobelPerfect implant. Case reports are important, but in the hierarchy of evidence-based medicine or dentistry, treated cases are the least important when considering the hierarchy of evidence.[5] Prospective, multicenter clinical studies concerning this implant are currently under way and will be reported on in the future.

Confounding Variables

There are a number of confounding variables in this case study. Forced orthodontic eruption, bone grafting, immediate implant placement, fabrication of temporary restoration in situ with acrylic, and immediate implant loading may alone or together account for the excessive reported bone loss. Ideally, in any study, the numbers of any variable that can impact outcome must be minimized; otherwise, the causes of adverse outcomes cannot be identified.

Site Development. The authors report that orthodontic therapy and/or autogenous ridge augmentation procedures were provided prior to implant placement. If successful, this procedure can result in a more coronal location of interproximal bone.[6,7] However, there are no data reported on how long the teeth need to be stabi-

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Disclosure: Dr. Wöhrle holds the patents on the scalloped hard and soft tissue apposition areas and has licensed them to Nobel Biocare Holding AG.

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lized prior to implant placement. This is important because we need to know if the vertical bone height gained will be retained or resorbed, independent of implant placement. This is especially true if multiple teeth are extruded and are determined to be hopeless. It is also unclear if that bone can be considered "host" bone or if it remodels at a different rate. No details concerning this aspect were presented in the article.

Implant Placement. In this article, the vast majority of the cases reported are extractions, immediate implant placement, and immediate provisionalization in occlusion. Hence, surgical procedures such as atraumatic extraction without enlargement of the site and orofacial implant placement within the extraction socket, the size of the implant placed within the socket, and bone apical to the extraction defect need to be identified. Most importantly, the gap between the host bed and the implant surface is critical.[8] With large roots, the surgeon faces a dilemma: either choose an implant that minimizes the gap (a large implant) or choose the appropriate-sized implant and deal with a gap larger than 1.5 mm. In addition, it is not clear from the report if the surgeon used taps or the countersink drill prior to implant placement. Both are critical in these types of cases: if no tap is used, the noncutting threads of the implant will, on insertion, move the way of least resistance, which is away from the dense palatal wall. The countersink is necessary so that the emerging neck of the implant can rest passively in the osteotomy; otherwise, an increase in pressure in the crestal area will most likely lead to increased remodeling of bone in that sensitive area.

No information is provided on implant sizes selected for the study, especially regarding the diameter of the implants in specific sites (central incisor vs lateral incisors).

Primary Implant Stability. Seating an implant passively in the osteotomy with adequate primary stability prior to immediate loading is paramount in achieving good implant survival.[9–11] Because the implant survival in the present study was 100% (no implants were reported to be lost), one can assume that implant stability was adequate in all cases. Primary implant stability in this patient population could withstand 45 Ncm of torque, which means that this was the minimum torque used to seat the implants.

Interestingly, the evaluations did not include resonance frequency analysis (RFA), [10] a commonly used tool to determine primary implant stability at the time of insertion. The issue of torque versus resonance frequency must be addressed in prospective clinical trials. The Osstellk™ (Integration Diagnostics AB, Göteborg, Sweden) for measuring implant resistance to the surrounding bone is measured in implant stability quotient units. The resonance frequency of an implant/transducer system is related to the height of the implant not surrounded by bone and the stability of the implant-tissue interface as determined by the absence of clinical mobility.[12] Ideally, torque and RFA measurements should be used in any prospective trial evaluating immediate loading of implants placed at the time of extraction.

Three-Dimensional Implant Positioning. Coronal-apical implant positioning is one of the most crucial dimensions when placing a two-piece implant, and this is true for the scalloped implant as well. The smooth soft tissue apposition area on the implant is designed to allow for the connective tissue zone immediately above the osseous crest to establish itself without the potential of being disrupted when exchanging prosthetic components. Placing this smooth surface into the bone will lead to bone loss.[13,14] If this area needs to be placed into osseous tissue because of the location of the predetermined emergence of the restoration out of the tissue, then it is because there is too much bone in the area. Countersinking the implant with the soft tissue apposition area below the crest of the ridge is equivalent to a crown lengthening procedure: deliberately removing bone to gain a more esthetic relationship between the white and pink esthetic components.

It is interesting to note that the two-stage implants in the study were described as follows: ". . . at the time of second-stage surgery, all of these implants were covered by bone."[4] Clinically, this can only mean that they were countersunk (ie, placed below the crest of bone) at the time of placement because supracrestal or even equicrestal placement without grafting at the time of surgery does not result in bone overgrowth.

Prosthetic Treatment. Most implants were immediately restored with interim restorations. The prefabricated coping was used as a basis for an overlying, self-curing resin restoration, which was cured in situ. Although the

restoration was brought to full contour outside the patient's mouth, the potential for contamination of the gap between the implant and the extraction defect is real. One way of eliminating the chance for contamination of the surgical wound with methylmethacrylate is the use of a flowable composite to intraorally register a prefabricated shell to the prefabricated coping. Contouring should occur as described extraoral registering. The provisional restorations were then adjusted to "light contact in maximal intercuspal position . . . and to avoid excursions where possible."[4] This, of course, adds force transfer and thus micromotion along the bone-implant interface, leading to fibroblast cell proliferation once the threshold is reached and passed.[15–17] Single-tooth implants in an extraction site, especially in the maxillary anterior region, where remaining roots are typically large, are only in direct bone-implant contact in the apical extension and palatal wall areas, possibly toward the interproximal walls. There are, however, significant gaps between the host bone and the implant surface, especially in the coronal regions. Why take the risk of inducing additional micromotion on the implant? Excursive movements are also important, and elimination of these destructive forces on a single, immediately restored single-tooth implant or short-span bridge without the benefits of cross-arch stabilization is advisable.

Radiographic Evaluation

The core of the data presented in the article centers around radiographic evaluations. Interproximal bone levels were recorded at different time intervals by calibrated examiners using nonstandardized films. The error of measurement remained undefined.

The reference lines from which measurements were obtained are not clearly defined. Evaluations at the time of implant placement showed a lot of variation, ranging from 0.8 to −7.1 mm. This indicates that in some patients, the top of the interproximal shoulder of the implant was 0.8 mm below the osseous crest (countersinking or, more appropriately, a deliberate crown lengthening procedure), whereas in other patients, the top of the interproximal shoulder was 7.1 mm above the osseous crest or, in other words, the implant was placed into a 7.1 mm deep defect. This large variation in initial implant placement cannot be expected to result in an objective, reproducible outcome.

The initial bone loss documented in Figure 1 that occurs within the first 6 months is due to the fact that

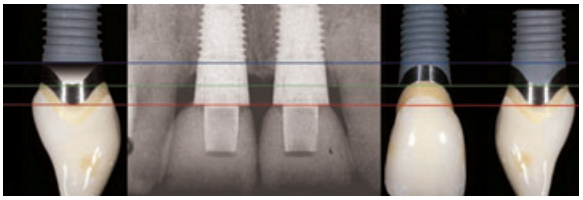

Figure 1 Radiographic evaluation of the radiograph presented in the article, comparing it with landmarks on the NobelPerfect implant: interproximal top of implant shoulder (*red line*); interproximal top of bone apposition area and facial/palatal top of soft tissue apposition area (*green line*); top of facial/palatal bone apposition area and start of planar, ie, 360° around the implant bone apposition area (*blue line*).

the smooth soft tissue apposition area cannot maintain bone next to it, and it was designed as such. On the NobelPerfect implant, the soft tissue apposition area has a width of 1.5 mm, which means that this initial bone loss was predictable from the time the implant was placed at that coronal-apical location. This exact scenario was first described by Hammerle and colleagues in their article on the effect of subcrestal placement of the polished surface of ITI implants on marginal soft and hard tissues.[14] A 1 mm subcrestal placement of the polished surface resulted in a loss of 2.26 mm of bone during the first year, whereas the control implants (placed with the smooth-rough border at bone level) lost 1.02 mm of bone. Remarkably, this was observed in healed sites and at a 1 mm subcrestal placement. The article by Nowzari and colleagues deals with fresh extraction sites after grafting, immediate loading, and deeper placement of the smooth surface into bone.

Radiographic analysis of scalloped implants differs significantly from the analysis of the traditional flat-top implants. As demonstrated in Figure 1, the three-dimensional platform appears as a solid post in the one-dimensional radiograph. The top of the implant, indicated by the red line, is the most coronal part of the soft tissue apposition area. As such, bone cannot be maintained next to it. The soft tissue apposition area moves apically toward the facial and palatal regions and almost lines up with its midfacial and midpalatal height of contour to the interproximal most coronal height of contour of the interproximal hard tissue apposition area (green line). The interproximal hard tissue apposition area is narrow at its coronal peak and widens toward the apical region until it reaches full circumference of the hard tissue apposition area immediately above the threads of the implant (blue line). Clearly, interproximal

bone will appear as a variety of lighter and darker grays in the radiographs, correlating to the different widths of bone. Changing the contrast and brightness in digital radiography, or kVp and exposure time in traditional radiography, can enhance or reduce the radiographic appearance. In addition, we have observed the possibility of the burnout syndrome, in which a normal radiographic appearance is mimicked by the density of the adjacent structures, [18] especially with the larger-diameter implants. Therefore, selecting the most coronal point of obvious bone-implant contact as practiced with traditional two-stage flat-top implants might not result in an adequate interpretation of the three-dimensional platform and remodeled bone topography. Clinically, the interproximal bone volume between the implant and adjacent structures seems to be much more relevant for the ultimate design feature of the implant: improved support for soft tissue for a better esthetic outcome.

Statistical Analysis

No statistical analysis of the data is provided. Common analysis, such as standard deviations for all time intervals, including placement, should be included. Explanations for missing data points need to be given. Eighteen-month mean bone-level measurements are reported for fewer sites, without explanation.

References Cited for Comparison

The authors attempted to substantiate the statement that the scalloped implants lost more bone compared with flat-top implants by citing numerous studies: Adell and colleagues (reference 26) investigated implants and abutments placed in the edentulous jaws, Cochran's study (reference 27) evaluated implants placed in dogs, Aalam and colleagues (reference 28) studied the response to immediately loaded implants in the edentulous mandible, Vanden Bogaerde and colleagues (reference 29) studied implant response in the edentulous maxilla and posterior mandible, Ostman and colleagues (reference 30) studied the edentulous maxilla, Friberg and colleagues (reference 31) worked in predominantly healed sites, Glauser and colleagues (reference 32) placed immediately loaded restorations on implants placed in predominantly healed sites, and Rocci and colleagues (reference 33) placed implants for immediate function into healed sites of partially edentulous cases.

None of the cited studies placed implants into fresh extraction sockets, and none of the cited articles employed forced orthodontic eruption or bone grafting. Only some reported on immediate loading at the time of implant placement. Therefore, any comparisons made based on the above-referenced data pool are scientifically invalid and misleading.

LEARNING CURVE

One of the main issues in this article is that the patients included in the study received NobelPerfect implants without the benefit of the doctors gaining treatment experience through the learning curve. Placement of this implant requires knowledge and experience, as described above, and the manufacturer suggests that doctors placing this implant place a minimum of 200 implants per year. Starting a study without the benefit of gaining experience through the learning curve may lead to unknown surgical and prosthetic errors. For example, if the implant sites are exposed for too long a period, there may be bone loss from surgical trauma. The surgical time is not accounted for in this case series.

CONCLUSIONS

The Nowzari and colleagues article is a retrospective case series of adjacent NobelPerfect implants, placed by a surgeon, without previous experience with scalloped implants, into fresh extraction sites after orthodontic hypererruption and/or surgical augmentation procedures, restored with immediate interims restorations under occlusal load, and followed up with nonstandardized radiographs for up to 18 months. The implant survival rate was 100%. The conclusion that the scalloped design did not promote superior interproximal bone and papilla height compared with conventional flat-platform designed implants is not supported by any data. No control implants were placed.

References cited to support claims of expected bone loss with nonscalloped implants are misleading because they do not deal with implants placed immediately at the time of extraction and under immediate loading.

Reported bone loss can have a multifactorial origin owing to the large number of confounding variables within the study. Bone loss owing to placement of the smooth titanium soft tissue apposition area is expected when placed subcrestally.

The clinical outcome, that is, an evaluation of the overall esthetic result in terms of papillae, the height and

form of the gingival contour, and the color and consistency of gingival tissues (ie, the Pink Esthetic Score[2]), was not reported. However, despite initial deep placement of the implants, the soft tissue contours of the patient presented in the pictorial seem to be better than adequate considering initial clinical presentation.

The ultimate measure, however, is harmony and continuity of the soft tissues, and future studies should include assessments of outcome based on the Pink Esthetic Score.

I agree with the authors that further studies are needed. These prospective, multicenter studies should have a standardized cohort of patients and should limit confounding variables.

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