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A Report of Three Cases from an Ongoing Prospective Clinical Study on a Novel Pink Biomimetic Implant System

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Abstract: While, overall, dental implants are highly efficacious, consistently achieving predictable esthetic results can pose color-driven challenges at implant/soft-tissue interface, particularly in the esthetic zone. An ongoing, multicenter (eight sites) prospective study is following a total of 168 implants placed in 120 patients using a novel biomimetic (osteoconductive) implant system with pink collars and abutments that afford better gingival color enhanced design variability, and streamlined fabrication and customization at abutment/implant-tissue interface. The full results of this study will be published at the 3-year and 5-year timepoints; however, clinical analyses of the 18-month interim survival rates, marginal bone and soft-tissue level changes, and esthetics have been completed, showing an overall success rate among all of the implanted sites of 95.8%. For the three representative cases described in article (two anterior, one posterior), all of the implant site probing depths were ≤1.11 mm at the final crown placement as well as at 6, 12, and 18 months after placement. Facial soft-tissue heights were stable or increased by ≥0.86 mm and lingual soft-tissue heights were reduced by ≤1.11 mm. Facial and lingual

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attached-gingiva widths were reduced by ≤ 1.20 mm and ≤ 0.63 mm, respectively. Interproximal marginal alveolar bone levels were stable (gain/range: +0.40 to -1.1 mm) from the start of the study through 18 months. Inflammation, bleeding on probing, and plaque were infrequently observed. Esthetic results were uniformly excellent at the 18-month follow-up visit.

BACKGROUND

Predictable treatment outcomes, especially in dental implant esthetics, can be compromised when bone and soft-tissue volume at the implant site and the adjacent teeth are compromised. Soft- or hard-tissue deficiencies of the edentulous space are the most common obstacles to achieving gingival esthetics around the final restoration. Published work on thin peri-implant mucosa around dental implants has demonstrated a distinguishable gray show-through effect of the underlying titanium implant abutment.

Attempts have been made by various manufacturers to compensate for this effect with white ceramic abutments (zirconia) or pink¹ or yellow² coloring of the neck/abutment through anodizing processes.^{3,4} The use of dental implants in the treatment of partially edentulous patients has demonstrated a high degree of success, with documented survival rates of 90% to 97%.⁵⁻⁹

For the past three decades, dental implants have been a routine and clinically predictable treatment method for the functional replacement of missing teeth. Challenges frequently arise for the prosthodontist, restorative dentist, and periodontist regarding the visible (or, ideally, indistinguishable) facial implant/soft-tissue interface, a particular concern in the esthetic zone.

The implant system used in the following three cases (Genesis®, Keystone Dental, www.keystonedental.com) has been in global use since November 2010. In addition to its osteoconductive implant–bone interface, produced by application of anodic deposition or discharge (ASD) to the titanium–implant surface (BioSpark™, Keystone Dental),¹⁰⁻¹³ the main distinguishing feature of this implant system is the pink coloring of its restorative components, including the implant collar and match prefabricated customizable titanium abutments. Since the initiation of this study, additional custom abutments with a pink subgingival portion and a white zirconia top have become available for this system.

Published studies evaluating the chemistry and roughness of this implant system surface include three animal studies on bone-to-implant contact,^{10,14,15} two in vitro studies on cell behavior,^{11,12} and three studies on the effects of pink on the gi-

esthetics.^{1,2,16}

An additional treatment to the threaded portion of the implant surface involve also known as microarc oxidation or glow discharge deposition. This process an osteoconductive implant surface rich in calcium and phosphorus ions as a interface.^{11,13}

The pink color of this implant system is produced on the implant surface by a proprietary electrochemical anodization process (AnaTite™, Keystone Dental produces a layer of titanium oxide on the implant surface. The resulting pink reduces the potential of gray soft tissue, thus offering the clinician an alternative zirconia for creating, enhancing, and refining gingival esthetics.

Ishikawa et al^{18,19} quantitatively characterized color variabilities in healthy and marginal gingiva; these analyses helped establish a basis for critical assessment colorimetric influence of various implant, abutment, and restoration materials such a soft-tissue color parameter range.

Spectrophotometric analyses published by Park et al confirmed that there is a measurable difference between the colors of natural maxillary labial gingiva and surfaces of conventional titanium implants.¹⁶ More specifically, colorimetric data by Ishikawa-Nagai et al suggest that, in comparison to other colors, light pink color of the implant neck produces an optimal color that is clinically indistinguishable from natural-tooth gingiva.¹ Patient-specific shading of the implant collar using a similar approach has also been described in a three-case series published by Sumi et al. They reported such specificity to provide stable gingival esthetics at a 1.5-year follow-up, especially in patients with a thin gingival biotype.⁴

Yellow/gold and pink can both produce harmonious esthetics when juxtaposed to natural gingiva. However, pink usually offers more of an advantage, ie, the closer the shades are mimicked, the better the esthetic result.

Another case report by Polack²⁰ specifically evaluated the pink nano-rough implant system presented in the current case series (Genesis). An excellent result was achieved in an esthetically demanding case requiring multiple extractions and site development for the replacement of two maxillary lateral incisors (using narrow-diameter, 3.0-13-mm fixtures) in a severely resorbed ridge.²⁰

Similarly to other implant systems from a functional standpoint, the aggressive pitch of this implant fixture, in these authors' experience, also facilitates its use in immediate placement and loading scenarios. Of note, a substantial proportion of implants in this study population have reached or surpassed 3 years of survival function.

Platform Switching

Platform switching (PS) has become a standard feature in the design of conventional implant systems, and has expanded the clinician's control over crestal bone preservation. Numerous studies²¹⁻²⁶ and systematic reviews²⁷⁻²⁹ have reported reduced bone resorption for platform-switched implants compared with platform-matched implants. The implant system used in this study incorporates a platform-switch between 0.50 mm to 1.38 mm, depending on implant fixture diameter (IFD):

- IFD = Ø3.8 mm: 0.50 mm PS
- IFD = Ø4.5 mm: 0.57 mm PS
- IFD = Ø5.5 mm: 0.70 mm PS
- IFD = Ø6.5 mm: 1.38 mm PS

Cappiello et al reported a significant bone-protective effect of platform-switching to 0.72 mm in a controlled clinical trial of 131 implants (all placed at the crestal site in edentulous patients).²⁴ Clinical studies by Prosper et al³⁰ and Canullo et al²⁵ have also demonstrated advantages of platform-switched implants over regular implants with respect to crestal bone stability, with a minimum of 24 months' follow-up. Recent systematic reviews consistently confirm that implants with platform-switched abutments are associated with better crestal bone preservation than implants with platform-matched abutments.^{28,29,31}

Five-Year Prospective Clinical Study

An ongoing 5-year study continues to evaluate the use of this implant system (implants placed in 120 partially edentulous patients). Its objectives include assessment of the 5-year survival rate of this implant system, implant success, incidence of excessive bone loss, peri-implant infection and other complications, incidence of adverse device effects, change in marginal bone level, soft-tissue esthetic outcome, and the number and nature of prosthetic revisions.

Alignment, orientation, and magnification of the periapical radiographic images of subjects' implants and alveolar bone levels were standardized by rotating and translating each image such that all were uniformly aligned, oriented, and scaled using a semi-automated program (MATLAB®, MathWorks, Inc; <http://www.mathworks.com/products/matlab/>).

For angles, imaging differences in both elevation (above or below correct plane) and azimuth (mesial–distal) between images in the same series were computed. All images in this data set have a percentage error of less than 3.5%.

Consistent with other implant designs, most osseointegration failures occurred at the time of placement or shortly after prosthetic loading. However, unlike other designs,

length of the implant had no effect on the survival rate. After loading, this imp based on the 18-month interim data collected from all subjects in the multice

This article presents the 18-month interim results of three representative case esthetic and hard- and soft-tissue study endpoints in two esthetic-zone and i system.

CASE REPORTS

Demographics, medical histories, and implant indications for these three pati subjects signed an informed consent document prior to enrollment in the stu study center approved the informed consent document and study protocol. 7 with the United States 21 CFR Parts 11, 50, 56; the Health Insurance Portab and the Declaration of Helsinki and its amendments per the most recent asse

Case 1

In November 2011 a healthy nonsmoking 52-year-old perimenopausal African Scheyer's periodontal practice on referral from her restorative dentist with a s history of amalgam retrofill) maxillary right central incisor (tooth No. 8); in addi a failing porcelain jacket crown (recurrent caries) over a pin-retained resin buil the mid-facial and bleeding on probing (BOP) were observed.

She was taking enalapril for hypertension and progesterone USP for perimen drug allergies, and an otherwise unremarkable medical history other than rou administered beginning the day before surgery and continued for 5 days pos

With the patient under conscious sedation, a surgical extraction of tooth No. Bleeding on probing and purulence were noted at the implant placement visit

There was a narrow bony defect in the facial cortical plate measuring approxi bone heights. The implant osteotomy was prepared along the lingual cortical placement of a 4.5-mm x 16-mm Genesis implant (Figure 2). The implant wa: Ncm of insertion torque). A temporary cylinder abutment was used to fabrica (Figure 3). The retention screw for the provisional was torqued to 20 Ncm.

The facial ridge deficiency was grafted with mineralized freeze-dried bone allc collagen membrane using minimally invasive facial tunneling to allow for plac occlusion was adjusted, and there were no centric or excursive contacts. An parafunctional stresses on the implant-supported provisional restoration. A p confirmed full seating of the provisional abutment. The patient responded we the 10-day follow-up visit.

Restorative treatment began in February 2012. The implant-supported provis technique was used to fabricate a customized coping for the final impression

sculpted with the provisional (Figure 4). The objective was to mimic this emergence profile. The patient visited the laboratory to obtain a custom shade match. A custom-prepared L-shaped wax block was used to fabricate a 30 Ncm, and a custom-layered all-ceramic crown (IPS e.max® Ceram, Ivoclar) was cemented with RelyX™ Ultimate adhesive cement (3M www.3m.com/3M/en_us). The patient was very pleased with the restorative outcome, and all gingival tissues were healthy at the 18-month follow-up visit (Figure 5 through Figure 7).

Table 2 through Table 4 show the soft-tissue height, attached-gingiva width, and recession at final crown placement, as well as 6, 12, and 18 months after the start of treatment. No recession was noted at the 18-month follow-up visit.

Case 2

In December 2011, a healthy 54-year-old Caucasian woman who is a heavy smoker visited a periodontal-prosthodontics practice. She was taking over-the-counter omeprazole for reflux with an otherwise unremarkable medical history, and had no known drug allergies (probably smoking-related), with no probing depth ≥ 3 mm.

The maxillary left lateral incisor (tooth No. 10) was partially supporting a 4-unit fixed prosthesis through 10, and had fractured at its gingival margin. Moderate gingival inflammation and a probing depth of approximately 2 mm at Visit 1 (Figure 8 and Figure 9). Because of the poor prognosis, the patient opted for extraction and implant placement.

A CAD/CAM-created surgical guide was fabricated using 3D diagnostic software and used to manage the osteotomy preparation of the socket, followed by insertion of a Genesis implant (Figure 10) at an insertion torque of 45 Ncm.

The “one abutment-one time” technique (as described by Mandelaris and Vliet) was used in the final-impression phase (and, importantly, the need to pack retraction cord in a separate phase of fabrication of the definitive abutment, thus saving chair and laboratory time). Using standard impression techniques, this approach proved to be a faster, easier, and more accurate way of customizing the fit of the final pink abutment for this case.

A stock Esthetic-contour Ti abutment (Genesis) was tried in at the time of implant placement. A transfer impression was used to create a laboratory model by attaching the abutment to the implant and pouring stone around the transfer (Figure 12).

After adjusting the abutment for appropriate marginal and interproximal contours, the abutment was repositioned on the laboratory model and scanned using an esthetic scanner with a working digital file. The model was then used to fabricate the 4-unit provisional restoration.

This same abutment was subsequently torqued into the implant at 35 Ncm and the provisional restoration was inserted and cemented with temporary cement.

During the integration period, a NobelProcera zirconia coping (Nobel Biocare)

Three months after implant placement, the coping was tried in to verify the fit polyether impression material. From this impression, the final working model

The final all-ceramic restoration (IPS e.max Ceram) was layered onto a Nobel cemented with RelyX Unicem Self-Adhesive Universal Resin Cement (3M). The restorative outcome, and all gingival tissues were healthy with no probing depth (see subject SJH-02, Table 2 through Table 4; Figure 14 and Figure 15).

Case 3

In November 2011, a healthy, nonsmoking 59-year-old Hispanic man (who had been in a prosthodontic practice since 2007) presented with a partially edentulous maxilla after a recent extraction (in September 2011) of non-restorable teeth Nos. 28 and 30 except for a detached retina in 2005; he was taking no medications and had never had supported a bridge (pontic was position No. 29) that had been recemented. He decided to have implants placed. Figure 17 shows a pre-extraction periapical radiograph deemed nonrestorable, and was extracted by the consulting oral surgeon Dr. [redacted] in the implant phase.

In January 2011, alveolar regenerative therapy was performed for preservation of the extensive loss of buccal alveolar bone. An organic bovine bone matrix was used to fill defects (Class B bone quantity in position Nos. 29 and 30) during osteotomy and placement of three pink Genesis implants (4.5 mm × 11.5 mm, 4.5 × 11.5 mm, 28, 29, and 30, respectively) in November 2011.

Prefabricated pink abutments were customized by preparing them just below the gingiva (two 4.5-mm and one 5.5-mm prefabricated Genesis Ti Temporary Abutments) used in this case. A final impression was obtained using the closed-tray technique.

After placement of Teflon tape in the access holes, the final porcelain-fused-to-metal restoration was placed in February 2012 with RelyX™ Unicem. The patient was very pleased with the result. The gingiva were healthy with no probing depth ≥3 mm at the 18-month follow-up visit. The probing measurements, and periapical radiograph are shown in Figure 19 through Figure 20 for soft-tissue and marginal-bone levels (subject AT-05).

Conclusion

This article presents three cases offering the first published data from this 5-year implant system. A representative case series such as this provides early and multicenter studies evaluating dental implant designs. Such preliminary data afford new functional and esthetic implant technologies in advance of the publication of prospective studies. This can benefit patients earlier. McGuire et al recently published data from a comparative study of three different implant designs that is current

Overall, the three cases presented here (all of which are currently considered favorable) provide further clinical evidence of favorable esthetic results, maintenance of marginal bone levels, and are in addition to those already observed in the first clinical study of this system.

All three cases have been followed well into 2015; all continue to maintain healthy gingiva at the proscribed study endpoints, as well as good gingival health and excellent esthetic results.

Importantly, our study's endpoints do not include superiority or comparisons to other systems. This study is a snapshot of esthetics and marginal bone stability after 18 months of follow-up under various esthetic challenges. Future studies should address potential advantages of this system in periodontally compromised cases.

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Disclosure

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