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

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ABSTRACT:

Color discrepancies between peri-implant soft tissues and materials used implants, abutments, and restorations may influence overall esthetics at t implant–soft-tissue interface, particularly in the esthetic zone. In an ongoir year multicenter prospective post-marketing surveillance study of 120 adu and female participants at eight sites in the United States (total of 168 imp placed), the authors have been evaluating anterior and posterior single-to implants using a novel pink osteoconductive implant system (in clinical us 2010) that features a variety of pink components, developed with the obje improving peri-implant soft-tissue esthetics. Clinical analyses of the 18-m interim survival rates, marginal bone and soft-tissue level changes, and es have been completed, showing an overall success rate among all of the implanted sites of 95.8%. This case series aims to summarize data on imp

Infection Control

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survival, probing-derived and radiographically assessed marginal bone an tissue level changes, and qualitative photographic evidence of post-resto soft-tissue esthetic outcomes by presenting a snapshot of five representa cases (two anterior and three posterior), at 18 months from the start of th study. Four of the five cases described here involve teeth visible in full smi comprise three maxillary incisors and two maxillary premolars. The remain case was a relatively straightforward mandibular first-molar replacement. However, all scenarios posed unique esthetic challenges. Three subjects received immediate implants; the remaining two required post-extraction regenerative procedures. Gingival inflammation, bleeding on probing, and were infrequently observed throughout the treatment period. Implant succ and stability, alveolar bone-level stability, soft-tissue height and attached-g width stability, and peri-implant soft-tissue esthetic outcomes were unifor excellent at the 18-month follow-up visit. Data from the entire ongoing multicenter study population will be published both at 3 years and at stud completion at 5 years. Those results will be necessary to assess any stati differences in tissue changes and/or bone levels and apply meaningful interpretation to aggregate observed qualitative colorimetric soft-tissue parameters associated with this implant system.

Introduction

Despite the high predictability of tooth replacement with osseointegrated imp management of tissue esthetics at the facial restoration margin can pose sign challenges for the prosthodontist, restorative dentist, periodontist, and oral a maxillofacial surgeon, and is of particular concern in the esthetic zone. In gen closer natural shades of hard and soft tissue can be mimicked, the better the result. Gingival esthetic challenges have been addressed specifically using ex placed pink porcelain on prosthetic components to simulate natural gingiva, v degrees of success.[6-8] The current system (Genesis®, Keystone Dental, Inc, www.keystonedental.com) addresses a similar goal by modifying internal esth within the implant/abutment–free gingival interface.

The proximity of the facial implant–soft-tissue interface to that of a crown ma an intense focus on harmonization of compatibilities among the inherent colo various metals, ceramics, and gingiva in a variety of soft-tissue scenarios. Th treatment objective is to make this convergence visually indistinguishable.

Esthetic impact of implant–abutment interface design has been reported in a published case series by McGuire et al[9]; specifically, adherence to a standard treatment protocol yielded good esthetics with the three different interface de tested (conical, flat, or platform-switched). One-year results from the larger 5-

randomized clinical trial by Cooper et al[10] represented by those cases demor that difference in interface design had significant impact on marginal bone sta not on gingival mucosal architecture or position (including the apical-most as facial gingival margin contour, ie, zenith).[10]

The case series presented here represents another ongoing 5-year clinical st comprising 120 patients who required replacement of one or more anterior o teeth, now approaching completion of 4 years of follow-up to evaluate clinica efficacy and soft-tissue esthetics of this unique implant system developed wi objective of overcoming color discrepancy-driven challenges. Three additiona representative case reports from this study have been published.[11]

This system uses a biomimetic implant–bone interface produced by anodic s deposition or discharge (ASD; also known as microarc oxidation or glow disc deposition) to the threaded titanium implant surface (BioSpark™, Keystone D Inc)[12-16] via electrochemical anodization to form a nanorough, osteoconducti oxide implant surface rich in calcium and phosphorus ions as a bone interfac global use since November 2010, this system also features a variety of prefab and customizable pink abutments and other restorative components, includir collars and matching prefabricated customizable titanium abutments. Unless customized, the transmucosal portion of the abutment and/or the implant co uniformly pink throughout the system.

The pink color is produced on the implant surface by a proprietary electroche anodization process (AnaTite™, Keystone Dental, Inc), which produces a lay titanium oxide on the implant surface. The resulting pink coloration also helps gray hue that could be observed with conventional implants under the gingiva biotype patients, thus offering the clinician an alternative to zirconia for creati enhancing, and refining gingival esthetics.

Published preclinical studies have evaluated this implant system's surface in r bone-to-implant contact.[12,17,18] In vitro studies on cell behavior[13,14] and studie effects of pink on gingival esthetics have evaluated this system from clinical[19] animal-tissue perspectives.[21]

Spectrophotometric analyses published by Park et al confirmed that there is measurable difference between the colors of natural maxillary labial gingiva a surfaces of conventional titanium implants.[19] More specifically, colorimetric da reported by Ishikawa-Nagai et al suggest that (in comparison to other colors) coloration of the implant neck produces an optimal color that is clinically indistinguishable from that of natural gingiva.[20] Patient-specific shading of the collar using a similar approach has also been described in a three-case series

by Sumi et al, who reported such specificity to provide stable gingival esthetic year follow-up, especially in patients with a thin gingival biotype.[22]

A case report by Polack published in 2012 specifically evaluated the pink nar implant system presented in the current case series (Genesis). An excellent re achieved in an esthetically demanding case that required multiple extractions development for the replacement of four maxillary incisors (using narrow-dian mm x 13-mm fixtures to replace two laterals, creating a four-unit implant brid severely resorbed ridge.[23]

Functional Considerations of Immediate Implant Placeme

In the authors' experience, the aggressive thread pitch of the implant fixture u case series also facilitates its efficacy in immediate placement and loading sc note, all implants in this multicenter study population have surpassed 3 years function, and success; the vast majority of them were immediate placements 22% were staged).

Results of a meta-analysis published by Kinaia et al in 2014 comprising 16 co studies suggests that immediate implant placement preserves crestal bone s more effectively than implant placement in healed bone after at least 12 mont functional loading.[24] Furthermore, this meta-analysis also identified a significa advantage for the use of platform switching in such immediate placement sce

Preliminary results from an ongoing randomized clinical study by Huynh-Ba e no short-term differences in esthetic outcomes in immediate versus early imp placements.[25] Cosyn et al also reported minimal midfacial recession (in two o patients after 3-years' follow-up) following an immediate implant placement p the anterior maxilla in patients with thick gingival biotypes.[26] A recent systema by Slagter et al that also encompassed immediate provisionalization reported findings.[27] Another systematic review by Cosyn et al found conflicting evidenc regarding contributory factors to midfacial recession after immediate implant but suggested this risk is lowest in patients who have a thick biotype and an buccal bone wall and receive immediate provisionalization.[28]

The implant system used in the current multicenter study incorporates a platf ranging between 0.50 mm and 1.38 mm, depending on implant fixture diame

- 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

Platform switching has become a standard feature in implant component des has expanded the clinician's control over crestal bone preservation. Numerou [33] and systematic reviews[24,34-37] have reported reduced alveolar crestal bone for platform-switched implants compared with platform-matched implants.

Considerable clinical evidence suggests platform switching has a bone-prote Cappiello et al reported a significant preservation effect (vertical bone loss wa less with platform-switched healing abutments versus controls) in a controlle trial of 131 implants (all placed at the crest) in 45 patients.[32] Clinical studies b et al[38] and Canullo et al[39] have also demonstrated advantages of platform-sw implants over regular implants with respect to crestal bone stability, with a mi 24 months' follow-up. Recent systematic reviews consistently confirm that im platform-switched abutments are associated with better crestal bone preserv implants with platform-matched abutments.[35-37]

While platform-switched implant configurations also appear to preserve soft t provide increased control over gingival esthetics according to some reports,[4 recent studies tend toward reporting similar tissue-esthetics preservation with switched and other abutment–implant interface designs,[9,10,42] which suggest platform switching favors stable tissue dynamics. However, a study by Zuider found platform switching to have no effect on midbuccal mucosal (MBM) mea 1 year after crown placement; rather, the buccopalatal positioning of the impl (ie, more toward the buccal) resulted in a more apically positioned MBM.[43]

Findings of a systematic review by Prasad et al emphasize the importance of considering a synthesis of factors comprising implant design, occlusal forces and soft-tissue volumes in optimally preserving crestal bone.[44] As a further ca the authors of some recent systematic reviews raise notes of caution about r unknowns as to functional specifics of platform switching and stress the neec and more specific data from clinical studies to evaluate them.[34,35]

Taken together, these findings offer evidence that the functionality of this impl in various placement protocols may complement bone- and soft-tissue-prese effects, with immediate placement in combination with platform switching.

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 as of the 5-year survival rate of this implant system, implant success, incidence excessive bone loss, peri-implant infection and other complications, incidenc adverse device effects, change in marginal bone level, visual soft-tissue esthe

outcomes, and the number and nature of prosthetic revisions.

Alignment, orientation, and magnification of the periapical radiographic image subjects' implants and alveolar bone levels were standardized by rotating and translating each image such that all were uniformly aligned, oriented, and sca semi-automated program (MATLAB®, MathWorks, Inc, www.mathworks.com/products/matlab/). For angles, imaging differences in b elevation (above or below correct plane) and azimuth (mesial–distal) between the same series were computed. All of the images in this data set have a per error of less than 3.5%. Clinical analyses of the investigator-reported 18-mon survival rates, marginal bone and soft-tissue level changes, and esthetics est overall success rate among all sites of 95.8%.

Consistent with other implant designs, the few osseointegration failures obse study occurred during the healing period following placement or shortly after loading. However, unlike other designs, the location (mandible versus maxilla) length of the implant[46-49] had no apparent effect on the survival rate. After loa implant system has demonstrated a survival rate of more than 99%, based o data from this ongoing study.

This is primarily a clinical implant survival and efficacy study with hard- and so metric endpoints. The study protocol defines implant success as peri-implant ≤3 mm. Its descriptive endpoints require radiographic and photographic doc only, and the esthetic results are presented as clinical photographs.

Implant Success and Restorative/Esthetic Results: 18 Mor

Four female and one male subjects who were either missing or required extra one or more natural teeth, who were enrolled in this single-arm multicenter st of all enrolled subjects received immediate implants; the remaining 78% recei implants placed with a delayed/staged protocol) according to the inclusion ar exclusion criteria listed in Table 1, were selected as representative cases. The system evaluated, and both placement approaches, met all criteria for inclusi study, as per the study protocol (Table 1).

Baseline characteristics for these five study participants are summarized in Ta subjects were healthy nonsmokers and had unremarkable medical histories e routine surgeries, treatment of chronic conditions such as hypertension, hypercholesterolemia, and seasonal allergies, and other conditions specified

Extraction indications comprised periodontitis (N = 2) and endodontic pathos fractured/nonrestorable teeth (N = 4); two patients had combined periodontic endodontic involvement of the proposed implant sites.

Table 3 and Table 4 summarize implant dimensions, placement protocol, and characteristics at Visit 2, and restoration and soft-tissue measurements (inclu probing depths [PD]) at final crown placement (Visit 4). Table 5 shows PD at 6 months; Table 6 shows peri-implant PD and other soft-tissue changes at the assessment (Visit 7). Table 7 summarizes the static marginal bone observatio 7 (ie, positive or negative distance between implant platform shoulder and m distal crestal bone level) compared with dynamic changes that occurred in th between implant placement and final restoration placement (Visit 2 to Visit 4) between final restoration placement and 18-month follow-up (Visit 4 to Visit 7 calculated by the MATLAB analysis of radiographic assessments at those tim implants were placed at the crest except for Case 1 (mesial) and Case 2 (dist 7).

Case Reports

Across all five cases reported here, buccal or labial soft-tissue height was sta increased by ≥1.23 mm; lingual soft-tissue height was reduced by ≤0.54 mm and lingual attached-gingiva widths were reduced by ≤1.09 mm and ≤0.52 m respectively. Implant-site PDs were ≤4.5 mm at final crown placement and at 18 months after implant placement. The maximum PD at 18 months was one measurement of 3.5 mm; overall, gingival inflammation, bleeding, and plaque infrequently observed, and esthetic results were uniformly excellent at the 18- follow-up visit.

All subjects signed an informed consent document prior to enrollment in the s document and the study protocol were approved by an institutional review bo each study center. The study is being conducted in accordance with the Unit 21 CFR Parts 11, 50, 56; the Health Insurance Portability & Accountability Ac (HIPAA); and the Declaration of Helsinki and its amendments, as specified in recent meeting of the World Medical Assembly. Figure 1 presents the study fl diagram.

Case 1

A healthy 69-year-old nonsmoking Caucasian woman presented to one auth periodontal practice with periodontitis involving tooth No. 4. Figure 2 shows a PD of 3 mm at Visit 1. A PD of 5 mm to 7 mm was present interproximally, w attachment loss of 2 mm to 4 mm; this tooth was also fractured and had a d sinus tract, and a 7-mm intrabony defect was present on the mesial aspect, s combined periodontic–endodontic involvement (Figure 3). The patient was ta aspirin, trazodone, sertraline, simvastatin, and a calcium supplement (see Tab additional history).

With the patient under local anesthesia and intravenous (IV) sedation, tooth N

extracted atraumatically, osteotomy was performed for immediate placement mm x 11.5-mm implant (Genesis) (Figure 4 and Figure 5), followed by bone g using a corticocancellous mineralized freeze-dried bone allograft to manage t implant–alveolus discrepancy, and a healing cap was placed. At Visit 3, norm and good tissue tone were observed (Figure 6).

In July 2012 the stock abutment (using the standard platform-switched conn final porcelain-fused-to-metal (PFM) crown were placed; gingival health was e and showed a midfacial PD of 1 mm (Figure 7). At 18 months (Visit 7) a midfa probing depth of 3 mm without bleeding was noted (Figure 8). Endodontic tre was performed on tooth No. 5 after completion of the implant restoration (Fig subsequent follow-up photograph from January 2015 (Figure 10) shows the f of the final crown in occlusion.

Case 2

A healthy 67-year-old nonsmoking Caucasian woman presented to one auth periodontal/prosthodontic practice in January 2012 with a symptomatic maxi lateral incisor (tooth No. 7). Her biotype was deemed to be within normal limi attached tissue thickness estimated to be greater than 2 mm, and there was bleeding on probing (Figure 11).

A periapical radiograph (Figure 12) revealed previous endodontic treatment a periapical pathology. After an endodontic specialist consultation and the poo prognosis being established, the patient elected extraction of this tooth and replacement with an immediate implant. Following an extraction procedure th minimized the trauma to the labial portion of the alveolus of tooth No. 7, an o was prepared using a SICAT CAD/CAM-generated surgical guide (SICAT/Siro www.sicat.com), and a 3.8-mm x 16-mm implant (Genesis) was placed with torque of 45 Ncm (Figure 13). The osteotomy was performed through the api the alveolus and within the palatal wall. An implant–socket gap approximately wide and 5 mm in depth was evident on the distal aspect of the osteotomy ir after implant placement (Figure 14). No bone graft was used in the osteotom the labial plate thickness was deemed to be about 2 mm, and the distal sock wall had a thick (>2 mm), dense lamina dura; this presentation, in the author's experience, has a high degree of predictability of bone fill.

Immediate provisionalization was accomplished with a stock Esthetic Contou Abutment (Genesis), which was tried in at the time of implant placement. An type provisional was relined over the abutment with a methylmethacrylate sel resin. The immediate provisional restoration was inserted and cemented with temporary cement (Temrex, Temrex Corp, www.temrex.com).

A secondary permanent Esthetic Contour Ti Abutment was modified to recei

ceramic restoration (IPS e.max® Ceram, Ivoclar Vivadent, www.ivoclarvivade layered upon a Procera zirconia coping (NobelProcera, Nobel Biocare, www.nobelbiocare.com). The abutment was 3.3 mm in diameter at the impla abutment interface, resulting in a 0.5-mm platform switch.

Figure 15 shows the periapical radiograph at final crown placement (Visit 4). abutment was screwed in place to a torque of 35 Ncm and the cement-retai was placed with RelyX™ Unicem (3MESPE, www.3MESPE.com); at this time gingival inflammation was observed (Figure 16). One year later (18-month foll excellent esthetic result was observed from the facial aspect, with good tissu no gingival recession (Figure 17).

Three years postoperatively, radiographic interpretation suggested maintenan crestal bone level and a stable thickness of the labial plate, from the time of i placement throughout the follow-up period (Figure 18).

Case 3

A healthy 67-year-old nonsmoking Caucasian woman presented to one auth prosthodontic practice in December 2011. Her medical history was significan several chronic but managed conditions (Table 2); she was taking losartan/hydrochlorothiazide for hypertension, fluoxetine for depression, and nitrofurantoin to treat a bladder infection that was present at the time of her i surgery.

She had preexisting PFM restorations on teeth Nos. 8 and 9 (Figure 19), both had been endodontically treated (Figure 20). In August 2011 the crown on N dislodged and was recemented on an emergency basis; in November 2011 b crowns (Nos. 8 and 9) dislodged, and both teeth were given a questionable p

Accordingly, the patient enrolled in the multicenter study in December 2011. for extraction, immediate provisionalization, and immediate loading, and visite oral surgeon (JMA) and prosthodontist (MAP) authors' practices on the same January 2012 to consolidate these phases. Teeth Nos. 8 and 9 were extracte local anesthesia (infiltration with lidocaine 2% with 1:100,000 epinephrine, 3.6 crowns were removed, then the roots were elevated and extracted. Osteotor made in type II (moderate) bone with Class A bone quality; all socket walls w After tapping the sites, two 4.5-mm x 13-mm tapered implants (Genesis) wer with primary stability of 40 Ncm (Figure 21) and 5-mm healing covers were pl (Figure 22 and Figure 23). The buccal socket gaps were grafted with spongio substitute (Bio-Oss®, Geistlich Pharma North America, www.geistlich-na.cor gingival margins were reapproximated with 4-0 chromic sutures. Postoperati radiographs confirmed proper positioning in the alveolar bone.

Immediately after surgery, the prosthodontist attached prefabricated polymethylmethacrylate (PMMA, tooth-colored) provisional abutments (Temp Abutment®, Keystone Dental, Inc) with screws. The abutments were hand-ti and minimally prepared with a diamond bur. Laboratory-fabricated splinted p crowns were relined with Jet Acrylic (Lang Dental Manufacturing Co, Inc, www.langdental.com), adjusted, and cemented with eugenol-free zinc-oxide cement (RelyX™ Temp NE, 3M ESPE) on the PMMA temporary abutments. T used to seal the access holes. The patient was instructed to minimize chewir teeth and restrict hard food for 6 weeks.

The final impression (closed tray) was obtained in April 2012. The final ceram (IPS e.max Ceram) and custom porcelain-veneered, regular-diameter (RD) U abutments (Genesis; and Creation CC, Jensen Dental, www.jensendental.co 24, shown with PFM crowns and retention screws) were delivered in May 20 platform-switched connection, the abutments were torqued to 30 Ncm, the a holes sealed with Teflon, and the final crowns cemented with RelyX Unicem. through Figure 28 show the final IPS e.max Ceram crowns from periapical, fa incisal views, with a midfacial PD of 3 mm at the 18-month follow-up (Visit 7). biotype is evident in Figure 26, as determined by the inability to detect the ou periodontal probe inserted below the restoration's gingival margin.[50] This ima demonstrates an excellent esthetic outcome.

After this visit, additional restorative work was completed on teeth Nos. 6 an 29 and Figure 30 (retracted and smile views, respectively, at 3 years, Visit 8) excellent esthetic outcome registered during the 3-year postoperative period

Case 4

A healthy 65-year-old nonsmoking Caucasian woman was seen by her resto dentist in December 2011 for a symptomatic maxillary right second premolar 4). The preoperative radiograph showed extensive periapical pathology and r (Figure 31).

Her medical history was unremarkable for current conditions; several prior ro 2). She was taking raloxifene for osteoporosis prevention and an estradiol ho

In January 2012 tooth No. 4 was extracted. The site was grafted with minera (OraGraft®, LifeNet Health, www.lifenethealth.org) and covered with resorba Zimmer Biomet, www.zimmerbiomet.com), which was secured with 5-0 plain 4-0 plain-gut sutures.

In February 2012 the patient enrolled in the multicenter study. Using a flaples nitrous-oxide sedation, one of the periodontist authors (ETS) removed keratin using a 4-mm biopsy punch. Osteotomy was prepared using a surgical guide

tapered implant (Genesis), which was anchored in the floor of the maxillary si stability, at an insertion torque of 45 Ncm (Figure 32).

A temporary cylinder abutment was used to fabricate a screw-retained provis an appropriate esthetic emergence profile. Once this was accomplished, the which was torqued to 20 Ncm. The occlusion was adjusted to eliminate any

In June 2012 the provisional was removed, implant insertion torque was verif patient was given the impression parts to bring with her to the fixture-level im dentist.

One month later, the custom UCLA abutment (Figure 33) was attached to the connection, with an insertion torque of 35 Ncm. The final PFM crown was ce Metabond® Quick! Cement System, Parkell, www.parkell.com). The occlusic checked and adjusted to the new restoration.

The midfacial PD at Visit 7 (18-month follow-up) was 2.5 mm, with no bleedir radiographic osseointegration (Figure 35) and excellent soft-tissue and restor (Figure 36 through Figure 38). The patient was last seen in February 2015 (al which time favorable hard- and soft-tissue levels and optimal esthetics were (Figure 39 and Figure 40).

Case 5

A healthy 43-year-old nonsmoking Caucasian man was seen in the periodon February 2012. His medical history was unremarkable except as noted in Tab had no known drug allergies.

The patient presented with a symptomatic, fractured endodontically treated r The tooth had gross caries and a primary periodontal abscess with secondar periapical pathology was present on the mesial roots, and all roots showed e deemed nonrestorable.

In May 2011 the tooth was extracted using local infiltration anesthesia and IV grafted with a cortical and cancellous particulate bone allograft (Puros®, Zim growth factor. A resorbable collagen membrane with signaling growth factors placed prior to primary closure. Figure 41 shows a radiographic view of the g

In February 2012 the patient enrolled in the multicenter study, and a 5.5-mm (Figure 42). Minor contour bone grafting of the site was also performed using buccal cortex and layered thereafter with a corticocancellous allograft (Puros) was done to increase the peri-implant bone and mucosal thickness (existing aspect) in an effort to improve parameters that would reduce the incidence o

The 5.5-mm implant platform was used to accommodate the high occlusal lo

and to optimize the esthetic emergence profile of the final restoration, neither narrower implant, even in the presence of more robust socket augmentation.

A high implant stability quotient (Osstell® ISQ = 80) (Osstell, www.osstell.com allowed the prosthetic phase to begin in April 2012 (Visit 3). Figure 44 shows 45 shows good healing and tissue tone at this visit as well.

The final open-tray polyvinylsiloxane impression (Aquasil®, DENTSPLY Intern obtained at Visit 3. The impression coping was radiographically verified for ac placed into the laboratory model, and a stock abutment (Genesis) was used with a screw-access hole in its occlusal surface (Figure 46).

In the prosthetic phase, the restorative dentist chose to use an indirect ceme cement entrapment/sepsis if the crown were to be cemented intraorally. In Au tried in and, once proper seating and fit had been verified radiographically (Fi the crown cemented extraorally with resin-modified glass-ionomer cement (F www.gcamerica.com). After removal of excess cement, the abutment–crown torqued into the implant fixture to 35 Ncm using the standard platform-switch access hole was sealed with Teflon tape and, after etching with 9.5% hydrofl resin (Renamel® NANO™, Cosmedent, www.cosmedent.com). The crown w

Figure 47 shows the stock abutment connected to the implant prior to extrac which was followed by screw-retained placement (Visit 4). Figure 48 shows a health, and a PD of 1 mm approximately 3 weeks after cementation (6-month excellent esthetics and good occlusion at the 18-month follow-up visit (Visit 7

Figure 50 shows the final periapical view of the osseointegrated implant, abut at the 18-month follow-up (Visit 7). Bone loss of 1 mm to 2 mm is radiograph view, as compared to 2 months post-implant placement (Figure 44). Howeve significance, because no PD recorded at 18 months exceeded 3 mm (Table 6 probably occurred is discussed below.

Discussion

Maintenance of marginal bone levels and soft-tissue dimensions has been er study of this biomimetic pink implant system. The five cases presented here p soft-tissue stability associated with this system according to the proscribed s health and excellent gingival/restorative esthetics. All cases in this multicente final crown placement. This article (and its companion case series by Murphy published data from this 5-year prospective study.

The two most extensively reported variables in the literature for osseointegrat placement[51-55] and platform switching.[34,37,39,56-60] Both of these variables were Three of the five cases presented here were immediate implant placements; t

post-extraction graft integration. All cases incorporated the standard platform routinely used for this implant system. All received some combination of auto This implant system was associated with good preservation of hard and soft variables.

A systematic review and meta-analysis by den Hartog et al[61] identified no diff metric outcomes among immediate or delayed placement. Importantly, the a and soft-tissue assessments were underrepresented in studies that qualified post-treatment surveys, patient-satisfaction levels with outcomes in the curre

The recent meta-analysis by Kinaia et al[24] identified lesser degrees of crestal immediate placement and platform switching. Other systematic reviews by H implant soft-tissue preservation effect for platform switching as well.

The hard- and soft-tissue assessments observed in this case series are cons gingival height was decreased by 0.1 mm to 0.5 mm among subjects who re suggests good soft-tissue stability. Facial and lingual PDs at 18 months were range of observed stability of alveolar crestal bone among these cases displa Visit 7, 0 to -1.75 mm for mesial and -0.2 mm to -2.04 mm for distal margina patient series range for this study at Visit 7 was -1.1 mm to 0.4 mm11).

Not unexpectedly, changes in interproximal marginal bone-to-implant distanc restoration (Visits 2 and 4, respectively) reflected minor crestal bone loss (≤ -2 timepoint (-2.03 mm) was observed in Case 3, which involved the use of a xe adjacent implants to replace two maxillary central incisors.

Between final restoration and 18-month follow-up (Visits 4 and 7, respectively degree was observed over all five cases (≤ -0.55 mm). Interestingly, Case 3 (Visit 4) also reflected small bone gains between Visit 4 and Visit 7 (Table 7).

Clearly, the crestal bone levels maintained 18 months postoperatively in Case provided by the xenograft material used during implant placement (Figure 25) clinical comparative studies have addressed differences that might be expect autogenous bone. With regard to graft material and implant surface, a scanni Rocchietta et al identified no measurable differences in bone formation obser and no differences in bone apposition to oxidized versus machined implants.

Although Case 3 showed an 18-month PD of 3.5 mm on the facial aspect of recorded at this timepoint), good gingival tone and excellent esthetics were a

Of note, for Case 2, a socket gap observed on the distal aspect at implant pl bone fill between Visits 2 and 4 (Figure 15) and remained stable not only thro (Table 7 and Figure 18).

As noted in the systematic review by Cosyn et al,[28] as well as in a 3-year follo placement in the esthetic zone by Cosyn et al,[26] the critical implant-esthetic c while sometimes equivocal, is minimized in the presence of thick biotype, inta provisionalization. This case-selection paradigm is echoed in a case series by results observed in Case 3, in which all of these features were present or per

Against such a backdrop of "ideal" case selection, it should be noted that no case series nor in the earlier one from this multicenter study,[11] captured all of displayed a challenging range of clinical variations that probably better appro esthetic implant practice. Based upon clinical observations, all of these patien gingival thickness ≥2 mm through which a periodontal probe could, at most t were Case 3 at Visit 2, and Case 5 at Visit 6), including the 18-month assess

It could be hypothesized that the esthetic properties of a pink implant system color harmony at the gingival margin in a thin-biotype patient. Such biotype c specifically in the design of future studies of this implant system.

In addition, some subjects in this series received immediate provisionalizatior range of bone grafting and regenerative interventions, all of which appeared, to demonstrate a uniformly pleasant and lasting esthetic impact at timepoints implant placement.

For Case 5, it is unlikely that high insertion torque (>50 Ncm) resulted in the c and Figure 50). Rather, this is more likely a function of the quality of the bone distant peripheral position from the vascular base during socket augmentatio resultant lateral walls and apex). This portion may not have become fully vasc having forces applied to it. The bone loss was likely the response force applic vascularized bone (which explains why mechanotransduction responded in c was applied to the least integrated, least vascularized, and/or least consolida true functional matrix). It is also possible that the bone graft had not complete placement and continued to solidify and condense after the implant was plac probably not clinically significant, as no PD recorded at 18 months exceeded radiographic angulation at successive visits resulted in distortion of bone leve study, this case will be monitored for changes in bone level throughout the 5- follow-up, crestal bone appeared stable and the grafted area surrounding the cortex (Figure 50).

Across all cases, excellent esthetic outcomes (including soft-tissue emergenc current series, two subjects enrolled in the study with the presence or history involvement of the tooth to be replaced. One of these received an immediate followed a brief yet fairly aggressive regenerative course (TS-03, tooth No. 30 outcomes (Figure 9, Figure 11, Figure 49, and Figure 50; Table 6), with bucca together, these hard- and soft-tissue observations are consistent with good t

associated benchmarks in the literature. Furthermore, after 18 months' follow study protocol definition for implant success (bone loss ≤3 mm; Table 7), thus rate.

This five-case series offers multiple and disparate clinical variables for the use satisfactory to excellent outcomes and running a gamut from two-stage impla replacement (Case 5) to immediate replacements in the esthetic zone, one of while the other required no grafting (Case 2). Given such a broad range of clin of cases, attribution of outcome to any of these factors amounts to speculati series article.

Statistical analyses of the entire study population, which are to be presented this multicenter study, will be necessary to reliably assess any significance of prosthetic, and qualitative variables and associated observations presented in based on this case series, this implant system has demonstrated clinically an hands of periodontists, prosthodontists, and restorative dentists over a 3-yea patient and clinician satisfaction.

Ongoing multicenter studies of esthetic implant variables for this system are a white esthetic scores and quantitative reporting of patient-satisfaction survey from representative case series such as the one presented here, as they prov progress prospective multicenter studies evaluating novel dental implant desi

Conclusion

The novel pink implant system used in these five cases produced uniformly e periodontal and restorative outcomes, as well as consistent marginal alveolar variety of real-life clinical situations. In ongoing follow-up observations approa continues to maintain consistent clinical performance and patient satisfaction continue to deliver similar high-quality results spanning the diverse implant-re

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