A five-case representative cohort from an ongoing five-year study of marginal bone level and soft-tissue parameters of a novel pink biomimetic implant system

Abstract

Color discrepancies between peri-implant soft tissues and materials used in implants, abutments, and restorations may influence overall esthetics at the implant–soft-tissue interface, particularly in the esthetic zone. In an ongoing five-year multicenter prospective post-marketing surveillance study of 120 adult male and female participants at eight sites in the United States (total of 168 implants placed), the authors have been evaluating anterior and posterior single-tooth implants using a novel pink osteoconductive implant system (in clinical use since 2010) that features a variety of pink components, developed with the objective of improving peri-implant soft-tissue esthetics.

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 percent. This case series aims to summarize data on implant survival, probing-derived and radiographically assessed marginal bone and soft-tissue level changes, and qualitative photographic evidence of post-restorative soft-tissue esthetic outcomes by presenting a snapshot of five representative cases (two anterior and three posterior), at 18 months from the start of this study.

Four of the five cases described here involve teeth visible in full smile and comprise three maxillary incisors and two maxillary premolars. The remaining case was a relatively straightforward mandibular first-molar replacement. The remaining two required post-extraction regenerative procedures. Gingival inflammation, bleeding on probing and plaque were infrequently observed throughout the treatment period. Implant success and stability, alveolar bone-level stability, soft-tissue height and attached-gingiva width stability, and peri-implant soft-tissue esthetic outcomes were uniformly excellent at the 18-month follow-up visit. Data from the entire ongoing multicenter study population will be published both at three years and at study completion at five years. Those results will be necessary to assess any statistical 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 implants, management of tissue esthetics at the facial restoration margin can pose significant challenges for the prosthodontist, restorative dentist and periodontist, and is of particular concern in the esthetic zone. In general, the closer natural shades of hard and soft tissue can be mimicked, the better the esthetic result. Gingival esthetic challenges have been addressed specifically using externally placed pink porcelain on prosthetic components to simulate natural gingiva, with varying degrees of success. The current system (Genesis®, Keystone Dental, Inc, www.keystonedental.com) addresses a similar goal by modifying internal esthetics within the implant/abutment–free gingival interface.

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

Esthetic impact of implant–abutment interface design has been reported in a recently published case series by McGuire et al; specifically, adherence
to a specific treatment protocol yielded good esthetics with the three different interface designs tested (conical, flat or platform-switched). One-year results from the larger five-year randomized clinical trial by Cooper et al.\(^{10}\) represented by those cases demonstrated that difference in interface design had significant impact on marginal bone stability but not on gingival mucosal architecture or position (including the apical-most aspect of the facial gingival margin contour, i.e., zenith).\(^{10}\)

The case series presented here represents another ongoing five-year clinical study comprising 120 patients who required replacement of one or more anterior or posterior teeth, now in its third year of post-marketing surveillance to evaluate clinical implant efficacy and soft-tissue esthetics of this unique implant system developed with the objective of overcoming color discrepancy-driven challenges. Three additional representative case reports from this study have been published.\(^{11}\)

This system uses a biomimetic implant–bone interface produced by anodic spark deposition or discharge (ASD, also known as microarc oxidation or glow discharge deposition) to the threaded titanium implant surface (BioSpark\(^{10}\), Keystone Dental, Inc.)\(^{12-16}\) via electrochemical anodization to form a nanorough, osteoconductive titanium-oxide implant surface rich in calcium and phosphorus ions as a bone interface.\(^{13,15,16}\)

In global use since November 2010, this system also features a variety of prefabricated and customizable pink abutments and other restorative components, including implant collars and matching prefabricated customizable titanium abutments. Unless otherwise customized, the transmucosal portion of the abutment and/or the implant collar are uniformly pink throughout the system.

The pink color is produced on the implant surface by a proprietary electrochemical anodization process (AnaTite\(^{10}\), Keystone Dental, Inc.), which produces a layer of titanium oxide on the implant surface. The resulting pink coloration also helps mask the gray hue that could be observed with conventional implants under the gingiva of thin-biotype patients, thus offering the clinician an alternative to zirconia for the apical-most aspect of the facial gingival margin contour, i.e., zenith.\(^{10}\)

The case series presented here represents another ongoing five-year clinical study comprising 120 patients who required replacement of one or more anterior or posterior teeth, now in its third year of post-marketing surveillance to evaluate clinical implant efficacy and soft-tissue esthetics of this unique implant system developed with the objective of overcoming color discrepancy-driven challenges. Three additional representative case reports from this study have been published.\(^{11}\)

This system uses a biomimetic implant–bone interface produced by anodic spark deposition or discharge (ASD, also known as microarc oxidation or glow discharge deposition) to the threaded titanium implant surface (BioSpark\(^{10}\), Keystone Dental, Inc.)\(^{12-16}\) via electrochemical anodization to form a nanorough, osteoconductive titanium-oxide implant surface rich in calcium and phosphorus ions as a bone interface.\(^{13,15,16}\)

In global use since November 2010, this system also features a variety of prefabricated and customizable pink abutments and other restorative components, including implant collars and matching prefabricated customizable titanium abutments. Unless otherwise customized, the transmucosal portion of the abutment and/or the implant collar are uniformly pink throughout the system.

The pink color is produced on the implant surface by a proprietary electrochemical anodization process (AnaTite\(^{10}\), Keystone Dental, Inc.), which produces a layer of titanium oxide on the implant surface. The resulting pink coloration also helps mask the gray hue that could be observed with conventional implants under the gingiva of thin-biotype patients, thus offering the clinician an alternative to zirconia for creating, enhancing and refining gingival esthetics.

Published preclinical studies have evaluated this implant system’s surface in regard to bone-to-implant contact.\(^{12,17,18}\) In vitro studies on cell behavior\(^{13,14}\) and studies on the effects of pink on gingival esthetics have evaluated this system from clinical\(^{19,20}\) and animal–tissue perspectives.\(^{21}\)

Spectrophotometric analyses published by Park et al. confirmed that there is a measurable difference between the colors of natural maxillary/labial gingiva and the surfaces of conventional titanium implants.\(^{19}\) More specifically, colorimetric data reported by Ishikawa-Nagai, et al, suggest that (in comparison to other colors) light pink coloration of the implant neck produces an optimal color that is clinically indistinguishable from that of natural gingiva.\(^{20}\)

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, who reported such specificity to provide stable gingival esthetics at a 1.5-year follow-up, especially in patients with a thin gingival biotype.\(^{22}\)

A case report by Polack published in 2012 specifically evaluated the pink nanorough implant system presented in the current case series (Genesis). An excellent result was achieved in an esthetically demanding case that required multiple extractions and site development for the replacement of four maxillary incisors (using narrow-diameter, 3.8-mm x 13-mm fixtures to replace two laterals, creating a four-unit implant bridge) in a severely resorbed ridge.\(^{23}\)

### Functional considerations of immediate implant placement

In the authors’ experience, the aggressive thread pitch of the implant fixture used in this case series also facilitates its efficacy in immediate placement and loading scenarios. Of note, all implants in this multicenter study population have surpassed three years of survival, function and success; the vast majority of them were immediate placements (78 percent; 22 percent were staged).

Results of a meta-analysis published by Kinaia, et al, in 2014 comprising 16 controlled studies suggests that immediate implant placement preserves crestal bone significantly more effectively than implant placement in healed bone after at least 12 months of functional loading.\(^{24}\) Furthermore, this meta-analysis also identified a significant advantage for the use of platform switching in such immediate placement scenarios.\(^{24}\)

Preliminary results from an ongoing randomized clinical study by Huynh-Ba, et al, showed no short-term differences in esthetic outcomes in immediate vs. early implant placements.\(^{25}\) Cosyn, et al, also reported minimal midfacial recession (in two of 25 patients after three-years’ follow-up) following an immediate implant placement protocol in the anterior maxilla in patients with thick gingival biotypes.\(^{26}\)

A recent systematic review by Slagter, et al, that also encompassed immediate provisionalization reported similar findings.\(^{27}\) Another systematic review by Cosyn, et al, found conflicting evidence regarding contributory factors to midfacial recession after immediate implant placement but suggested this risk is lowest in patients who have a thick biotype and an intact buccal bone wall and receive immediate implants.

‘... All implants in this multicenter study population have surpassed three years of survival, function and success; the vast majority of them were immediate placements.’
Recent systematic reviews consistently confirm that implants with platform-switched abutments are associated with better crestal bone preservation than implants with platform-matched abutments.

Platform switching has become a standard feature in implant component design and has expanded the clinician’s control over crestal bone preservation. Numerous studies\textsuperscript{29-33} and systematic reviews\textsuperscript{34-37} have reported reduced alveolar crestal bone resorption for platform-switched implants compared with platform-matched implants.

Considerable clinical evidence suggests platform switching has a bone-protective effect. Cappiello, et al reported a significant preservation effect (vertical bone loss was 0.72 mm less with platform-switched healing abutments versus controls) in a controlled clinical trial of 131 implants (all placed at the crest) in 45 patients.\textsuperscript{32} Clinical studies by Prosper, et al\textsuperscript{38} and Canullo et al\textsuperscript{39} 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.\textsuperscript{35-37}

While platform-switched implant configurations also appear to preserve soft tissue and provide increased control over gingival esthetics according to some reports,\textsuperscript{40,41} several recent studies tend toward reporting similar tissue-esthetics preservation with platform-switched and other abutment-implant interface designs.\textsuperscript{3,42} which suggests that platform switching favors stable tissue dynamics. However, a study by Zuiderveld, et al, found platform switching to have no effect on midbuccal mucosal (MBM) measurements one year after crown placement; rather, the buccopalatal positioning of the implant itself (i.e., more toward the buccal) resulted in a more apically positioned MBM.\textsuperscript{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 bone and soft-tissue volumes in optimally preserving crestal bone.\textsuperscript{44} As a further caveat, even the authors of some recent systematic reviews raise notes of caution about remaining unknowns as to functional specifics of platform switching and stress the need for further and more specific data from clinical studies to evaluate them.\textsuperscript{34,35}

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

\textbf{Five-year prospective clinical study}

An ongoing five-year study continues to evaluate the use of this implant system (168 implants placed in 120 partially edentulous patients). Its objectives include assessment of the five-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, visual soft-tissue esthetic outcomes, and the number and nature of prosthetic revisions.

Alignment, orientation and magnification of the periapical radiographic images of all 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, 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 of the images in this data set have a percentage error of less than 3.5 percent. Clinical analyses of the investigator-reported 18-month interim survival rates, marginal bone and soft-tissue level changes, and esthetics estimate an overall success rate among all sites of 95.8 percent.

Consistent with other implant designs, most osseointegration failures in the study occurred during the healing period following placement or shortly after prosthetic loading. However, unlike other designs, the location (mandible versus maxilla),\textsuperscript{46-48} and length of the implant\textsuperscript{46-48} had no apparent effect on the survival rate. After loading, this implant system has demonstrated a survival rate of more than 99 percent, based on available data from this ongoing study.

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

*Note: Please see Implants C.E. magazine’s next edition, 02/2018, for Part 2 of this article.

References available upon request from the publisher.