The Custom Endosteal Implant: Histology and Case Report of a Retrieved Maxillary Custom Osseous-Integrated Implant Nine Years in Service

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The Custom Endosteal Implant (CEI) is a custom-cast osseo-integrated implant that has evolved to replace the "old" fibro-integrated subperiosteal variant. This newly developed implant achieves osseous integration by utilizing a hydroxyapatite (HA) coating, and a specialized grafting technique that produces much improved success rates relative to its fibro-integrated subperiosteal predecessor. This case reported here represents a maxillary CEI implant that was placed and in functional service for 9 years before being retrieved and processed for histologic examination subsequent to the patient's demise. In addition, due to infection that occurred shortly after placement, an early provisional procedure with fluoridated HA was also performed. Histologic analysis of the postmortem specimen revealed a fully integrated new bone formation intimately surrounding the previously dehisced implant strut. The latter had previously been decontaminated and grafted with a thin layer of fluorapatite (FA) material. Results including histologic analysis confirmed complete osseo-integration of the implant following successful FA graft revision.

Key Words: Custom Endosteal Implant, subperiosteal implant, osseous integration, fluoridated HA, revision surgery, dental implant

INTRODUCTION

The Custom Endosteal Implant (CEI) is a custom cast, osseo-integrated implant that has been developed to replace the now obsolete fibro-integrated subperiosteal device. This implant achieves osseous integration by utilizing a hydroxyapatite (HA) coating, and a specialized grafting technique that produces much improved success rates relative to its fibro-integrated counterpart. The purpose of this article was to document histologic features of a clinically placed CEI implant and surrounding tissues after 9 years of functional service. Specifically, we endeavored to demonstrate unequivocally that the union of the HA-coated, FA-grafted implant with surrounding bone was complete and osseous in nature, and, therefore supports and validates the use of the CEI implant procedure in clinical practice.

Historical evolution of the subperiosteal implant to the CEI

Subperiosteal dental implants have undergone a long process of continuous evolution since they were first put to clinical use. Historically, the technique was first advocated and employed by Dahl,[1] and was continually developed by many others as documented by later studies.[2–9] Perhaps even more important were the subsequent contributions of Linkow, which includes modernized designs of subperiosteal implants with regard to supportive structures for the maxilla and the tripodal design for the mandible.[10–13] Other American dentists (Bodine, Mentag, Mena, Riviera, and

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DOI: 10.1563/AAID-JOI-D-11-00218

Weber) have also made significant contributions to advanced substructure design, and these innovations have become more accepted over the years.[14]

The idea that some substances were biologically active in attracting or stimulating the growth of new bone represented an important advancement in the field of implant technology. For example, Golec was one of the first to report that hydroxylapatite (HA)-coated subperiosteal implants may help to establish an osseous union of the implant to the surrounding bone.[15] This finding was later supported by the results of other studies.[16] Further, it was found that porous HA (Interpore BioMed Interpore Cross International, Irvine, Calif) attracted internal bone growth when placed on the surface of viable bone.[17] Not only did HA granules become attached to the HA coating on strut sections,[18] but new bone growth occurred in the space between HA particles, and this bone was firmly attached to the HA coating.[19] Golec, Kay, and Benjamin were the first investigators to describe and document techniques of actual osseo-integration that resulted in higher success rates using custom cast hydroxyapatite-coated endosteal implants.

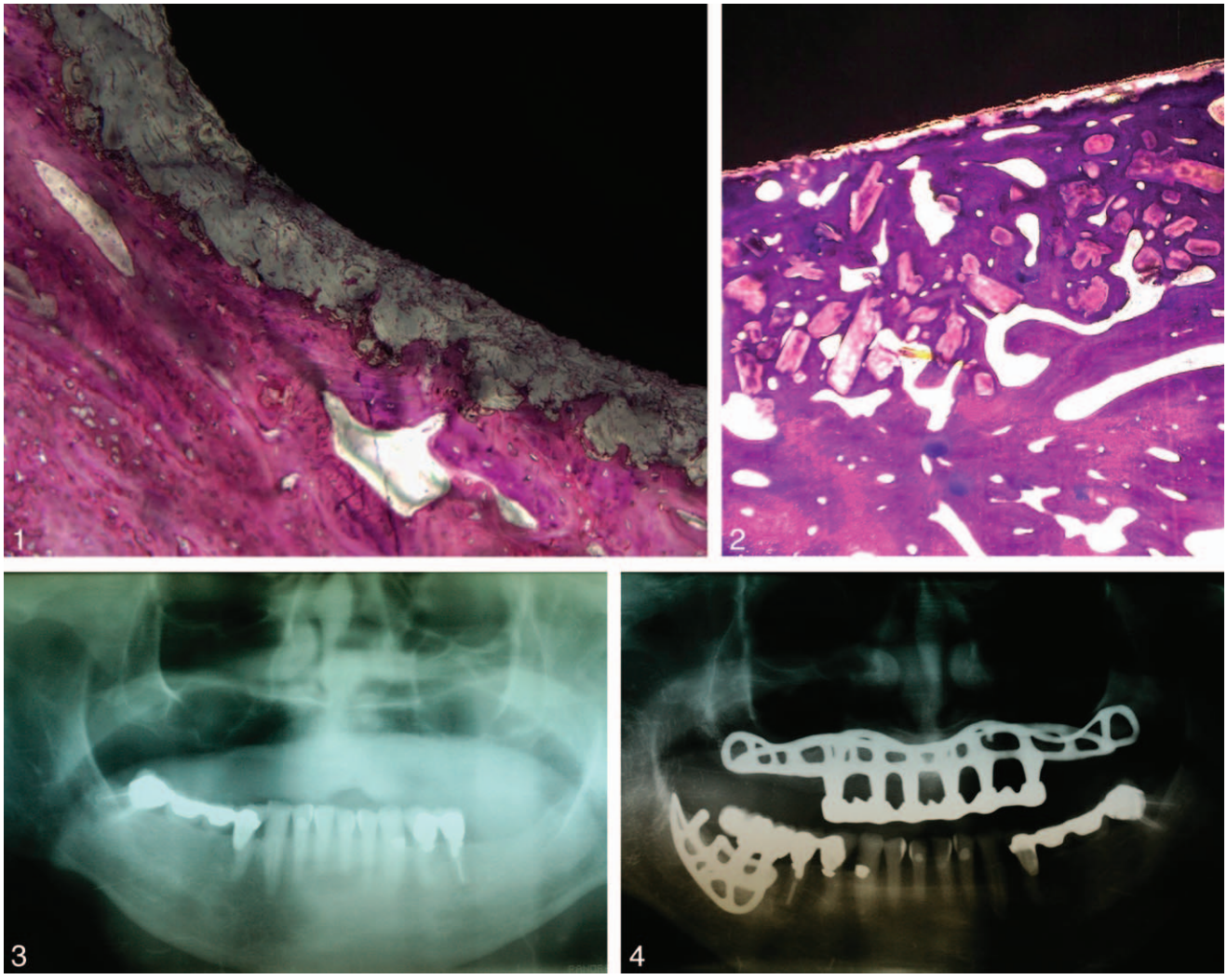
Later studies were likewise illuminating. For example, in 2000, it was reported that a 70%–80% increase in bone height was achievable between the anterior and posterior sections of a tripodal HA-coated subperiosteal implant over what initially was present at the time of implant placement.[20] Also, (although not discussed in the article), published photographs showed that the struts appeared to meld into solid bone as they connected to the distal portion of the implant. This is consistent with a previous report[21] that showed that "When the loose HA granules are curetted away solid bone was observed growing up and over the subperiosteal struts," demonstrating that HA-coated implants have become a true osseo-integrated union.

In 1997, a panel of 9 Diplomats of the American Board of Oral Implantology/Implant Dentistry held a collective conference on subperiosteal implants in implant dentistry in 1997[22] in an effort to adopt a consensus of accepted principles regarding the use of the subperiosteal implant. The panel adopted item #15, which stated: "Almost all subperiosteal implants are fibro-integrated. The consensus of this group is that this implant modality functions best in a fibro-integrated state." Later, when speaking to one member of the panel, Mena (in conversation with Raul Mena) offered a different view of this consensus and stated that there was controversy on this important point of fibrous verses osseous integration. Many of the members argued to include osseous integration in the consensus report; however, the panel members favoring fibro-integration prevailed and no mention of osseous integration was included in the final publication. It was apparent that with no published histological proof of actual osseous integration, the concept was considered anecdotal and thus was not considered scientifically acceptable at that time.

Clearly, if this technique were to gain acceptability by the profession, it would have to be documented beyond any doubt by histologic proof. In an effort to do so, Lemons and Martin[23] focused on outcomes from 3 cadaveric specimens with longevities of about 11 years each.[24]

Histomorphometry of three 11-year human donor cadaveric mandibular implants showed retained, osseous-integrated HA coatings and particulates including some resorption and surface alterations.[25] There was osseous integration of cobalt alloy regions and an overall construct arrangement indicating functional force transfers through all components. Clinical, radiographic and histologic results of this study showed that the implants were clinically functional and osseo-integrated over the 11-year period of clinical use.

Recently completed histology studies[26] on canine mandibles with grafted custom osseous integrated implants confirmed the osseous integration potential of HA-coated titanium (Figure 1). These studies compared the relative osseous integration potential of nanocrystals of HA (OsteoGen cluster, Impladent Ltd, Holliswood, NY) fluorapatite-coated HA (FA) grafting material in custom cast titanium cages, which were placed over and firmly fixed to large, precisely prepared bony osteotomies. Results of this experiment showed that the HA coated titanium framework mesh and struts of these implants integrated similarly to Marin and Lemon's mandibles described above. Further, the results showed that bone reacted to and equally engulfed the two nanocrystalline lattices (of HA and FA grafting material; Figure 2). Furthermore, the fluoride ion in the form of fluorapatite could be used as an



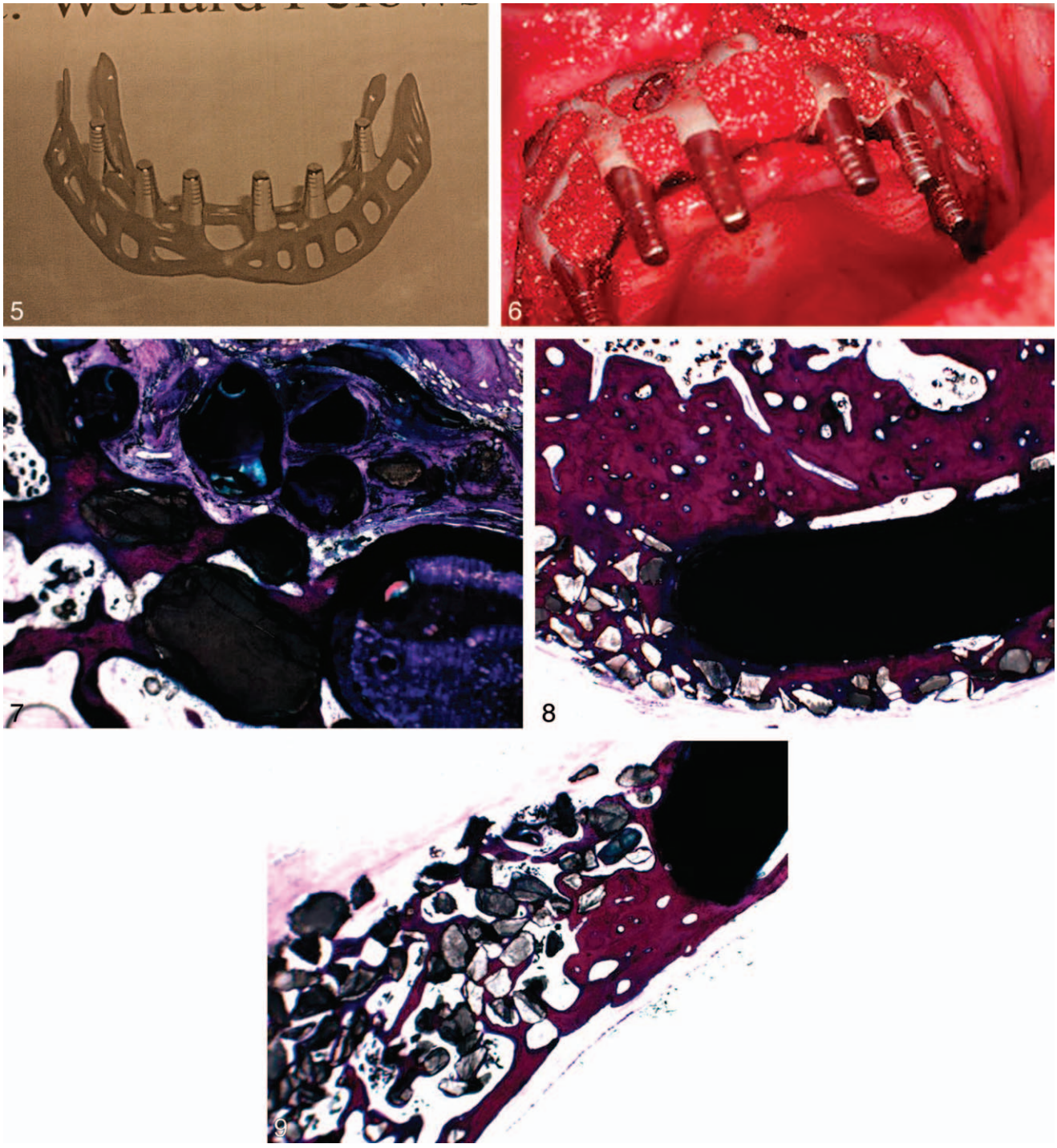
Figures 1–4. Figure 1 shows an osseous-integrated hydroxyapatite (HA) coated titanium strut in dog mandible. **Figure 2** shows osseous integration of fluorapatite crystals in an HA coated titanium custom endosteal implant in a dog mandible. **Figure 3** shows the pretreatment panographic X ray. The maxillary bone is so atrophic that it is almost entirely indiscernible on this X ray. **Figure 4** shows the maxillary and mandibular implants in place after 2 years of service.

adjunct to inhibit infections associated with grafting failure. Thus, fluoridated hydroxylapatite (fluorapatite) is now used as a grafting material during the initial placement of the CEI.[27]

Success rates of HA-coated CEI

In 1991, it was reported that after years of clinical experience with over 300 cases of HA-coated subperiosteal implants,[28] overall success rates gradually improved to 98.2% using the bone impression technique and computerized tomography (CT) scan–fabricated subperiosteal implants. In 1992, Benjamin[29] reported a 6-year retrospective study on over 700 CT-scanned, HA-coated subperiosteal implants. Success rates were reportedly 98% with only 10% suffering relatively minor complications. A more recent publication reported success rates of 85%–100% on 362 subperiosteal implants over a 6–10-year period.[30] Clearly, through an abundance of case studies, the CEI has been shown to be a successful technique both clinically and biologically.

It is relatively uncommon for complications to occur, and they are minor. Soderstrom[31] reported a 100% success rate on of 73 mandibular bilateral subperiosteal implants, included complications as follows:



Figures 5–9. Figure 5 shows the finished Vitallium Custom Endosteal Implant (CEIT) implant preceding the HA coating process. **Figure 6** shows the placed CEI implant subsequent to grafting. Notice the grafting material just covers the implant struts and is not liberally applied. **Figure 7** shows a distinct randomized ''honeycomb'' bone structure integrated to the surface of the HA coated Vitallium implant struts. **Figure 8** shows the osseous integrated HA strut plus HA granules complete engulfed in viable bone. **Figure 9** shows bone growth around grafted fluoridated HA granules used in a revision surgery to correct bone loss due to infection after 9 years in service. Also note the osseous integration of the implant strut.

- Required removal of 7 bone screws
- 3 struts became exposed, which were later spontaneously covered
- One strut was removed at 8 years postop in area of bone screw removal 2 years postop
- There was 1 case of an exposed strut with purulent exudate that spontaneously healed after the removal of a pituitary adenoma
- 2 patients passed away from unrelated causes at 3 years postop; the other at 5 years postop
- 9 patients were lost to followup: 4 at 2 years, 1 at 3 years, 2 at 5 years, 1 at 6 years, and 1 at 8 years postoperatively
- One case was eliminated from the study due to resumption of tobacco smoking of over one pack per day—All cases were otherwise successful.

Today, because of the osseo-integration character of this implant, clinical success rates are very high and similar to those seen with endosseous root form implants.

Nine-year full maxillary CEI retrieval: Case report

The case reported here was placed and grafted comparably to that previously described[21]. Subsequent to the patient's demise, the complete maxilla (including the integrated CEI) was surgically harvested at 9 years of service. This implant was initially placed in 2001 using the protocol previously described[34] (Figures 3 through 5) with the exception that fluoridated HA was used in the form of dense 20–40 HA Calcitite granules (Figure 6). The latter was the sole grafting material used. Once collected, the maxilla specimen was preserved in a formalin solution and sent to the University of Alabama Birmingham and routinely processed. Then the maxilla specimen was sectioned by Exakt (EXAKT Technologies, Inc, Oklahoma City, Okla) processing and imaged by Bioquant optical microscopy (UAB-IRB X050823001). Histologic sections revealed osseous-integration identical to previously reported studies of Lemon and Martin.[25] In this case, the only difference was that the histology of bone from the maxilla demonstrated a randomized "honeycomb" structure compared to the dense cortical nature of bone shown in the previously published mandibular case (Figure 7). Other areas showed dense fluoridated HA granules engulfed within bone (Figures 8). Also note that the HA-coated strut was fully integrated within surrounding bone.

Discussion

It is important to understand keys to the clinical success of the maxillary CEI. One factor is that since maxillary bone is less dense, it is less supportive of full masticatory loads. Thus implants placed in the maxilla can constitute a clinical challenge to proper function, and thus constitute a problem for the patient. Also, the edentulous maxilla is quite often atrophic and rarely exhibits sufficient bone for solid root-form implants. Accordingly, patients with edentulous maxillae are often passed over by implant dentists as poor risks and as such, are often neglected. In the latter instance, patients are usually left with no choice other than the wearing of dentures since the dentist is unwilling or unable to deal with the lack of bone. Further, judging from the number of cases presenting for treatment (Nordquist's office) with mandibular implants opposing upper dentures, it must be concluded that dentists feel that a denture is the best alternative for the atrophic edentulous maxilla. However, patients are living longer, and with each year of extended life, patients continue to suffer increasing bone loss and problems inherent with such under the full denture.

One of us (WDN) encounters far too many patients in his implant practice at this late, atrophic stage that require more extensive and difficult surgical procedures in order to place the CEI appliance. In some cases, sinus elevation procedures are performed with a subsequent wait of 6 months before root forms are then placed into grafted bone. To help support the latter root-form implants, a CEI is sometimes constructed in which the implants are subsequently connected to one another with a common superstructure bar during the restorative phase. This procedure is used routinely in order to successfully treat severely atrophic maxillae. The amount of bone loss that occurs over the years due to denture wear is extensive and seems to depend essentially on how long the patient lives. Keys to success of jaw implants, particularly those of the maxilla would seem to include:

(1) Timeliness. The dentist should perform the CEI procedure as soon as possible, before additional bone is lost due to denture wear.
(2) Awareness of adverse conditions. Experience has shown that in order to achieve optimal success,

it is advisable to place a CEI into patients who do not smoke.

(3) Complicating issues. Health histories of patients who have lost bone sufficient enough to require the CEI usually reveal pre-existent periodontal disease as the root cause of their problem. Further, the vast majority of these patients are older individuals who also have a health history of one or more systemic chronic inflammatory diseases, and, as a result, tend to be at least partially immunosuppressed.[32,33] As the relationship between these chronic systemic problems and periodontal disease has become more suspect in recent years, it is now imperative to understand the potential linkage of these disorders. That is, it has become clear that a variety of systemic conditions could well impact both healing from surgery as well as precipitate complicating infection in the area of the implant. Therefore dentists who place implants must be aware that such patients are especially predisposed to local infection, and thus be prepared to perform surgical revision to mitigate infections that tend to occur in bone surrounding implants.

(4) Implant design. Crossover struts (placed posterior to the bicuspid) must be notched into the bone for additional strength to avoid imposition of posterior loading forces to the thin bone proximal to the maxillary sinuses. In conversations with Linkow, earlier designs that included posterior struts over this thin bone have proven to be problematic as they tend to dehisce if dentures are not designed to avoid these areas. For fixed appliances, the crossover struts can be incorporated within notches cut as windows into the sinus, and thus be used to complete sinus augmentation using the inferior approach. Once the sinus is grafted, the CEI implant is placed in such a manner that the crossover struts transverse the bottom of the sinus within the augmentation graft material. Once healed and integrated, these struts add substantial strength to the posterior section of the implant system.

An excellent HA implant-bone approximation is essential and is obtained by utilizing a direct bone impression. CT scan-generated model technology can also be used, but caution must be exercised since it is difficult for present computer-based tomographic methods to discern the presence of thin atrophic maxillary bone. The authors concur with previous reports (Benjamin; Golec) which state that FA-HA augmentation material placed between the implant struts allows for bone growth up and around the FA-HA granules and around the HA coating of the implant. This process envelops the major portion of HA-coated struts, and because it embeds the CEI in dense bone, it adds substantial strength and functional enhancement to the entire implant system.

The re-entry surgical procedure performed 6 weeks after placement of the maxillary CEI was done in order to treat an initial infection that occurred early in the integration process of this implant. This procedure was accomplished by reflecting a flap, removing any contaminated HA, and decontaminating the implant with citric acid. The struts and bone were then treated with a wash of 4.3 % NaF and washed thoroughly with sterile water. Dense HA granules were fluoridated as previously discussed and used as a graft around the struts.[26,34] This procedure worked remarkably well in that after 9 years in function, the interstrut areas and the dehisced strut were observed to be filled in and re-integrated with new, viable bone. Histologic study also revealed that new bone had surrounded previously grafted fluoridated HA granules and exposed strut (Figures 9). Clearly, the revision surgery proved successful in that there was no subsequent infection of this implant, and the CEI served the patient well for 9 years prior to his death from other causes.

Summary

The CEI is an osseous-integrated implant that becomes firmly embedded in newly formed bone. Twenty years of experience with the implant has shown that the implant is capable of supporting both removable and fixed appliances. Once the many constituent factors of this process are understood and taken into account, the maxillary CEI becomes a powerful device in the armamentarium of the implant dentist and sometimes represents the only tool that can be employed to successfully correct cases involving severely atrophic maxillae.

Abbreviations

CEI: custom endosteal implant

CT: computerized tomography
FA: fluorapatite
HA: hydroxyapatite

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