Clinical Evaluation of 262 Osseointegrated Implants Placed in Sites Grafted With Calcium Phosphosilicate Putty: A Retrospective Study

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Along with the widespread use of dental implants, regenerative procedures have become an indispensable tool for implant surgeons in managing residual ridges and the surrounding bone. Putty bone grafts have significantly superior handling characteristics in comparison to particulates. These include ease of placement, enhanced particle containment, and a viscous consistency that has allowed for unique delivery systems to be developed. The aim of this study was to report the clinical efficacy of calcium phosphosilicate (CPS) putty in a wide variety of indications related to implant reconstruction and to report the survival rate of implants placed in these grafted sites. The CPS putty was used as the graft material of choice. Treatments were categorized into following groups: extraction graft, extraction with immediate implant placement, all-on-four concept, peri-implantitis treatment, bone augmentation before implant placement, implant replacement graft, and grafting around implant placed in resorbed ridges. Included in the analysis were 65 patients (36 men, 29 women) with a mean age of 63 ± 12 years. In total, 262 implants were placed. Four implants were diagnosed with peri-implantitis and were treated as described in category 4, for a total of 266 grafted sites. Two implants from the extraction graft category and 3 implants from the all-on-four group were lost and replaced with successfully osseointegrated implants during a mean study follow-up period of 12.24 ± 2.32 months. The implant success rate at 1 year was 98.1% (257/262). Based on results of this large-scale, retrospective study we conclude that (1) the use of putty bone grafts can simplify bone-grafting procedures and reduce intraoperative time in various grafting indications, (2) this study verified the efficacy of a CPS putty bone graft biomaterial in a large array of implant-related surgical indications, and (3) implants placed in sites grafted with CPS putty yield very high survival rates.

Key Words: bone grafting, implant dentistry, maxillofacial surgery, oral surgery, prosthodontics

INTRODUCTION

Along with the widespread use of dental implants, regenerative procedures have become an indispensable tool for implant surgeons in managing residual ridges and surrounding bone.[1] Bone augmentation procedures are advanced and highly technique sensitive oral surgical procedures. Varying success rates for such procedures have been reported in the literature. These variations can be attributed in part to the different techniques used, the experience of the operator, and the various biomaterials used.[2–4] A common dilemma that clinicians deal with during bone augmentation procedures is the overcondensation or undercondensation of the particles of the graft materials.[5] Recent data point out the detrimental effect of overcondensation of the graft particles in the surgical site.[5] When the distance between the particles is diminished the diffuse distance for oxygen and other nutrients is increased; therefore, the regenerative potential is diminished.[5] The inability to standardize the distribution of the particles in the graft materials during packing in various defects is a drawback of such biomaterials. Ultimately, the regeneration potential of these grafts varies depending on the condensation force each clinician applies. Incorporating calcium sulfate as a binder for these materials has been suggested in an attempt to overcome this problem.[6] Adding calcium sulfate alters the consistency of the graft material, however. The cost of the additional biomaterial (calcium sulfate) also has to be added to the cost of the surgical procedure.

Recently, a new generation of putty graft materials has been used in bone regeneration procedures with promising results.[7] Putty bone biomaterials have significantly superior handling characteristics compared with particulates. These include ease of placement, enhanced particle containment, and a viscous consistency that has allowed for unique delivery systems to be developed.[8,9]

A calcium phosphosilicate (CPS) putty bone substitute has recently been shown to yield very good results in bone regeneration procedures.[10,11] This CPS putty is composed of a 70% calcium phosphosilicate particulate and 30% synthetic absorbable binder, and it has been shown in vitro to possess

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the capability to facilitate differentiation osteoprogenitor cells into osteoblasts, which may aid in bone regeneration in the grafted area.[12] The ionic dissolution products of biologically active silicon and calcium released from the CPS particles stimulate the genes that control osteoblast differentiation and proliferation.[13,14] Gene array analysis has confirmed that when human primary osteoblasts are exposed to extracts of CPS particulate, upregulation of several gene families occurs.[14]

In the field of implant reconstructive surgery, numerous procedures and techniques have been used to aid in the placement of implants.[1] In addition, in some cases it is necessary to prepare or enhance the alveolar ridge and/or the extraction socket for simultaneous or staged implant placement. Furthermore, in some cases complications or failures might develop in concert with a variety of pathological conditions. Keeping all of these factors in mind develops a group of categories that broadly cover the scope of dental implant reconstructive procedures.

The aim of this study was to report the clinical efficacy of CPS putty in a wide variety of indications related to implant reconstruction and to report the survival rate of implants placed in these grafted sites.

Materials and Methods

Sixty-five patients with bone deficiencies that had been treated with grafting with CPS putty from May 2012 to February 2013 in a single, private-practice setting were selected for this retrospective evaluation.

Grafting with CPS putty was performed as part of the routine protocol. All patients were informed as to risks versus benefits of treatment and signed a consent form. All patients were treated according to the Medical Declaration of Helsinki for Medical studies.

The following group of treatment categories was used for this study:

- Extraction graft
- Extraction with immediate implant placement
- All-on-four concept
- Peri-implantitis treatment
- Bone augmentation before implant placement
- Implant replacement graft
- Grafting around implant placed in resorbed ridges

Patients were excluded from the data analysis if they presented with bone-related diseases and/or if a different type of bone graft (such as autograft) was used in conjunction with CPS putty for grafting.

Treatment description

Treatment Category 1: Extraction Graft

Grafting was carried out when a tooth was surgically removed and the defect was too large to accommodate an implant. The socket was then grafted and either primary closure was attained or the socket-plug technique was performed.[9] A waiting period of 4 months was allowed for bone regeneration and subsequent placement of an implant.

Treatment Category 2: Extraction With Immediate Implant Placement

The procedure was carried out when a tooth was surgically removed and the defect was favorable for immediate implant placement with good primary stability. Bony defects, voids, dehiscences, or fenestrations that resulted in exposed threads of the implant after immediate placement were included in this category.

Treatment Category 3: All-on-Four

This concept of restoring the total arch in the maxilla, the mandible, or both is frequently used in our practice. The procedure can be used with an edentulous ridge, or a dentate nonrestorable arch. In the latter situation the surgical excision of all remaining teeth is required. Subsequently, extraction grafts (treatment category 1) and immediate implant placement (treatment category 2) are employed, and bone grafts are used to fill the extraction sockets as well as any osseous defects or deficiencies surrounding the 4 implants in each arch. Extraction sockets that received bone grafts as a ridge preservation procedure to reduce postoperative discomfort, minimize bleeding, and aid in long-term maintenance of tissue contours, but did not receive an implant after healing, were excluded from the analysis.

Treatment Category 4: Peri-Implantitis Treatment

In cases where peri-implant osseous defects were identified and bone regeneration was indicated, implant surface decontamination and bone grafting around the exposed implant threads were performed according to Babbush.[1] Briefly, the contaminated implant surfaces were treated with cotton pellets soaked in sterile saline, followed by burnishing of the titanium surface with 1% citric acid. The defects were then rinsed with sterile saline, and grafting of the defect was performed with CPS putty.

Treatment Category 5: Bone Augmentation Before Implant Placement

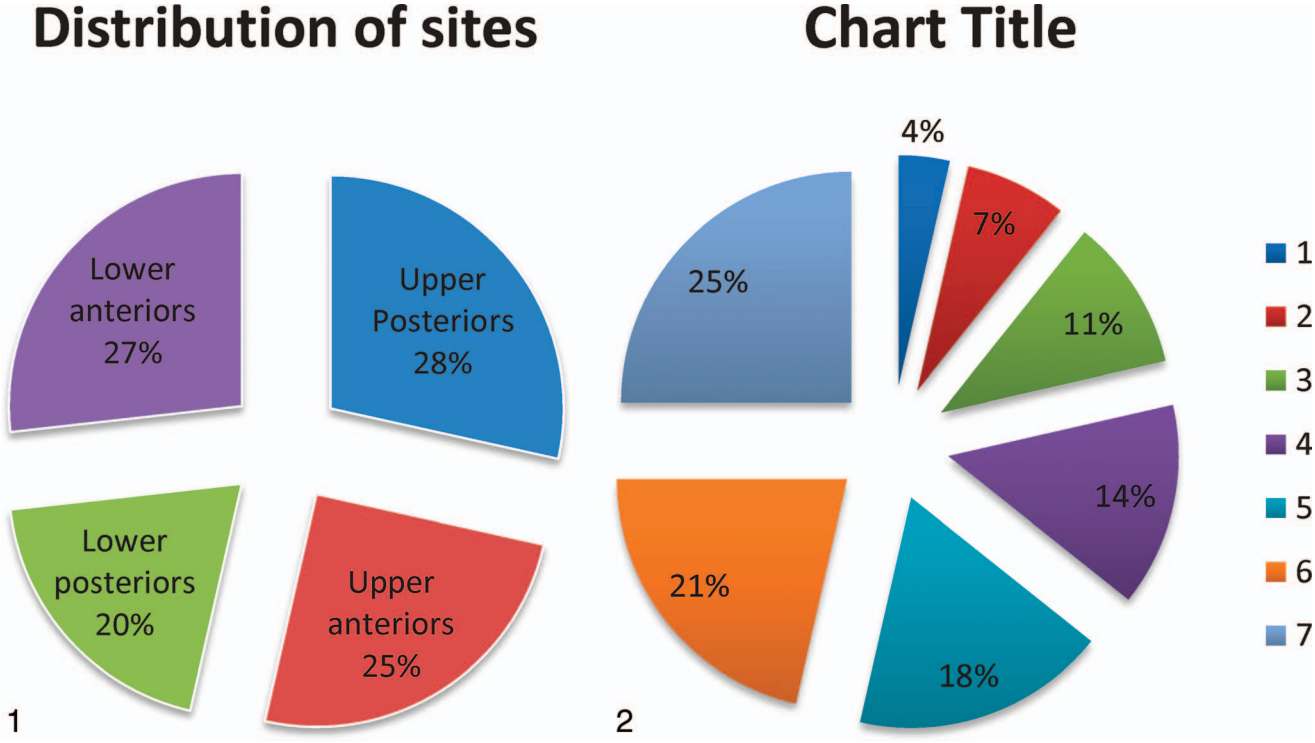
When deficient ridges where encountered before implant placement and the surgeon's judgment dictated that a staged approach should be used, the sites were treated with bone grafting. A 4-month healing period was allowed until implant insertion.

Treatment Category 6: Implant Replacement Graft

When an implant failed, another implant of the same or larger size was used to replace it after enucleation of granulation tissue. Grafting was performed as necessary around the implant to cover any bone defects or voids similar to immediate implant placement.

Treatment Category 7: Grafting Around Implants Placed in Resorbed Ridges

During late implant placement in residual ridges, if bone dehiscences or fenestrations occurred, or even if exposed threads remained at the coronal aspect of the implant, grafting was performed to fill these voids or defects.



Figures 1 and 2. Figure 1. Frequency of distribution of grafted sites in the oral cavity. **Figure 2.** Treatment category 1 = extraction graft; treatment category 2 = extraction with immediate implant placement; treatment category 3 = all-on-four; treatment category 4 = peri-implantitis treatment; treatment category 5 = bone augmentation before implant placement; treatment category 6 = implant replacement graft; treatment category 7 = grafting around implants placed in resorbed ridges.

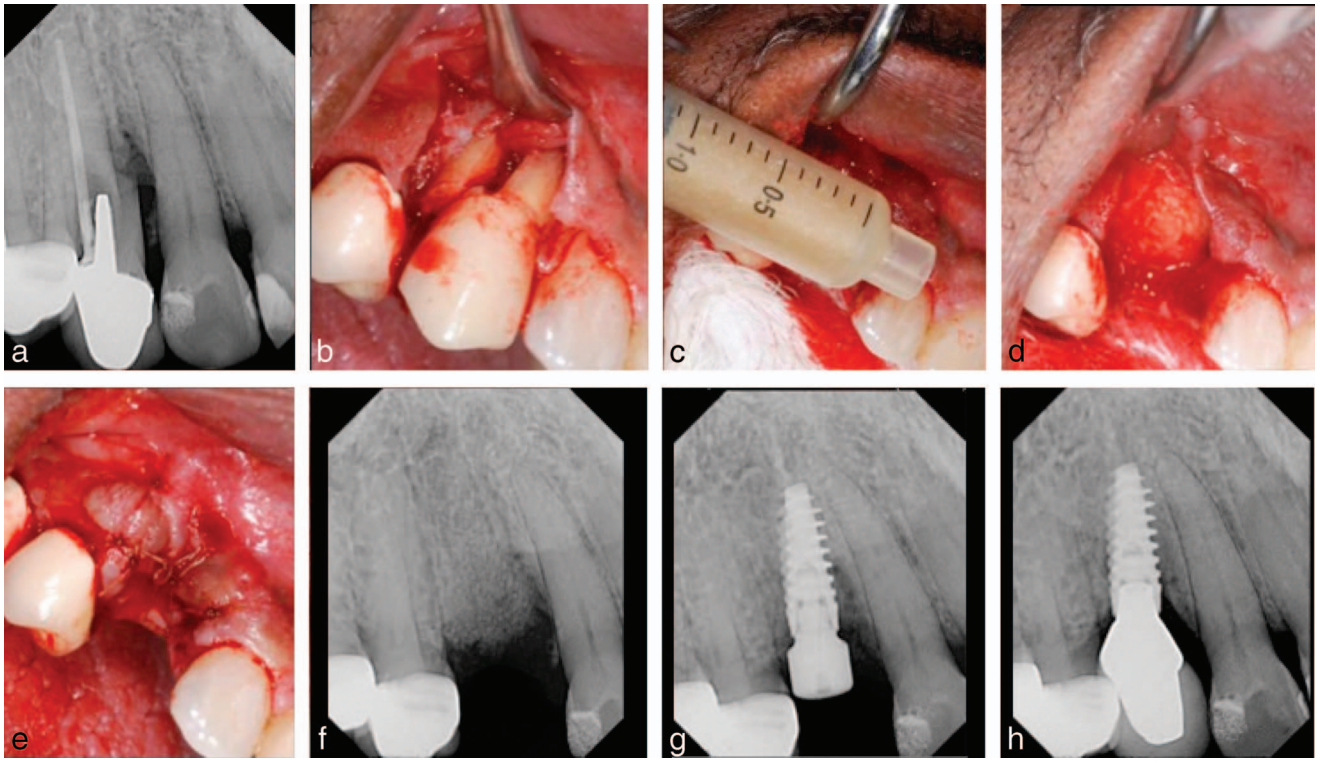


Figure 3. (a) Preoperative periapical radiograph demonstrating nonrestorable tooth. (b) Clinical view of fractured tooth. (c) Calcium phosphosilicate putty syringe at the surgical site. (d) Defect filled with graft material. (e) Clinical view after suturing. (f) Four-month postextraction radiograph. (g) Periapical radiograph with implant and healing abutment in a 1-stage procedure. (h) Periapical radiograph of completed case at 7 months after implant placement and 12 months after grafting.

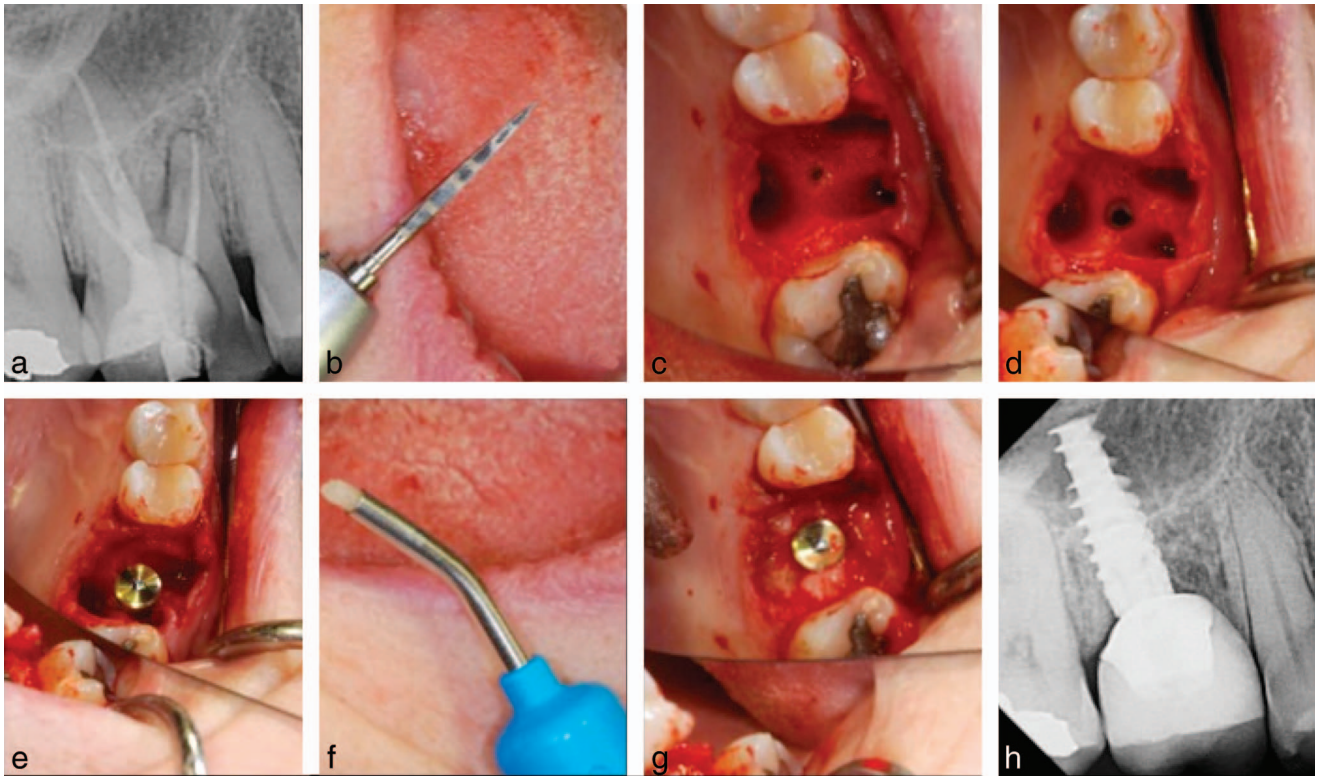


Figure 4. (a) Preoperative periapical radiograph demonstrating nonrestorable tooth. (b) Precision drill used to create the initial implant receptor site in very compromised bone. (c) Clinical view of initial bony receptor site. (d) Final receptor site preparation. Note that the sinus membrane is visible. (e) The implant in position with a healing abutment in a 1-stage procedure. (f) Calcium phosphosilicate (CPS) putty cartridge delivering graft material. (g) Clinical view of socket filled with CPS putty. (h) Periapical radiograph of final crown in position at 7 months after immediate implant placement.

Treatment evaluation

The primary treatment outcome in this study was implant survival in bone regenerated with CPS putty. Clinical examination was performed during each patient's routine maintenance visits that included assessment of implant mobility and/or signs of peri-implantitis.[15] Mobility was estimated by engaging the implant-supported prosthesis with the blunt end of 2 dental mirrors and applying lateral forces. Signs of peri-implantitis were assessed using a graded periodontal probe to evaluate the pocket depth and record for signs of inflammation (bleeding and/or suppuration). A diagnosis of peri-implantitis was established in cases with >5 mm of probing depth with coexisting bleeding on probing and/or suppuration. Additionally, radiographic evaluation using periapical radiographs was performed to evaluate bone loss around implants compared with baseline radiographs taken at the time of loading. Evaluation of patient-reported symptoms was also performed (eg, pain, altered sensation).

Statistical analysis

Demographic and clinical data were reported descriptively using mean as a measure of central tendency followed by the standard deviation as a measure of variability. The 2-year implant survival curve was estimated using Kaplan-Meier survival analysis.[16]

Results

Data from 65 patients (36 men, 29 women) with a mean age of 63 $\pm$ 12 years were included in the analysis. The largest group of surgical sites was located in the maxillary posterior region (28%), followed by the mandibular anterior (27%), the maxillary anterior (25%), and the mandibular posterior (20%) (Figure 1).

In total, 262 implants were placed. Four implants were diagnosed with peri-implantitis and were treated as described in category 4, for a total of 266 grafted sites. The frequency of sites for each indication where the graft was used is shown in Figure 2.

In all cases NovaBone Dental Putty (CPS putty; NovaBone Products, LLC, Alachua, Fla) was used as the bone graft material and patients received Nobel Active implants (Nobel Biocare USA, LLC, Yorba Linda, Calif). Two implants from the extraction graft category and 3 implants from the all-on-four group were lost and replaced with successfully osseointegrated implants during a mean study follow-up period of 12.24 $\pm$ 2.32 months (Figures 3 through 7),

The implant success rate at 1 year was 98.1% (257/262). The Kaplan-Meier implant survival curve for 2 years of follow-up is shown in Figure 8.

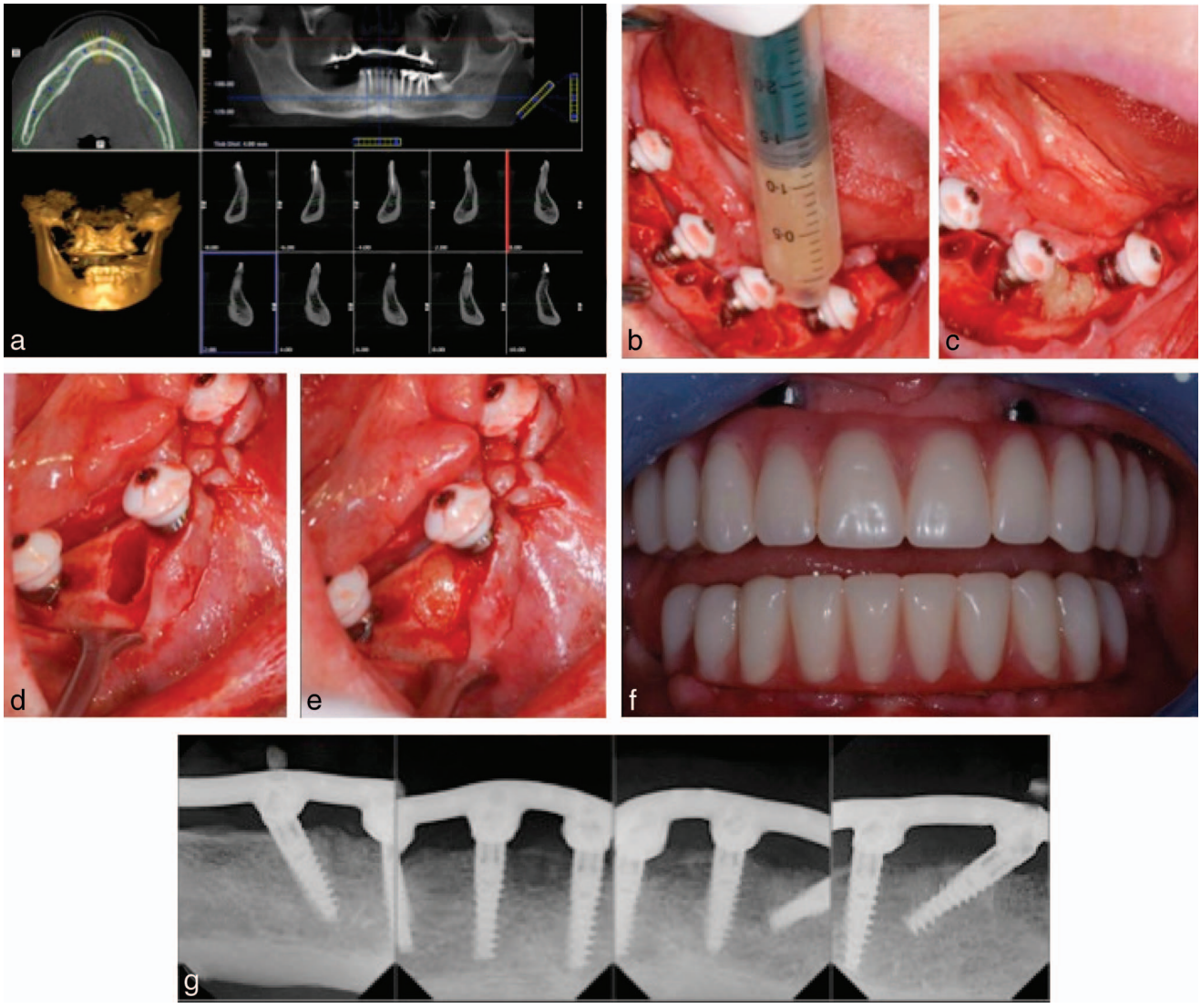


Figure 5. (a) Preoperative cone beam computed tomography scan. (b–d) Clinical view of postextraction sockets and all-on-four implant positions. Calcium phosphosilicate (CPS) putty graft filling extraction sockets. (c and e) Clinical view of postextraction sockets filled with CPS putty. (f) Clinical view of fixed screw-retained maxillary and mandibular definitive prosthesis. (g) Postoperative periapical radiographs demonstrating bone levels and homogenous bony profile at the 12-month follow-up appointment.

Discussion

As bone graft materials constantly evolve to better serve patients' needs, new formulations are put to the test to help clinicians simplify bone augmentation procedures.[12] In the past decade, handling characteristics of bone grafts have been revolutionized with the introduction of bone graft formulations delivered with putty carriers.[7–10]

Babbush[17] was the first author to report the successful use of putty bone grafts for bone augmentation in postextraction sockets and has elucidated the advantages of graft containment by the resorbable carrier. Kotsakis et al[18] have also discussed the benefits associated with the use of an alloplastic bone putty in postextraction sockets, such as ease of handling, no need for the rehydration of the graft, and direct placement in the socket via a cartridge delivery system that minimizes intraoperative time thus minimizing patient discomfort.

These findings are commensurate with findings from this study that showed a significant effect of the CPS putty in simplifying the grafting procedure. Technical issues, such as packing the graft in the defect, containment of the graft particles so that they remain away from sensitive anatomical landmarks (eg, the mental neurovascular bundle), and resistance of the graft to dislodgment as the flap is sutured back into position, are easy to overcome when using a putty graft compared with a particulate one.[19]

In this study a broad category of intraoral defects were treated, ranging from postextraction defects to peri-implant defects and large ridge deficiencies associated with the extraction of ailing implants, among others. Successful bone regeneration yielded in all cases verified the versatile clinical profile of CPS putty. As putty bone substitutes have recently emerged in the market, their broad spectrum of clinical indications has not been explicitly defined. This study presents

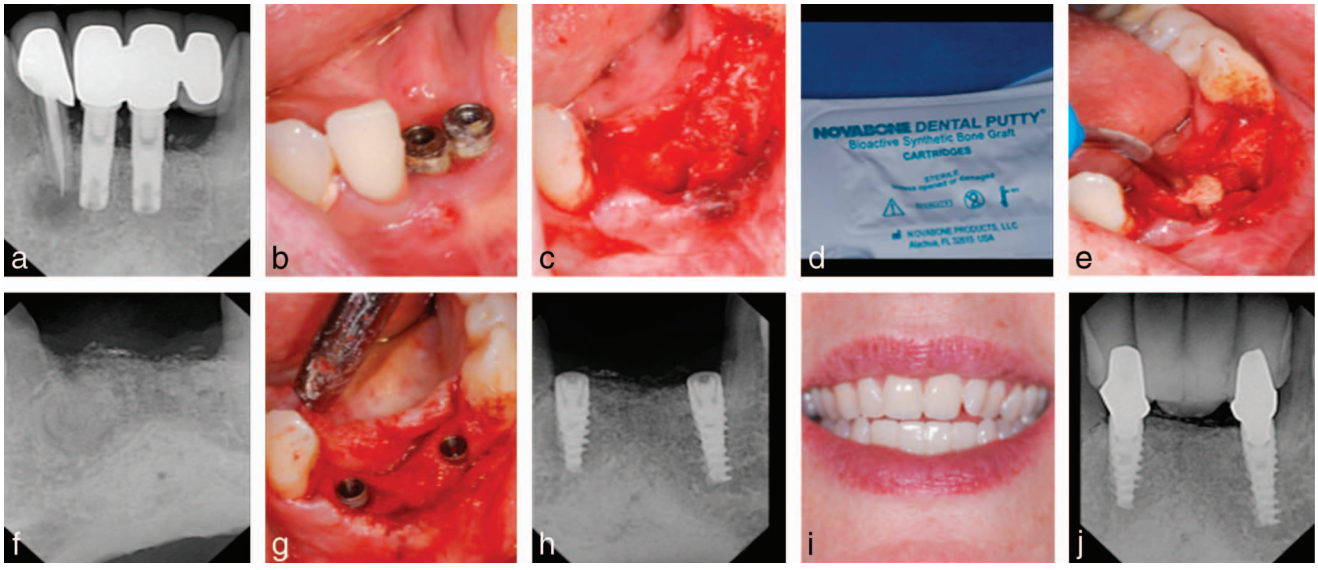


Figure 6. (a) Preoperative clinical view of 2 failing implants and lateral incisor with a periapical lesion. (b) Clinical view of mandibular ridge with nonrestorable implants. (c) Clinical view of residual bony defects after extraction of the 2 implants and lateral incisor. (d and e) Cartridge delivery system used to fill bony defects. (f) Periapical radiograph 5 months after the extraction graft procedure. (g) Clinical view of 2 Nobel Active implants. (h) Periapical radiograph with 2 Nobel Active implants in place in a classic 2-stage procedure at 6 months. (I and j) Clinical and periapical radiograph at final prosthetic reconstruction (8 months after loading).

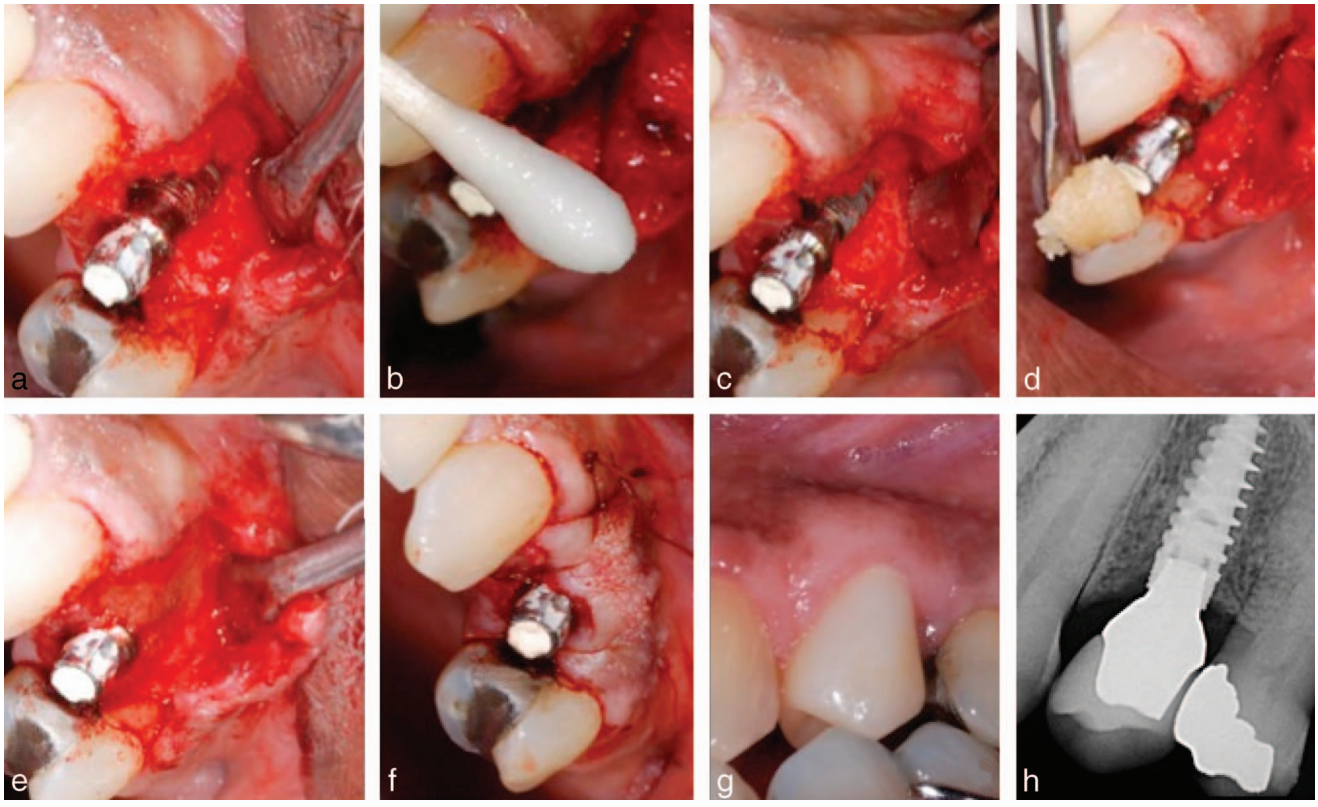


Figure 7. (a) Clinical view with mucoperiosteal flap reflected to expose the buccal bone defect. (b) The 1% citric acid solution used to cleanse the area following debridement. (c) Clinical view of the bone defect. (d) Calcium phosphosilicate putty graft material at osseous defect area. (d) Graft material in final position filling osseous defect. (f) Mucoperiosteal flap repositioned and sutured. (g) Clinical appearance of the healed area 18 months later. (h) Periapical radiograph with final prosthesis at 14 months.

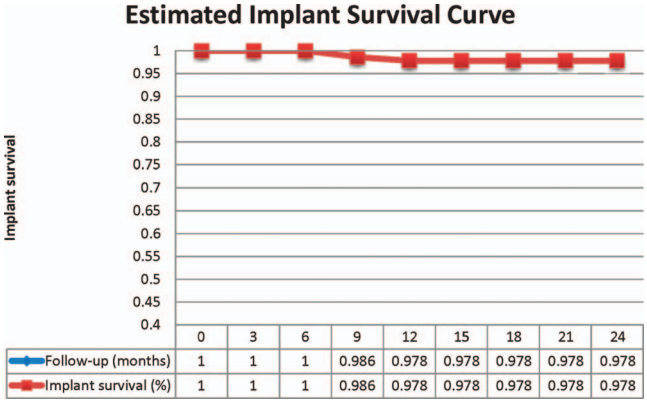


Figure 8. Two-year implant survival curve following Kaplan-Meier survival analysis

the largest array of clinical indications for the use of putty bone grafts to date. Based on histologic data,[7,11] putty bone grafts seem to perform equal or superior to particulate bone grafts.

The general clinical impression from the application of CPS putty in the 266 sites included in this study is that bone grafting can be easily incorporated in any surgical treatment without adding significant time and without requiring specialized techniques or equipment for graft placement. The clinical impression in all cases where reentry was performed was that the newly regenerated tissue was practically indiscernible to the neighboring native bone. When drilling in sites regenerated with the CPS putty the bone density was consistently found to be type D2, or type D3.[19]

All implants placed in the regenerated bone achieved optimal primary stability in both maxillary and mandibular sites. Even though our clinical findings were largely in favor of CPS putty, a limitation of this study is that no histologic analysis of the regenerated bone was performed. Our clinical observations are supported by the histologic findings of Mahesh et al[10,11] who, in a series of studies, noted a very high percentage of new bone growth, around 40% at 4 to 6 months after grafting. Kotsakis et al.[21] also reported more than 30% new bone growth in sockets augmented with CPS putty after a mean healing period of 5.7 months. The authors concluded that the adequate amount of vital bone that was regenerated, in combination with the graft's timely absorption rate, suggest that CPS putty can be a reliable choice for osseous regeneration.[21]

Conclusions

The use of putty bone grafts can simplify bone-grafting procedures and reduce intraoperative time in various grafting indications, and this study verified the efficacy of a CPS putty bone graft biomaterial in a wide array of implant-related surgical indications with good survival rates.

Abbreviation

CPS: calcium phosphosilicate

Acknowledgment

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