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Case Study

Detection of Complete Osseointegration 8 Weeks After Implant Placement with the IPG-DET Technique in the Posterior Atrophic Area of the Maxilla Using Umbilical Cord Stem Cells - Case Report

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Abstract

The IPG-DET technique integrates precise implant positioning with controlled osteotomy, drills expansion and compactors - expanders, enabling implant placement into the sinus safely and minimally invasively - without Sinus Floor Elevation (S.F.E.) such as the need for a lateral window approach.

A clinical case reports a 60-year-old male patient who underwent implant placement in the atrophic posterior left maxilla with the innovative IPG-DET technique. This approach involves the intentional perforation of the Schneiderian membrane, followed by the application of autologous concentrated growth factors (CGF), a CD34+ stem cell matrix obtained via centrifugation and cell separation of the patient's intravenous blood, and mesenchymal stem cells (MSCs) derived from human umbilical cord tissue in the reconstruction of posterior maxilla.

The technique was developed as a minimally invasive alternative for posterior maxillary reconstruction, aiming to promote sinus regeneration, reduce intraoperative bleeding and both intra- and postoperative complications, and shorten the overall duration required for implant placement in the challenging posterior maxilla.

In this case, we investigate the effectiveness and healing response for osseointegration, associated with the integration of Mesenchymal Stem Cells (MSCs) derived from human umbilical cord blood in the reconstruction of the posterior atrophic maxilla. Preliminary outcomes indicate successful and safe bone regeneration within the sinus cavity.

Keywords: *Umbilical Cord Blood Stem Cells; Bone Augmentation; IPG-DET Technique; Intentional Sinus Membrane Perforation; Osseointegration; Concentrated Growth Factors and CD34+ Stem Cells*

Introduction

Sinus floor elevation is a widely utilized technique for augmenting the posterior maxilla when bone height is insufficient for dental implant placement. Traditional approaches, including the lateral window and transcrestal techniques, are often associated with complications such as membrane perforation and prolonged healing times. To address these challenges, IPG-DET technique (Ioannis P. Georgakopoulos - Dentist Education Institute) [1] has emerged as a minimally invasive approach, providing an effective alternative to the traditional sinus floor elevation methods.

Recent advancements in regenerative dentistry have highlighted the potential of stem cell-based therapies to enhance bone regeneration and improve the stability of dental implants. Among various stem cell sources, umbilical cord-derived mesenchymal stem cells (UC-MSCs) have shown notable osteogenic capabilities and immunomodulatory effects, making them a promising tool in bone tissue engineering [2]. Integrating UC-MSCs into the IPG-DET may significantly augment bone regeneration while reducing complications typically associated with sinus augmentation procedures.

This case report describes the clinical application of the IPG-DET technique combined with cryopreserved UC-MSCs and concentrated growth factors (CGFs) derived from the patient's autologous blood. The objective is to assess the efficacy of this novel regenerative strategy in promoting new bone formation and achieving successful implant osseointegration in a patient with substantial maxillary bone atrophy.

Goals, Materials and Methods

The aim of this prospective clinical study was to evaluate the possibility of full osseointegration of dental implant after placement in the posterior atrophic maxilla, 10 weeks postoperatively as diagnosed by the IPG-DET (Ioannis P. Georgakopoulos - Dentist Education Institute) method. The patient gave his written informed consent, and the study protocol was approved by institutional review board in accordance with the Declaration of Helsinki.

The implants were placed with a minimally invasive technique under local anesthesia. Human umbilical cord mesenchymal stem cells (HUC-MSCs) were conditioned in the sterile environment according to Good Manufacturing Practice (GMP) before implantation. The stem cells were mixed in suspension and implanted into sites of osteotomy for induction of osteogenesis and speeding up the process of early bone resorption.

The implant was a TC-R IESS-MultySystem diameter 4,2 and length 10, with system with incomplete primary stability in the site.

Post-operative management consisted of a soft meal diet and antibiotic prophylaxis.

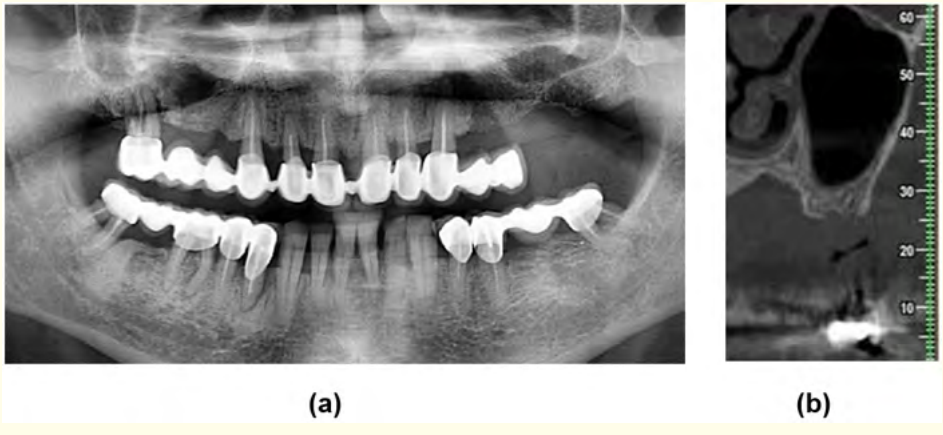

Figure 1: *(a) Pre-operative panoramic X-ray, (b) Detail of Pre-operative CBCT showing atrophic maxilla.*

Execution of treatment

IPG-DET technique and CGF protocol

Initially, the patient's blood is drawn and centrifuged using the Medifuge MF200 (Silfradent, Italy) in sterile 6 vials of 9 ml tubes. After centrifugation, among the produced three blood fractions, the intermediate one is selected, which contains a fibrin-rich gel comprising platelets, Concentrated Growth Factors (CGF), and CD34+ stem cells [2].

The osteotomy is carried out using the following sequence of drills: a) Pilot drill Ø 1,8 mm, initial drill Ø 2,55 mm, b) IESS-MultySystem compactor- expander 3, c) IESS-MultySystem compactor - expander 3,5 (IESS GROUP-MultySystem Dental implants, - Via della Salute 23, Pozzuolo del Friuli - UD, Italy), until intentional perforation of the Schneiderian membrane is achieved.

The drilling procedure with the first two burs should be performed under reduced irrigation using saline solution at room temperature and at the lowest possible speed to minimize bone loss. Therefore, the surgical micromotor control unit must be set to the minimum rotational speed, approximately 100-200 rpm. Subsequently, osteotomes are used manually with the IESS GROUP-MultySystem extralong screwdriver handle. Additionally, the insertion torque should be applied manually and should be measured between 35-40 Ncm for implant placement.

MSCs protocol

Mesenchymal Stem Cells (Invitra-DX Dental CBSC - cord blood stem cell Suspension-TM, Invitrx Therapeutics, Inc., USA) are stored in their original container (1 cc) at -80°C, allowing delivery and use in the operating room two hours prior to the procedure.

The preparation protocol is as follows:

- Remove the product from cold storage by opening the outer box.
- Extract the frozen vial from the container - It must not be placed directly on the sterile field.
- Once defrosted (using the assistant's hands while wearing sterile gloves), a sterile syringe is used to aseptically draw the vial's contents for surgical use.
- The Invitra-DX Dental CBSC Suspension-TM is now ready for application.

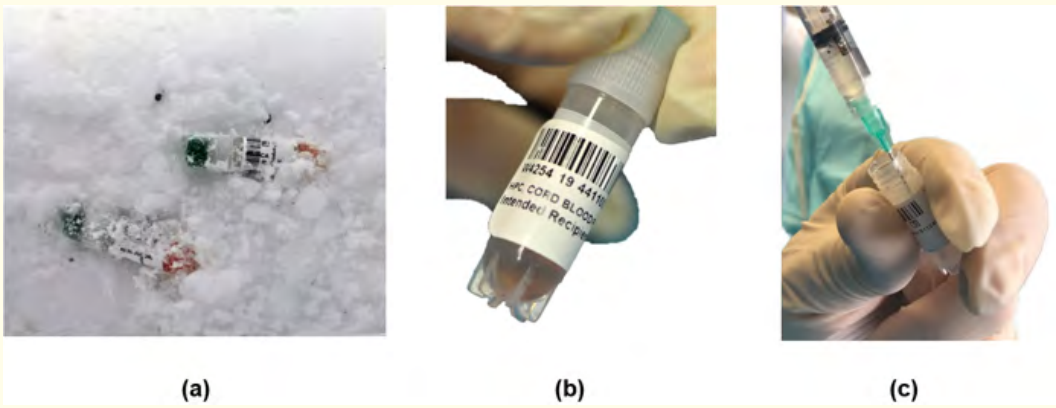

Figure 2: *(a) The Mesenchymal Stem are stored at -80°C. (b) Extraction of the frozen vial from the container using sterile gloves. (c) Sterile syringe is used to aseptically draw the vial's contents for surgical use.*

Continuing with the IPG-DET Technique along with the CGF and MSCs protocols, one or two CGF matrices are introduced through the osteotomy and membrane perforation into the sinus using a fibrin injector (Silfradent, Italy), prior to implant insertion (Biphasic implant TC-R diameter 4,2 and length 10 IESS-MultySystem Italy). The implant fixture is first immersed in the LPCGF (liquid phase concentrated growth factors) [10]. A "bioenergetic autologous membrane" around it, and subsequently in the Invitra-DX Dental CBSC Suspension-TM, prior to placement.

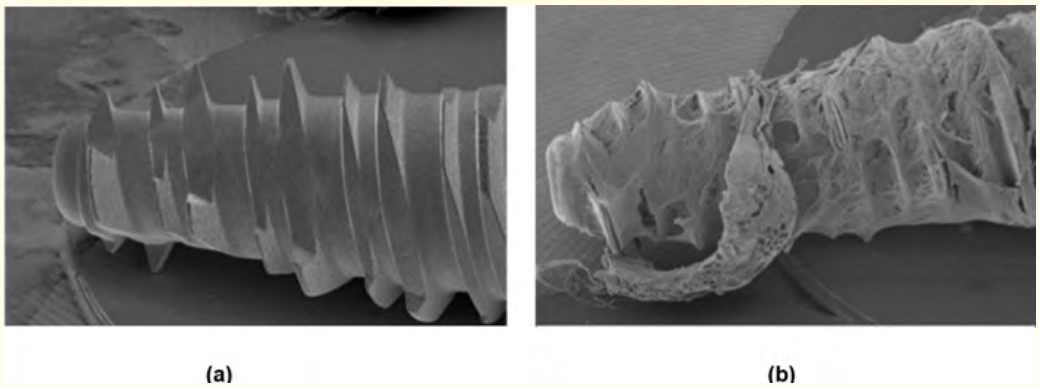

Figure 3: *(a) Electron Microscope image shows an implant before it's immersed in the LPCGF (EHT=10.00 kv, WD = 30 mm). (b) Electron Microscope image shows an implant after it's immersed in the LPCGF with the "bioenergetic autologous membrane" around it (EHT=10.00 kv, WD = 30 mm).*

Photos courtesy of Silfradent, Italy.

The TC-R implant is inserted into the osteotomy (1 mm subcrestally) with the IESS-MultySystem driver on the IESS-MultySystem extralong screwdriver manual key. (IESS-MultySystem, Italy) under controlled conditions. Following this, a wide cover screw IESS-iRES (screw 2,5 diameter 5,2) is placed, and the remaining Invitra-DX Dental CBSC SuspensionTM is injected around the surgical site and implant. Finally, the CGF membrane is positioned over the implant site and the area is sutured.

Due to an incorrect clinical decision, the surgeon immersed the cover screw in Betadine prior to its placement. As a result, approximately eight weeks later, during an attempt to evaluate implant stability using the Osstell device and Resonance Frequency Analysis (RFA), it was not possible to remove the cover screw.

The screw had become immobile and appeared to have fused with the implant, preventing its unscrewing.

This was attributed to corrosion [3,4] of the implant's titanium surface caused by the Betadine exposure. The case was referred to the WAGRO Dental clinic of Dr. Ioannis Georgakopoulos, in Athens-Greece. A renewed attempt to remove the sealing screw was unsuccessful, leading to the decision to proceed with the removal of the implant using a trephine bur Ø 6 mm. Upon extraction, the implant demonstrated excellent osseointegration and notably high bone quality, especially considering the short healing period of 10 weeks (2.5 months). The specimen was submitted for electron microscopy analysis, which confirmed the excellent quality of the bone.

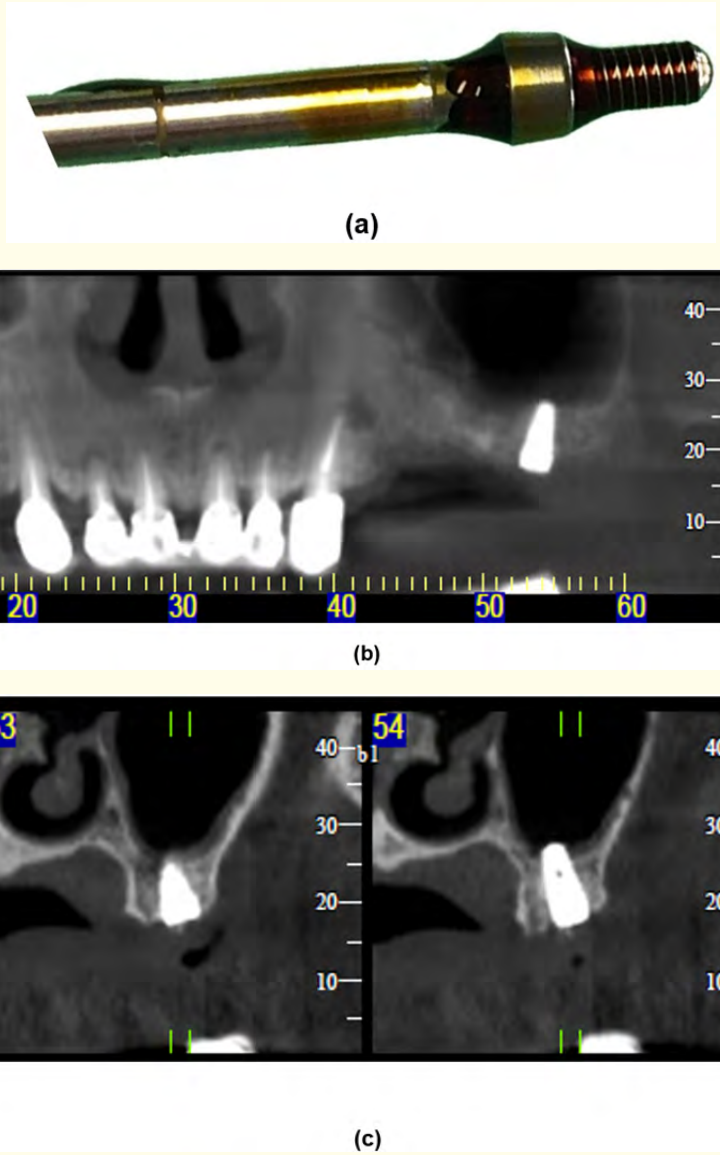

Figure 4: *(a) The screw became fused to the implant because it was mistakenly soaked in povidone-iodine (Betadine) before placement, causing corrosive reaction. (b) Detail of the Post-op CBCT following implants placement in the upper left maxilla. (c) Detail of the Post-op CBCT region 53-54 following implants placement in the upper left maxilla showing complete osseointegration and bone height of approximately 9 mm. A vertical bone regeneration was observed.*

Results

The implant site remained free of inflammation and infection while showing no signs of soft tissue dehiscence during the 8-week follow-up appointment which occurred two months after surgery. The cone-beam computed tomography (CBCT) radiographic evaluation showed radiodense peri-implant bone that indicated complete early osseointegration. The implant displayed stability because probing and percussion tests showed no signs of movement.

The attempt to remove the cover screw and perform an Osstell test, revealed that the screw had bonded to the implant, making it impossible to remove. The screw became fused to the implant because it was mistakenly soaked in povidone-iodine (Betadine) before placement which probably caused a corrosive reaction between titanium and the chemical resulting in chemical fusion.

The implant removal proceeded through trephining with a 6 mm trephine bur despite the existing complication. The extracted implant showed robust osseointegration and outstanding bone contact which could be seen through microscopic examination. The surrounding bone tissue displayed dense structure along with active blood vessels while remaining free from signs of infection and necrosis.

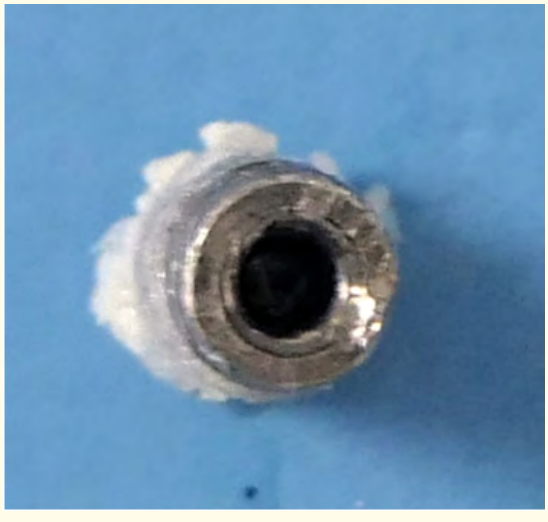

Figure 5: *The extracted implant showed its upper side damaged by the failed attempts to remove the cover screw.*

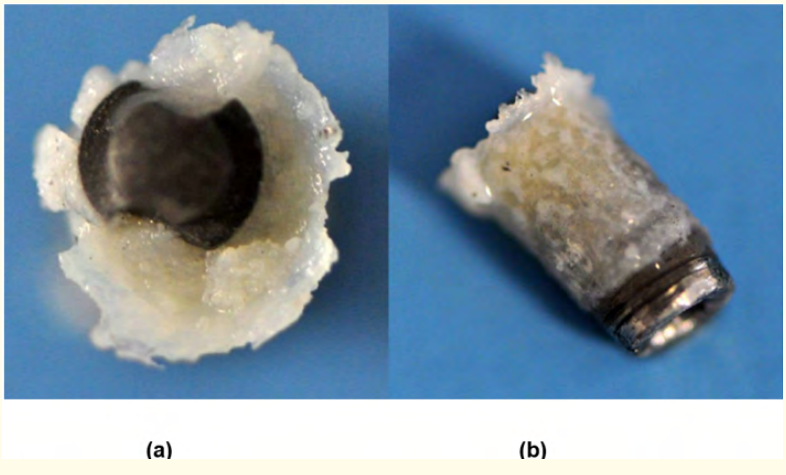

Figure 6a and 6b: *The extracted implant showed robust osseointegration and outstanding bone contact.*

The electron microscope images of bone-implant interface revealed mature lamellar bone with active osteoblastic activity and dense collagen matrix together with no inflammatory infiltrates. The E.M. results demonstrated fast and high-quality bone healing, which supported the effectiveness of IPG-DET procedure with CGF and umbilical cord-derived MSCs.

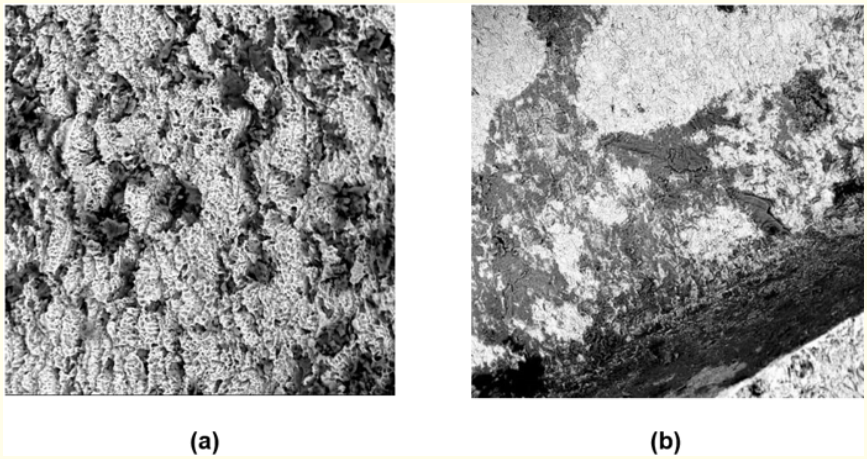

Figure 7: *Morphological analysis of the bone-implant interface was conducted using scanning electron microscopy (SEM). Histological examination of the interface revealed (a) mature lamellar bone with active osteoblastic activity, and (b) a dense collagen matrix with no evidence of inflammatory infiltrates.*

Discussion

Clinicians encounter maxillary bone loss in posterior regions as a frequent challenge during their everyday practice. The well-documented surgical procedure of sinus floor elevation involves membrane elevation for graft placement before implant placement in these specific regions. Since Hilt Tatum first described the lateral window procedure in 1975 multiple alternative methods emerged including the osteotomy approach (Summers RB, 1994) and the minimally invasive techniques which consist of Balloon elevation, Hydraulic pressure, Gel pressure, Piezoelectric system, Reamer mediators, Using CPS putty, Using osseodensification burs and CAD- CAM [5].

The literature identifies sinus membrane perforation as a complication in SFE procedures which occur at a rate of 15.7% according to Stacchi., *et al*. [6].

The IPG-DET technique introduces the immediate implant placement in the sinus cavity with intentional sinus membrane perforation by simultaneously employing concentrated growth factors (CGF and CD34+ stem cells) and bone grafting material that differs from traditional SFE procedures [7]. In that case, IPG-DET does not lift the membrane, it punctures it.

This case study demonstrates how IPG-DET combined with CGF and CD34+ stem cells and MSCs from umbilical cord blood allows successful and fast bone healing in atrophic posterior maxilla areas.

The traditional process of sinus floor elevation together with bone grafting in severely atrophic maxilla requires a healing time of 4-6 months. This patient showed complete osseointegration in just 8 weeks which indicates an accelerated healing process compared to traditional methods. The combined action of concentrated growth factors together with CD34+ progenitor cells and MSCs likely accelerated the process by:

- The enhancement of angiogenesis and cellular proliferation process.
- Osteoblastic cells transformed into bone cells which produced bone matrices.
- The immune response became regulated to reduce inflammation.

This case also highlights the importance of following the surgical protocols. The application of Betadine on the sealing screw led to corrosion which caused permanent mechanical binding of the titanium components. Research shows that povidone-iodine damage titanium passive oxide layers particularly when combined with chlorides which leads to galvanic and pitting corrosion [8,9].

The electron microscopy became possible because of the explanation procedure even though this error occurred. This unique regenerative method yielded valuable information about its healing quality.

Conclusion

The IPG-DET technique, which shows strong potential, leverages the regenerative properties of autologous CGF-CD34+ cells only or in combination with the clinical use of stem cells from umbilical cord blood. This approach has demonstrated encouraging results, including faster osseointegration, fewer post-surgical infections and less pain for patients. Nevertheless, studies involving larger groups of patients and extended follow-up periods are needed to confirm these findings and establish more conclusive evidence.

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