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Review Article

New Generation Dental Implants Based on Transformational Low-Cost/Multifunctional/ Outstanding Biocompatible Ultrananocrystalline Diamond (UNCD) Coating of Current Commercial Metal Implants

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Abstract

Dental implants (DIs)' materials should exhibit osseointegration (strong attachment to maxillary bone, via bone cells' growth on DIs'surface), resistance to oral fluids' chemical corrosion, mechanical strenght, biocomptibility via biochemical interaction with oral system. Materials currently used in DIs include:

- Ti-6Al-4V alloy, exhibiting relative mechanical strength, suitable biocompatibility and osseontigration. However, no attention focused on the fact that Ti-alloys have TiO_2 surface layers, via atmospheric exposure, resulting in oral fluids-induced desorption of TiO_2 particles, killing mouth tissue's cells, resulting in ~ 15% DIs' failure, worldwide, in first 4-5 years, requiring replacement with extra cost and patient disconfort.
- Ceramic ZrO_2 gained popularity for patients prefering metal-free DI. However, ZrO_2 DIs revealed similar problem as TiO_2.

Based on the above information, new materials with order of magnitude better multifunctionalities, may provide pathway for superior DIs. Thus, this article focuses on reviewing R&D that addressed issues discussed below:

1) Demonstration that oral fluids eject TiO_2 particles from DIs' TiO_2 slayer, injecting in maxillary tissue, killing natural cells, inducing DIs' failure.

2) Coating Ti-6Al-4V - DIs with unique transformational low-cost Ultrananocrystalline Diamond (UNCD) coating, with unique combined properties for DIs, namely:

- Lowest friction coefficient (0.03) vs. other materials (≥ 0.5) and NO mechanical degradation because 98 GPa hardness, similar to 100 GPa hardness of diamond gem.
- Oustanding resistance to chemical corrosion revealed by Raman and X-ray photoelectron Spectroscpy analysis of UNCD coating exposed to oral fluids.
- Outstanding biocomptibility because UNCD is made of C atoms-element of life in human's DNA/cells/molecules, enabling superior bio-chemical interacton with natural maxillary bone and tissue's cells formed by C atoms.
- UNCD coatings are grown by microwave induced plasma cracking CH_4 molecules flown in air evacuated chamber, producing C-based species linking chemically on Ti-alloy DIs' surfaces.

Clinical trials implanting 51 patients with UNCD-coated Ti-alloy DIs, demonstrated outstanding performance discussed through this **review.**

Keywords: Titanium-alloy; Dental Implants; TiO_2 Film; TiO_2 Particles; Maxillary Tissue Degradation; Best Biocompatible; Strongest; Chemical Corrosion Resistant; Ultrananocrystalline Diamond (UNCD); Coating; Superior DIs

Introduction

A Brief History on Dental Implants‘ Materials and Their Effects When Implanted in Human Maxillary Bone

- Carved bamboo pegs were used, as first known dental implants (DIs), in China, **four thousand years ago**, to replace missing teeth.
- Human remains from 3000 years ago, discovered in Egypt, showed that Egyptians used metals, like copper, as prosthetic teeth. The Egyptians were the first culture to use metal implants replacinmg destroyed teeth.
- A 2300-year-old DI was discovered in a skeleton’s mouth in a Celtic grave in France. The DI was held by an iron (Fe) pin, which may induce extreme painf during implantation. Ancient Romans used gold (Au) pins.
- About 2000 years ago, human teeth were replaced with animals teeth (today defined as heteroplastic implant) or slaves or poor people’s teeth (today defined as homoplastic implant). In many cases, animal or human replacement teeth are rejectes by the host human body, inducing infection.
- Archaeologists, looking in 1931, at a young Mayan woman’s remains, from 630 AD, discovered 3 missing natural incisors replaced with pieces of seashell. The investigation revealed growth of bone’s cells around 2 of the implants, providing evidence of osseointegration.

In the 20 Century (1960s), Dr. Brånemark and colleagues discovered, accidentally, that a metal could stick to a human bone, when introducing a camera in a rabbit’s tibia, to observe circulatory and celular changes in living tissue. They used a camera with an external cover made of Titanium (Ti), implanted in a rabbit’s bone. When removing the camera, they found that the bone was very well adhered to the titanium metal surface, which demonstrated that Ti could have good integration with human bones, providing a key material for prostheses, including DIs, implantable in human maxillary bones. The phenomenon of metal integration with bones was named Osseointegration and extensively investigated initially for DIs by Brånemark and colleagues [1-3].

Ti or Ti-alloys are currently extensively used for fabrication of prostheses to replace degraded/destroyed natural bone-based parts of the human body (e.g., teeth, hips, knees). The use of Ti-based materials is based on early R&D, which demonstrated that these materials exhibit relatively good biocompatibility and are potentially resistant to chemical and mechanical effects induced by the human body. However, many studies, in recent years, by academic, industrial and medical re-searchers demonstrated that metal-based prostheses undergo several types of failure, mainly induced by the combined chemi-cal/mechanical environment of the human body.

Extensive R&D revealed failure of metal DIs due to combined chemical reaction of atoms on the metal’s surface with biomolcules in the oral system and mechanical stress induced on the DIs’ metal by the biting action during food eating in the human mouth (see selective references [3-14]. It has been shown that Ti-based implants, already covered by a TiO_2 layer, from exposure to atmosphere, may exhibit TiO_2 particles ejection from the oxidized layer, upon exposure to body fluids, resulting in insertion into surrounding tissues, inducing inflammation and tissue death (necrosis), as shown for Ti-alloy DIs [7-11]. In addition, TiO_2 particles ejected from Ti-alloys prostheses may enter into the blood stream and insert into organs (e.g., liver, spleen, and abdominal lymph nodes) [15], and in body fluids [16] and blood streams [17], producing serious biological deleterious effects, as shown in recent studies by Tasat et al., who compared the effect of TiO_2 and ultrananocrsytalline diamond (UNCD) (3-5 nm dimensions) particles injected in lung and liver of Wistar rats [18]. TiO_2 caused areas compatible with foci of necrosis in the liver and renal hyaline cylinders, while UNCD particles did not induce any membrane damage (thiobar-bituric acid reactive substances (TBARS)) or mobilization of enzymatic antioxidants either in the lung or liver samples [18].

Chemical/Biological Process Destroying Natural Teeth

According to the American Dental Association (ADA), teeth’s degradation is induced by acids and carbohydrates, such as sugars and starches in foods, such as milk, fruit, cookies, and/or candy, left on the teeth’s surface after eating. Bacteria in the mouth react chemically with foods to produce acids, which can destroy the teeth’s enamel, via chemical reaction inducing teeth’s material degradation [19], thus, development of caries, also known as cavities, on the teeth. In addition to the biological induced degradation described above, medications, such as antihistamines and anti-depressants, also affect teeth negatively. In addition, poorly cleaned teeth and receding gums may affect the roots of the teeth inducing caries [20-22].

Replacement of Destroyed Natural Teeth by Dental Implants

Currently, metal-based (mainly Ti-6Al-4V alloys) DIs are placed below the gum line anchored into the bone as shown in Figure 1 (right). A ceramic crown is insertod on top of the DI’s metal to reproduce the structure of the natural tooth (Figure 1-left). The main reason for replacing the missing natural tooth with a DI is to stop the jawbone from collapsing, re-stablish function and also for esthetics reasons [23]. The DI stimulates the normal jawbone functionality. In addition, for the bone to remain healthy, it needs stimulation [24], thus, immediate replacement of a destroid natural tooth with a DI, provides protection against bone resorption. Extensive worldwide research showed less bone resorption (about 75%) is produced when the empty tooth area in the maxillary bone is covered by a DI. In this sense, It is critical to insert a DI within a year after a tooth is lost, since most bone resorption occurs during this time [23].

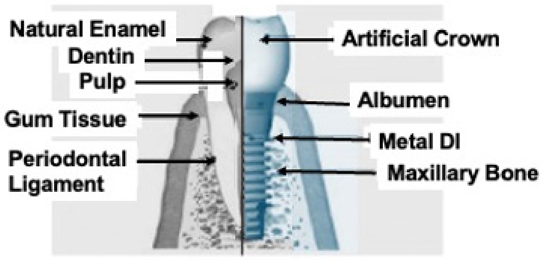

Figure 1: Schematic of Natural Tooth (left) and metal-based DI (right) + artificial crown inserted on top of the DI connected to maxillary bone.

Materials and Methods

Physical and Chemical Effects of Oral Fluids on Ti-Alloy Dental Implants (DIs) and Transformational/Best Biocompatible/Low-Cost Ultrananocrsytalline Diamond (UNCD™) Coating on Ti-Alloy DIs

Most metal DIs perform well. However, reports in the literature reveal that there is non-desirable relativel early rate of failure in first 4-5 years, reaching about 15% worldwide [1, 25], requiring DI replacement, mainly, due to corrosion by oral fluids. Figure 2 (a) shows a schematic of a Ti-alloy dental DI, and the materials components in the DI, i.e., metal Ti-alloy and the TiO_2 layer developed by exposure of the Ti-alloy metal to the atmospheric environment before insertion into the human mouth. Figure 2 (b) shows a picture of a commercial Ti-6Al-4V DI, extracted from a patient's mouth, revealing extensive corrosion induced by oral fluids. The undesirable outcome of DI failure is the extra cost and discomfort to the patient. A big problem relates to the corrosion of Ti-6A-4V DIs by oral fluids, which react chemically with the TiO_2 layer on the DIs' surface, inducing ejection of TiO_2 particles from the TiO_2 layer, inserting them into the mouth tissue, inducing death of live cells (Figures 2 (c) and 2 (d)). Studies by different groups have shown this deleterious phenomena [8, 12, 14, 26], In addition, studies by different groups revealed that TiO_2 particles, dislodged from the TiO_2 surface layer of the DIs, can migrate extensively though the human biological system via blood circula-tion [12, 17, 18, 26], potentially inducing biological deleterious effects in several organs, e.g., liver, spleen and abdoaminal lymph nodes [15].

Based on the tests done in the laboratory, shown in Figure 2 (d), biokinetics and biological effects were compared between UNCD and TiO_2 nanoparticles, using in vivo tests on Wistar rats (n=30), injected with TiO_2 and UNCD nanoparticles, or saline solution as control. Following six months period, blood, lung, liver and kidney samples, extracted from the rats, were analyzed by histological tests. Damage via membranes' lipidperoxidation formation of the byproduct Thiobarbituric Acid Reactive Substances (TBARS), generating reactive oxygen species (O_2), and antioxidant enzymes (SOD, CAT) were evaluated in the lung and liver samples. Histological observation showed agglomeration of TiO_2 or UNCD nanoparticles in the parenchyma of the studied organs. The Studies revealed that there were much fewer UNCD than TiO_2 nanoparticles deposits. In addition, it was observed that TiO_2 nanoparticles caused deleterious foci of necrosis areas [18]. On the contrary, related to effects of UNCD nanoparticles in the biological studies, no membrane damage nor TBARS byproducts or mobilization of enzymatic antioxidants was observed either in lung or liver samples [18], and no variations in O_2 generation were observed in the lung. On the contrary, expo-sure to TiO_2 nanoparticles caused production of O_2 in alveolar macrophages and consumption of catalase [18].

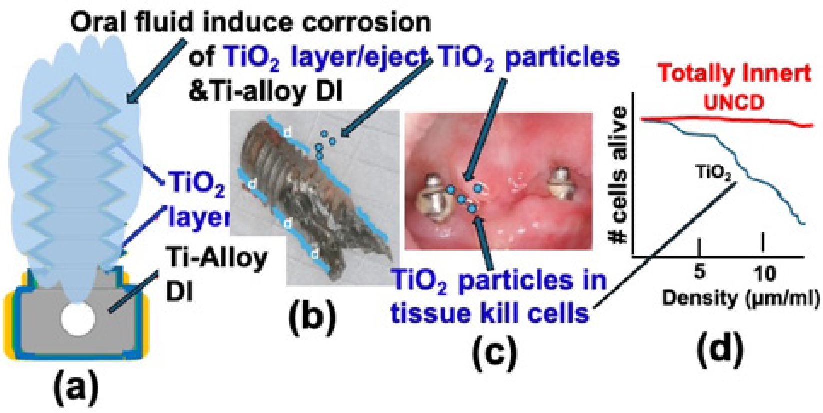

Figure 2: (a) Schematic of Ti or Ti-alloy DIs showing the TiO_2 layer grown on any Ti or Ti-alloy materials exposed to the atmospheric environment; which are chemically corroded by the oral fuids, which also corrode the underying Ti-based material, as shown in (b); (b) Oral fluids dislogue TiO_2 particles (blue dots) from the oxide layer; (c) TiO_2 particles insert into the mouth tissue (bue dots), inducing death of live cells as shown in Figure (d), representing experimental measurements in the lab environment where live cells were exposed to TiO_2 particles; in addtion Figure (d) shows that UNCD is totally chemically innert in the interaction with live cells of the mouth, confirming the supertior biocompatibility of UNCD.

Research by worldwide groups have shown that some DIs could have other problems, instead or in addition to those described above, such as no ossification (i.e., no strong adhesion to the maxillary bone, because low density bone's cell growth on the surface of metal DIs), bone infection, broken prosthesis and infection around the gum after DI's implantation. In addition, other biologically induced negative effects induced by smoking and antidepressants' intake may contribute to DIs' failure.

The information presented above reveals that metals used for DIs, although may perform appropriately in many human beings, they fail early than desirable (4-5 years) in a relatively undesirable ~ 15% of cases, as proven in worldwide statistics [1, 25]. Therefore, it is critical to develop new materials for DIs and eventualy for other Ti and Ti-alloy-based prostheses (e.g., hips, knees, elbows, and several more), which also exhibit undesirable relatively shorth lifetime, even if in relatively small percentage also, due to combined mechanical/chemical corrosion complementary effects [27].

A relatively straightforward pathway to solve the problem related to chemical corrosion-induced failure of metal prostheses is to coat them with a coating based on a material extremely resistant to chemical corrosion by any body fluids (oral fluids for DIs). In addition, the coating should provide a surface that induce superior density of bone cells growth to induce superior osseointegration in bones, and provide a complementary strong mechanical behavior when exposed to strong mechanical effects, as for DIs subjected to strong mechanical impact during food mastication, or hips and knees subjected to strong friction during walking. In this sense, the Ultrananocrystlline Diamond (UNCD™) coating described in this article has been demonstrated to exhibit unique complementary outstanding mechanical performance/total resistant to chemical corrosion by anybody or other fluids, including the strongest known acid (HF), and most important, UNCD™. exhibits the best biocompatibility, because it is made of C atoms (element of life in human DNA, cells, molecules), as described extensively in a recent book [28].

Transformational Best Biocompatible Nanocarbon-Based Coating Named Ultrananocrystalline Diamond (UNCD™)

Growth of UNCD Coatings on Surfaces Seeded with UNCD Particles:

The UNCD coating, grown by an originally unique Microwave Plasma Chemical Vapor Deposition (MPCVD) process was developed based on R&D directed by Auciello/Gruen/Krauss in the 90s [29] and patented for commercialization [30]. The name UNCD was trade-marked (UNCD™). However, to make the text simpler through this article, the used name will be UNCD. The original process, to grow UNCD films (coatings), involved two key steps:

1. Seeding the substrate surface with nanocrystalline diamond particles via insertion of the substrate in an ultrasonic system exposing the surface to a methanol solution containing UNCD (3-5 nm diameter) particles shacked by the waves that insert them on the substrate surface as seeds to induce the UNCD film growth.

2. Growth of UNCD film via a Microwave Plasma Chemical Vapor Deposition (MPCVD) process implemented in a MPCVD industrial system (Innovative Plasma System (IPLAS)-GMBH-Germany). The MPCVD process involves flowing a novel pa-tented [30] mixture of gases (Ar (99%)/CH4(1%), see References [29, 30] and Reviews [31, 32]) into an air evacuated chamber to pressures in the range 10^{-6}-10^{-8} Torr, which with the gas flow raises to pressures in the range 20-40 mbarr, and coupling microwave power to create a plasma that induce cracking of the CH_4 molecules into a mixture of (C=C) linked atoms, named carbon dimers (C_2), inducing a green light from the plasma, as determined via in situ/real-time optical emission spectroscopy of the plasma, and CHx (x=1, 2, 3) molecules. The named MPCVD process, involves reactions as shown in formulas (1) and (2) below:

$$2CH_4 \rightarrow C_2H_2 + 3H_2 \quad (1)$$

$$C_2H_2 \rightarrow C_2 + H_2 \quad (2)$$

Calculations predicted that the C_2 dimers provided low activation energy (~6 kcal/mol) for insertion into the surface of sub-strates to induce the unique nucleation on the seeded surface and subsequent growth of UNCD films. The formulas shown above indicate that the plasma contains very small quantities of hydrogen, arising mainly from thermal decomposition of methane to acetylene (C_2H_2) in the plasma (about 1.5%) and extremely small amount of H_2 (≤ 1 %) generated by Ar ions impacting on C_2H_2 molecules (see eq. (2)). The MPCVD process, for low-cost coating of commercial Ti-alloys DIs, is implemented in an industrial-type MPCVD system manufactured by IPLAS-GMBH (Germany), (see Figure 3 (a)), which grows UNCD films on up to 200 mm diameter substrates (see Figure 3 (b)) with outstanding uniformity in thickness (≤ 1%) and nanostructure. In addition, the MPCVD process can grow UNCD coatings extremely conformal on sharp structures, as demonstrated for the UNCD coating of sharp Si tips (see Figure 4 (b)), which is critical for coating screw-type structured metal DIs (see Figure 7 (a)), with extremely uni-form/dense UNCD coating, to inhibit any oral fluids flow to the underlying metal. R&D, using the IPLAS system in Auciello's la-boratory, demonstrated that several commercial Ti-6Al-4V DIs, positioned vertically on a 200 mm substrate holder, were coated simultaneously (see Figure 3 (c)) with extremely good uniformity. A substrate holder has now been designed to hold up to 300 DIs (10-15 mm long and 3-5 mm diameter each) distributed as shown in Figure 3 (d), which will enable production of UNCD-coated DIs at very low-cost per implant.

Growth of UNCD Coatings on Surfaces Biased with Positive Voltage for the Bias Enhanced Nucleation-Bias Enhanced Growth (BEN-BEG) Process:

A key new MPCVD growth process named Bias Enhanced Nucleation-Bias Enhanced Growth (BEN-BEG) was developed years ago, by Auciello and collaborators, to specifically produce UNCD coatings at lower cost than the process using surfaces seeded with UNCD particles, as described in Section 3.2 above, which increase cost by the ~ 1 hr. seeding process. The BEN-BEG process involves applying a negative (-) voltage on semiconductors to high electrical conductivity substrates to attract C^+, Ar^+, CHx^+ (x=1, 2, 3) ions created in the plasma (Figure 4 (a), enabling insertion of the energized ions into the substrate surface and nanoscale depth, inducing nucleation and growth of the UNCD films. In relation to the BEN-BEG process, the initial research fo-cused on exploring growing UNCD films with N atoms incorporated in the nanostructured films, which was demonstrated to pro-duce the first electrically conductive N-UNCD films, via N atoms linking to open C bonds on grain boundaries and providing elec-trons for electronic current flow to finally being ejected from the surface for electron field emission devices. These devices are based mainly on N-UNCD coated sharp tips like those shown in Figure 4 (b) [33]. The N-UNCD films were grown flowing a CH_4/N_2/very small H_2 gas mixture in an MPCVD-IPLAS system' chamber, coupling microwave power to create a plasma process and biasing the substrate with a negative voltage (-200 to -300 V) to attract C^+, CH^+_x (x=1, 2, 3)/N^+/H^+ positively charged ions (Figure 4 (a)) to impact the substrate surface, inserting C atoms, which induce nucleation and N-UNCD film growth without the seeding process (Figure 4 (b) and 4 (c).

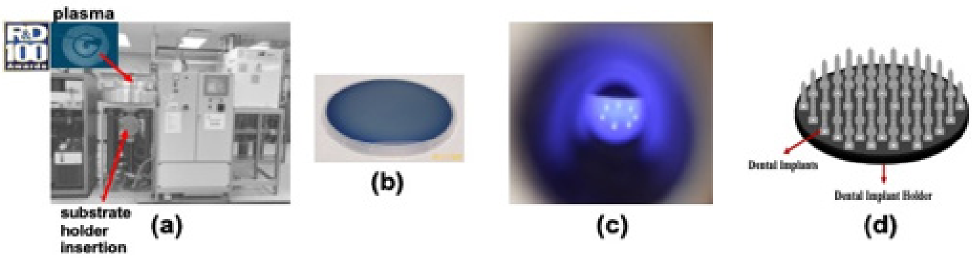

Figure 3: (a) Picture of industrial MPCVD (IPLAS) system showing the green plasma (top left inserted image); (b) Extremely uni-form UNCD coating on 200 mm Si wafer; (c) Seven commercial Ti-6Al-4V DIs vertically positioned on a substrate holder, ex-posed to an Ar (99%)/ CH_4(1%) plasma, demonstrating extremely uniform plasma distribution on all DIs, which enable growth of extremely uniform dense UNCD films simultaneously on many DIs to enable low-cost production; (d) Designed substrate holder to hold up to 300 DIs for low-cost simultaneous coating with UNCD films.

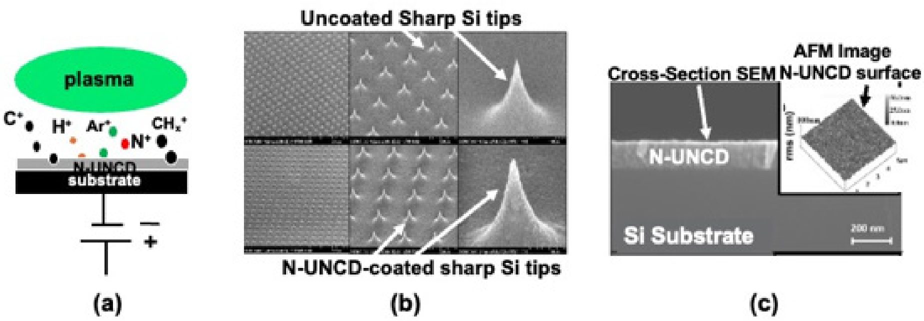

Figure 4: (a) Schematic of MPCVD plasma - electrically biased substrate surface interaction during BEN-BEGN-UNCD film growth process; (b) uncoated and BEN-BEG N-UNCD-coated sharp Si tips, the latter enabling electric field emission devices for many technological applications; (c) Cross-section SEM image showing extremlly dense nanoscale surface uniform N-UNCD film, grown by BEN-BEG on a Si substrate, similar to subsequently grown UNCD films, used for coating metal DIs, as shown in the Section on coating of DIs.

Subsequently to the demonstraiton of BEN-BEG growth of N-UNCD films, Auciello and colleagues first demonstrated growth of UNCD films. using low-pressure MPCVD-based BEN-BEG process, described in detail in [34], involving several steps, namely:

1) Etching of SiO_2 layer on the surface of high conductivity Si (100) substrate, using a pure H-based plasma, with the substrate biased at - 350 V;

2) In situ BEN-BEG, flowing a H_2 (93%)/CH_4 (7%) gas mixture, based on the hypothesis that H^0 atoms and H^+ ions in the plasma could help etch the impurity graphitic phase, which was observed in many cases growing simultaneously with the diamond phase when growing microcrystalline and nanocrystalline diamond films [35-37]). The UNCD film was grown using a plasma produced by 2.2 kW microwave power at low 25 mbar pressure, applying -350 V bias on a substrate heated to 850°C in a 2.45 GHz 6 in. IPLAS

CYRANNUS MPCVD system. The BEN-BEG process described above yielded UNCD films with low stress, smooth surfaces (~ 4-6 nm surface roughness), high growth rates (~ 1 µm/hr) and uniform grain size (3-7 nm) throughout the whole film area on 100 mm diameter Si wafers (see Figures. 2, 3, and 4 in [34]). The BEN-BEG process for UNCD films on Si substrate was used to grow UNCD coatings on Ti-6Al-4V DIs with extremelly uniform thickness and density across the whole DI (see Secton 3.3).

A critical property of the UNCD coating is that the surface enables efficient extensive growth and migration of embryonic epidermal stem cells, bone cells, and neural cells, as demonstrated in pioneering work by Auciello's group [38-40] and confirmed by other groups worldwide [41, 42]. In this sense, the main reason for the surface of UNCD coatings to induce strong human cells growth is that the UNCD coating surface is terminated in C atoms (the main life's element in human DNA, cells, molecules), which makes the UNCD coating surface extremely biocompatible [38-42]. From the point of view of UNCD-coated Ti-alloy DIs' integration into maxillary bones, the demonstrated superior growth of cells on the surface of UNCD coatings confirms the superi-or osseointegration demonstrated for UNCD-coated Ti-alloys DIs [26, 28].

Coating of Ti-Alloys Dental Implants (DIs) with Ultrananocrystalline Diamond (UNCD) Films

UNCD films were grown by the MPCVD process, using both the UNCD particles seeding process and the BEN-BEG process, on ncommercial Ti-6Al-4V DIs. An Ar (30 sccm)/CH4 (0.9 sccm) gas mixture was flown into the growth chamber to produce a total pressure of 20 mbar. A microwave power (1900 Watts) was applied to the gas, producing a plasma to grow the UNCD films, as described in Section 3.2. The DIs were positioned vertically on the substrate holder, first with the head of DI on top (Figure 5 (a)), growing UNCD films for 3 hours, with the DI heated to ~ 700°C, followed by cooling down in H2 gas flow. The DIs were subse-quently turned around positioning them with the screw head up (Figure 5 (b)) and the head down, coating with UNCD films for 3 hours. The total 6 hours growth of UNCD films resulted in DIs fully encapsulated with very uniform/dense/hermetic UNCD coat-ings.

Figure 5: Pictures of Ti-6Al-4V DIs on substrate holder with heads up (a) and screw side up (b)

Complementary Raman analysis (Figure 6) and cross-section Scanning Electron Microscopy (SEM) imaging (Figure 7 (a)) revealed that the MPCVD process produces very uniform-dense UNCD film all along the DI surface. This R&D showed the path-way for an industrial low-cost type coating process. Calculations, taking into consideration the size of the implants (~ 10-15 mm long / 3-5 mm in diameter) and the size of the substrate holder of the MPCVD system (200 mm in diameter), indicate that up 300 implants can be coated simultaneously with a cost per implant of about ≤ $2-3 dollars, very good cost for a high value product. Work is proceeding to optimize the UNCD film growth process by MPCVD, to try to minimize the coating growth time, optimize the implanted substrate holder geometry to accept the largest number of implants, and optimize the BEG-BEG process to eliminate the wet chemical seeding, and minimize growth time, while enhancing film adhesion on the surface of the Ti-alloy metal-based implant. Figure 3 (c) above shows a picture taken during growth of UNCD coatings on 7 Ti-alloy DIs simultaneously.

A more recent MPCVD process with increased gases flows and total pressure (patent under preparation) demonstrated that the total growth time to produce dense/hermetic UNCD coating on DIs can be reduce from 6 to 2 hrs., including the growth with tail and head tops, which can reduce substantially the cost for the growth process via MPCVD.

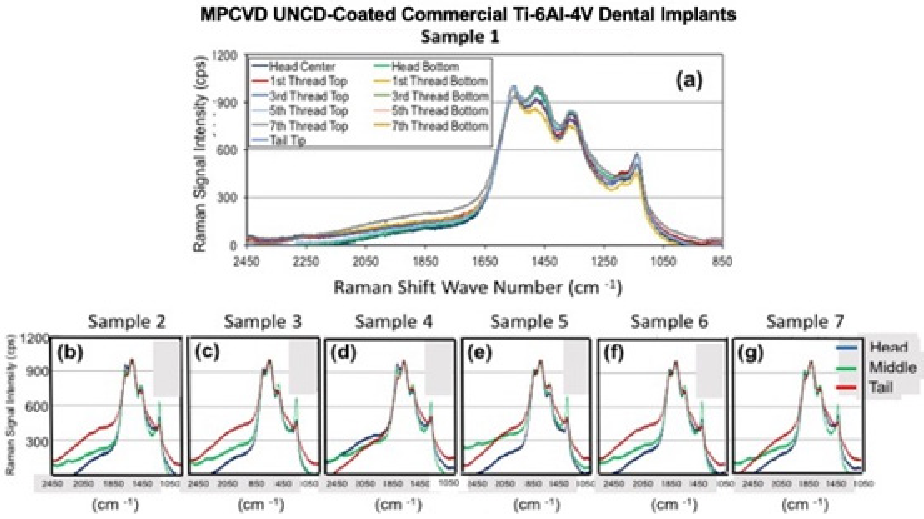

Figure 6: (a) - (g) Raman analysis of 7 samples of Ti-6Al-4V commercial DIs coated with UNCD via MPCVD process. involving the seeding process. The Raman spectra, extended from the top to the bottom end of the screw section; show superposiion of all spectra, which reveals that the UNCD coating thickness is extremelly uniform along the whole DIs structure.

Discussion and Findings

In Vitro Studies of Corrosion of Ti-6Al-4V and UNCD-Coated Ti-6Al-4V Dental Implants (DIs) in Saliva

Ti–6Al–4V alloy (main alloy used in commercial DIs) disks with 15 mm diameter and 2 mm thickness were used to study saliva induced corrosion on exposed metal surface and on UNCD-coated metal. Two uncoated and two UNCD-coated Ti–6Al–4V alloy samples were exposed to three different pH levels (3, 6.5 and 9) of artificial saliva as electrolyte. The sample disks were mechanically polished to produce a smooth mirror finish surface. Subsequently, the samples were subjected to sonication in 70% isopropanol for 10 min, followed by immersion in deionized water to remove surface impurities. A detailed description of experimental conditions an instrumentation used for the studies can be seen in Reference [43]. The electrochemical behavior of UNCD-coated and uncoated Ti–6Al–4V alloy samples were compared via immersion in artificial saliva with different pH levels. Open Circuit Potential (OCP) measurements in pH 3 artificial saliva showed that UNCD-coated Ti–6Al–4V alloy samples exhibit a higher potential (0.5 V) than the uncoated Ti-alloy samples (0.3-0.4 V), which reveals that the UNCD-coated Ti-alloy sample exhibits practically no electrochemical corrosion compared with the uncoated Titanium=alloy samples. Another important test involved measurements of surface roughness after exposure of samples to saliva. Uncoated Ti-alloy samples' surface roughness increased from ~ 0.1µm before saliva exposure to ~ 0.18 µm after exposure. On the contrary, UNCD coating surface roughness remained at ~ 0.4 nm before and after exposure to saliva. The smooth surface of UNCD coating inhibit growth of bacteria as it happens on roughened surfaces of the uncoated Ti-alloy DIs.

Biological Studies of UNCD-Coated Ti-Alloy Dental Implants (DIs) in Animals' Bones

Studies involving implantation of UNCD-coated commercial Ti-6Al-4V DIs in animals were done using *Male Wistar Rats* anesthetized intra-peritoneally with an 8 mg ketamine chlorhydrate/1.28 mg xylazine solution. A 1.5 cm incision was performed along the tibial crest. Subcutaneous tissue, muscles and ligaments were extracted to expose the external surface of the diaphyseal bone. A hole of 1.5 mm diameter was drill on the bone. UNCD-coated Ti-alloy DIs (6.0x1.0 x 0.1mm) were inserted in the bone. Uncoated Ti implants were placed in the left tibia, used as control. The animals were euthanized at 30 days post-implantation by intraperitoneal. High resolution cross section SEM image of UNCD-coated Ti-6Al-4V DI (Figure 7 (a)) shows high density uniform UNCD coating, which enable full protection from oral fluids, enabling the new tranformaiional DI technology. Figure 7 (b) shows the UNCD-coated DI in a Wistar Rat bone, showing dense growth of bone cells on the UNCD surface, inducing a superior strong osseointegration of the UNCD-coated Ti-alloy DIs.

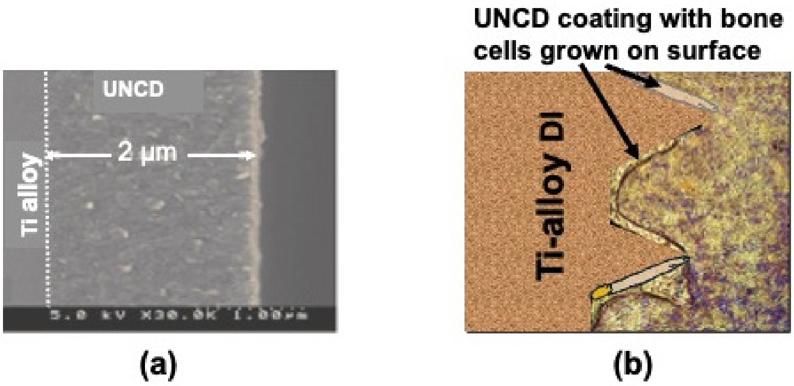

Figure 7: (a) High resolution cross-section SEM image of UNCD coating on Ti-6Al-4V DI implanted in animal bone as shown in (b) UNCD coated Ti-allloy DI implanted in animal bone shows extensive/dense growth of bone cells on UNCD surface providing evidence for the superior osseontingration in bones.

Clinical Trials on UNCD-Coated Ti-6Al-4V Dental Implants (DIs)

Following the extensive animal studies described in Section 4.2, Clinical Trials were performed implanting UNCD-coated commercial Ti-6V-4Al alloy DIs on 51 patients (2020-2024). UNCD coating on the Ti-alloys DIs, exhibited extremelly conformal-dense structure all across the screw-type topography of the DIs (Figures 8 (a) and 8 (b)). The Clinical studies, conducted in a world class clinic in Querétaro-México, demonstrated superior osteointegration (100% success for UNCD-coated DI, inserted in maxillary and jaw human bones of patients-Figures 8 (c) and 8 (d)). The UNCD-coated DI exhibit an exceptional attachment to the human bones, due to excellent bone cells growth on the C atoms terminated surface of the UNCD coating, as demonstrated in prior research [38, 39].

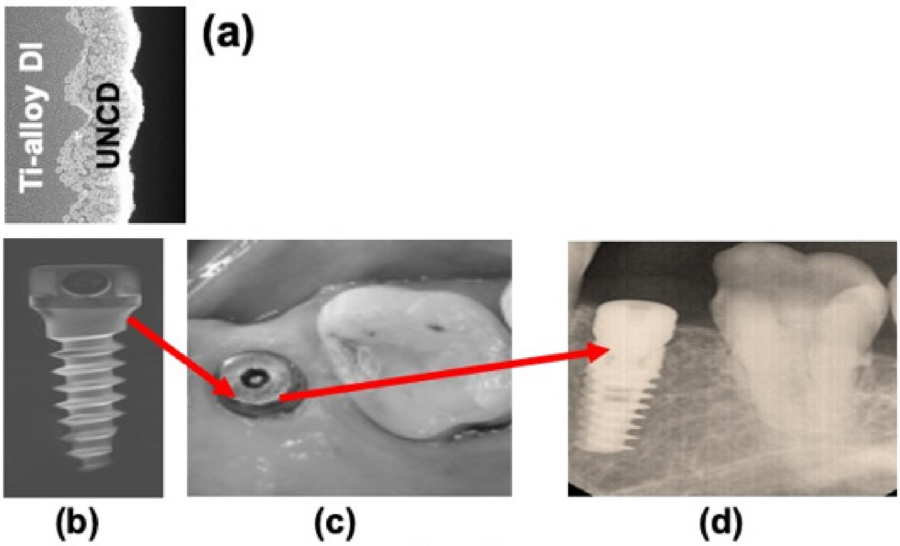

Figure 8: (a) Cross-section SEM image of a commercial Ti-6Al-4V DI coated with UNCD film, showing the extremelly uniform-dense film conformllly grown all across the screw-type structure; (b) Picture of a Ti-6Al-4V commercial DI coated with UNCD film via the MPCVD process; (c) UNCD-coated Ti-6Al-4V DI implanted in the maxillary bone of a patient involved in clinical trials; (d) X-ray image of the UNCD-coated DI shown in (c), revealing an excellent osseintegration in the maxillary bone, which is critical for lifetime performance of the DI.

Following implantation of the UNCD-coated DI in a patient, as shown in Figures 8 (c) and (d) above, six months period enabled development of osseointegration, which was confirmed by X-ray imaging (see Figure 8 (d). Another critical test proving the strong osseointegration of UNCD-coated Ti-alloy DI was provided in the clinical trials, performed by Dr. Gilberto López-Chávez in his clinic Bioingenieria Humana Aanzada (Quéretaro-México), inserting a torque meter on the head of a UNCD-coated Ti-alloy DI, inserted in a patient maxillary bone (Figure 9), and excerting the strongest force (55 Newtons) provided by the instrument, which revealed no motion of the implant and no pain in the patient, who did not had anestetic. In addition, clinical observations demonstrated no infection, no pain, and no tumefaction in the implant area. Excellent sealing of the gingival tissue on the surface of the UNCD coating was observed all around the UNCD-coated DI.

Figure 9: Test to determine osseontigration of UNCD-coated Ti-6A-4V DI, inserting a torque meter on the head of the DI inserted in a patient maxillary bone; the maximum torque of 55 Newtons did not induce any motion of the DI, proving the strong osseointegration (O. Auciello acknolwedges the great work in trials performed by Dr. Gilberto López-Chávez in his clinic Bioingeniería Humana Aanzada (Quéretaro-México) and providing the picture shown in this Figure).

The tests performed on the UNCD-coated commercial Ti-6Al-4V alloys DIs, described above, confirm that this new generation of transformational DIs will provide a far superior prostheses than the current metals based DI, since the UNCD coating, provides the best biocompatible matrial because it is made of C atoms (element of life in human DNA, cells, molecules).

Conclusions, Limitations and Recommendations

In conclusion, systematic analysis of materials science and technology issues related to DIs based on Ti-6Al-4V, which are supplied in about 80-85% DIs worldwide, revealed serios materials and DI technology issues, which result in ~15% DIs failure worldwide, due to combined chemical corrosion/mechanical degradation, inducing degradtion of DIs in maxillary bones. in about 4-5 years after first implantation, requiring DIs' replacement at extra cost and discomfort for patients.

Based on the information presented above, R&D, directed by O. Auciello, focused on investigating the potential solution to the problems via coating of the commercial Ti-6Al-4V DIs with a unique transformational **low-cost/best mechanical properties (similar to diamond gem-the strongest material on Earth) / fully chemical corrosion resistant / best biocompatible (because made of C atoms-element of life in human DNA, cells, molecules) coating named Ultrananocrystallinbe Diamond (UNCD)**.

Two processes were investigated/developwed to grow UNCD coatings on Ti-alloys DIs, namely: a) Microwave Chemical Vapor Deposition (MPCVD) [26, 30, 31, 32, 44], and b) Hot Filament Chemical Vapor Deposition (HFCVD) [44], based on prior RD related to developing both UNCD growth process [44], to determine which is the best to grow UNCD films on large number of Ti-alloy DIs, to develop a low-cost industrial UNCD growth process and production of low-cost DIs. The fully optimized MPCVD growth process produced dense/pinhole-free UNCD films with unique combination of properties, namely: a) excellent conformal growth on the screw-type structure of commercial Ti-alloys DIs, b) extreme resistance to chemical attack by any body fluids, including oral fluids, critical to degradation of metal-based DIs; c) excellent surface chemistry, based on C atoms, which was proven to induce efficient growth of biological cells, also inducing efficient maxillary bone cell growth on the UNCD surface to produce strong osseointegration of UNCD-coated Ti-alloy DIs in the maxillary bone; d) lowest coefficient of friction compared to any other current materials used in implantable prostheses, including DIs, which facilitate insertion of the screw-type DI into the maxillary bone with minimal mechanical induced degradation of the bone.

Raman analysis revealed that the surface of UNCD coatings are terminated with C-atoms with sp^3 fully satisfied chemical bonds characteristic of diamond inside the grains, providing excellent resistance to chemical attack because no open chemical bonds of C atoms are exposed for reaction with corroding fluids.

High resolution SEM imaging revealed that UNCD coatings exhibit extreme conformality and high density (pinholes free) on the screw-type structure of DIs, inducing full protection against chemical and mechanical environment of the human mouth.

The demonstration of simultaneous coating of 7 Ti-alloys DIs (10-15 mm long, 3-5 mm diameter), positioned vertically on the substrate holder (Figure 3 (c), showed that large number (~250-300) Ti-alloys DIs can be coated distributed in a 200-300 mm diameter holder, to produce low-cost industrial manufacturing of UNCD-coated Ti-alloy. However, the **current limitation** of the MPCVD process is that a larger than 200 mm diameter substrate should be developed to hold the largest possible number of vertical distributed DIs to enable the lowest possible fabrication cost.

A **limitation** of the original MPCVD process to grow UNCD films on Ti-alloy DIs is that it involves seeding the surface of the DIs with UNCD particles in a wet chemical process, which add about 1-hour extra time, thus extra cost in the overall UNCD coating process. Therefore, it is desirable to eliminate the wet chemical seeding process to reduce cost. In this respect, Auciello's group demonstrated the new process named Bias Enhanced Nucleation-Bias Enhanced Growth (BEN-BEG), using the MPCVD process, involving biasing the electrically conductive Ti-alloy DIs with a negative voltage, attracting positive C+ and CHx+ (x=1, 2 , 3) ions generated in a plasma, towards the substrate surface impacting with relatively low energy (~100-200 eV), resulting in sub-implantation of C and CHx (x=1, 2 , 3) ions on the surface of the Ti-alloy DI, or other prostheses, generating a TiC template layer that induce the growth of the UNCD film, without wet chemical diamond seeding process. The BEN-BEG process will reduce fabrication cost by at least an order of magnitude. The other big advantage of the BEN-BEG process is that because energetic insertion of the C-based ionic species on the surface of the implant, induce an order of magnitude higher UNCD coating adhesion than for the conventional growth process, eliminating potential generation of cracks or delamination of the UNCD coating. Based on the demonstrated potential better MPCVD BEN-BEG process, it is strongly **recommended** for full development.

In vitro studies, exposing UNCD-coated Ti-alloy plates to artificial saliva, similar to natural saliva, demonstrated that UNCD-coated Ti-alloy DIs are extremely resistant to chemical attack, as opposed to Ti-alloy uncoated DIs, that are substantially corroded by oral and other body fluids.

In vivo animal studies, involving implantation of UNCD-coated Ti-alloy DIs in rats' bones, showed excellent biocompatibility and osseointegration, plus outstanding resistance to chemical attack by body fluids.

Clinical trials, involving implantation of UNCD-coated commercial Ti-6Al-4V DIs in 51 patients, demonstrated the superior performance of this new transformational DI, which is ready to be inserted in the worldwide market to improve the quality of life of people needing DIs.

A strong recommendation is to apply for insertion of UNCD-coated DIs in countries outside the USA first (e.g., Latin America, EU, China, India) to get faster approval, which can induce subsequent faster approval by FDA in the USA. This recommendation is supported by a project, in which O. Auciello participated, involving researchers from 5 National Labs, 4 Universities and a CA company, developing a microchip implantable in the human eye, to restore partial vision to people blinded by gene-induced death of eye's photoreceptors. The device (Argus II) developed during a 10 years project (2000-2010), was first approved, in 6 months, for implantation in blind people, by the EU community, and subsequently approved by the FDA-US in 6 months, when informed that the device have been approved in EU (see detailed discussion of the project in Ref. [45])

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• Dr. José Luis Rubio-Pino, who covered the cost of clinical trials.

Appendix

Abbreviations

- American Dental Association (ADA)
- Bias Enhanced Nucleation-Bias Enhanced Growth (BEN-BEG)
- Dental implants (DIs)
- Hot Filament Chemical Vapor Deposition (HFCVD)
- High Resolution Transmission Electron Microscopy (HRTEM)
- Microwave Plasma Chemical Vapor Deposition (MPCVD)
- Thiobarbituric Acid Reactive Substances (TBARS)
- Scanning Electron Microscopy (SEM)
- Thiobarbituric Acid Reactive Substances (TBARS)
- Titanium (Ti)
- Titanium-6 Aluminum-4 Vanadium (Ti-6Al-4V)
- Titanium-Oxide (TiO)
- X-ray photoelectron Spectroscpy (XPS)
- Ultrananocrystalline Diamond (UNCD)

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