

Ultrananocrystalline Diamond (UNCD) Coating: A New Generation of Long-Life Metal-Based Dental Implant Surface with Unique Best Biocompatible/Corrosion Resistant/Low-Cost UNCD Coating.

Clinical Study Report by:

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Abstract

Titanium (Ti) and its alloys are currently used as biomaterials for dental implants. However, titanium and its alloys suffer electrochemical corrosion in the oral environment. **Ultrananocrystalline Diamond (UNCD) coating** is a promising low-cost / nanostructured carbon-based coating material with exceptional biocompatibility, excellent osseointegration, high wear resistance, and extreme resistance to chemical attack for producing a new generation of long-life **UNCD-coated dental implants**.

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Current Dental Implant Technology

Pure Titanium (Ti) or Titanium (Ti) alloys are used in orthopedic and DI (Fig. 1(a)), because previous not accurate materials science was interpreted as showing that Ti and Ti-alloys exhibited appropriate mechanical properties and biocompatibility. However, recent years' detailed scientific studies showed that an estimated 5% to 10% of Ti-alloy-based DI, worldwide, fail in the first 4-5 years, mainly due to chemical corrosion induced by oral fluids (Fig. 1(b)). Studies by Auciello's group and others worldwide (2000-2014) showed that Ti-alloys and other metal-based implant metals suffer from electrochemical corrosion when implanted in the body or the mouth, releasing metallic-oxide particles from oxidized Ti surface, inducing cells' death and promoting inflammation around the implant, resulting in implant failure.

Transformational New Metal-based Dental Implant (DI) Technology with UNCD Coating

The Novel UNCD coating is grown extremely dense / conformally on DIs (Fig. 1(c)), using microwave plasma chemical vapor deposition in an industrial system with the capability to coat up to 300 DI simultaneously at low cost (Fig. 1(d)). The **UNCD coating** exhibits **the best dental implant-to-bone biocompatibility due to its Carbon-atom structure (element of life in humans' DNA, cells, and molecules)**. Also, UNCD exhibits the strongest resistance of any material to chemical attack by body fluids. The UNCD coating acts as a protective barrier between the metal-based implant and the biological environment, preventing the release of metallic-oxide particles into the body. The research focused on investigating the Osseointegration rate of Ti and Ti-alloy DI and UNCD-coated Ti and Ti-alloy DIs, implanted in animal's bones, showed that the UNCD-coated implants exhibit orders of magnitude superior osseointegration due to orders of magnitude more dense growth of bone cells on the surface of UNCD (Fig. 1 (e)). Optical and SEM pictures showed superior osseointegration and resistance to chemical attack from body fluids (Fig. 1 (e)), for UNCD-coated metal dental implants over Ti-based uncoated DIs. Clinical trials (20 patients implanted / 2018-present), performed in the Word Class clinic of **Dr. Gilberto Lopez** in Querétaro-México showed orders of magnitude superior performance than for commercial Ti-alloys implanted in the same maxillary bones (Fig. 1 (f)).



Extensive X-ray analysis (Fig. 1 (g)) and completion of UNCD-coated Ti-alloy DIs with a ceramic crown (Fig. 1 (g)) demonstrated that UNCD-coated dental implants are the new revolutionary development over the prior 20-year-old Ti-alloy based DI technology.

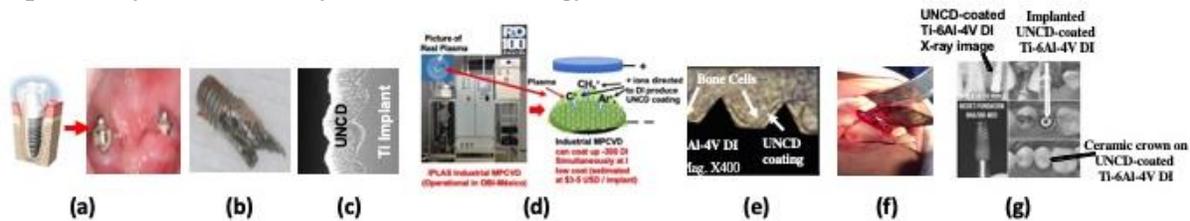


Figure 1. a) Current Ti-alloy dental implant in patient's mouth; b) oral fluid corroded current commercial Ti-alloy DI taken from patient's mouth; c) cross-section SEM picture of UNCD-coated commercial Ti-alloy DI, showing outstanding dense/conformal UNCD coating on metal; d) Left-industrial MPCVD system (operational in OBI-México) suitable for coating, simultaneously at a low cost per implant, up to 300 DI vertically distributed (right) on a large area holder; e) UNCD-coated commercial Ti-alloy DI in animal bone, for up to 3 years, showed no corrosion and outstanding osseointegration induced by dense bone's cell growth on the UNCD surface; f) first UNCD-coated commercial Ti-alloy DI, implanted next to commercial Ti-alloy UNCOATED DI, showed orders of magnitude superior performance of the UNCD-coated DI; g) X-ray analysis on many UNCD-coated DI and completed implant with crown showed outstanding performance on 20 patients implanted with UNCD-coated Ti-alloy DI (2018-present).

Broad Commercial Impact

Social impact: UNCD-coated Ti-based DI will eliminate corrosion-induced failure of current Ti-based DIs and substantially reduce or eliminate the risk of infection, inflammation, and pain, decreasing the need for medications and number of visits to the dentist improving patients' quality of life.

Commercial impact: In 2008, the global dental products market reached almost 8 billion dollars, with the fastest-growing segment being dental implantology. Current experts' estimations indicate robust DI industry projection, with expected growth at a CAGR of 16.3% in the US from 2004 to 2014 and 13.7% in the EU from 2003 to 2013 (**Global Information, Inc., Frost & Sullivan**). The market has grown steadily due to growth in disposable income, increased desire for aesthetics, demographic aging population, and peoples' desire to retain tooth structure later in life. The major players in the dental implants markets include Nobel Biocare Holdings AG (Switzerland), Straumann (Switzerland), Dentsply International (USA), Zimmer Dental (USA), Biomet 3i (USA), BioHorizons, Inc. (USA), Ivoclar Vivadent AG (Liechtenstein), and 3M Company (USA).

Other UNCD-Coated Implantable Prostheses

UNCD coatings will also impact a new generation of prostheses such screws for the spinal cord and artificial hips, knees, elbows, and more, which currently are made of metals and also exhibit early failure, as for DIs, due to chemical attack by body fluids.