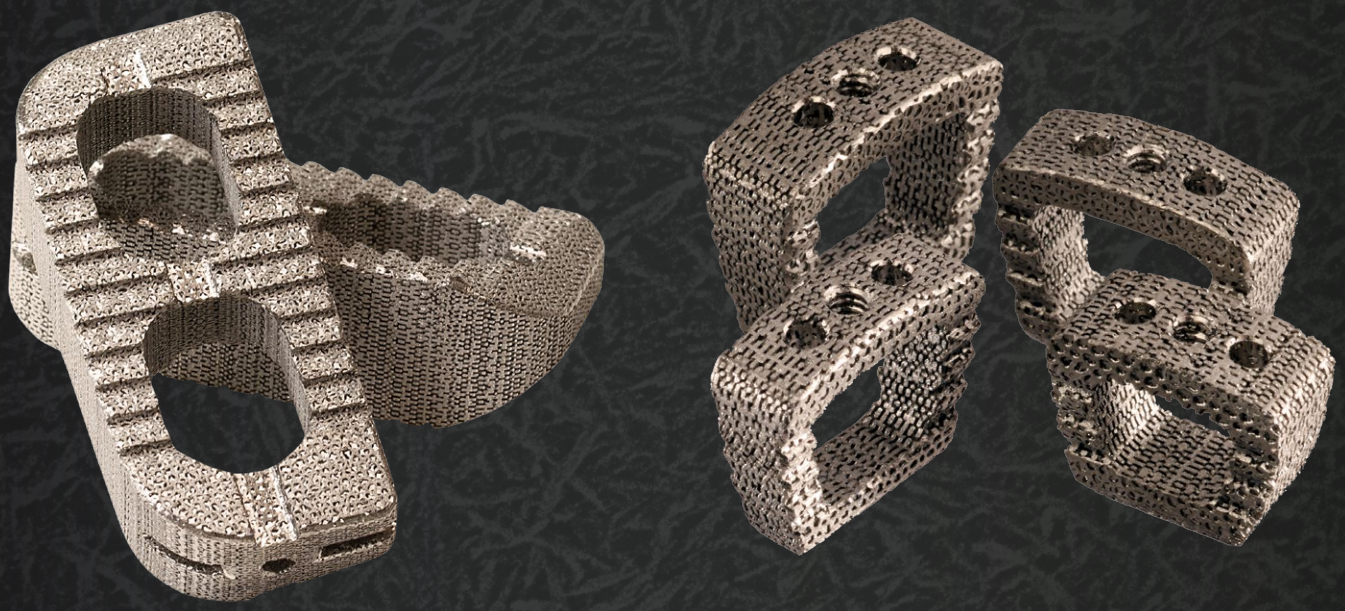
IdentiTi™

WITH ADVANCED **NANOTEC**™ TREATMENT



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IdentiTi™
WITH ADVANCED NANOTEC TREATMENT

A Surface Treatment with Deep Benefits

ATEC is proud to introduce NanoTec,™ a state-of-the-art nano surface treatment of IdentiTi™ implants. The NanoTec surface treatment is intended to speed the healing process and improve the quality of the bone-implant interface by creating a biomimetic implant surface.

- NanoTec surface treatment alters the surfaces of implants with 20 nm hydroxyapatite (HA) crystals that have the same shape, composition, and structure as HA found in human bone. The surface treatment lends a unique combination of properties that are intended to enhance osseointegration.
- Human bone mineral is composed of nanometer-sized HA crystals that are approximately 50 nm in length, 25 nm in width and 2-3 nm thick.[1] The NanoTec HA nanometer crystals influence protein interactions[2] and lead to favorable healing, osteoblast adhesion, proliferation, and differentiation.

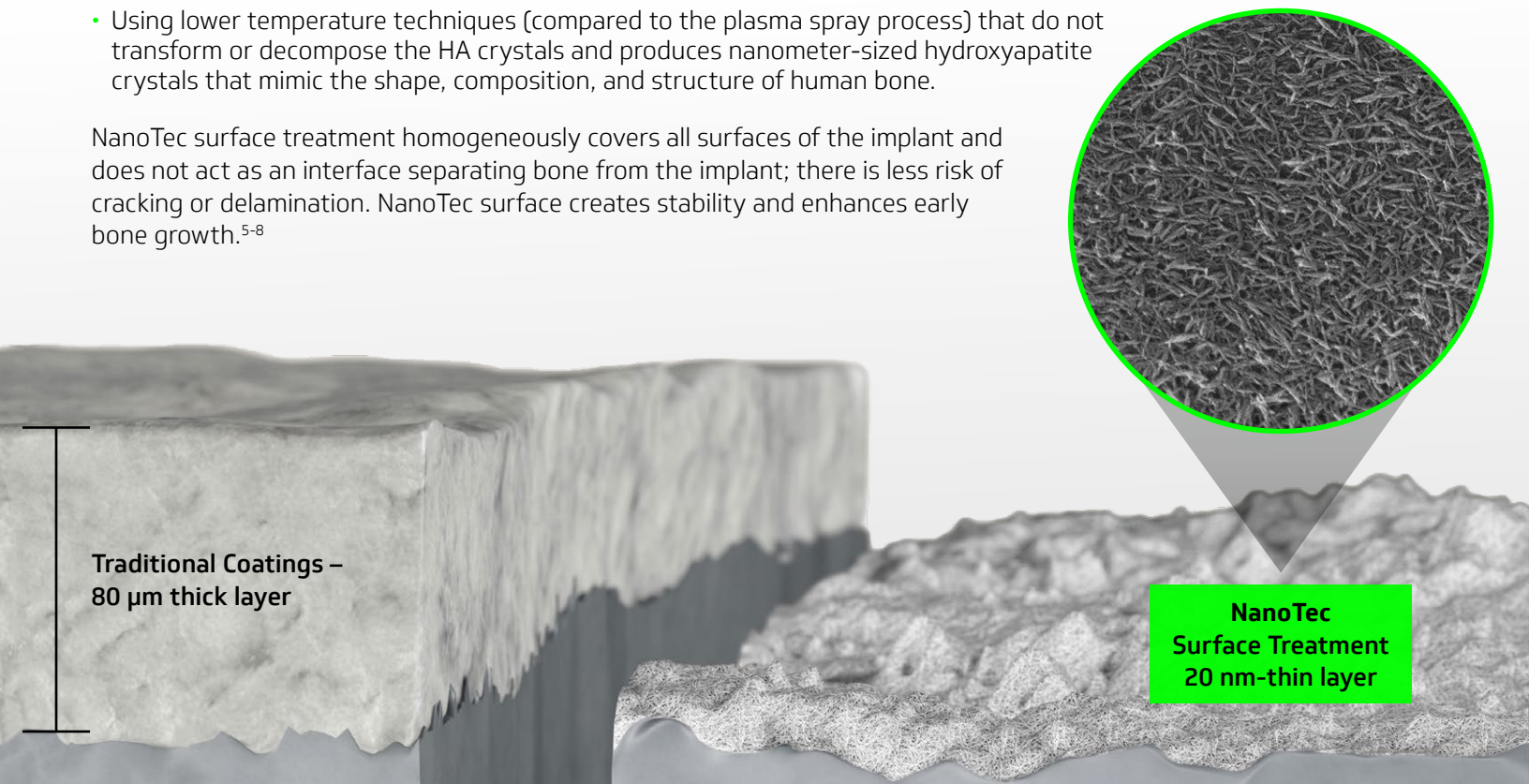
MORE RELIABLE THAN COATING

There are many HA deposition techniques. The most widely commercially used method is a plasma spray process that deposits an approximately 80 µm-thick HA layer onto a titanium surface. This thermal deposition process leads to phase transformation and decomposition of the initial HA powder causing poor adhesion of the coating on the titanium.[3] Clinically, coating failure by chipping and delamination has been observed.[4]

The NanoTec surface treatment significantly improves the bonding of hydroxyapatite by:

- Reducing the thickness of the surface layer (1000 times thinner than traditional HA coatings);
- Using lower temperature techniques (compared to the plasma spray process) that do not transform or decompose the HA crystals and produces nanometer-sized hydroxyapatite crystals that mimic the shape, composition, and structure of human bone.

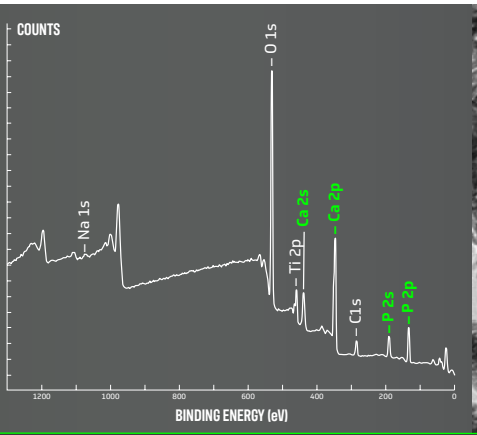
NanoTec surface treatment homogeneously covers all surfaces of the implant and does not act as an interface separating bone from the implant; there is less risk of cracking or delamination. NanoTec surface creates stability and enhances early bone growth.[5-8]



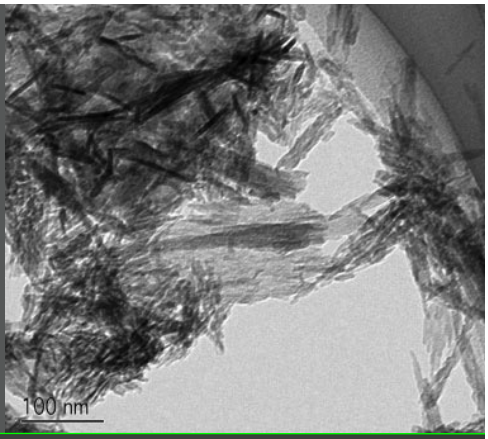
The NanoTec™ Difference

NANO TOPOGRAPHY

A wet chemical processing method forms a 20 nm-thin layer of hydroxyapatite on the surface that mimics shape, composition, and structure of the human bone.



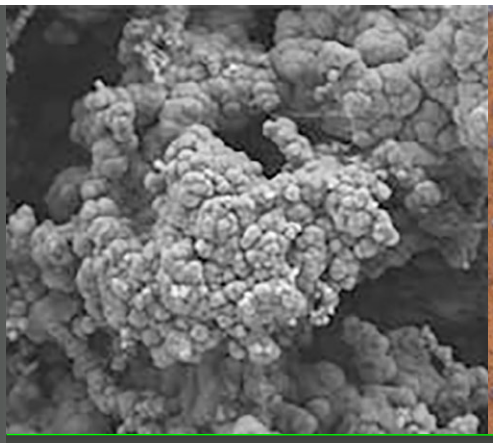
X-ray photoelectron spectroscopy (XPS) spectra showing formation of calcium and phosphate on titanium



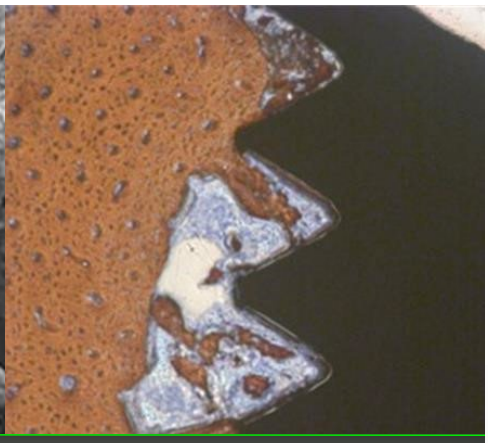
Morphology of nanocrystalline HA demonstrated by transmission electron microscope (TEM)

BIOACTIVE

Forms faster hydroxyapatite layer in vitro than titanium.[9]



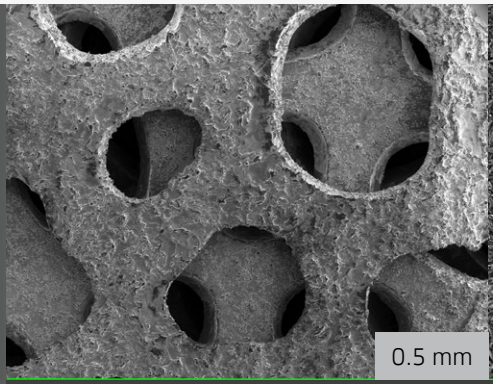
Surface after soaking in simulated body fluid solution showing the globules of apatite formed on the surface



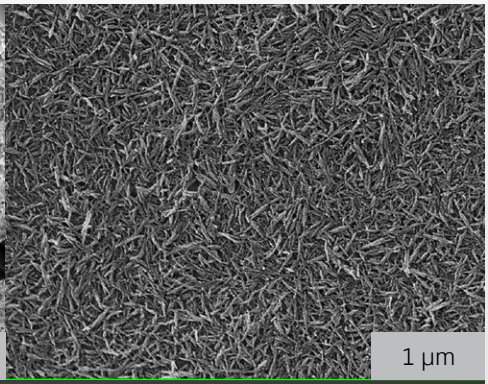
Bone formation directly on the implant surface after 7 days, a strong indication of osteoconductive healing

FULL SURFACE COVERAGE

Surface treatment is applied to all surfaces without compromising the porosity of the implants.



Low magnification scanning electron microscope (SEM) image of the IdentiTi NanoTec surface demonstrating open porosity. The macro-porosity was still maintained after NanoTec surface treatment



High magnification scanning electron microscope (SEM) image of the IdentiTi NanoTec surface demonstrating the nano-needles of hydroxyapatite on the surface of IdentiTi

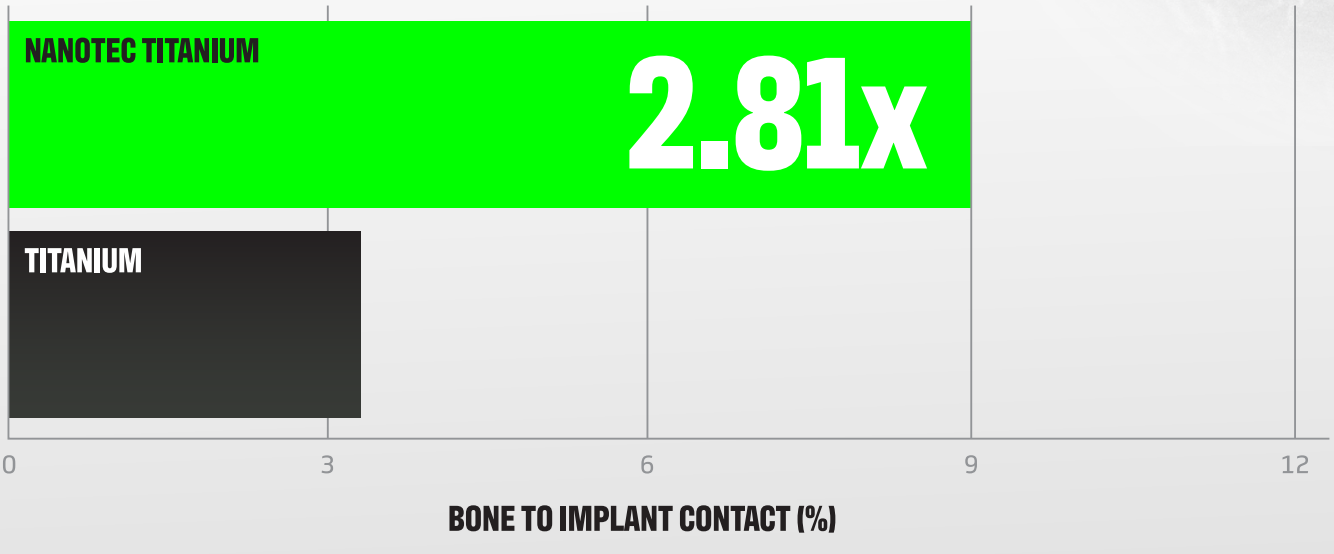
Improved Integration with NanoTec™

ULTRA-HYDROPHILICITY

- Hydrophilic surface increases protein absorption that leads to increase in cell attachment.[10] Hydrophilicity is measured using the contact angle measurement method; a lower contact angle indicates a more hydrophilic surface.
- Liquid absorption test on the IdentiTi™ surface revealed that the liquid was absorbed by the internal layer of the implant due to capillary forces but was not distributed on the surface of the implant.[11] In contrast, liquid was absorbed rapidly on the IdentiTi NanoTec surface as well as the internal layers.[11] IdentiTi NanoTec surface demonstrated an increase in hydrophilicity in comparison to the untreated IdentiTi surface.[11]

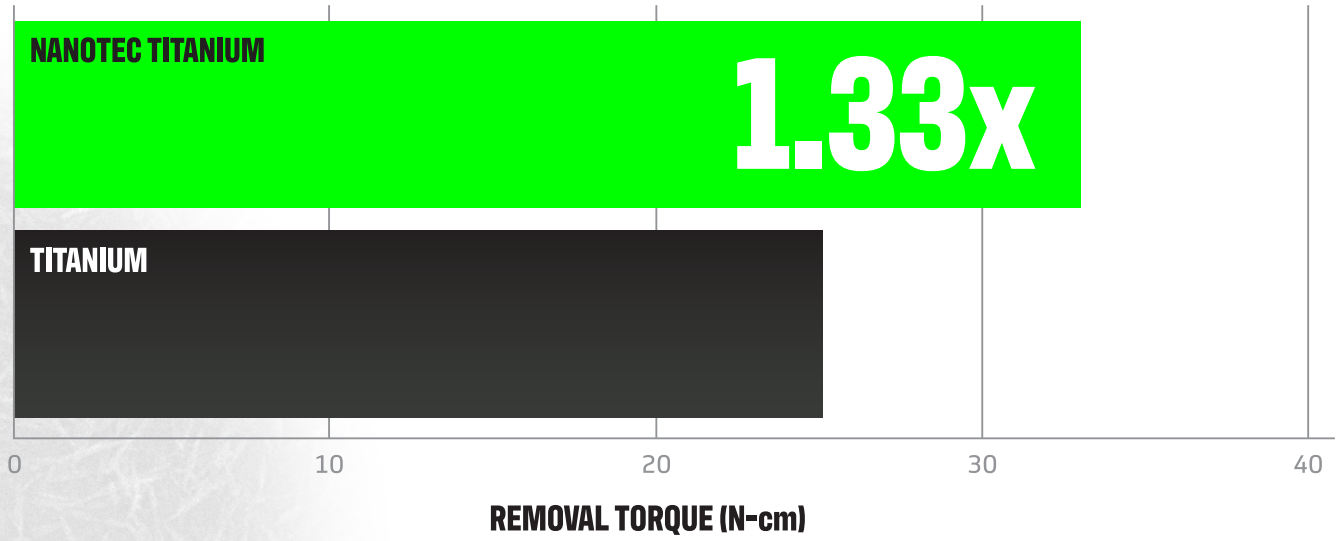
FASTER BONE FORMATION

- Faster bone formation is assessed by the amount of bone formed on the implant surface.
- Bone-to-implant contact (BIC) can measure the level of integration of the implant with the bone.[12] Higher BIC percentages indicate more interface stability.
- The NanoTec surface treatment has been shown to increase the BIC values of titanium implants by up to 181% at 4-weeks.[5]



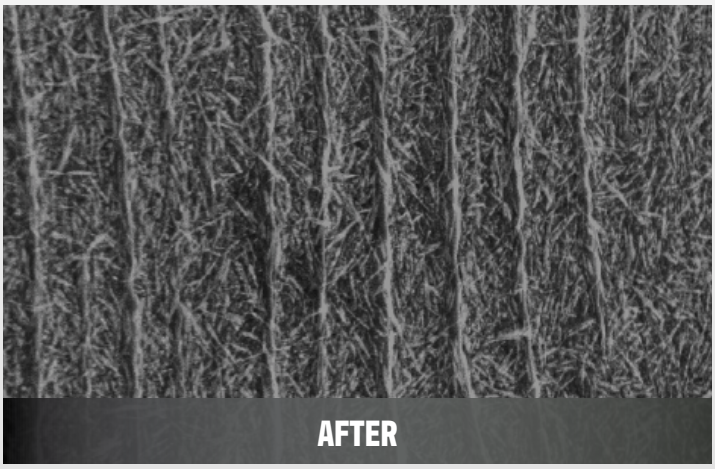
BONE IN- AND ON-GROWTH

- Implant integration with the surrounding bone can be evaluated by the load required to remove it. Removal torque is one way to measure implant removal from bone. Greater torque values are interpreted as an increase in bone-to-implant contact, leading to higher strength of osseointegration.[13]
- The NanoTec surface has been shown to increase removal torque by up to 33% in comparison to an untreated surface after 6 weeks implantation.[2]



NO DELAMINATION OR CRACKING

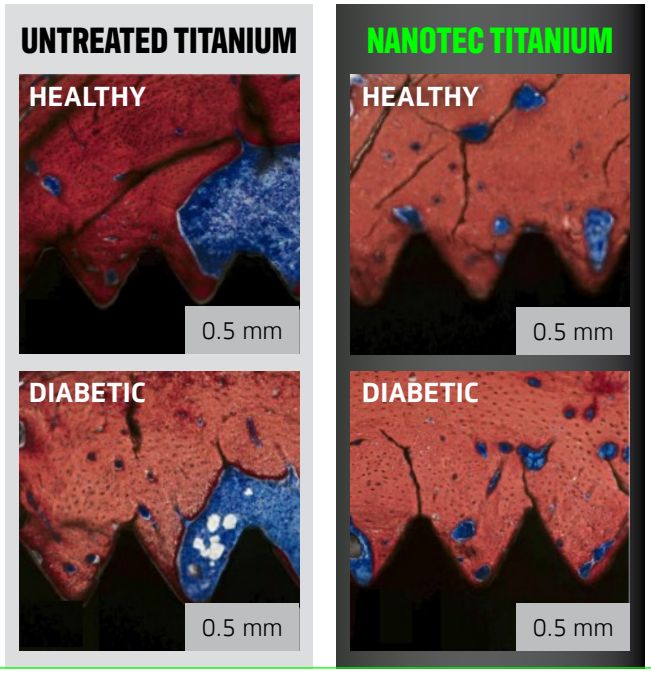
- Delamination or cracking of conventional HA coatings poses a risk to implant integration with surrounding bone. The delamination could potentially happen during insertion or could develop in vivo.
- Simulated insertion and removal technique tests were conducted with IdentiTi and IdentiTi NanoTec in Sawbones followed by SEM surface analysis.[11] IdentiTi NanoTec surface was not affected by insertion and removal from the Sawbones block.[11]
- Histological evaluation in a preclinical study demonstrated no delamination of NanoTec surface treatment.[14]



Critical Studies

Histological and Nanomechanical Properties of a New Nanometric Hydroxiapatite Implant Surface. An In Vivo Study in Diabetic Rats[6]

Adult male Wistar rats (250–300 g) were divided into 2 categories: healthy and diabetic (induced by a single intraperitoneal injection of streptozotocin). Titanium implants were compared before and after NanoTec surface treatment. Osseointegration was evaluated after 4 weeks with histologic sectioning and histomorphometry, comparing bone-to-implant contact and newly formed bone within the threads of the implants.

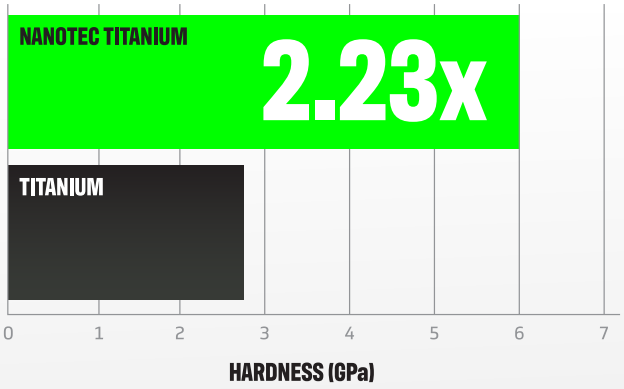


RESULTS

- At 30 days, the implants with NanoTec Surface in both healthy and diabetic rats were almost fully osseointegrated.
- Bone-to-implant contact with NanoTec implants was 80%, whereas the untreated surfaces had bone-to-implant contact of approximately 50%.

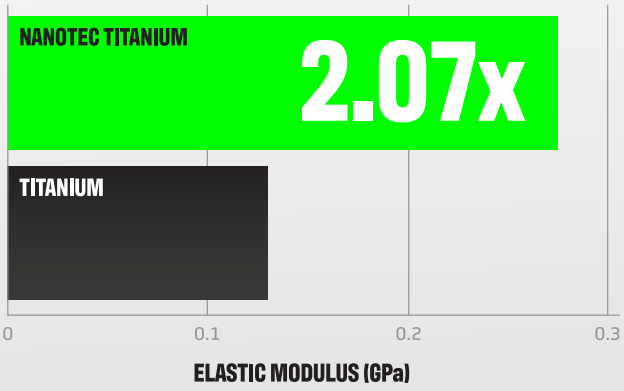
Nano Hydroxyapatite-Coated Implants Improve Bone Nanomechanical Properties[14]

NanoTec titanium and untreated titanium implants were implanted into 10 rabbit tibias. Each rabbit received one untreated titanium and one NanoTec titanium implant. Histological and nanomechanical properties (hardness and elastic modulus) of the newly formed bone around the implants were evaluated. Hardness and elastic modulus of the newly formed bone indicate the degree of calcification of the bone around the implant surface. Higher values indicate more mature bone formation.



RESULTS

- Nanoindentation testing of the newly formed bone revealed higher hardness and elastic modulus for the NanoTec titanium implants when compared to the titanium control. The tissue quality was significantly enhanced around the NanoTec titanium implants.
- There were no signs of inflammatory response in the proximity of the implant surface.



Competitive Comparison

FEATURES	DEFINITION	NanoTec™ (ATEC)	Titan Nanolock™[15] (Medtronic)	Tritanium®[16] (Stryker)	Trabecular Metal[17] (Zimmer Biomet)
Nanotopography	At least one external dimension or an internal of surface structure in the nanoscale range (approximately 1 nm to 100 nm)	✓	✓	✗	✗
Biomimetic	The surface layer resembles human bone both physically and chemically	✓	✗	✗	✗
Bioactive	Formation of an HA surface layer upon exposure to physiological fluids	✓	✗	✗	✗
Osteoconductive	Bone growth on a surface	✓	✓	✓	✓
Complete Surface Coverage	Surface treatment or coating is performed on all external and internal as well as macro- and micro-surfaces of the implant	✓	✗	✓	✓

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