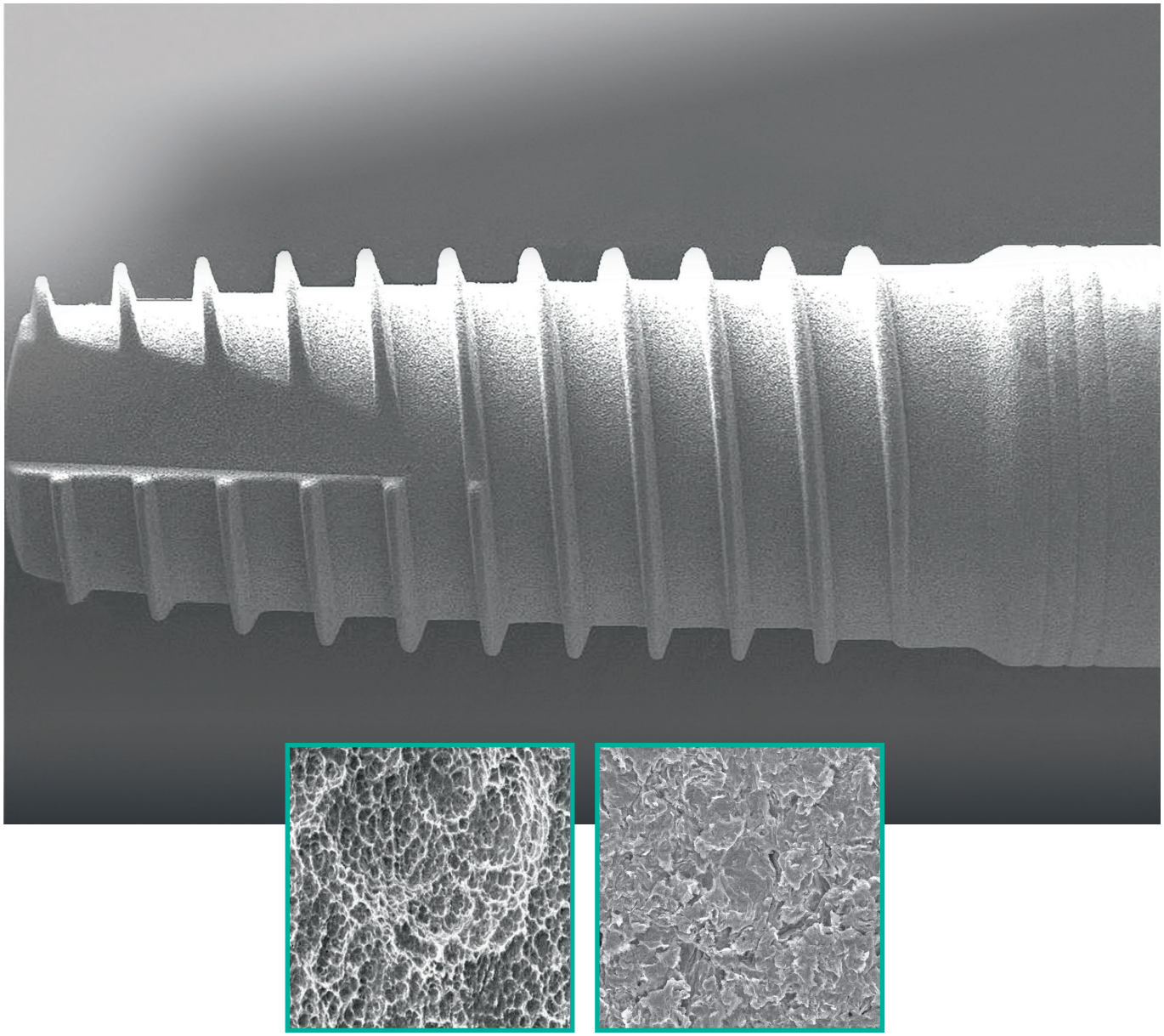
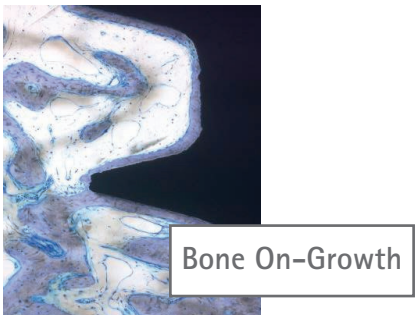
Innovative surface treatments for bone engaging implants



Bone On-Growth Surfaces

DOT America
medical implant solutions

Implant surface micron topography is a critical factor in achieving bone on-growth.

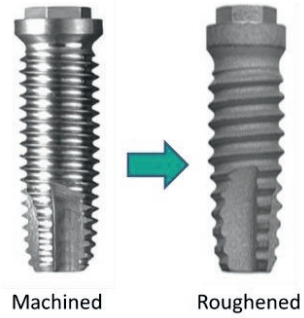


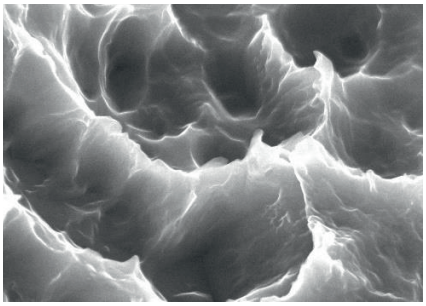
The success of many devices is dependent upon the "integration" or "fusion" of the implant into the natural bone structure. This integration may be accomplished through bone on-growth, bone in-growth, or a combination of both mechanisms.

Bone on-growth: the development of bone in direct apposition/contact with the surface (e.g. generally ≤ 100 micron scale).

Bone in-growth: the development of bone around, but not necessarily in direct contact with an implant macro feature **(e.g. thread or porous surface/scaffold).**

Bone on-growth surfaces





Background

In the 1970s, implant researchers first determined that roughening titanium implant improved their success rates.

Over the next few decades, many "roughening" technologies were developed and evaluated through research and practice. In the specific case of bone engaging screws, processes that create micron scale topographies were found to be extremely effective, and as such continue to dominate the market today.

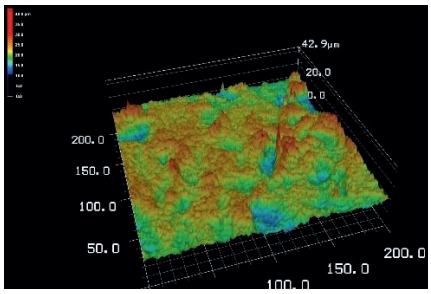
Bone on-growth surfaces are commonly utilized in dental, spine and orthopedics.

User needs met

- Biocompatible, maintaining original substrate properties.
- Impacts the mechanisms involved with the extent and rate of bone formation.
- Increases the interface bond strength between the implant and bone.
- Reduces the risk of screw loosening.

Characteristics

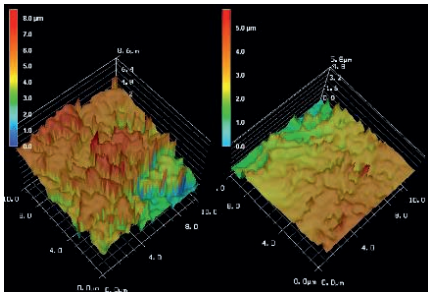
The characteristics of the bone on-growth surfaces are dependent upon the technology utilized.



RBM – Resorbable Blast Media Micro-blasting

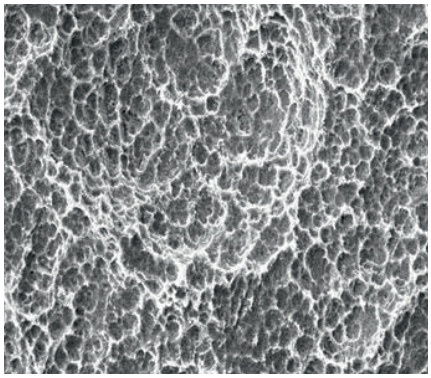
RBM is a subtractive surface technique, where the surface is modified by precision micro-blasting using a calcium phosphate based media. After blasting, the parts are processed through nitric acid to resorb residual media left on the surface.

The typical RBM process imparts a micron scale topographically complex surface, with primary features in the 10-50 micron range. The resulting surface roughness has a Sa of 1.5 +/- 0.5 microns.



RBM – Resorbable Blast Media Micro-blasting and Acid Etching

After RBM processing, the implants are subsequently acid etched to super-impose fine micron pits over the RBM surface. This secondary process results in a dual scale topography. The RBM + Etched surface is topographically complex in two scales including 10-50 micron primary features with 1-10 micron secondary pitting. The resulting surface roughness has a Sa 1.5 +/- 0.5 microns.



Corundum Blast Media Micro-Blasting and Acid Etching

In this process, corundum (aluminum oxide) is utilized in the place of RBM. The additional hardness of the corundum media permits the generation of a slightly deeper surface texture, with more angular facets. After corundum blasting the implants may be further acid etched to impart fine micron pitting over the blasted surface to create a dual surface topography. The Corundum + Etched surface is topographically complex in two scales including 10-100 micron primary features with 1-10 micron secondary pitting. The resulting surface roughness as measured has a Sa of 1.75 +/- 0.75 microns.

Customized Surface

Customized Surface Processing:
DOT commonly teams with its customers to analyze and duplicate their current surface technologies.
DOT will partner with your R&D team to develop customized surface designs for your specific device application.

Processing Technology

DOT America utilizes automated, precision micro-blasting with resorbable calcium phosphate based or aluminum oxide medias to impart micron scale topographies on implant surfaces.

As required, DOT may additionally acid etch titanium surfaces to develop a more definitive dual scale topography of micron (10-100 µm) and fine micron (1-10 µm) characteristics.

DOT's Experience

Since 1995, DOT has been processing implants with micron scale technologies for enhanced bone healing. Implants with DOT bone on-growth technologies have been cleared or approved in technology applications in the US, Europe, and Asia.

Bibliography

1. The Open Dentistry Journal 8, (Suppl 1-M2) 50-55. (2014) "*A Brief Historical Perspective on Dental Implants, Their Surface Coatings and Treatments.*" C. Abraham
2. A histomorphometric study in miniature pigs. J Biomed Mater Res 25, 889- 902. (1991) "*Influence of surface characteristics on bone integration of titanium implants.*" D. Buser, R. K. Schenk, S. Steinemann, J.P. Fiorellini, C.H. Fox, H. Stich
3. A study in rabbits. Med Oral Patol Oral Cir Bucal. 1;15 (1):e119-25. (2010) *"Early bone healing around implant surfaces treated with variations in the resorbable blasting media method."* R. Jeong, C. Marin, R. Granato, M. Suzuki, J.N. Gil, J.M. Granjeiro, P.G. Coelho
4. Crit Rev Oral Biol Med 7, 329. (1996) *"The role of implant surface characteristics in the healing of bone."* K. Kieswetter, Z. Schwartz, D.D. Dean, B.D. Boyan
5. J Bone Joint Surg Am. 90, 2485-98. (2008) *"Effect of Micrometer-Scale Roughness of the Surface of Ti6Al4V Pedicle Screws in Vitro and in Vivo."* Z. Schwartz, P. Raz, G. Zhao, Y. Barak, M. Tauber, H. Yao, B.D. Boyan
6. International Journal of Dentistry 2014, (2014) *"Evaluation of Bone Healing on Sandblasted and Acid Etched Implants Coated with Nano-crystalline Hydroxyapatite: An In Vivo Study in Rabbit Femur."* L.M. Svanborg, L. Meirelles, V.F. Stenport, P. Kjellin, F. Currie, M. Andersson, A. Wennerberg

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DOT's Quality System

DOT America's bone on-growth processes are validated and its quality system is ISO13485:2016 certified by the BSI Group America.

DOT America operates under US FDA facility registration #3011461101.

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