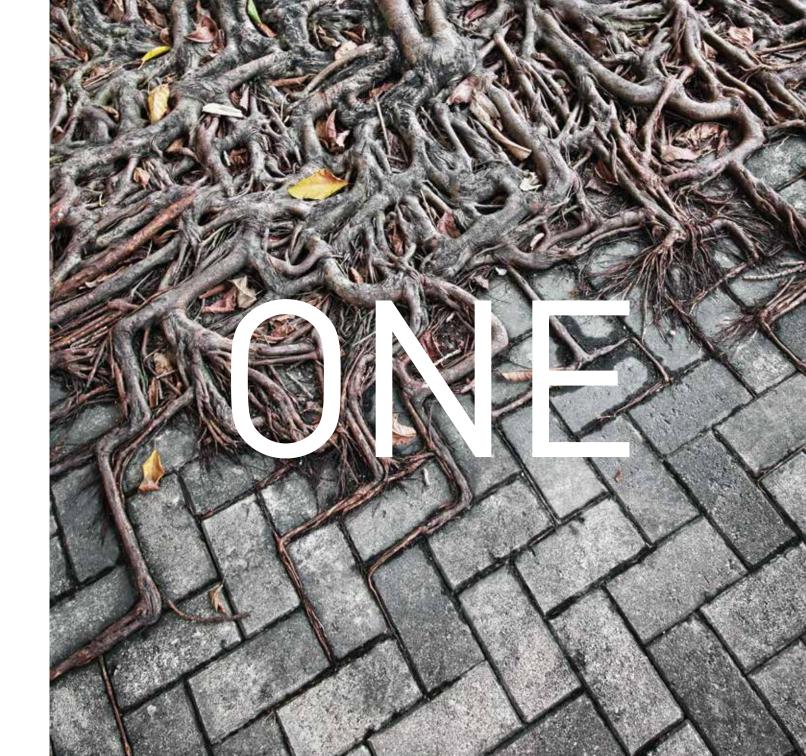


INSPIRATION

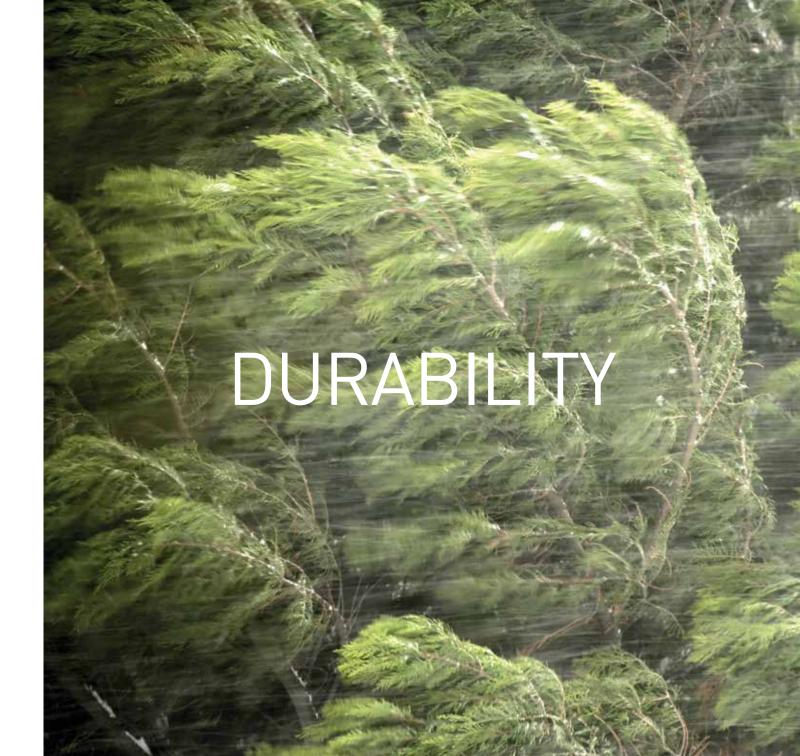
We were inspired by nature. The roots of a tree will grow through porous earth to support the tree's great strength and resilience. Those roots will get where they need to go, no matter the obstacles in their way. They will draw water from a distant source to feed the growth of that tree.



VISION

Creating a new generation of implants.

An implant that would promote the growth of bone through its porous surface. An implant that would simulate natural bone and stimulate the regenerative powers of the existing bone around it.



OBSERVATION

Nature always finds a way to support the strength and beauty of its creations.

To find sunlight.

To draw water.

Water, liquids, in nature, always find their way.



RESEARCH

We already understood tremendous amount about the mechanics of implants and the healing process after surgery, but we set out to learn more.

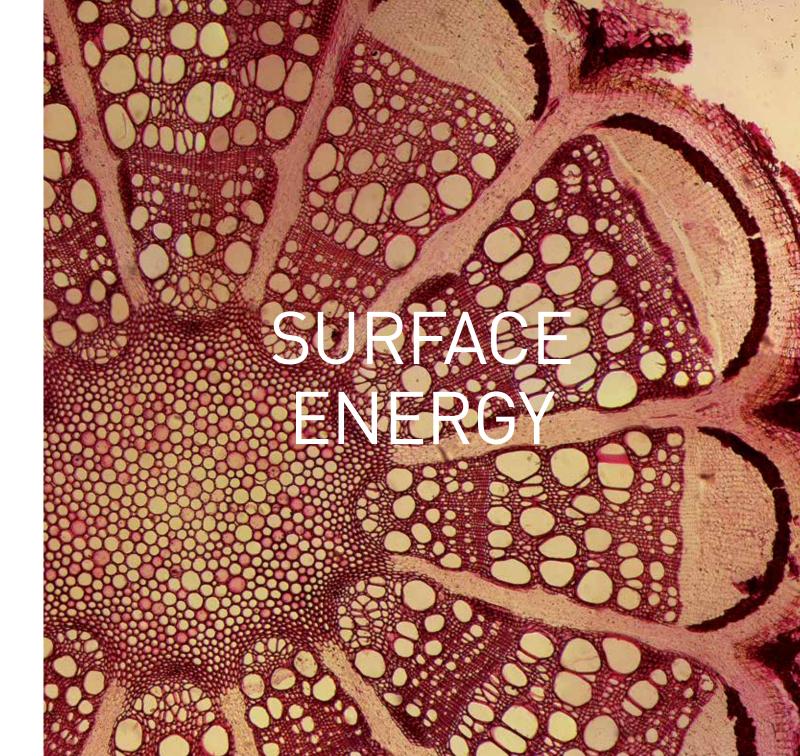
Surface roughness is key to promoting bone growth between existing bone and the surface of the implant. Extensive research revealed that when micro-roughness is enhanced with nanostructures, bone-to-implant adhesion is increasing.

Nanostructures generate the correct energy on the surface of the implant and stimulate cellular activity.

Nanostructures increase hydrophilia, drawing blood more quickly and efficiently allowing for the growth of a healthy vasculature to promote bone formation.

Increased hydrophilia and cellular activity means more successful osseointegration. With efficient cell selection, bone develops not only on the surface of the existing bone, but on the surface of the implant. This contact osteogenesis is vital for successful osseointegration and is critical in compromised cases.

We conducted both in-vitro and in-vivo studies under the direction of Prof. Zvi Schwartz to investigate whether in fact the implant would stimulate bone growth and osseointegration, and accelerate healing times.



PUBLICATION #1

Novel hydrophilic nanostructured microtexture on direct metal laser sintered Ti-6Al-4V surfaces enhances osteoblast response in vitro and osseointegration in a rabbit model

Sharon L. Hyzy, Alice Cheng, David J. Cohen, Gustavo Yatzkaier, Alexander J. Whitehead, Ryan M. Clohessy, Rolando A. Gittens, Barbara D. Boyan, Zvi Schwartz



Published in: Journal of Biomedical Materials Research (JBMR), Part A, 2016: ABSTRACT | The purpose of this study was to compare the biological effects in vivo of hierarchical surface roughness on laser sintered titanium-aluminum-vanadium (Ti-6Al-4V) implants to those of conventionally machined implants on osteoblast response in vitro and osseointegration.

Laser sintered disks were fabricated to have micro-/nano-roughness and wettability. Control disks were computer numerical control (CNC) milled and then polished to be smooth (CNC-M).

Laser sintered disks were polished smooth (LST-M), grit blasted (LST-B), or blasted and acid etched (LST-BE). LST-BE implants or implants manufactured by CNC milling and grit blasted (CNC-B) were implanted in the femurs of male New Zealand white rabbits. Most osteoblast differentiation markers and local factors were enhanced on rough LST-B and LST-BE surfaces in comparison to smooth CNC-M or LST-M surfaces for MG63 and normal human osteoblast cells.

To determine if LST-BE implants were osteogenic in vivo, we compared them to implant surfaces used clinically.

LST-BE implants had a unique surface with combined micro-/nano-roughness and higher wettability than conventional CNC-B implants.

Histomorphometric analysis demonstrated a significant improvement in cortical bone-implant contact of LST-BE implants compared to CNC-B implants after 3 and 6 weeks. However, mechanical testing revealed no differences between implant pullout forces at those time points. LST surfaces enhanced osteoblast differentiation and production of local factors in vitro and improved the osseointegration process in vivo.

PUBLICATION #2

Novel osteogenic Ti-6Al-4V device for restoration of dental function in patients with large bone deficiencies: design, development and implementation

D.J. Cohen, A. Cheng, A. Kahn, M. A viram, A. J. Whitehead, S. L. Hyzy, R. M. Clohessy, B. D. Boyan & Z. Schwartz



Published in: SCIENTIFIC REPORTS magazine, 08 February 2016 ABSTRACT | Custom devices supporting bone regeneration and implant placement are needed for edentulous patients with large mandibular deficiencies where endosteal implantation is not possible.

We developed a novel subperiosteal titanium-aluminum-vanadium bone onlay device produced by additive manufacturing (AM) and post-fabrication osteogenic micro/nanoscale surface texture modification.

Human osteoblasts produced osteogenic and angiogenic factors when grown on lasersintered nano-/micro-textured surfaces compared to smooth surfaces.

Surface-processed constructs caused higher bone-to-implant contact, vertical bone growth into disk pores (microCT and histomorphometry), and mechanical pull-out force at 5 and 10 won rat calvaria compared to non-surface-modified constructs, even when pre-treating the bone to stimulate osteogenesis. Surfacemodified wrap-implants placed around rabbit tibias osseointegrated by 6 w.

Finally, patient-specific constructs designed to support dental implants produced via AM and surface-processing were implanted on edentulous mandibular bone. 3 and 8 month post-operative images showed new bone formation and osseointegration of the device and indicated stability of the dental implants.

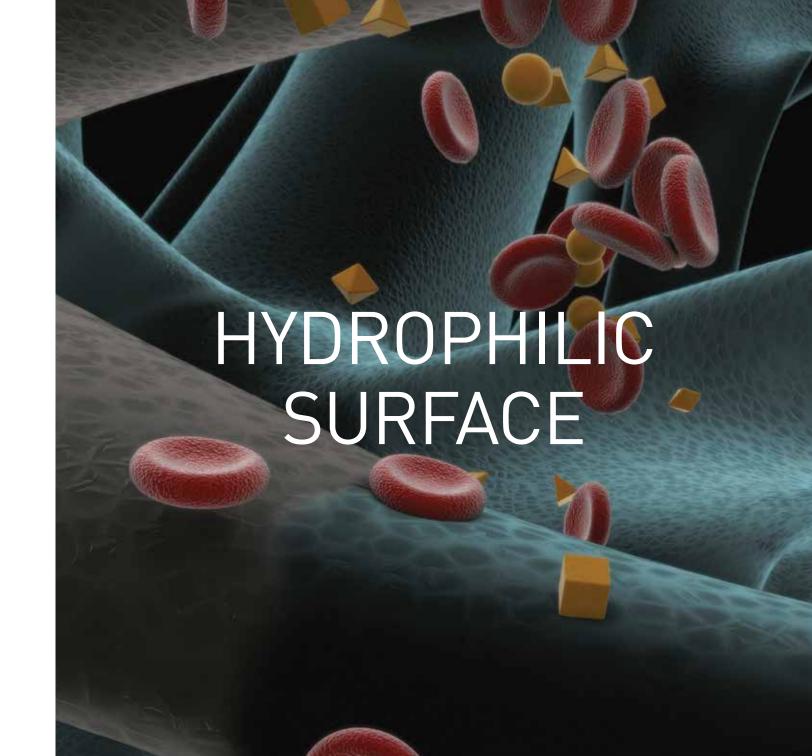
CLINICAL STUDY

GENERAL INFORMATION

- + The implants were inserted in 61 patients.
- + 30 men, 31 women.
- + Average patient age 61.6: average men>s age 63.4, average women>s age 60.7.
- + 144 implants were inserted. 64 in the maxilla, 80 in the mandible, 12 in the interior area, 132 in the posterior area.
- + 24 patients were implanted with single implant, 20 patients with 2 implants and 28 patients with over 2 implants.
- + Follow up is between 519- months. Average 11.9 months, median 12.5 months.
- + In the follow-up 76 implants have been restored and are fully functioning, 54 of them in the mandible.
- + 61 implants were inserted in areas with bone regeneration.
- + 0 implants with immediate loading

THE SUCCESS OF THE IMPLANTS

- + 6 of 144 implants failed, 3 of them in 1 patient.
- + Success rate 95.8%. Excluding the 1 patient with 3 failed implants, success rate is 97.9%.

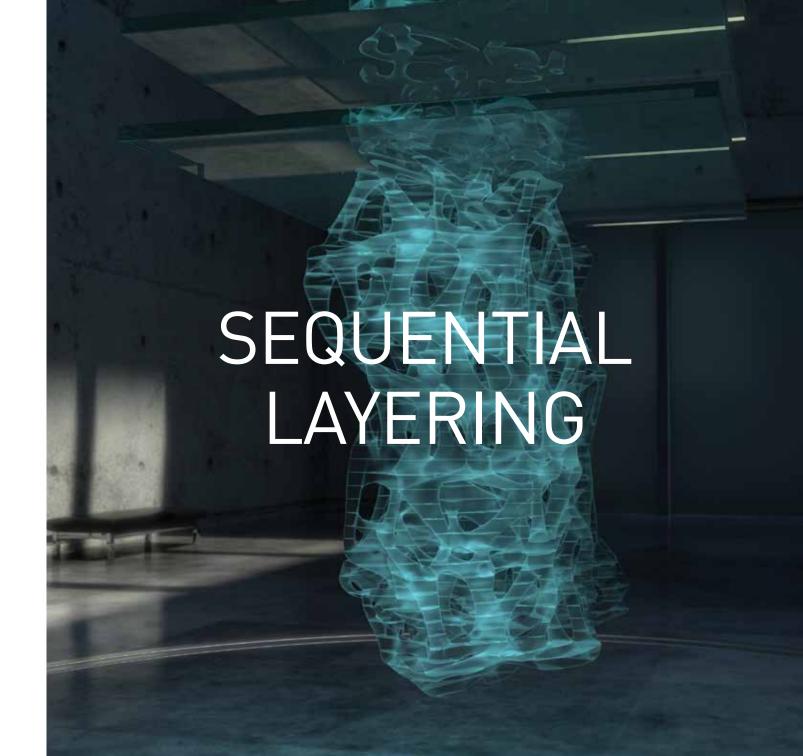


TECHNOLOGICAL SOLUTION

The existing methods of manufacturing implants don't allow the control at the nano level and the correct surface energy that we were looking for.

We were determined to create something from scratch – to build an implant according to our precise design. We weren't willing to compromise.

Our search brought us to 3D printing, a new manufacturing technique that had never before been used to build dental implants of this kind. For the first time, we could manufacture a form from titanium dust in a sequential layering process that allows for unprecedented precision.



SUCCESS

The outcome is an implant with a hydrophilic surface that enhances osseointegration as never before.

The results of our research are astounding. Our new implant draws blood and promotes protein selection as never before. The nanostructure we have perfected have the correct surface energy and hydrophilic properties to simulate natural bone.

3D printing means we are achieving successful restoration results not only in standard cases, but in complicated, compromised cases as well, and we are doing it with shorter healing times.

We achieved what we were after. We found a technological solution to simulate nature.

