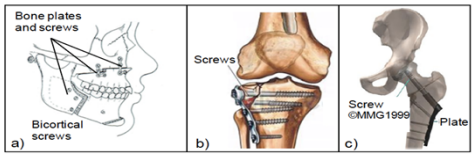
DREXEL UNIVERSITY
School of
Biomedical Engineering,
Science and Health Systems

SST–Smart Surgical Tools: Bioactive Surgical Fixation Devices for EnhancedBone and Tissue Regeneration

Peter I. Lelkes, PhD[1], Norman Johanson, MD[2], Jack Zhou, PhD[3], Yury Gogotsi, PhD [4], Kurt Hankenson, DVM, PhD[5], Qingwei Zhang, PhD[6], Anna Katsman, MD[7], Sean Devlin[8]

Unmet Clinical Need

Orthopedic/Musculoskeletal surgeries, specifically following musculoskeletal trauma and sports injury, are amongst the most common emergency surgical procedures (Millions / year in USA). A large fraction will require the use of stabilizing surgical "interference devices".

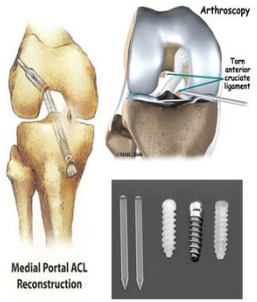


Human jaw fixation screws and plate installation
contour plate and 5 metal screws for a fractured tibial plateau
screw compression fixation for a fractured hip

Unmet Clinical Need: ACL Repair

Current surgical fixation devices, e.g. from the repair of the anterior cruciate ligament (ACL), are metallic and polymeric screws or pins, and have a series of distinct disadvantages

"Passive" permanent (metallic) devices,
Slowly biodegradable, of questionable mechanical strength
Slow healing process



Required: Novel "smart" tools to overcome these disad-vantages and allow for improved healing, accelerated patient recovery and avoidance of secondary (revision) surgeries.

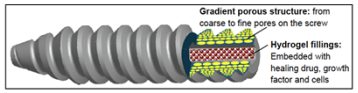
Envisioned Future Health Care Product: Smart Surgical Interference Screw

An innovative design of bioactive surgical screw with gradient porosity, based on 2 recent publications:

•Generation of biodegradable biomaterials with gradient cellular structures (Zhang et al., 2010).

•Reinforcement of biodegradable biopolymers using functionalized nanodiamonds (Zhang et al., 2011).

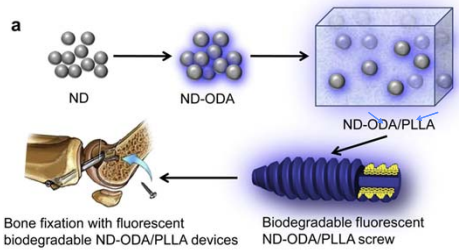
Gradient cellular structure of natural bone

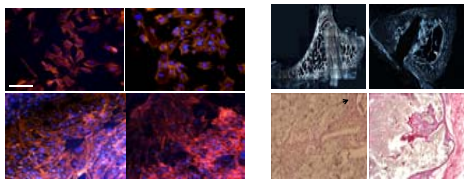


Bioactive Polymer with Gradient- Cellular Porous Structure, Reinforced with Nanodiamonds

OPTIONAL: Drug-releasing capability to further stimulate tissue regeneration

Technical-Science Aspects





RIGHT PANELS: Lack of cytotoxicity (in vitro osteoblastic cell culture)
LEFT PANELS: Implantation into dog tibia of gradient-cellular pins
left: porous,**right**: bioactive - porous + HA –enhanced new bone formation

Target Market / Patient Population

Approx. 100,000 ACL reconstructions surgeries are performed annually in the USA, with an average cost of ~ $ 5,000 /arthroscopic procedure (not including the costs for hospitalization, follow-up visits and potential revision surgeries.)

Procedure is accompanied with many weeks of costly and painful rehabilitation, tantamount to billions of dollars in lost productivity and revenue for the economy.

A smart surgical interference device (screw/pin/plate)

improving the healing process

accelerate patient recovery

help to avoid secondary (revision) surgeries

Tens of millions of dollars annually in direct revenue for the manufacturer and hundreds of millions of dollars in expenses saved for the health care industry.

Current Regulatory and Third-Party Reimbursement Assessment

Regulatory: Precedence for 510(k) pathway for biodegradable interference screws, PLLA / HA in clinical use

Unknowns: Porous structure, ODA-modified ND (ND are being considered for cancer treatment and gene therapy), Careful toxicity assays

Reimbursement strategy: Follow the reimbursement strategy of companies like Arthrex and Stryker. If the product gets FDA approval, it will be reimbursed.

Affiliations

1) Chair of Bioengineering at Temple University
2) Drexel University College of Medicine
3) Department of Mechanical Engineering and Mechanics , Drexel University
4) Department of Materials Science and Engineering, Drexel University
5) University of Pennsylvania School of Veterinary Medicine
6) Drexel University College of Medicine
7) Drexel University College of Medicine
8) School of Biomedical Engineering, Science and Health Systems, Drexel University

Coulter-Drexel Translational Research Partnership Program