

TECHNOLOGY AVAILABLE FOR TRANSFER

Orthopedic implant for sustained drug release



Key Features

- Concurrently, prevents infection and promotes osseointegration
- Sustained release of drug up to 180 hours
- Enhanced fracture toughness by 29%
- Improved mechanical and tribological properties

Stage of Development

This is a lab scale validated technology

- Biocompatibility found to be favorable
- Validated the antimicrobial activity of the implant
- Validated increase in fracture toughness

Applications

Bone Replacement for

- Severe Arthritis
- Sports Injury
- Accidental bone damage

Intellectual Property

- Patent Pending in India

Inventors

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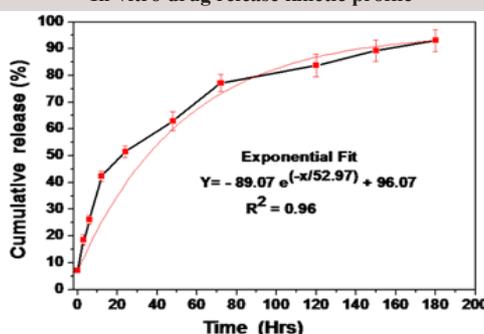
Background

Presently used all metallic implants are biologically compatible but inert. This may lead to weak interface with the bone causing aseptic loosening. On the other hand, infection of orthopedic implants can cause rejection and/or costly revision surgery. Aseptic loosening and periprosthetic bacterial infection are the two foremost causes of implant failure. Most of the new studies focused on designing of ceramic coatings on metal implants to improve the osseointegration and stability of the implant, while ignoring microbial susceptibility or *vice versa*, to prevent implant related infection while ignoring bone mineralization. However, both osseointegration and antibacterial functionalities are required for implant coating to attain long-term success of the implant, which is presently lacking in the existing implants and leads to about 10% implant failure rate.

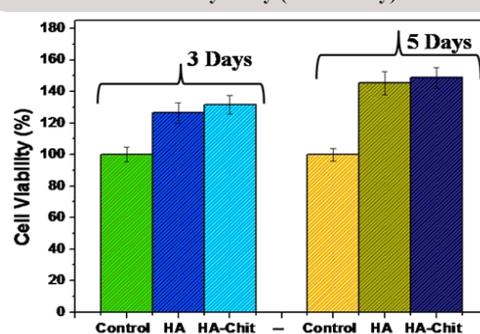
Technology

Present invention improves the present orthopedic implant system quality by simultaneously promoting osseointegration and inhibiting microbial cells and biofilm formation. This invention is planned to increase the success rate of orthopedic implants by reducing the early implant failure due to infection. These are generally used to replace a damaged bone permanently and providing immediate relief of pain to patient and helping to rejoin active life. The new implant comprises a metal implant with Hydroxyapatite (HA) coating loaded with antibiotics using a novel method to maintain osseointegration while providing sustained release of antibiotic to prevent infection.

In-vitro drug release kinetic profile



Cell viability assay (MTT assay)



Results of the Mechanical behavior analysis of the Implant

| Coatings | Hardness (GPa) | Elastic modulus (GPa) | Fracture Toughness (MPa.m ^{0.5}) |
|------------------------|----------------|-----------------------|--|
| HA | 0.485 ± 0.11 | 14.18 ± 1.91 | 1.30 ± 0.381 |
| Polymer impregnated HA | 0.413 ± 0.094 | 12.98 ± 1.74 | 1.85 ± 0.254 |

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Validation

This novel implant has been validated in lab through a no. of tests including the following:

| Tests | Results |
|---------------------------------------|---|
| In vitro drug release kinetics | <ul style="list-style-type: none"> • Fastest release of drug about 51% within fits 24 hrs by diffusion mechanism • Around 80% drug is released within first 120 hrs • Sustained release up to 180 hrs through degradation of polymer |
| Mechanical behaviour | <p>Tested using Nanovea M1 mechanical tester & Vickers diamond indenter</p> <ul style="list-style-type: none"> • Insignificant decrease in hardness and elastic modulus • Increase in fracture toughness |
| Antimicrobial activity | <p>Tested using Agar disc diffusion method by exposing implants to culture of S. aureus</p> <ul style="list-style-type: none"> • Distinctly clear and bacteria free zone observed around the novel implant |

Market

Increase in the aging population and sedentary lifestyle, musculoskeletal (MSK) disorders are the second most cause of disability worldwide, Musculoskeletal conditions, which affect over 1.7 billion people globally, include joint diseases, such as, osteoarthritis, osteoporosis, fragility fractures, back and neck pain, soft tissue rheumatism, injuries due to sports, workplace and road traffic accidents. In India, 12-15% of the population seems to suffer from MSK.

The global biomaterials market, including medical device and implants, is estimated to be greater than \$130.17 billion US Dollars by the end of 2021 and is expected to increase by 13.2 % every year. The largest market size amongst all biomaterial products belongs to orthopedic devices which is expected to reach \$41.2 billion US Dollars by 2019. The current size of the Indian orthopedic devices market is ~\$375 million US Dollars (Rs. 2,400 crores) and it will grow ~20% every year for the next decade to reach \$2.5 billion US Dollars (Rs. 16,000 crores) by 2030. The invention offers itself as an opportunity to tap the untapped markets by meeting the unmet need for a better orthopedic implant. *