A PROCESS FOR FABRICATION OF PURE/MACROPOROUS APATITIC (CDHA) BONE CEMENT FOR NON-LOAD BEARING ORTHOPEDIC APPLICATIONS

IITM Technology Available for Licensing

Problem Statement

- Addressing bone tissue defects and loss is a significant concern in orthopedics, requiring advanced regenerative procedures.
- Highlighting the promising features of CPCs, such as higher biocompatibility, bioactivity, and bioresorbability, for bone grafting applications.
- Exploring the potential of utilizing eggshell waste as a rich source of calcium for deriving calcium phosphate materials with trace elements mimicking human bone composition.
- Further, Recognizing limitations in current bone cement technologies and proposing a novel process for fabricating calcium deficient hydroxyapatite (CDHA) bone cements with improved injectability, macroporosity, and resorbability properties for effective bone grafting applications.

Technology Category/ Market

Biomaterials and Biomedical Engineering Applications- Bone Grafting, Implant Fixations, Void Filling, Orthopedic Coating
Industry - Orthopedic Devices and Implants.

Market- Global orthopedic biomaterials market size was estimated at USD 19.2 billion in 2022 and is expected to grow at a **CAGR of 7.8%** from 2023 to 2030.

Research Lab

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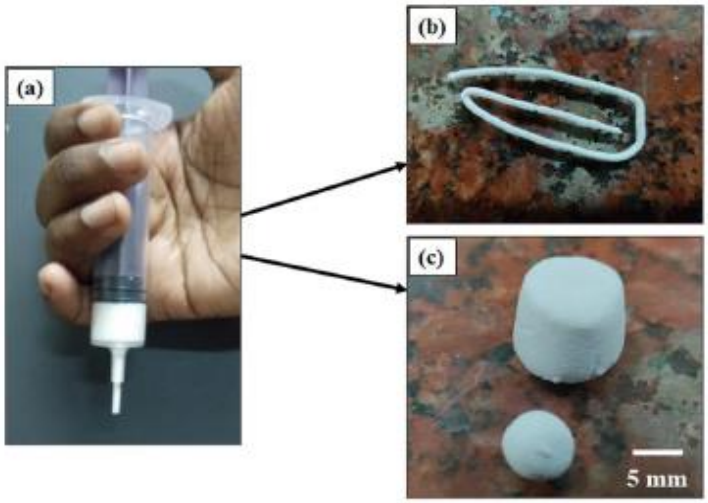

Fig. 1. Represents (a) Syringe containing cement paste, (b) Extruded injectable bone cement paste and (c) Cylindrical and round shaped molds of synthetic bone cement.

Intellectual Property

- IITM IDF Ref. **2276**
- **IN 410938 - Patent Granted**

TRL (Technology Readiness Level)

TRL - 4: Technology validated in lab scale.

Technology

- The present invention provides **a process for fabrication of macroporous apatitic (CDHA) bone cement** comprising steps of:
- (i) Synthesizing Nanocrystalline Hydroxyapatite (HA) using calcium nitrate ($Ca_3(NO_4)_2{\cdot}4H_2O$) and di-ammonium hydrogen phosphate ($(NH_4)_2HPO_4$) which are mixed and subjected to irradiation in a microwave oven of 800 W for 30 minutes. Thereafter, washing the precipitate with distilled water followed by oven dried at 100 °C overnight and powdered finely.

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Technology (Contd.)

- (ii) Synthesizing pure eggshell derived tricalcium phosphate (ESDβ-TCP) by heating a mixture of CaO extracted from eggshell and anhydrous dicalcium phosphate in 1:2 molar ratio at 1000 °C for 12 hours.
- (iii) Preparing a workable dough of the cements by mixing solid phase (β-TCP and HA) and liquid phase with a porogen agent, wherein cements (after homogenous mixing) were allowed to set for 1 hour and then, incubated in the PBS (pH ~7.4) solution at physiological conditions for certain time intervals; thereafter, the cements were processed for its further characterization and biocompatibilities investigations.

Key Features / Value Proposition

Innovative Synthesis Methodology
- The process introduces a microwave-accelerated wet chemical synthesis for nano-crystalline hydroxyapatite, ensuring efficient and controlled production.

Eggshell-Derived β-TCP Synthesis
- Utilizing eggshell waste for synthesizing pure β-tricalcium phosphate (ESD β-TCP) adds sustainability and cost-effectiveness to the manufacturing process.

Tailored Cement Formulation
- The cement preparation involves a precisely formulated combination of synthetic and eggshell-derived components, providing versatility and adaptability for varied orthopedic applications.

Polymeric Liquid Phase Enhancement
- Incorporating disodium hydrogen phosphate, gelatin, and chitosan in the liquid phase enhances the mechanical and biological properties of the resulting bone cement.

Innovative Porogen Agent Integration
- The inclusion of mannitol or polysorbate as a porogen agent introduces a controlled porosity element, contributing to improved macroporosity in the final product.

Optimized CDHA Phase Formation
- The process ensures the formation of a pure apatitic (CDHA) phase in bone cement with defined dimensions, allowing for efficient bioresorption and enhanced biocompatibility.

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