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TITLE:

EVALUATION OF NOVEL BIOMATERIALS FOR ORTHOPAEDIC IMPLANTS TO IMPROVE DURABILITY AND REDUCE COMPLICATIONS

INTRODUCTION

Orthopedic implants are the most commonly used fracture fixation medical devices manufactured to replace a missing joint or bone or to support a damaged joint.

A biomaterial is any substance or combination of substances (other than a drug), synthetic or natural in origin, that can be used for any period of time as a whole or part of a system that treats, assists or replaces any tissue, organ or function of the body. A material to be used in such applications must exhibit adequate mechanical properties coupled with controlled degradation rates and an appropriate biological behavior in terms of interaction with living tissues.

Bone tissue is the natural implantation environment when the in vivo strength retention of fracture fixation devices is evaluated. However, the removal of the implant from bone tissue for strength tests is a problem after some time which makes a reliable alternative method necessary. The scarcity of polymers that meet these demanding requirements motivated a search for novel biodegradable materials with improved mechanical properties.

Artificial biomaterials are the solutions for these problems, as surgical implantation of these artificial biomaterials of appropriate shapes, mechanical, chemical and biological properties help in restoring the function of the otherwise functionally compromised structures.

CLINICAL APPLICATIONS OF ORTHOPAEDIC IMPLANTS.

- Osteosynthesis
- Joint replacements
- Nonconventional modular tumor implants
- Spine implants.

An efficient orthopedic implant fulfills the following criteria;

1 Chemically inert

2 Non-toxic to the body

3 Great loading strength (equal to or more than the weight of the individual)

4 high ultimate tensile strength

5 young's modulus of the biomaterial should be equal or lesser than that of bone (higher young's modulus prevents stress transfer to adjacent bones leading to bone resorption and implant loosening.)

6 The implant should be light in weight to assist smooth locomotion and movement to the patients

7 High fatigue resistance

8 Absolutely corrosion- proof

9 Good wear resistance

10 Inexpensive

These notable novel biomaterials are going to be extensively studied and compared based on the above-mentioned properties to evaluate the more efficient orthopedic implant that can improve durability and reduce complications in patients.

- Composites: carbon fiber-reinforced polymers
- Bioactive glasses: 45S5 bioglass.
- Bioactive ceramics: hydroxyapatite.
- 3D- printed biomaterials.
- Cobalt -chromium alloys
- Ceramics: Alumina (Al_2O_3), Zirconia (ZrO_2),
- Polymers: ultra-high-molecular-weight polyethylene (UHMWPE), polyetheretherketone (PEEK)
- Titanium alloys: Ti-6Al-4V, Beta titanium alloys.
- Magnesium alloys.

OBJECTIVE:

Primary objective:

1) To evaluate the ***mechanical strength, wear resistance, corrosion resistance, allergic response*** of novel biomaterials with a focus on improving implant durability and reducing complications (revision surgeries).

2) Different novel biomaterials will be simulated **in-vitro.** (MOU between the medical institution and a renowned engineering institution in Chennai exists, who's resources will be used for simulation studies).

Secondary objective:

1) To assess the cost-effectiveness of adopting the novel biomaterials compared to standard implants.

MATERIALS AND METHODS:

STUDY DESIGN: Experimental study

STUDY SETTING: Engineering institution in Chennai & Tertiary health care center in Chennai.

STUDY DURATION: **Two years** after ethical committee approval.

PARTICIPANT SELECTION:

Principal data: pre-existing case records of implant surgery outcomes (complications and failures) via review of literature will be collected and used after informed consent from patients.

Supplementary data: From patients admitted for orthopedic implant surgery at Tertiary health care center , Chennai due to any etiology during the year 2024 .

INCLUSION CRITERIA:

AGE – 20 to 60 years old

SEX**-** Both males and females.

EXCLUSION CRITERIA:

Poor Bone Quality - Severe osteoporosis or various other conditions causing inadequate bone quality that may not support an implant.

Obesity - Morbid obesity (BMI ≥ 40) which can increase surgical risks and affect outcomes.

STUDY TOOL:

Conducting a detailed evaluation of novel biomaterials for orthopedic implants requires a wide range of advanced tools and methodologies to assess their properties, performance, and clinical outcomes .

1. mechanical testing equipment

- Universal Testing Machines (UTMs): Used to measure the mechanical properties of biomaterials, such as tensile strength, compressive strength, and elasticity.

- Fatigue Testing Machines: Evaluate the durability of biomaterials under cyclic loading conditions, simulating the repetitive stresses experienced by implants in the body.

- Wear Testing Machines: Assess the wear resistance of biomaterials, essential for joint replacements that experience constant movement and friction.

2. microscopy and imaging tools:

- Scanning Electron Microscopy (SEM): Provides high-resolution images of the biomaterial surfaces, giving an analysis of surface morphology and wear patterns.

- Transmission Electron Microscopy (TEM): Provides insights into the internal structure and composition of biomaterials at the nanoscale.

3. clinical evaluation tools:

- Patient-Reported Outcome Measures (PROMs): Surveys and questionnaires to assess patient satisfaction, pain levels, and functional outcomes post-implantation.

- Radiographic Analysis: Regular imaging e.g. X-rays, MRI to monitor implant position, integration, and potential complications over time.

4. Finite element analysis (FEA): Simulates mechanical behavior and stress distribution in implants under various loading conditions, helping to predict performance and identify potential failure points.

METHODOLOGY:

After Obtaining clearance from Institutional Ethics Committee, permission from the Dean of the institution and the approval from MEU to collaborate with the engineering institution in Chennai, Informed written consent from the participants shall be obtained before enrolling the participant or using their data in this research. Once the participant has given consent for the study, information will be collected by using the questionnaire under full privacy and confidentiality.

This study shall incorporate patient data into testing novel biomaterials in vitro.

Phase 1: Pre and Post operative conditions of the patients undergoing implant surgery using traditional biomaterials such as ***stainless steel*** and ***titanium*** shall be collected via review of literatures, pre-existing articles and also from patients undergoing implant surgeries at tertiary health care center in Chennai.

Phase 2: Patient conditions shall be analyzed. Based on complications and risks posed by the traditional implant materials, novel biomaterials will be examined in vitro considering its biological, physical and chemical aspects.

1) **Biomaterial Selection**: to compare and contrast the various available novel biomaterial and chose the ideal material.
   These include :
   - Composites: carbon fiber-reinforced polymers
   - Bioactive glass:45S5 bioglass
   - Bioactive ceramics: hydroxyapatite
   - 3D- printed biomaterials
   - Cobalt-chromium alloys
   - Polymers

2) **Preclinical Testing (stimulation studies in laboratories)**: Conduct preclinical evaluations of the selected biomaterials using in-vitro models to evaluate biocompatibility, mechanical testing to evaluate material strength and fatigue resistance, and corrosion testing to measure material stability.

3) **Assessment of Novel Coatings and Surface Modifications:** helps to improve the properties of orthopedic implants, such as promoting osteointegration, decreasing wear, or preventing bacterial adhesion.

4) **Infection Resistance Testing:** Investigate the antimicrobial properties and infection resistance of biomaterials through in-vitro assays (e.g., bacterial adhesion assays, biofilm formation assays) Assess the ability of biomaterials to inhibit bacterial colonization, prevent biofilm formation, and reduce the risk of implant-associated infections.

This phase of the research will be assisted by the engineering institution in Chennai with the approval of MEU.

SAMPLE SIZE : Sample size **n =38+38=76** (using **open epi software**)

STATISTICAL ANALYSIS : Data will be recorded in MS Excel.

Inferential and descriptive analysis will be done using SPSS (statistical package for social sciences) (version 22.0). The data is summarized, as means and proportions with their 95% confidence interval (CI) for continuous and categorical variables, respectively. The Chi-square test is used to test associations and the odds ratio is used to express the strengths of associations.

IMPLICATIONS:

This study aims to Identify and examine novel biomaterials with better durability that can lead to implants that last longer, reducing the frequency of revision surgeries and improving long-term patient outcomes.

Long-lasting and more reliable implants can reduce the overall expense by reducing the need for revision surgeries, extended hospital stays, and additional treatments, thereby lowering healthcare expenditure.

The implication of this research is to educate patients about the benefits and potential risks of novel biomaterials and empower them to make informed decisions about their treatment options.

This research can lead to collaboration between material scientists, biomedical engineers, and clinical researchers, leading to a multidisciplinary approach to implant development and optimization.

CONFIDENTIALITY:

Identity and personal details of participants will be kept confidential. Anonymity and confidentiality will be maintained throughout the study.

STRENGTHS:

- ✓ Identifying the best suited novel biomaterial with very minimal complication and revision surgeries can be a game changer in the field of orthopedic surgical implantation.

- ✓ It improves the quality of life of the patients making them more independent.

LIMITATIONS:

- ✓ Developing new biomaterials can be expensive due to the high costs associated with research and development, testing, and regulatory approval processes.

- ✓ There may be limited clinical data on the longterm success and complications associated with new biomaterials, making it hard to predict their performance over time.

ETHICAL CONSIDERATION: Nil

CONFLICT OF INTEREST: Nil

SOURCE OF SUPPORT: Nil

REFERENCES

1) Ong KL, Yun BM, White JB. New biomaterials for orthopedic implants. Orthopedic Research and Reviews. 2015 Sep 8:107-30.
2) Bandyopadhyay A, Mitra I, Goodman SB, Kumar M, Bose S. Improving biocompatibility for next generation of metallic implants. Progress in materials science. 2023 Mar 1;133:101053.
3) Liang W, Zhou C, Bai J, Zhang H, Long H, Jiang B, Dai H, Wang J, Zhang H, Zhao J. Current developments and future perspectives of nanotechnology in orthopedic implants: an updated review. Frontiers in Bioengineering and Biotechnology. 2024 Mar 18;12:1342340.
4) Sanjuán M, Brizuela-Velasco A, Gil J, Cerrolaza M, Montalvillo E, Fernández-Hernández S, Robles D. Hybrid surface implants: Influence of residual stress on mechanical behavior, evaluated by finite element analysis and validation by fatigue tests. Dental Materials. 2024 Jan 1;40(1):9-18.

5) Szczęsny G, Kopec M, Politis DJ, Kowalewski ZL, Łazarski A, Szolc T. A review on biomaterials for orthopaedic surgery and traumatology: from past to present. Materials. 2022 May 18;15(10):3622.
6) Filip N, Radu I, Veliceasa B, Filip C, Pertea M, Clim A, Pinzariu AC, Drochioi IC, Hilitanu RL, Serban IL. Biomaterials in orthopedic devices: current issues and future perspectives. Coatings. 2022 Oct 14;12(10):1544.
7) Yadav D, Garg RK, Ahlawat A, Chhabra D. 3D printable biomaterials for orthopedic implants: Solution for sustainable and circular economy. Resources Policy. 2020 Oct 1;68:101767.
8) Mendes SC, Reis RL, Bovell YP, Cunha AM, van Blitterswijk CA, de Bruijn JD. Biocompatibility testing of novel starch-based materials with potential application in orthopaedic surgery: a preliminary study. Biomaterials. 2001 Jan 1;22(14):2057-64.
9) Vasenius J, Vainionpää S, Vihtonen K, Mäkelä A, Rokkanen P, Mero M, Törmälä P. Comparison of in vitro hydrolysis, subcutaneous and intramedullary implantation to evaluate the strength retention of absorbable osteosynthesis implants. Biomaterials. 1990 Sep 1;11(7):501-4.
10) Wenz LM, Merritt K, Brown SA, Moet A, Steffee AD. In vitro biocompatibility of polyetheretherketone and polysulfone composites. Journal of biomedical materials research. 1990 Feb;24(2):207-15.