

Executive Summary



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1. Title of the Project: Design, manufacturing, pre-clinical/clinical validation of novel metallic/ ceramic dental implants
2. Date of Start of the Project: February 1, 2020
3. Aims and Objectives:
 - a. To design and to manufacture the 3-piece and single piece dental implant system
 - b. To conduct Finite Element Method (*in silico*) based biomechanical study of the implant to investigate periprosthetic bone response.
 - c. To optimize surface topography of the implant using sand blasting and acid-etching method
 - d. Pre-clinical study using dental chewing simulator to understand long cycle fatigue damage
 - e. To investigate *in vitro* cytocompatibility using human gingival fibroblast cells.
 - f. To conduct pre-clinical study (*in vivo*) using designed implants in rabbit condyle to understand osseointegration
 - g. To perform clinical trial (pilot study) on limited number of human subjects and to record clinical outcome (quantitative and qualitative).
 - h. To assess the scaling up of manufacturing process by a startup incubated by the nominee or TATA Steels New Materials Business.

4. Significant achievements (not more than 500 words to include List of patents, publications, prototype, deployment etc.)

4.1. Outputs from research work done in 2022

According to a Helpage India report in 2015, by 2021, the elderly in the country is projected to be around 324 million by the year 2050, with 7.7% of its population being more than 60 years. Higher edentulism (partial or complete toothloss) in both urban and rural elderly population is around 91.2% in elderly above the age of 65 years. In order to address the nationwide availability and affordability of the dental implants, the major outcome of this project is believed to bridge the critical gap, by putting efforts to design, manufacture and clinical translation of ‘make-in-India’ dental implants with better osseointegration (integration with jawbone) promoting design features.

In particular, a complete implant assembly together with the instrumentation or accessories for the dental implantation surgery, is designed and implant prototypes are manufactured and tested for performance-limiting properties. The primary stability following implantation is established using a combination of the pre-clinical testing, using a torque testier and dental fatigue test set up under clinically relevant test conditions. The insertion and removal torque during the implantation were measured with bone mimicking synthetic materials with varying densities (sawbone™) along with natural bones of porcine (pig) and human cadaver. The pre-clinical studies in rabbit condyle established better osseointegration of the indigenous implants, than the commercial Straumann implants. In addition, the clinical studies in three hospitals are planned and have received all the necessary approval from the hospitals and IISc. In addition, CTRI approval- is obtained. The CDSCO recently approved the trial manufacturing license for the implants manufacturing at ISO 13485-compliant facilities at ARKA Medical Devices Pvt. Ltd/, Hyderabad – the manufacturing partner of our project.

4.2. Other tangible outputs (NDAs, approvals etc.)

- a) NDA has been signed with ARKA Medical devices Pvt. Ltd., Bangalore for pilot scale manufacturing of metallic implant system. ARKA has received its trial manufacturing license from CDSCO/DCGI.
- b) For conducting human clinical study of metallic implants, approval from respective Institutional Review Boards of King George's Medical University, Lucknow; Datta Meghe Institute of Medical Sciences, Wardha; and M S Ramaiah University of Applied Science, Bangalore have been approved and obtained. Clinical studies will be started soon (by December 2022)
- c) CTRI (Clinical Trial Registry of India) approval is obtained for conducting the human clinical trials.
- d) A national conclave was organized in June 2022 at ARKA medical Devices Pvt Ltd, where clinician (from different hospital), industrialist (manufacturing partner) and delegated from TATA Steels Pvt Ltd (business partner) were present. The main idea of having this conclave was to fill the gap between industries and hospitals. Clinicians witnessed the implant development process at manufacturing site and they put forward their requirements which they usually face while restoring teeth.
- e) Manuscript based the biomechanical simulation of ceramic dental implant system has been under review at ASME J. Biomechanical Engineering and one research paper is published in Int. J. Appl. Cer. Tech. One US patent has been filed.

5. Concluding remarks

At the closure, I would like to mention that the technology development program in my research group at IISc on the indigenous dental implant with novel design features and with validated performance-limiting biocompatibility assessment, has started with the funding from Department of Biotechnology through center for excellence funding. This activity has been clearly augmented over last three years with Abdul Kalam Technology Innovation National fellowship. The technology of metallic dental implant has been transferred to ARKA Medical Devices Pvt Ltd, Hyderabad. In particular, the academic clinical studies at two Government hospitals (Lucknow and Wardha) and one private hospital (Bangalore) are already planned and required approvals have obtained from both IISc and respective hospital's review board. One such study is going to start by December 2022. One year follow up observations after final crown placement will be reported as clinical evidence.