

Executive Summary

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1. Title of the Project: Design, manufacturing, pre-clinical/clinical validation of novel metallic/ ceramic dental implants

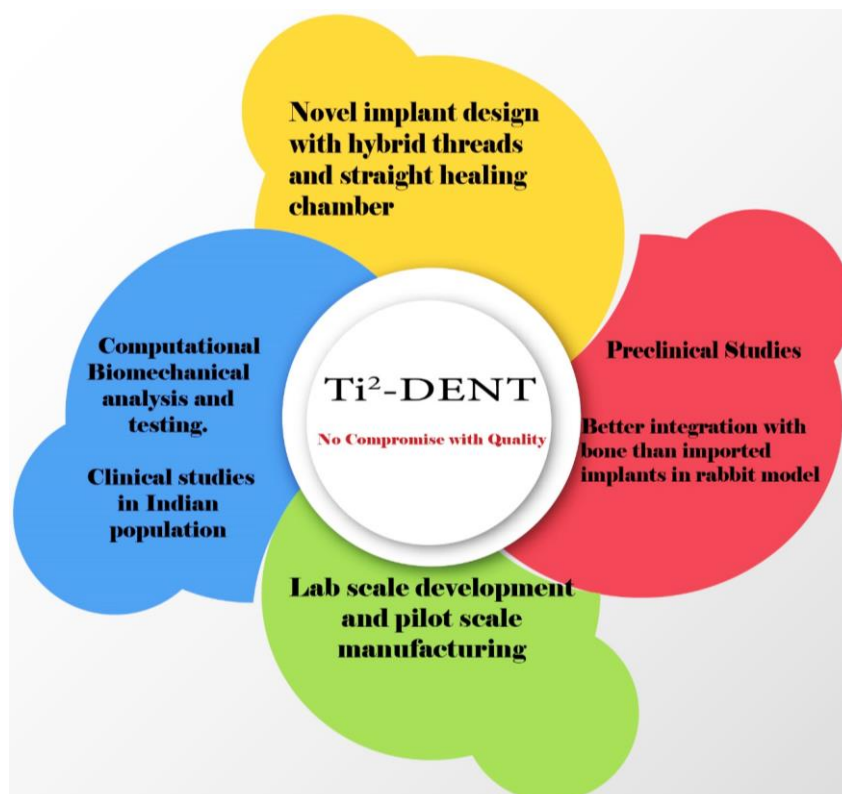
2. Date of Start of the Project: February 1, 2020 to January 3, 2023 (3 years)

3. Aims and Objectives:

- i. To design and to manufacture the 3-piece and single piece dental implant system
- ii. To conduct FEA based biomechanical study of the implant to investigate periprosthetic bone response.
- iii. To optimize surface topography of the implant using sand blasting and acid-etching method
- iv. Pre-clinical study using dental chewing simulator to understand long cycle fatigue damage
- v. To investigate *in-vitro* cytocompatibility using human gingival fibroblast cells.
- vi. To conduct pre-clinical study using designed implants in rabbit condyle to understand osseointegration
- vii. To perform clinical trial (pilot study) on limited number of human subjects and to record clinical outcome (quantitative and qualitative).
- viii. 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). The key highlights include,

- a) FEA based biomechanical analysis indicated that the implant design models can generate an osseointegration-promoting biomechanical environment by uniformly distributing stress in all components and in the peri prosthetic region, which allows improved primary and secondary stability.
- b) Fatigue analysis of implants as per ISO 14801:2016 ensures that implants are sturdy enough to bear the masticatory loading for a long time in the physiological condition of the jawbone.
- c) Pre-clinical study of surface modified implants in the rabbit condyle advocates that the new design features of the implant enhance the process of osseointegration and uniform stress distribution in the periprosthetic bone. Histopathology and histomorphometry results suggest enhanced neobone formation and mineralization of neobone in the peri-prosthetic region of the surface-modified indigenous implant when compared to the commercial control implant.
- d) NDA has been signed with Arka Medical dvces Pvt. Ltd., Bangalore for pilot scale manufacturing of metallic implant system.
- e) For metallic dental implants, TRL analysis is complete up to pre-clinical validation phase (TRL 6) and is ready for multicentric clinical evaluation.



Research papers, wherein the fellowship is acknowledged:

1. Kottan, N., Gowtham, N. H., and Basu, B. ASME. *J Biomech Eng.* 2022; 144(3): 031001.
2. Sharma, Swati, and Bikramjit Basu; *Biomaterials* (2021): 121331.
3. Asish Kumar Panda and Bikramjit Basu; *ACS Applied Bio Materials* 2021 4 (12), 8543-8558;
4. Barui, S, Hadagalli, K, Mukherjee, S, Roy, S, Bhattacharjee, D, Basu, B. *Int. J. Appl. Ceram. Technol.* 2022; 19: 762– 772.

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 two years with Abdul Kalam Technology Innovation National fellowship.

In particular, the academic clinical studies at two Government hospitals (Lucknow and Wardha) and one private hospital (Bangalore) are already planned and one such study is going to start by March, 2022. One year follow up observations after final crown placement will be reported as clinical evidence. The trial license from DCGI/ CDSCO for manufacturing test implants at the GMP-compliant facility of the Arka Medical Devices Pvt. Ltd. is under progress. The commercialization plan to reach the market has been conceived. We have discussed this a certified regulatory consultant, currently engaged with TATA Steel New Materials Business (TSLNMB). The business plan between Arka Medical Devices Pvt. Ltd. And TATA Steel are currently under progress. Also, the technology transfer to TATA Steel New Materials business will be completed by March, 2022.

As Abdul Kalam National Innovation fellow, I invested significant effort to advise TSLNMB in developing their business in ‘Medical Materials and Devices’ domain. In fact, TSLNMB has recent marketed phase pure and thermal sprayed grades of hydroxyapatite, with technology transferred from my research group at IISc, Bangalore.