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PROJECT COMPLETION REPORT

1. **Project Number** : 6205
2. **Title of the Project** : **Biphasic Hydroxyapatite based keratoprosthesis evaluation in a rabbit model (proof of concept).**
3. **Funding Agency Name** : Technology Development Fund, SCTIMST
4. **Project Reference Number provided by the Funding Agency:**

   Sanction Number:TDF- 6205(2013-14)
5. **Principal Investigator (Name & Address) :**

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6. **Co-Investigators (Name & Address):**
   i. **Dr Vinay Sukumaran Pillai, Chaithanya Eye Hospital,** Thiruvananthapuram, Kerala 695012
   ii. **Dr. Hari Krishna Varma**, Bioceramics lab, BMT wing, SCTIMST.
   iii. **Dr. Sachin J Shenoy, Division of In vivo Models and Testing**, BMT wing, SCTIMST
   iv. **Mr.S .Vijayan**, Bioceramics lab, BMT wing, SCTIMST
7. **Implementing Institution** :

   Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala 695012
8. **Collaborating Institutions** : Chaithanya Eye Hospital
9. **Date of Commencement** : 18.05.2013
10. **Duration** : 2 years
11. **Date of Completion** : 17.05.2015

12. Objectives as approved :

1. To study the biointegration, biostability, biocompatibility of the Biphasic Hydroxyapatite Skirt keratoprosthesis

13. Deviation made from original objectives if any, while implementing the project and reasons thereof :

Biphasic keratoprosthesis was synthesised successfully. Two stage OOKP procedure was performed in four rabbits and due to eye anatomy (exophthalmic) limitation the outcome was not as expected. However, the first stage of implantation study was successful.

14. Field/Experimental work giving full details of summary of methods adopted, data collected supported by necessary tables, charts, diagrams and photographs :

NA

15. Detailed anaylsis of results :

NA

16. Summary sheet of not more than 2 pages under following heads :
(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)

Title: Biphasic Hydroxyapatite based keratoprosthesis evaluation in a rabbit model (proof of concept).

Corneal opacification is the fourth most common cause of world blindness (WHO 2010). The cornea may be damaged from infection, diseases or trauma. The prognosis for successful visual rehabilitation with conventional corneal grafting in these patients is often poor and most of them have no access to allograft donor material. An artificial cornea or keratoprosthesis procedure thus represents a viable alternative for treatment in many of these patients. The Osteo-Odonto Keratoprosthesis (OOKP) operation was developed by Strampelli, is a complex two-stage surgical procedure that can be used to restore vision in end stage cases of severe corneal, ocular surface and dry eye states. Numerous synthetic keratoprosthesis devices have been developed as total replacements of the cornea for the treatment of corneal blindness. Keratoprostheses incorporate a clear central optic and an annular porous surround, or skirt element, designed to provide tissue integration. The major challenges facing these keratoprosthesis devices is that a sufficient amount of cellular invasion is needed to anchor the implant firmly in place as stable tissue integration is crucial for the survival of a keratoprosthesis.

Various bioactive materials and bioinert materials such as platinum, titanium and aluminum alloys have been developed for keratoprosthesis skirt substitution. Bioactive materials, including glass ceramic and hydroxyapatite (HA) ceramic, have both shown good tissue integration. However, serious complications such as aqueous leakage, retroprosthetic membrane formation and endophthalmitis are frequently observed due to the degradation of these bioactive materials. Present study is planned to evaluate a biphasic modified hydroxyapatite with much reduced resorption potential.

NEED

OOKP surgery is extremely complex and is limited by the availability of any healthy canine teeth in adults, or in children who have yet to develop adult dentition. Dimensional limitations of an autologous lamina also restrict the design and size of the OOKP optical device to either a 3.5 or 4mm opening, significantly restricting the field of view. These issues have led to an increased search for alternatives, and one promising solution to this is the development of novel biomaterials to be used as skirt material. This would enhance the use of the OOKP procedure and make it accessible to a wider group of patients.

OBJECTIVE

1. To study the biointegration, biostability, biocompatibility of the Biphasic Hydroxyapatite Skirt keratoprosthesis

METHODOLOGY

Materials.

Biphasic Hydroxyapatite Skirt Keratoprosthesis (BHA Kpro) with modified surface for better tissue integration and core having reduced resorption potential will be designed by the investigator in consultation with the ophthalmic surgeon and synthesized at Bioceramic laboratory, BMT wing, SCTIMST.

Method

The studies were performed after approved by the Institutional Animal Ethics Committee. Six adult rabbits, each weighing 3.5 to 4.5 kg, will be used (one implant per animal). Opthalmic surgeon (co-investigator) specialized in corneal surgery will be performing the keratoprosthesis implantation procedure.

The surgical procedure will be performed in two stages separated by minimum of three months.

17. **Contributions made towards increasing the state of knowledge in the subject :**

- Synthesised biphasic keratoprosthesis
- Standardised the two stage OOKP procedure in rabbit model

18. **Conclusions summarising the achievements and indication of scope for future work :**

Keratoprosthesis was prepared and the surgical procedure consists of two stages. In first stage, the lens removal was done in all six animals and subcutaneous implantation of keratoprosthesis for fibrovascularisation in five animals. Second stage of surgery has been completed in two animals. Yet to complete second stage procedure in two animals. Funds were utilized completely.

Future work: Perform the 2 stage OOKP procedure in pig model.

19. **Science and Technology benefits accrued :**
    a. **List of research publications with complete details : Nil**

    b. **Manpower trained on the project :**
        i. **Research Scientists or Research Fellows : Nil**
        ii. **No. of PhD's produced : Nil**
        iii. **Other Technical Personnel trained : Nil**
    c. **Patents taken, if any : Nil**
    d. **Products developed, if any : Nil**

20. **Abstract: (In 300 words for possible publication in ..... Bulletin)**
    a. **Background:** OOKP surgery is extremely complex and is limited by the availability of any healthy canine teeth in adults, or in children who have yet to develop adult dentition. Dimensional limitations of an autologous lamina also restrict the design and size of the OOKP optical device to either a 3.5 or 4mm opening, significantly restricting the field of view. These issues have led to an increased search for alternatives, and one promising solution to this is the development of novel biomaterials to be used as skirt material. This would enhance the use of the OOKP procedure and make it accessible to a wider group of patients

    b. **Materials: Biphasic Hydroxyapatite Skirt Keratoprosthesis (BHA Kpro)** with modified surface for better tissue integration and core having reduced resorption potential will be designed by the investigator in consultation with the ophthalmic surgeon and synthesized at Bioceramic laboratory, BMT wing, SCTIMST

    c. **Results:** Keratoprosthesis was prepared and the surgical procedure consists of two stages. In first stage, the lens removal was done in all six animals and subcutaneous implantation of keratoprosthesis for fibrovascularisation in five animals. Second stage of surgery has been completed in two animals.

    d. **Conclusion:** Keratoprosthesis was prepared and the surgical procedure consists of two stages were carried out in two small animal model(Rabbit).

21. **Procurement/Usage of Equipment: NIL**

a. **Details of Equipment:**

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown
1	Vitrectomy set	AA1, Appasamyassociates	66,893	2013	Used for surgical procedure	Nil
2	Cryoprobe	AAV5, Appasamy associates				

b. **Suggestions for disposal of equipment(s):**

NA

7/12/23

Dr. A. SABAREESWARAN
Scientist
Histopathology Lab

(Name and Signature of PIs with date)

Routing: *Signed copy of "Project completion Report" by PI → root@sctimst.ac.in, rpc@sctimst.ac.in*