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PROJECT COMPLETION REPORT

1. **Project Number** : 8181

2. **Title of the Project** : DEVELOPMENT OF AN INDIGENOUS VOICE PROSTHESIS FOR REHABILITATION OF LARYNGECTOMEES

3. **Funding Agency Name** : Kerala State Council for Science, Technology & Environment (KSCSTE).

4. **Project Reference Number provided by the Funding Agency**:

   No. 936/DIR/2016-17/KSCSTE dtd 31.12.2016

5. **Principal Investigator (Name & Address) :**

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7. **Implementing Institution** : Regional Cancer Centre, Trivandrum

8. Collaborating Institutions : SCTIMST, Trivandrum.

9. Date of Commencement : 01 May 2017

10. Duration : 3 years, 10 months.

11. Date of Completion : 31 Mar 2021

12. Objectives as approved :

1. Consolidate our evolved strategy for cost effective post laryngectomy voice rehabilitation in our patients.
2. Head on comparison of those patients who have undergone organ preservation protocols with those of surgery and voice restoration by QOL study.
3. Design, development and in vitro testing of a novel voice prosthesis as a cost effective alternative device.
4. Clinical application of developed instruments in consenting patients.

(Only Objective 3 pertains to SCTIMST.)

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

Objective 3 completed.

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

- Survey of Voice restoration techniques post laryngectomy was performed.
- Prosthetic voice restoration was reviewed in terms of both clinical, technical, patents, and existing products in the market.
- Key failure modes and improvements identified.
- Predicate samples were tested for surface roughness, radiopacity, hardness, elemental / chemical analysis.
- The tensile property of the material used for prototyping was characterized using UTM.
- Several concepts for the Voice Prosthesis devices were put forth (six), CAD models generated and reviewed qualitatively.
- Design Concept 3 was optimized *in silico.* The performance was optimized based on three factors.
- The design concept 5 was chosen and mould fabricated based on the in silico performance. However, the in vitro performance was not satisfactory.
- The design concept 2 was chosen next and further refined and prototyped. Two such iterations were performed.
- CFD study using FSI was performed for assessing the performance during simulated air flow.
- Prototypes were fabricated and tested. Forward flow tests were satisfactory. However, the precision of the moulds needs to be improved for completion of tests.
- Several design concepts for the delivery system were also developed. However, their practical realization is pending.

- Two sets of moulds were made for Design Concept 2.2. A metal printed mould component was also attempted.
- Forward flow test: This test is to study the opening pressure characteristics. The test setup consists of a tube (acting as a wind tunnel) and associated fixtures as shown in Figure 1 below, a compressed air supply, a flow meter to regulate the air flow through the tube, a calibrated transducer to find out the pressure acting on the valve. The output values are recorded using LabView software.

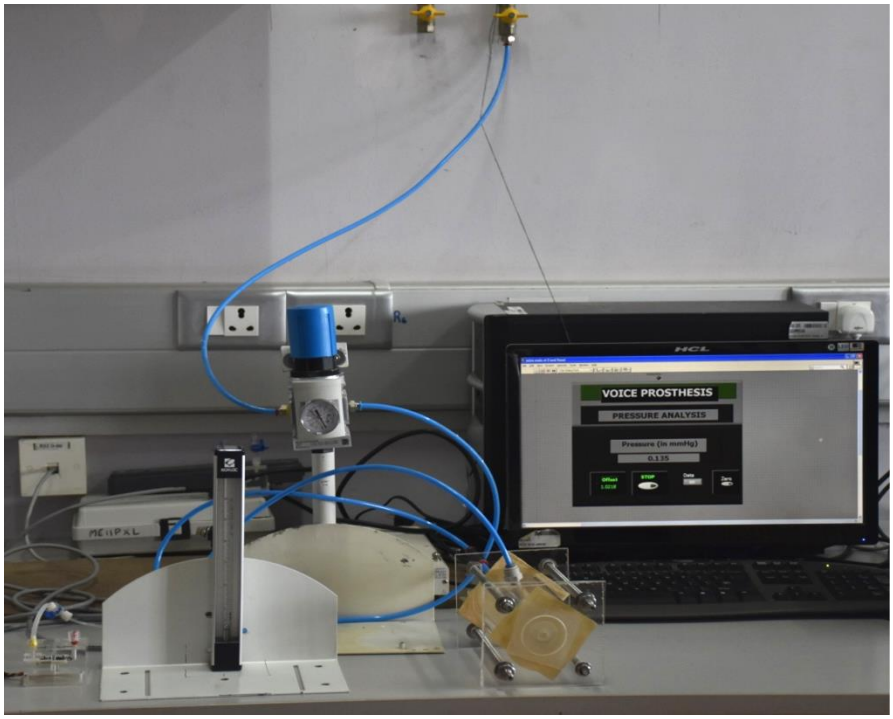

Figure 1: Test setup for forward flow study of voice prosthesis.

15. Detailed anaylsis of results :

Prototypes of Voice prosthesis (V2.3) were made using silicone molding process. 3D printed mold core was used. The dimensional quality for the component needs improvement.

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

Several conceptual designs of the device and its delivery system were realized. Two design iteration for the device were performed (V1.0 and V2.0). V2.0 was further refined to v2.3 by

changing the shape of the valve leaflet. Both V2.2 and V2.3 were moulded and prototyped. When comparing the test results, the device V 2.3 compared well with the control device for forward flow characteristics.

The delivery system was conceptualized, and CAD models developed for three different concepts. The concepts were fabricated using 3D printing. However, better surface smoothness, and tolerances are required to validate these mechanisms. This required high precision 3D printing or moulding techniques which have not been pursued.

The mould core realized through 3D printing did not have sufficient dimensional accuracy so as to provide leakage prevention during backflow testing. The following work needs to be taken up in a Phase II project to realize appropriate readiness for technology transfer of the product developed:

- A new mould needs to be designed to realize the valve geometry and reduce leakage while preserving the forward flow characteristics.
- The second step would involve modifying the delivery system to facilitate easy insertion.

Finally, as part of Phase II the device materials can be tested for biocompatibility, radiopacity and antimicrobial resistance to attain TRL5.

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

Saurabh S. Nair, S. Sujesh, Bipin T. Varghese, Akhil, K. R. Mahesh, Fluid Structure interaction study for the performance evaluation of a newly developed voice prosthesis device, NAFEMS WORLD CONGRESS 2021.

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

- Device concepts designed, prototyped and tested.
- Delivery system concepts designed and fabricated.
- Leakage resistance to be improved.
- Forward flow characteristics found good.

Future work:

- A new mould needs to be designed to realize the valve geometry accurately and reduce leakage while preserving the forward flow characteristics.
- The second step would involve modifying the delivery system to facilitate easy insertion.

19. Science and Technology benefits accrued :

a. List of research publications with complete details :

- Saurabh S. Nair, S. Sujesh, Bipin T. Varghese, Akhil, K. R. Mahesh, Fluid Structure interaction study for the performance evaluation of a newly developed voice prosthesis device, NAFEMS WORLD CONGRESS 2021 (Conference paper).
- A Voice prosthesis device with a one-way shunt valve. Indian Patent Appl. No: 201941003328.

b. Manpower trained on the project :

i.	**Research Scientists or Research Fellows**	**:**	2 research staff – Sr. Project Engineers trained.
ii.	**No. of PhD's produced**	**:**	NIL
iii.	**Other Technical Personnel trained**	**:**	1 M.Tech student.

c. Patents taken, if any :

- A Voice prosthesis device with a one-way shunt valve. Indian Patent Appl. No: 201941003328.

d. Products developed, if any : Prototype tested.

20. Abstract: (In 300 words for possible publication in ..... Bulletin)

Product details are not disclosed for publication as product refinement for fluid leakage prevention is pending.

21. Procurement/Usage of Equipment:

a. Details of Equipment:

Sl. No.	Name of Equipment	Make/ Model	Cost (Rs.)	Date of Installation	Utilisation	Remarks regarding maintenance breakdown
1.	Workstation	Fujitsu	140118.30	09.05.2018	Yes	Nil.
2.	Mini Lathe	Amit Engg.	121800.00	12.11.2019	Yes	Nil

b. Suggestions for disposal of equipment(s):

Equipment working and being used.

30.11.23

(Name and Signature of PIs with date)

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