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PROJECT COMPLETION REPORT

1. **Project Number** : P8134

2. **Title of the Project** : Hydrocephalus Shunt with Flat Type Adjustabe Differential Pressure Valve

3. **Funding Agency Name** : TRC Phase 1 SCTIMST

4. **Project Reference Number provided by the Funding Agency**: P8134

5. **Principal Investigator (Name & Address) : Er Anoop Gopinathan, DMDE, BMT Wing, SCTIMST**

6. **Co-Investigators (Name & Address):**
   i. Er Muraleedharan C V, DMDE BMT Wing SCTIMST

7. **Implementing Institution** : SCTIMST

8. Collaborating Institutions : None

9. Date of Commencement : 10/04/2018

10. Duration : 5 years

11. Date of Completion : March 2023

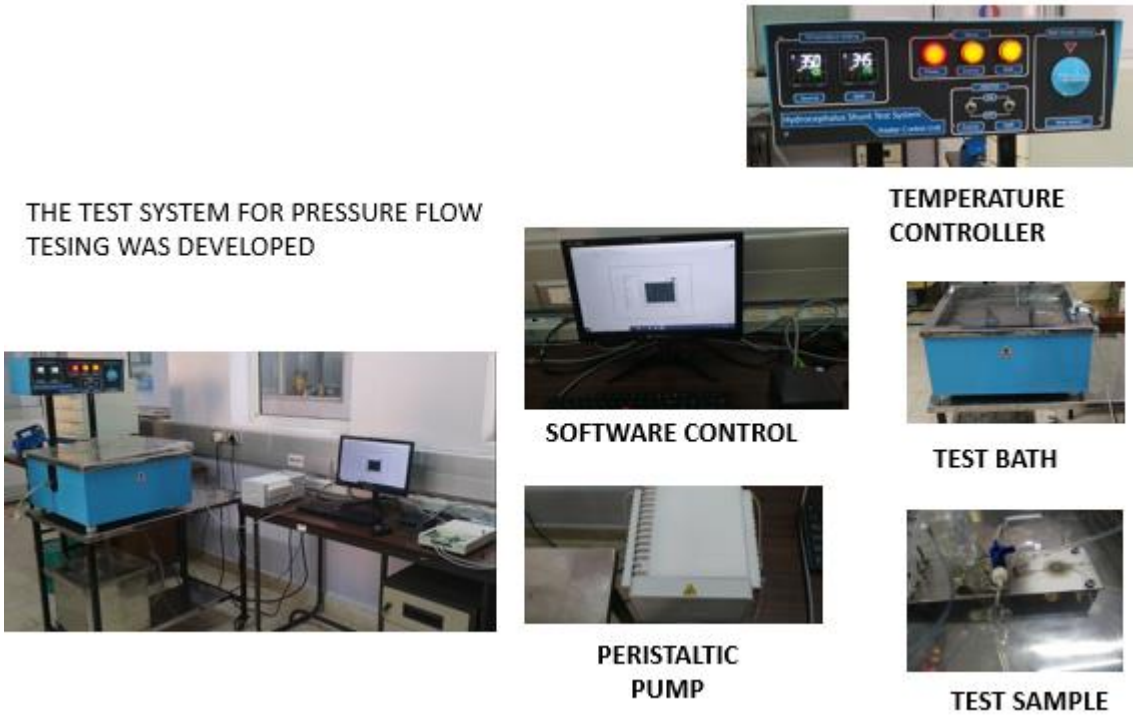
12. Objectives as approved:

Design and Development of Hydrocephalus Shunt with Flat Type Adjustable Differential Pressure Valve or Programmable Hydrocephalus Shunt

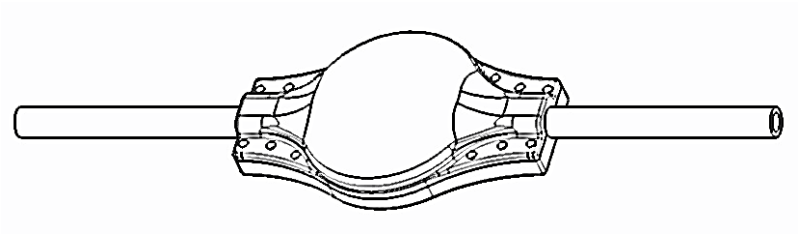
13. Deviation made from original objectives if any, while implementing the project and reasons thereof : None

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

The Design was done for a new mechanism of Hydrocephalus shunt Valve for Pressure flow adjustment. The test system was developed, and the mechanism was tested for performance. The continuous consistency is results is demanded long term prior to further invitro, invivo and preclinical studies.



Figure/Image 1: Test Setup for Shunt Performance testing



Figure/Image 2: Design of the Shunt Prepared

Figure/Image 3: Pressure Flow Testing of the noval mechanism

15. Detailed anaylsis of results :

The mechanism developed shows variation in pressure. However consistency in results is demanded

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

Introduction:

The project focuses on developing an adjustable hydrocephalus shunt to address the need for a customizable solution in patients with raised intracranial pressure. In contrast to existing non-adjustable shunts, this project introduces a flat-type adjustable differential pressure valve.

Rationale:

The shunt aims to overcome limitations of current market options (Medtronic's Strata Shunt, Codman Hakim Shunt) with a novel mechanism, minimal metallic components, MRI compatibility, and a unique polymer valve plug. This design innovation offers distinct advantages in terms of reduced metallic components, enhanced MRI compatibility, and a robust axisymmetric mechanism.

Objectives:

The primary objectives include developing a shunt with adjustable opening pressure in five steps, consistent results, and adherence to ISO 7197 standards. The benchmark for success involves comparing pressure results with competitor devices and ensuring compliance with industry standards.

Methodology:

Utilizing established processes like compression molding for silicone elastomer parts, injection molding, and machining for polymer components, the project employs well-established manufacturing techniques.

Results:

The device demonstrates the capability to vary opening pressure in five steps, providing consistent results. Success is measured by comparing pressures with competitor devices (Medtronic, Codman) and ensuring compliance with ISO 7197 standards.

Translational Potential:

With nominally 40,000-50,000 hydrocephalus surgeries annually in India and a prevalence of nominally 1-2 cases per 1000 births, the project aims to offer an affordable and robust shunt solution, addressing a significant medical need in the country.

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

The project on the Hydrocephalus Shunt with Flat Type Adjustable Differential Pressure Valve significantly contributes to advancing the field of hydrocephalus treatment. By introducing a novel mechanism with minimal metallic components and a polymer valve plug, the project expands the understanding of shunt design and functionality. The incorporation of a robust axisymmetric mechanism, achieved through well-established manufacturing processes, further enhances the understanding of designing reliable and cost-effective shunt devices. This research not only addresses the current gaps in the field but also sets a foundation for future innovations in hydrocephalus treatment.

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

The Hydrocephalus Shunt with Flat Type Adjustable Differential Pressure Valve project has achieved a breakthrough by introducing a novel mechanism, reducing metallic components, and ensuring MRI compatibility. The design adheres to ISO 7197 standards, emphasizing reliability. Future work should focus on optimizing the consistency in results, manufacturing for scalability and cost-effectiveness. Continued research, clinical trials, and collaboration with healthcare and industry partners are essential for validating long-term efficacy and facilitating widespread adoption, addressing the critical need for improved hydrocephalus treatment.

19. Science and Technology benefits accrued :

a. List of research publications with complete details :

- Gopinathan A, Nair S S, Muraleedharan C V. *Fluid-Structure Interaction Study for a Low Reynolds Number, Low Gap Flow Across a Pressure Opening Spring-Loaded Valve.* In: Proceedings of NAFEMS World Congress. 2023 May 16.

- Anoop Gopinathan, Vipin Dev V, Sukanya L J, Muraleedharan C V *"The Analytical and Numerical Model to Predict Low Reynold's Number Pressure Flow Characteristics of a Valve With Non-Linear Opening Boundaries"* Presented this topic for NAFEMS World Congress 2021

- Anoop Gopinathan, Vipin Dev V, Jithu Raj R, Subhash Kumar M S, Sukanya L J, Muraleedharan C V, (2023) *Low Reynolds number pressure-flow analysis across a valve: Comparison between three-point and multipoint gap functions with CFD results* , NAFEMS International Journal for CFD Case studies

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**	**:**	**Mrs Sukanya (Sr Project Engineer)** **Mr Vipin Dev V (Project Assistant)** **Mr Jithu Raj (Project Assistant)**

c. Patents taken, if any **: 1 patents applied**

India1, Patent Application No. 202241048796 of 26.08.2022
"A FLUID FLOW CONTROL DEVICE WITH FLAT TYPE ADJUSTABLE DIFFERENTIAL PRESSURE VALVE "

d. Products developed, if any **: Hydrocephalus Shunt with Flat Type Adjustable Differential Valve (Alpha Prototype)**

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

a.

Background: This project introduces a Hydrocephalus Shunt with Flat Type Adjustable Differential Pressure Valve, addressing limitations in existing shunt technologies. The novel design minimizes metallic components and incorporates a unique polymer valve plug, providing a robust solution for patients with raised intracranial pressure.

b. Materials: The shunt features complete silicone elastomer diaphragms and polymer rigid parts, ensuring enhanced MRI compatibility. Manufacturing processes include compression molding for elastomer parts and injection molding for polymer components.

c. Results: The shunt achieves adjustable opening pressure in five steps. However more efforts are required delivering consistent and reliable outcomes. Benchmarking against competitors and adhering to ISO 7197 standards establishes a new standard in shunt functionality and design.

d. Conclusion:

The Hydrocephalus Shunt project represents a significant advancement. The novel mechanism, advanced materials, and adherence to standards position it as a promising solution. Future work should focus on scalable manufacturing, extensive clinical validation, and collaboration for widespread implementation, addressing critical medical challenges associated with hydrocephalus

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
	Peristaltic Pump and Accesories	**ISMATEC**	**9.4 lakhs**	18/05/2022	**Used for Test setup**	
	Data Acquisition Card (USB) – 3 Nos	**National Instruments**	**4.8 lakhs**	28/01/2022	**Used for test setup**	

Mobile Workstation	**HP**	**1.5 lakhs**	15/01/2022	**Used for Design**

b. Suggestions for disposal of equipment(s):

The disposal strategy followed in Electronic and Electrical items could be followed.

(Name and Signature of PIs with date)

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