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(एक राष्ट्रीय महत्त्व का संस्थान, विज्ञान और प्रौद्योगिकी विभाग, भारत सरकार)
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PROJECT COMPLETION REPORT

1.	**Project Number**	:	6230
2.	**Title of the Project**	:	Cavity Conformable Surgical Space Stent Retractor (SSSR) design and proof of concept
3.	**Funding Agency Name**	:	Technology Development Fund (TDF)Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.
4.	**Project Reference Number provided by the Funding Agency**:		
	6230		
5.	**Principal Investigator (Name & Address) :**		
	Dr. George. C. Vilanilam (Clinical-PI), Neurosurgery Department, Hospital wing, SCTIMST, and Er. Arvind Kumar Prajapati (Technical-PI), Division of Artificial Internal Organs, Department of Medical Devices Engineering, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.		
6.	**Co-Investigators (Name & Address):**		
	i.		Er. Muraleedharan C. V., Division of Artificial Internal Organs, Department of Medical Devices Engineering, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.
7.	**Implementing Institution**	:	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Department of Science and Technology, Govt. of India
8.	**Collaborating Institutions**	:	Refer to translational potential section
9.	**Date of Commencement**	:	10th January 2020
10.	**Duration**	:	Two years 3 months
11.	**Date of Completion**	:	30 April 2022
12.	**Objectives as approved:**		
	To develop a cost-effective surgical retractor that is easy to deploy, sleek, and can be used to excise deeply located brain tumours.		
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:**		

A summary of various methods used for each milestone is listed below.

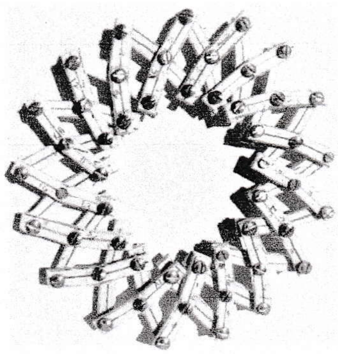
1. **Retractor specification**

   a) **Product and literature survey**

   The survey was done to gain knowledge of contemporary designs and to understand the working principles of various retractors.

   b) **Measurements of the control device (Leyla Retractor)**

	Various methods (vernier, micro meter, etc) were used to determine the critical dimension of the self-retaining Leyla Retractor. 2. **Concept development** The cavity conformable retractor with multiple components was designed using the analytical method, and governing equations were developed to obtain the desired opening diameter. 3. **CAD models/Drawings** Computer-aided design software (PTC Creo) was employed for modelling the various designs of retractors. 4. **Prototype development** Conventional manufacturing methods were used for the development of the retractor. 5. **Prototype evaluation** a. A prototype of a circumferential 360-degree expansion mechanism was fabricated using a PVC foam board with an open position radius of R_0 = 80mm, link width (W) of 5 mm, half link length (X_0) of 15mm. b. Link length, width, and bend angle measurement A vernier calipers (M/s Mitutoyo, Japan) was used for length and width measurement, and a protractor for bend angle measurement in fabricated prototype. c. Measurement of Pitch diameter in closed and open position A vernier caliper (M/s Mitutoyo, Japan) was used for closed and open-position pitch diameter measurement.
15.	**Detailed analysis of results:**
	A detailed analysis of the experimental outcomes is given below. 1. **Analytical model** The governing equations were used to determine the theoretical values of variables to fabricate a prototype for an open position radius of R_0 = 80mm. The number of links required (N) = 34.19 ~ 34 links Pitch diameter "closed position" (2 * R1) = 68.38 mm The link bend angle is = 158.88° Expansion ratio (m) = R_0/R_1 = (80/34.19) ~ 2.3

	Using values of values, a prototype was fabricated as shown below.  **2. Link length, width, and bend angle** The repeated measurements were conducted using vernier calipers, which resulted in an average half-link length of 16.17 ± 0.26 mm, a width of 6.406 ± 0.28 mm and a bend angle of 163.8 ± 0.84 degrees. **3. Pitch diameter in closed and open position** The measurement using vernier callipers resulted in open and closed position pitch diameters with average values of 81.95 ± 2.2 mm and 167.6 ± 2.30 mm, respectively. The open position pitch diameter was approximately close to two times of open position radius of R_0 = 80mm. **4. Retraction pressure** The safe limit of brain retraction pressure in clinical practice ranges 20 mmHg to 40 mmHg, which can be translated to 7.6 to 15.4 N. The total surface area of the device was approximately 2828 ± 0.10 mm^2 (eight flanges), corresponds to force range of 7.5 to 15.0 N.
16.	**Summary sheet of not more than 2 pages under the following heads :** **(Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)**
	Title Development and evaluation of expandable brain retractor with tunable expansion ratio **Introduction** Brain tumour treatment is challenging and requires a highly skilled neurosurgeon. These tumours are surgically excised by isolating them from normal tissue using surgical retractors. The retractors provide maximal and safe exposure of the surgical field to the surgeon, which evolved from the handheld retraction system. **Rationale** Most brain surgeries use Leyla and Greenberg retract. These traditional retractors-induced ischemia, edema, and parenchymal trauma are well known and result in brain tissue injury in up to 29% of cases. The authors conceptualized a single-unit circumferential 360-degree

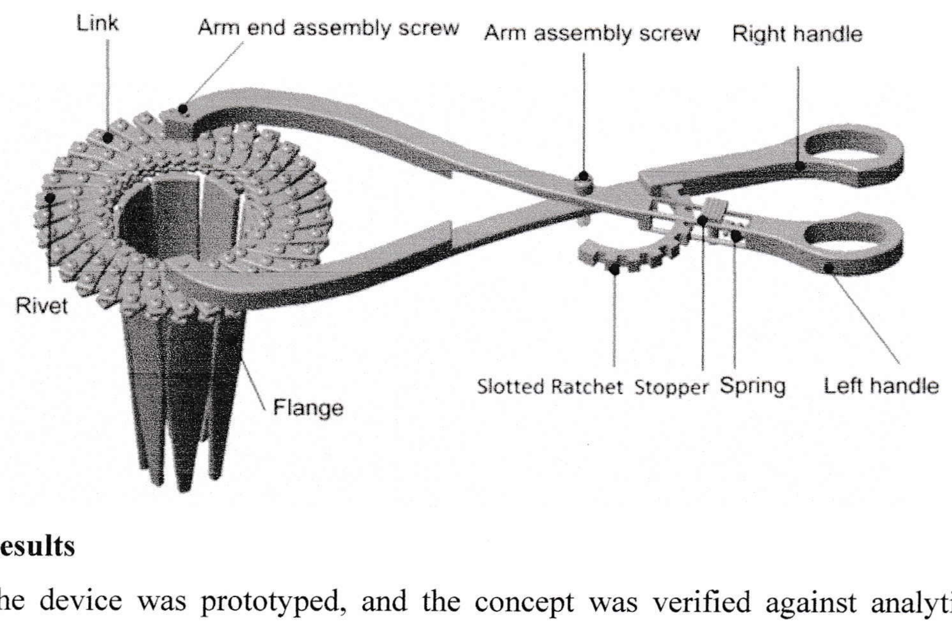
expansion mechanism to reduce brain injuries. Further, the surface area is optimized to keep brain tissue retraction pressure within the limit of the Leyla retractor. The design equations are derived for smooth manufacturing, and a simple locking mechanism maintains the retractor to a certain deployed diameter in a stable and steady manner.

Objectives

To develop a cost-effective surgical retractor that is easy to deploy, sleek, and can be used to excise deeply located brain tumours.

Methodology

The expandable brain retractor with a single-unit circumferential 360-degree expansion mechanism was developed. This mechanism was an assembly of interconnected links in a specific pattern. The assembly opens and closes through the translation of two diagonally opposite hinge points. Links are held together using rivets at multiple places, which create hinge points. Each hinge point in the Link rotates freely about its axis. The unique assembly pattern and dimensions of links allow the mechanism to expand from small to large diameter. The curved flanges are assembled on the bottom side of the mechanism. The flanges are designed and arranged to form a conical shape in the closed position. The conical geometry of links distributes strain uniformly on retracted brain tissues, which reduces the exertion of focal pressure on tissues. The radial opening of flanges also allows tumour/lesion excision in between the flanges, and dimensions are chosen to achieve optimum retraction pressure during use. The expandable brain retractor has a simple locking mechanism consisting of a slotted ratchet on the right handle and a stopper spring on the left Handle. The pulling stopper away from the slotted ratchet allows the surgeon to maneuver the handles.



Results

The device was prototyped, and the concept was verified against analytical models. It is conceived as a cost-effective, efficient, and easily manufacturable concept using design

	equations. The findings demonstrated the advantage of the proposed retractor over existing retractors in terms of optimal retraction pressure, facile handling, universal size, and workspace between the retractor flanges. Its applications may also extend to other surgical specialities and visceral organ sites. **Translational Potential** The design has been picked up by a potential industry partner who is currently revising the prototype for manufacturing.
17.	**Contributions made towards increasing the state of knowledge in the subject:**
	The proposed design envisions a 360-degree expansion mechanism that can be used to reduce brain injuries. This has enhanced our understanding of expansion mechanisms. Further work is underway, and when used in surgical settings, it will have a significant societal impact.
18.	**Conclusions summarising the achievements and indication of scope for future work:**
	This work resulted in two patent filings and one publication. The technology is being further improved and will be manufactured by the industrial partner.
19.	**Science and Technology benefits accrued :**

	a.	**List of research publications with complete details :**			
		Prajapati AK, Vilanilam GC, and Vayalappil MC. Development and Evaluation of Expandable Brain Retractor with Tunable Expansion Ratio. Trends in Biomaterials & Artificial Organs, 36(1), 21-26.			
	b.	**Manpower trained on the project :**			
		i.	**Research Scientists or Research Fellows**	: 01 Project scientist	
		ii.	**No. of PhD's produced**	: None	
		iii.	**Other Technical Personnel trained**	: None	
	c.	**Patents taken, if any**		: None	
	d.	**Products developed, if any**		: None	
20.	**Abstract: (In 300 words for possible publication in ...... Bulletin)**				
	a.	**Background:**			
		Published			
	b.	**Materials:**			
		Published			
	c.	**Results:**			
		Published			
	d.	**Conclusion:**			
		Published			
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	
-		-	-	-	-	-	-	-	
	b.	**Suggestions for disposal of equipment(s):**							
		None							

Dr.George C Vilanilam
(Clinical PI)
07/11/2023

Er. Arvind kumar Prajapati
(Technical - PI)
07/11/2023

(Name and Signature of PIs with date)

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