



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम, तिरुवनन्तपुरम - 695 011, केरल, भारत
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(एक राष्ट्रीय महत्त्व का संस्थान, विज्ञान और प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)

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PROJECT COMPLETION REPORT

1.	Project Number	:	6234
2.	Title of the Project	:	Design of novel polyaxial screws for thoracolumbar stabilization: a pilot study
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:		
			6234
5.	Principal Investigator (Name & Address) :		
	Er. Arvind Kumar Prajapati, Division of Artificial Internal Organs, Department of Medical Devices Engineering, Biomedical Technology Wing, SCTIMST		
6.	Co-Investigators (Name & Address):		
	i.	Dr. Krishna Kumar K. (Clinical Investigator), Neurosurgery Department, Hospital Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.	
	ii.	Mr. Muraleedharan C. V. (Co-investigator -device development), Division of Artificial Internal Organs, Department of Medical Devices Engineering, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.	
	iii.	Dr. Ganesh Divakar (Co-investigator -clinical), Neurosurgery Department, Hospital Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.	
	iv.	Dr. Sachin J. Shenoy (Co-investigator – animal experiment), Department of Applied Biology, Division of In Vivo Models and Testing, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.	
	v.	Dr. Sivakumar K. G. V. (Co-Investigator -material), 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	:	None
9.	Date of Commencement	:	04 January 2020
10.	Duration	:	18 months, with a six-month extension
11.	Date of Completion	:	31 December 2021
12.	Objectives as approved:		
	1. Design a novel polyaxial pedicle screw configuration & conduct design verification using an axial pull-out test.		
	2. Optimize design parameters for better mechanical properties.		

	3. Generate test result data.
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:
	<p>A summary of various methods used for each milestone is listed below.</p> <ol style="list-style-type: none"> 1. Pedicle screw design specification <ol style="list-style-type: none"> a) Product and literature survey <p>The survey was done to gain knowledge of contemporary designs and to understand the working principle of a pedicle screw-based system.</p> b) Measurements using Micro CT <p>This method was used to determine the critical dimension of the control device (pedicle screw)</p> 2. Concept development <ol style="list-style-type: none"> a) Analytical method <p>The analytical method was used for designing the pedicle screw thread profile.</p> 3. CAD models/Drawings <ol style="list-style-type: none"> a) Method for model development <p>Computer-aided design software (PTC Creo) was employed for modelling the pedicle screw variants.</p> 4. Test methods for material investigation <ol style="list-style-type: none"> a) Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments (ASTM 1839) <p>This standard was used for density and compressive strength measurement of polyurethane foam.</p> b) Inductively coupled plasma mass spectrometry (ICP-MS) and atomic absorption spectroscopy (AAS) <p>These methods were used for elemental analysis.</p> 5. Plastic/metal prototype <ol style="list-style-type: none"> a) Method for three-dimensional shape <p>A 3D printing process (Plastic) was used for the prototype.</p> 6. Finite element method <ol style="list-style-type: none"> a) This method was used for a simulation study to evaluate the pull-out strength of various pedicle screw variants.
15.	Detailed analysis of results:
	A detailed analysis of the experimental outcomes is given below.

Pedicle screw design specification

1. The micro-CT (Micro CT 40®, SCANCO Medical AG, Switzerland) was used to scan the control device (pedicle screw). The micro-CT generated an .stl file, which was imported into the software. We performed dimensional measurements on the imported file to determine the critical dimension of the control device.

Concept document

1. Based on the literature survey and micro-CT measurements, a total of 38 concepts were developed. These concepts included different thread types, varying numbers of starts, screw profiles, tapping types, and angles.

CAD models/Drawings

1. Creo® (PTC Inc., USA) was used for developing the pedicle screw assembly. The assembly consisted of a screw, head, sleeve, retainer ring, rods, and head cap.

Material testing

1. **Polyurethane foam:**

Density

We prepared specimens conforming to ASTM F1839 for all four grades and measured the dimensions of each block to calculate density. The density of polyurethane foam was calculated using the formula $D = M/V$, where D represents density, M stands for mass, and V stands for volume.

Compressive strength

The compressive strength of different grades of polyurethane foam was determined using INSTRON®, USA, in accordance with the relevant ASTM standard. The specimens were oriented such that the axis of the compressive load was applied parallel to the direction of foam rise.

Our findings indicate that average density and compressive strength values were within the range of the ASTM standard range.

2. **Control device (pedicle screw)**

For control device material investigation, we analysed the control device samples using Optical emission spectroscopy (OES) and inductively coupled plasma mass spectrometry (ICP-MS). The results indicate the presence of elemental matches to the Titanium Alloy (Ti6Al4V) material.


Plastic/metal prototype

1. The screw models were 3D printed using VeroClear, a transparent material that simulates PMMA (polymethyl methacrylate). The dimensions of these models were to the outcomes of micro-CT measurements.

	<p>Simulation study:</p> <ol style="list-style-type: none"> 1. FEM analysis was performed on all 38 variants of pedicle screw using bilinear Isotropic hardening material properties. The stress and strain on the bone were evaluated.
16.	<p>Summary sheet of not more than 2 pages under the following heads : (Title, Introduction, Rationale, Objectives, Methodology, Results, Translational Potential)</p>
	<p>Title: Design of novel polyaxial screws for thoracolumbar stabilization: a pilot study</p> <p>Introduction</p> <p>Pedicle screws are widely used to correct spinal deformities. Their effectiveness has been proven over the years, resulting in wide acceptance of screws for spine correction. The pedicle screw-based system is used to achieve solid bone fusion in patients with scoliosis, kyphosis, fractures, spondylolisthesis, degenerative arthritis or tumours.</p> <p>Rationale</p> <p>However, there are reported incidents of pedicle screw loosening up to 15% and breakage up to 7.1%. To minimize these limitations, the novel pedicle screw variants were conceptualized and analysed. The project work involved altering pedicle screw design parameters to create various concepts. The project began with a product and literature survey, which was important in specification development.</p> <p>Objectives</p> <p>Three objectives were proposed.</p> <ol style="list-style-type: none"> 1. To design a novel polyaxial pedicle screw configuration 2. To optimise the design parameters using an axial pull-out simulation study 3. Generate test results for future work. <p>Methodology</p> <p>The micro-CT was used to determine the pedicle screw critical dimensions. The micro-CT generated .stl file, which was imported into the software and critical dimensions were obtained. The thirty-eight variants of pedicle screws were conceptualized and modelled using Creo® (PTC Inc., USA) software. The critical dimensions of the screw models were the measured values from the micro-CT. These models were assembled with the simulated vertebral cortical and cancellous bone. The mechanical properties of cortical and cancellous bones were derived from a literature survey. A mesh sensitivity was performed for the assembly, and an appropriate element size was set. An incremental displacement was applied to the screw in several steps, and the pull-out force was determined.</p> <p>Polyurethane foam of various grades was evaluated for an in-vitro study according to ASTM standards. Ten samples were prepared for density and compressive strength measurements. The compressive strength was measured using a universal testing machine (INSTRON®,</p>

	<p>USA). For material investigation, the control device was analysed using Optical Emission Spectroscopy (OES) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS).</p> <p>Results</p> <p>Based on the simulation study, the buttress-type thread with a large pitch and depth resulted in a high pull-out force. Moreover, the density and compressive strength values of all the purchased grades fell within the range specified by ASTM F1839. Additionally, the experimental results obtained from Optical Emission Spectroscopy (OES) and Inductively Coupled Plasma Mass Spectrometry (ICP-MS) indicate that the control device was made of Ti6AL4V material.</p> <p>Translational Potential</p> <p>The proposed design has high translational potential since the unique design addresses the current limitations of the pedicle screw system and provides ways for improvements.</p>		
17.	Contributions made towards increasing the state of knowledge in the subject:		
	The study findings indicate an altering design parameter can increase pedicle screw pull-out strength. This work may motivate researchers to implement and expand the research outcomes.		
18.	Conclusions summarising the achievements and indication of scope for future work:		
	It was observed that the proposed design, with some geometric parameter changes, resulted in a significantly higher pullout strength. However, it is important to conduct further studies to verify the outcomes of the proposed design. These studies should include pull-out force testing in polyurethane foam, torsion strength testing, fatigue testing, and animal studies.		
19.	Science and Technology benefits accrued :		
	a.	List of research publications with complete details :	
		None	
	b.	Manpower trained on the project :	
	i.	Research Scientists or Research Fellows	: 01 Project Assistant
	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:	
		Pedicle screws are widely used to correct spinal deformities. The pedicle screw-based system aims to achieve solid bone fusion in patients with scoliosis, kyphosis, fractures, spondylolisthesis, degenerative arthritis, or tumours. However, screw loosening and	

		breakage have been reported up to 15% and 7.1% respectively. To minimise these limitations, novel screw variants were conceptualized and analyzed using the finite element method.					
	b. Materials:	The critical dimensions of pedicle screws were determined using micro-CT after scanning the control device. Thirty-eight variants of pedicle screws were then modelled using Creo® software. The screw models were based on the micro-CT measurements and assembled with simulated vertebral cortical and cancellous bone. The mechanical properties of the cortical and cancellous bones were derived from a literature survey. A mesh sensitivity analysis was performed for the screw assembly, and appropriate element sizes were set. The pull-out force was determined by applying an incremental displacement to the screw in several steps.					
	c. Results:	The simulation study shows that a buttress-type thread with a larger pitch and depth results in a higher pull-out force.					
	d. Conclusion:	A buttress thread design with a large pitch and depth demonstrated significantly higher pullout strength compared to the control device. However, to confirm these findings, further studies are required, including a pull-out force study conducted in polyurethane foam, torsion strength testing, fatigue testing, and animal trials.					
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					


 08/11/2023
 Er. Arvind Kumar Pragyapati
 (Name and Signature of PIs with date)

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