



**INDIUS**  
MEDICAL TECHNOLOGIES

# Proof Of Concept Validation of a Self Actuated Natural Growth Driven Growing Rod Technology for EOS

*Aditya Ingalhalikar<sup>1</sup>, PhD, Sajan Hegde<sup>2</sup>, MS, Dilip Sengupta<sup>3</sup>, MD, PhD, Manali Kunte<sup>1</sup>, BE, Sagar Sathaye<sup>1</sup>, MS, Suken A. Shah<sup>4</sup>, MD*

*1. Indius Medical Technologies, Pune, India 2. Apollo Hospitals, Chennai, India, 3. Center for Scoliosis and Advanced Spine Center, Mansfield, TX, USA, 4. Nemours/Alfred I. DuPont Hospital for Children, Wilmington, DE, USA*

# Clinical Problem: Early Onset Scoliosis

## EOS Definition

- S shaped spinal deformity affecting children in age group 1 - 9 years.

## EOS Symptoms

- Reduction in thoracic cavity space
- Severely compromised lung growth and function and consequently Quality of Life.
- Increased risk of early death due to lung and heart disease.
- Strong psychologically painful effect on the children as well as parents.

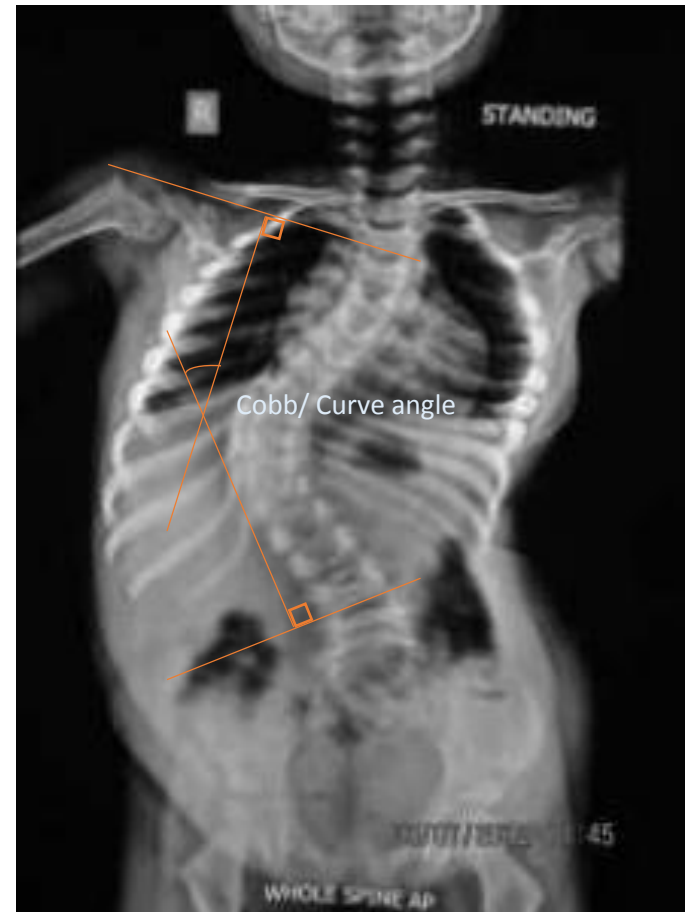


Fig 1: Standing X-Ray of a 4 year old suffering from EOS

# Goal of the Technology

- Improve Quality of Life by reducing / eliminating repeat lengthening.
- Reduce complications associated with surgical lengthening.
- Eliminate or reduce tissue necrosis.
- Reduce skin infections and implant protrusion.
- Reduce rod breakage.
- Enable increased access of technology to all patients due to cost efficient pricing.

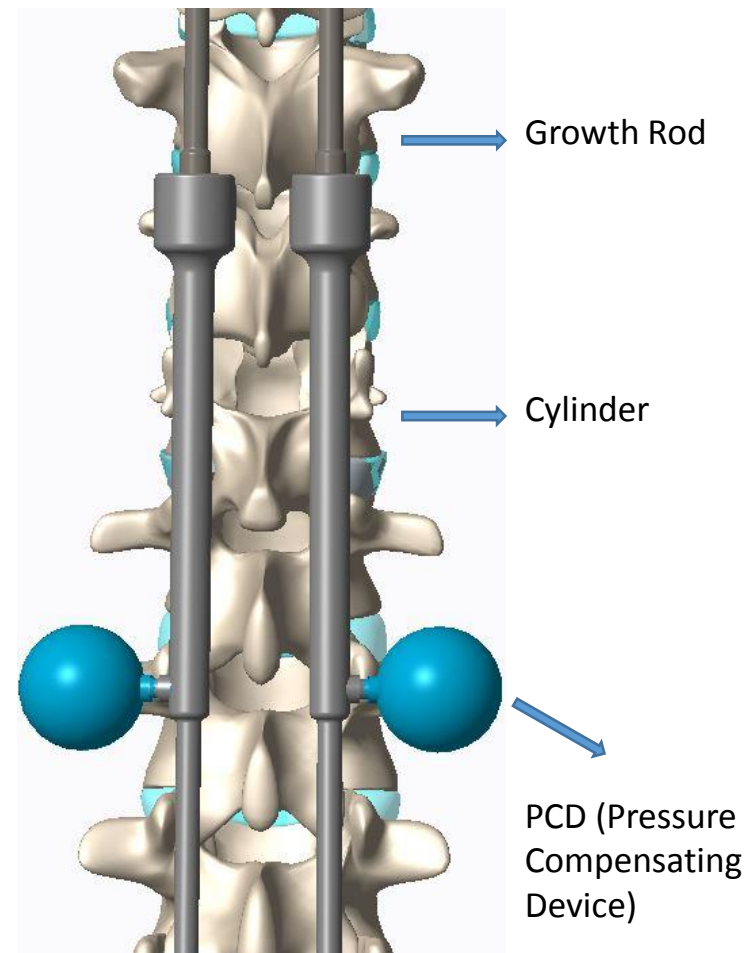


Fig 2: Schematic of Assembly on Spine

## Assembly Hydraulic Testing

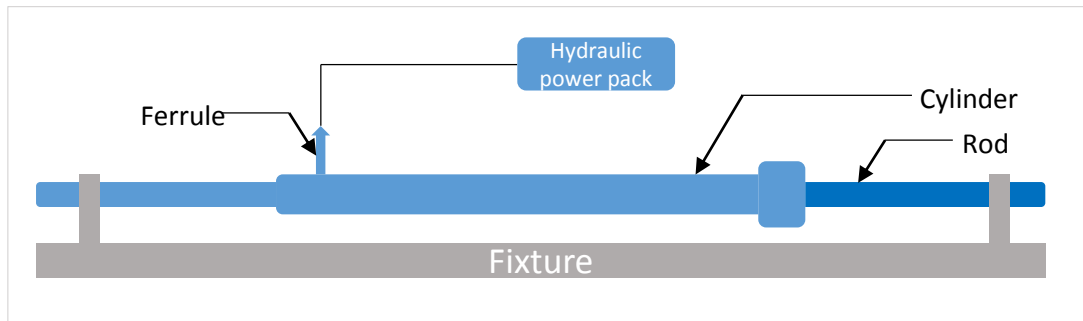


Fig 3: Schematic of Assembly Used for Testing

- Rod – Cylinder arrangement was connected to a hydraulic power pack and pressurized up to twice the working pressure
- The test was conducted to ensure that the system is leak – proof and can sustain higher loads than those intended.

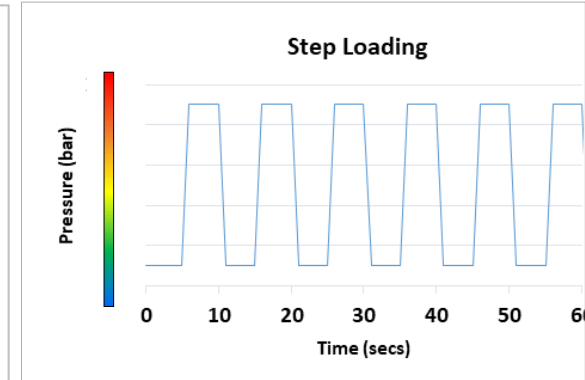
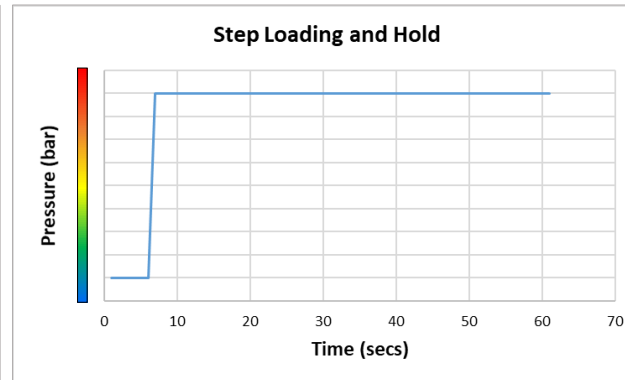
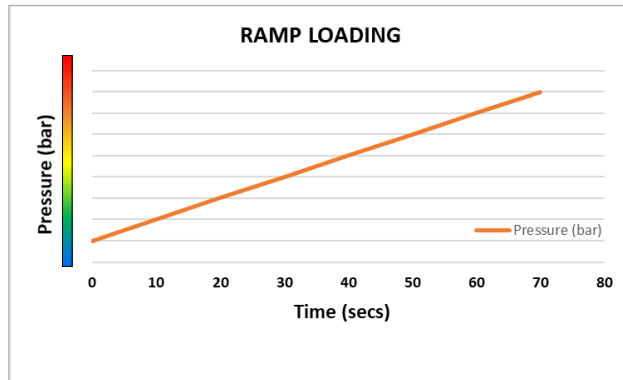
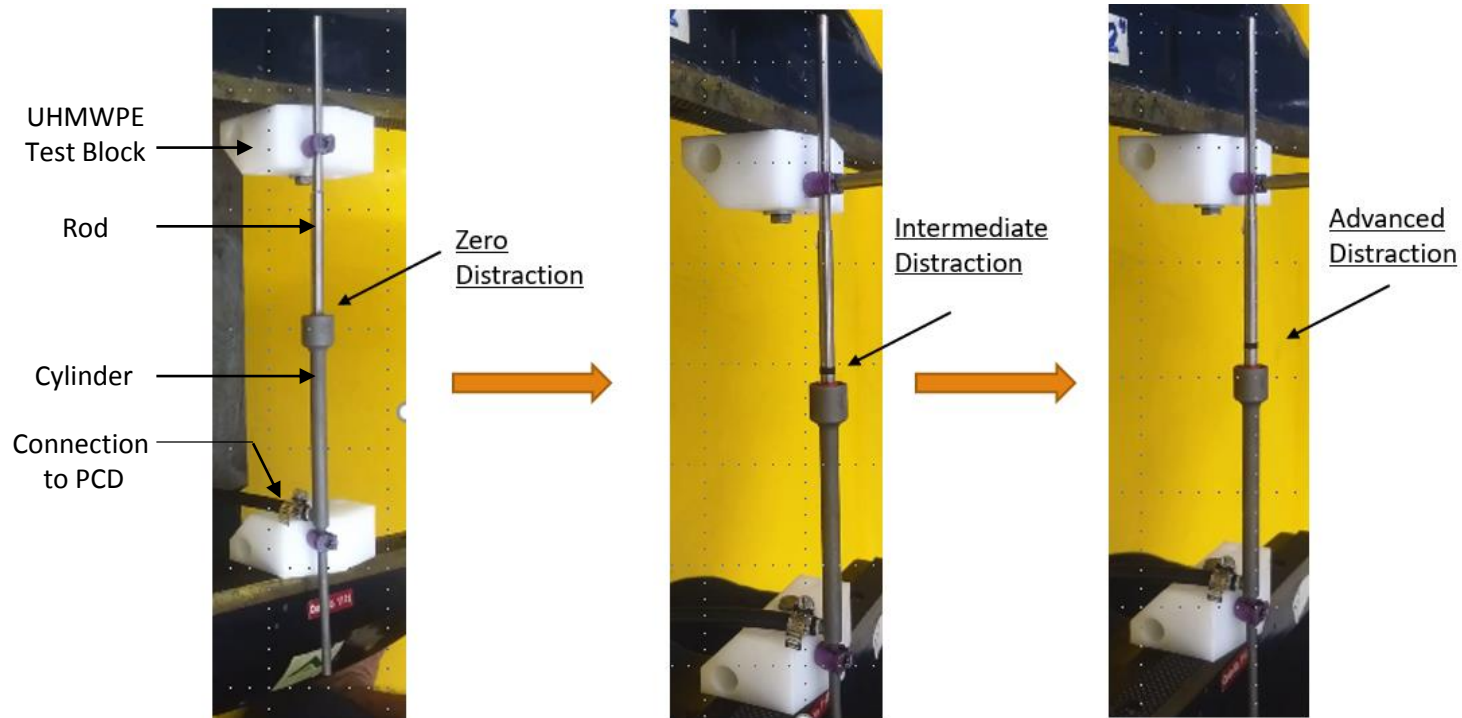


Fig 4: Hydraulic Testing of the Assembly: Load Graphs

## Simulated Hydraulic Testing

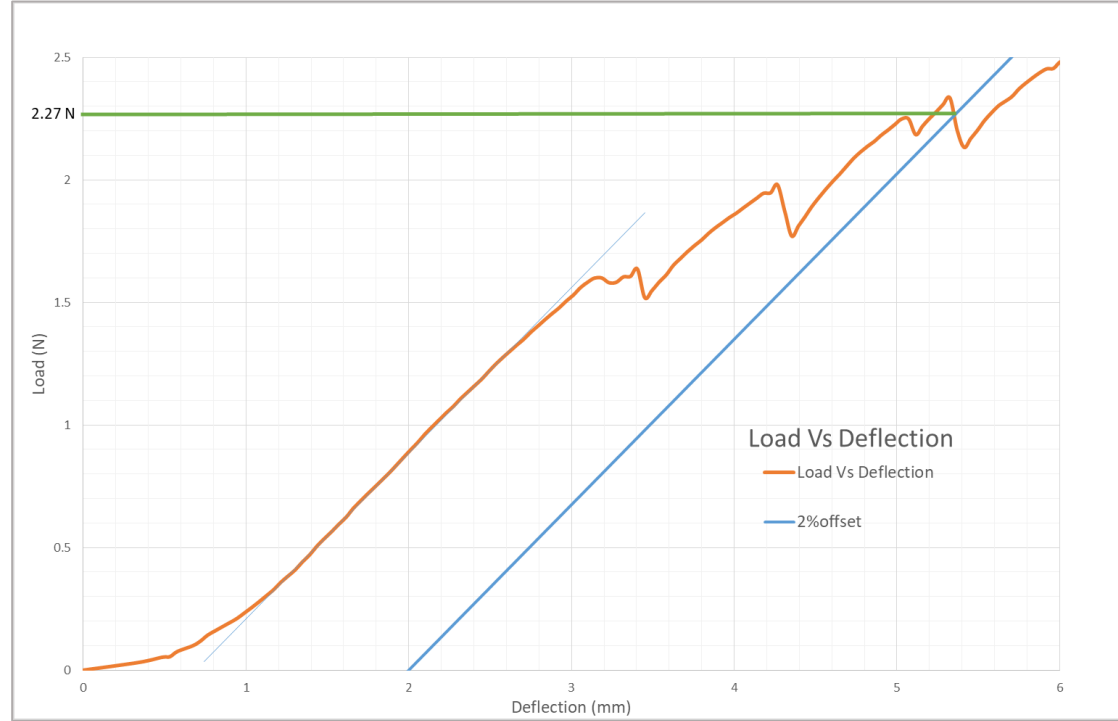
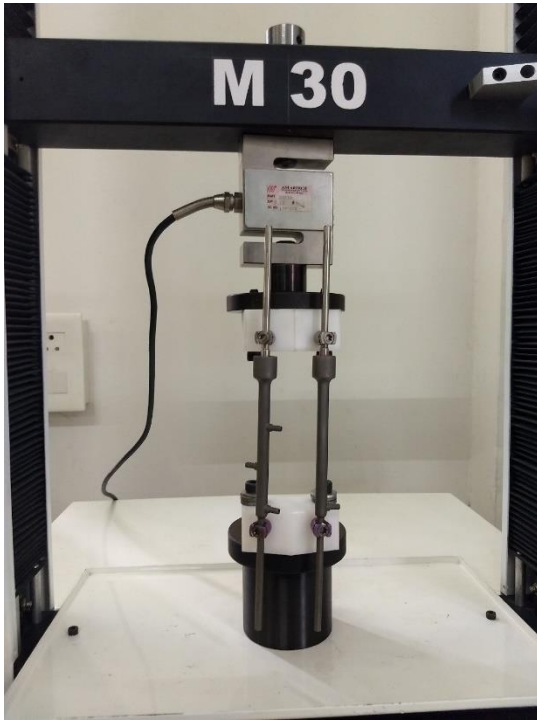
When connected to the growing rod, the PCD gives gradual distraction & holds the distraction force till the test setup (simulated spine) further expands to simulate natural growth thus making the process a quasistatic one.



*Fig 5: Hydraulic Testing of the Assembly*

## Mechanical Testing

Successfully tested the Growing Rod system in a modified F1717 construct. Yield load observed was 5 times the load acting on an adult lumbar spine, which is substantially higher force than predicate testing of standard Pedicle Screw Rod construct.



*Fig 6: Mechanical Testing of the Assembly*

# Technology Value Addition

CONSIDERATIONS	SOLUTION
Avoid / Eliminate invasive externally controlled distraction	Natural – Growth Driven, Self-Actuating Quasi-static distraction of the system
Continuous Active Distraction Force	Staged PCDs which supply increasing force as growth occurs
Prevent implant protrusion and thus subsequent skin infection	Sub – muscular implantation
Prevent metallosis and thus tissue necrosis	Ensure no metal-on-metal wear interface and contain any debris within the system through seals
Efficient Healthcare Economics	Reduce / eliminate multiple invasive procedures

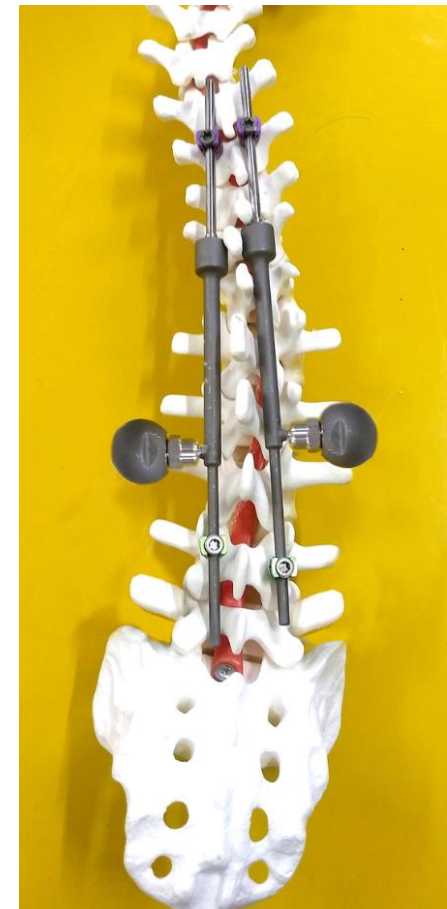


Fig 7: Implantation on a Scoliotic Sawbone Model

## INDIUS Patent Portfolio (Patents Pending)

1. USPTO Application
2. PCT International Application
3. INDIA Application





- Proof of Concept to DFM (Design For Manufacturability)
  
- Any design modifications based on Laboratory Testing
  
- Preclinical Testing:
  - Mechanical Testing
  - Animal Studies
  - Biocompatibility Studies

# THANK YOU!

## Contact Details

Aditya Ingalhalikar, PhD  
Founder & CEO  
Email: [iaditya@indiusmedical.com](mailto:iaditya@indiusmedical.com)  
Phone: +91 839-087-3873

## INDIA Office

Unit No. 12,  
Electronic Co – op Estate,  
Pune-Satara Road, Pune  
MH, India – 411009

## US Office

160, Greentree Drive – Suite 101,  
Dover, DE 19904,  
Kent County, USA