



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

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# 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.

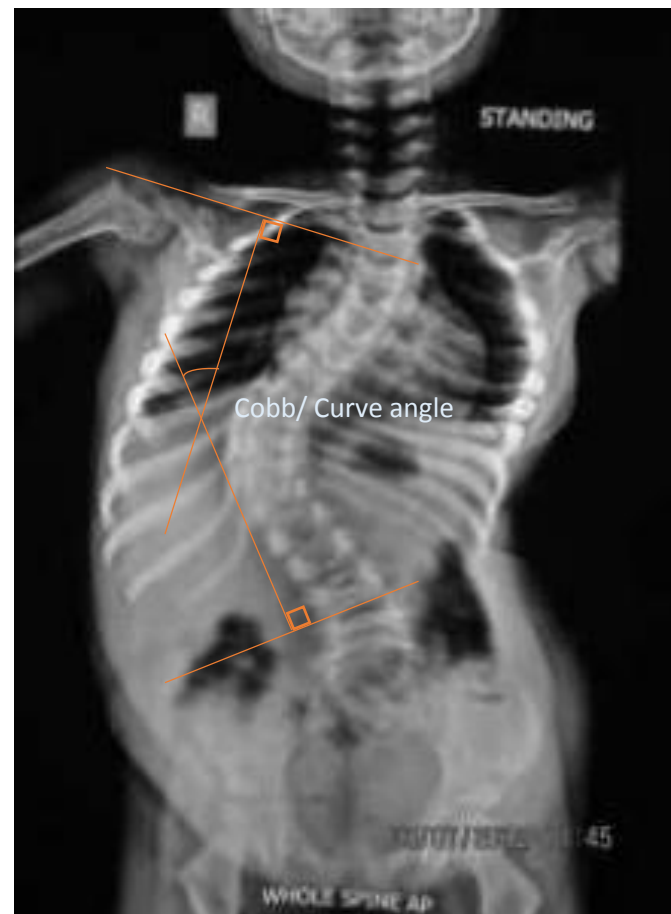


Fig 1: Standing X-Ray of a 4 year old suffering from EOS

# 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.

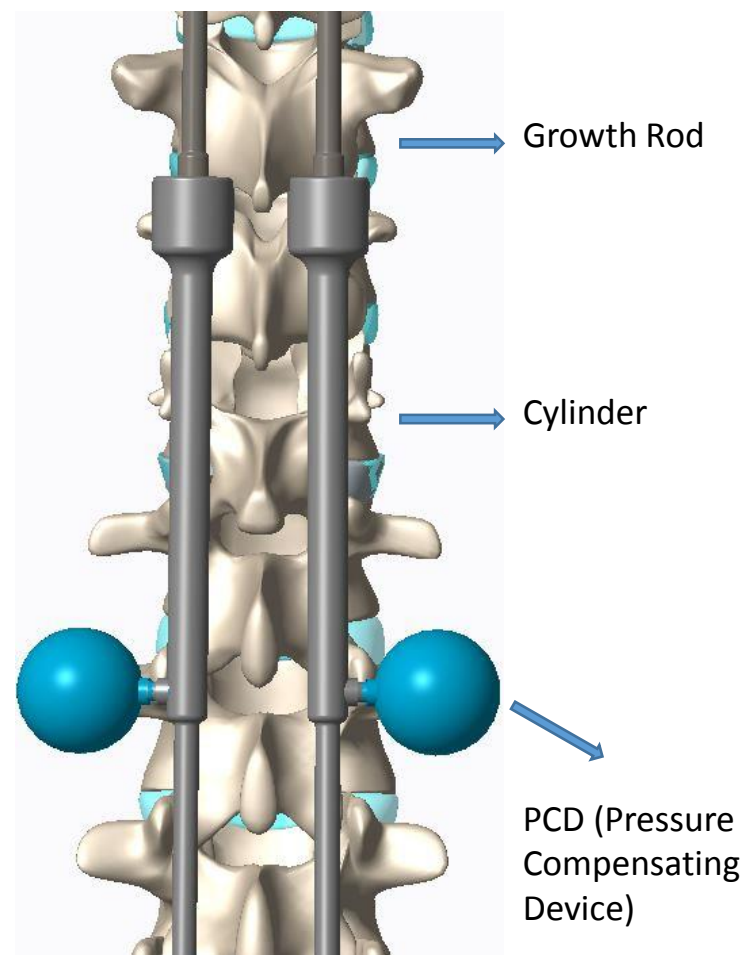
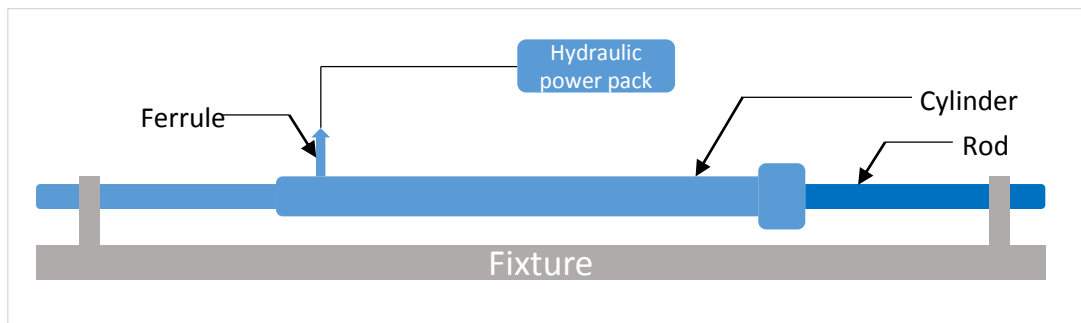


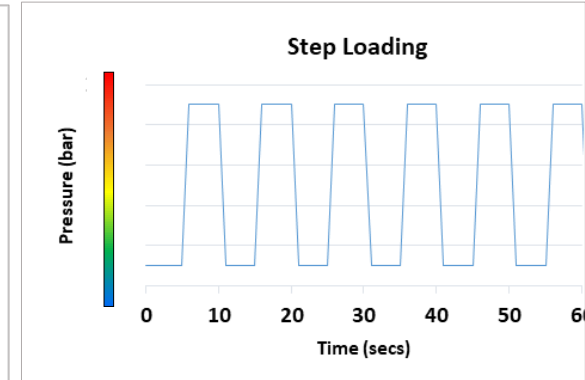
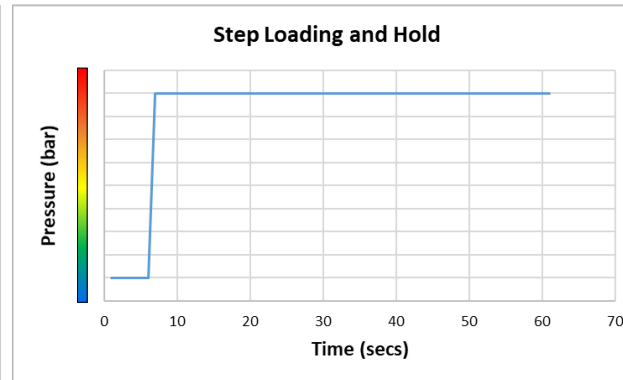
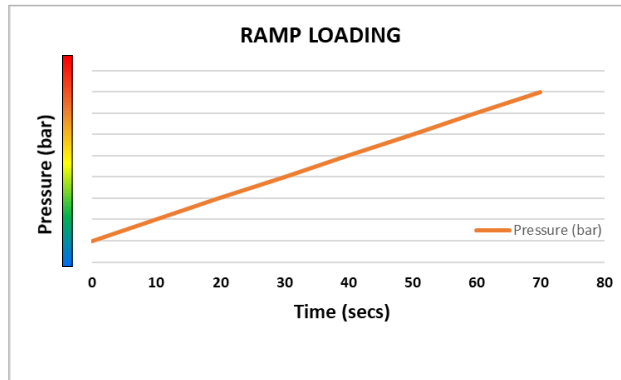
Fig 2: Schematic of Assembly on Spine

## Assembly Hydraulic Testing



*Fig 3: Schematic of Assembly Used for Testing*

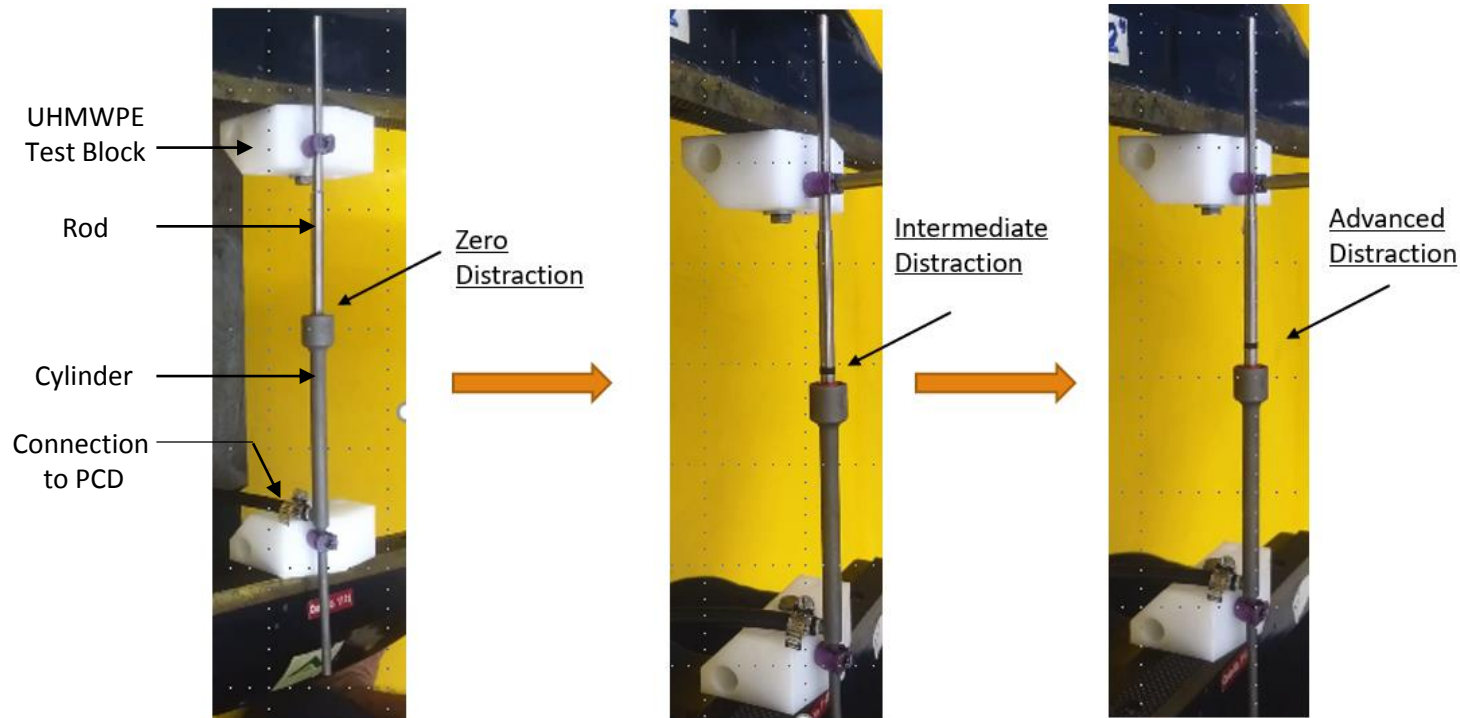
- Rod – Cylinder arrangement was connected to a hydraulic power pack and pressurized up to twice the working pressure
- The test was conducted to ensure that the system is leak – proof and can sustain higher loads than those intended.



*Fig 4: Hydraulic Testing of the Assembly: Load Graphs*

## Simulated Hydraulic Testing

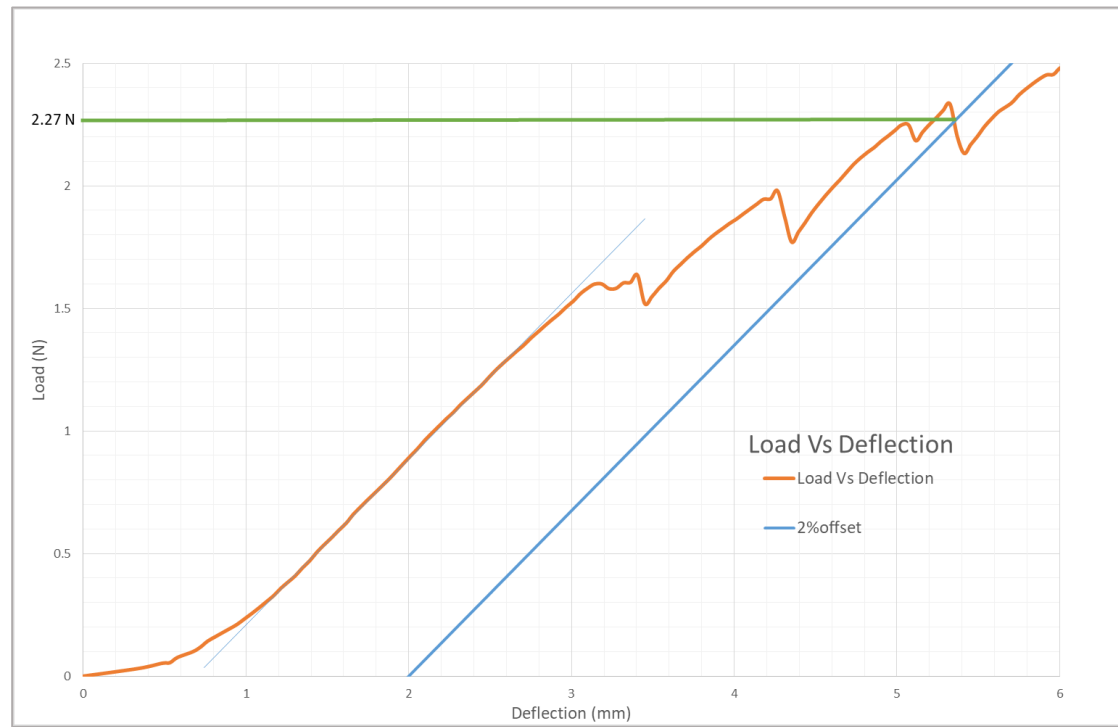
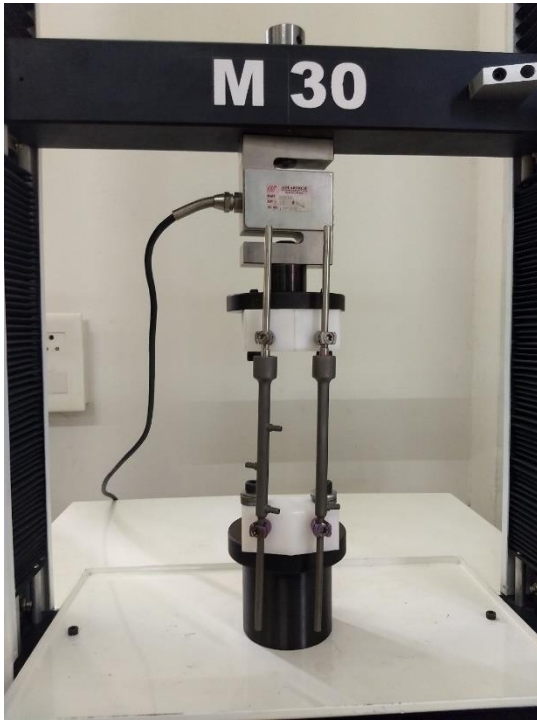
When connected to the growing rod, the PCD gives gradual distraction & holds the distraction force till the test setup (simulated spine) further expands to simulate natural growth thus making the process a quasistatic one.



*Fig 5: Hydraulic Testing of the Assembly*

## Mechanical Testing

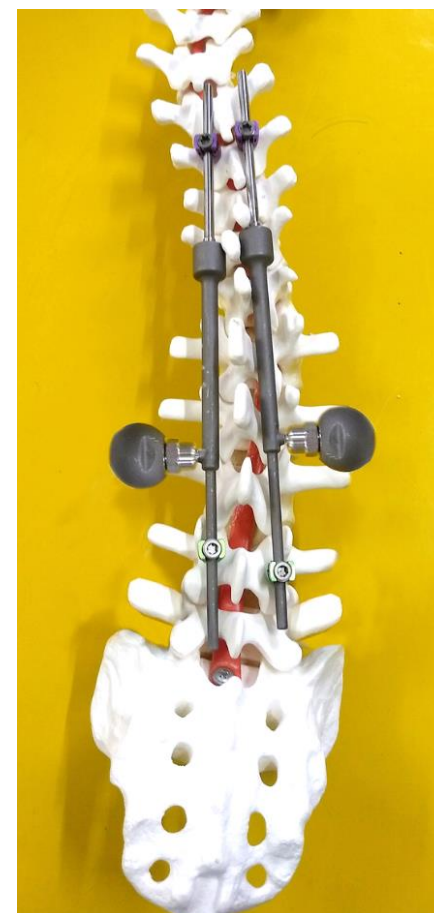
Successfully tested the Growing Rod system in a modified F1717 construct. Yield load observed was 5 times the load acting on an adult lumbar spine, which is substantially higher force than predicate testing of standard Pedicle Screw Rod construct.



*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!

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