

# A Prospective Analysis of Long-Term Clinical Outcomes and 3D Spine Growth in Anterior Vertebral Body Tethering

NCT04914507

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Pediatric Spine Foundation
Enrollment	106 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Diagnosis of idiopathic scoliosis
- Planned recipient of AVBT surgical treatment
- Skeletally immature
- Major Cobb angle  $\geq 30^\circ$  and  $\geq 65^\circ$
- Osseous structure dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging
- ... and 1 more (see full listing online)

### Exclusion (6)

- Presence of any systemic infection, local infection, or skin compromise at the anticipated surgical site
- Prior spinal surgery at the level(s) to be treated
- Evidence of documented poor bone quality
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as coagulation disorders, allergies to the implant materials, and patient's unwillingness or inability to cooperate with post-operative care instructions as determined by the treating physician
- Unwillingness, inability, or living situation (e.g. custody arrangements, homelessness, detention) that would preclude ability to return to the study site for follow-up visits as described in protocol and Informed Consent
- ... and 1 more (see full listing online)

## Locations (12 total)

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Children's National Hospital, Washington D.C., District of Columbia, United States  
Shriners Children's Chicago, Chicago, Illinois, United States  
Gillette Children's Specialty Healthcare, Saint Paul, Minnesota, United States  
... and 9 more locations