

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

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 18 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria: Skeletally immature patients that receive AVBT surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis. Specifically:

- Diagnosis of idiopathic scoliosis
- Planned recipient of AVBT surgical treatment
- Skeletally immature
- Major Cobb angle $\geq 30^\circ$ and $\leq 65^\circ$
- Osseous structure dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging
- Failed or intolerant to bracing

Exclusion Criteria:

- 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
- Unwillingness to sign Informed Consent Form and participate in study procedures

Conditions & Interventions

Interventions:

DEVICE: Anterior Vertebral Body Tethering

Conditions:

Scoliosis Idiopathic

Keywords:

anterior vertebral body tethering

More Information

Description:

Anterior vertebral body tethering (AVBT) is a novel, minimally invasive, growth modulation technique that was recently approved by the FDA under a Humanitarian Device Exemption (HDE). The goal of AVBT is to control curve progression by applying compression on the convex side of the spine deformity. While there has been great initial enthusiasm about the technique as an alternate treatment option to spinal fusion for skeletally immature children with scoliosis, there is a need to better understand the long-term outcomes. The purpose of this study is to report the long-term clinical outcomes of skeletally immature patients treated with AVBT, specifically: 1. The effect on three-dimensional spine growth as compared to normal controls 2. Maintenance of major Cobb angle less than or equal to 50 degrees at skeletal maturity 3. Complications associated with both the procedure and the device

Contact(s): Nichole Leitsinger - nichole.leitsinger@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT04914507

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