ScoliScore - Saliva Based Prognostic Test for Adolescent Idiopathic Scoliosis

Six million people (estimate from the National Scoliosis Foundation) have scoliosis in one form or another. Of these, 90% have the idiopathic Adolescent form. Research has verified that the Idiopathic Adolescent form of scoliosis is a genetically driven disorder. As such, much effort has been focused on identifying the specific genetic alterations which predispose to the development of this condition. After years of development and testing DNA samples from more than 9,000 patients, tracking billions of genotypes, and making trillions of calculations, the Axial Biotech Company has found specific, genetic markers for adolescent idiopathic scoliosis. In fact, thus far, 53 distinct single nucleotide polymorphisms have been identified.

The primary value of identifying these genetic markers relates to their role in predicting the risk of scoliosis progression. Until now, the ability to predict who will develop severe scoliosis has been crude at best. Indirect measures of progression risk such as patient age, rate of growth, curve magnitude and skeletal maturity indicators have been the only means by which to estimate who is at greatest risk.

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The ScoliScore test is the first prognostic test that allows a more direct means of quantifying the risk of progression. So, how does ScoliScore work? The child with scoliosis is given a specimen container in which they supply a sample of their saliva. The endothelial cells from the lining of the mouth which end up in the saliva are extracted. The DNA of the endothelial cells is isolated and analyzed for the presence of the 53 known genetic markers associated with Adolescent Idiopathic Scoliosis. Using a sophisticated mathematical algorithm a score is then calculated based upon the number of markers identified. The score represents a “likelihood of progression” of scoliosis to a degree which would require surgical intervention (essentially a curve magnitude of > 40 degrees).

How accurate is the Axial Biotech ScoliScore? Based on data from over 6,500 AIS patients:
- Sensitivity of ScoliScore is 90% (87–93)
- Specificity of ScoliScore is 88% (86–90)

The ScoliScore is reported on a scale of 0 to 200. A lower score is associated with a better prognosis.

Existing data allows the following prognostic insight for a given patient:
- Score 0 to 50 = 99% chance that the curve will not progress to > 40 degrees
- Score 180 to 200 = 99% chance the curve will progress to > 40 degrees
- Score 51 to 179 = Indeterminate. Not enough data yet exists to validate a risk of progression in this score range. Over time, as further data is accumulated, risk of progression for this range will be refined.

Sensitivity and specificity were confirmed in two clinical trials, with each trial including over 400 scoliosis patients. The Negative Predictive Value in the intended use population is 93%–98% (89–100), as confirmed by the clinical trials.

ScoliScore testing will enable physicians and health care providers to use a simple test to accurately identify which patients will progress to the severe curve magnitude. Access to this information about a patient will change the treatment paradigm of Adolescent Idiopathic Scoliosis in that it will allow less intervention in those not at risk while conversely allowing earlier, less extensive intervention in those truly at risk.

Dr. Bret Baynham, Pediatric Spine Deformity Surgeon, Palm Beach Orthopedic Institute offers this new and exciting approach to scoliosis care. Please feel free to consult Dr. Bret Baynham if you have scoliosis patients who might be interested in learning more about scoliosis stapling or any other scoliosis related issues.