Minimally invasive treatment based on electrical muscle stimulation corrects spinal curvature in children

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Adolescent idiopathic scoliosis (AIS) affects 2 to 3% of children aged

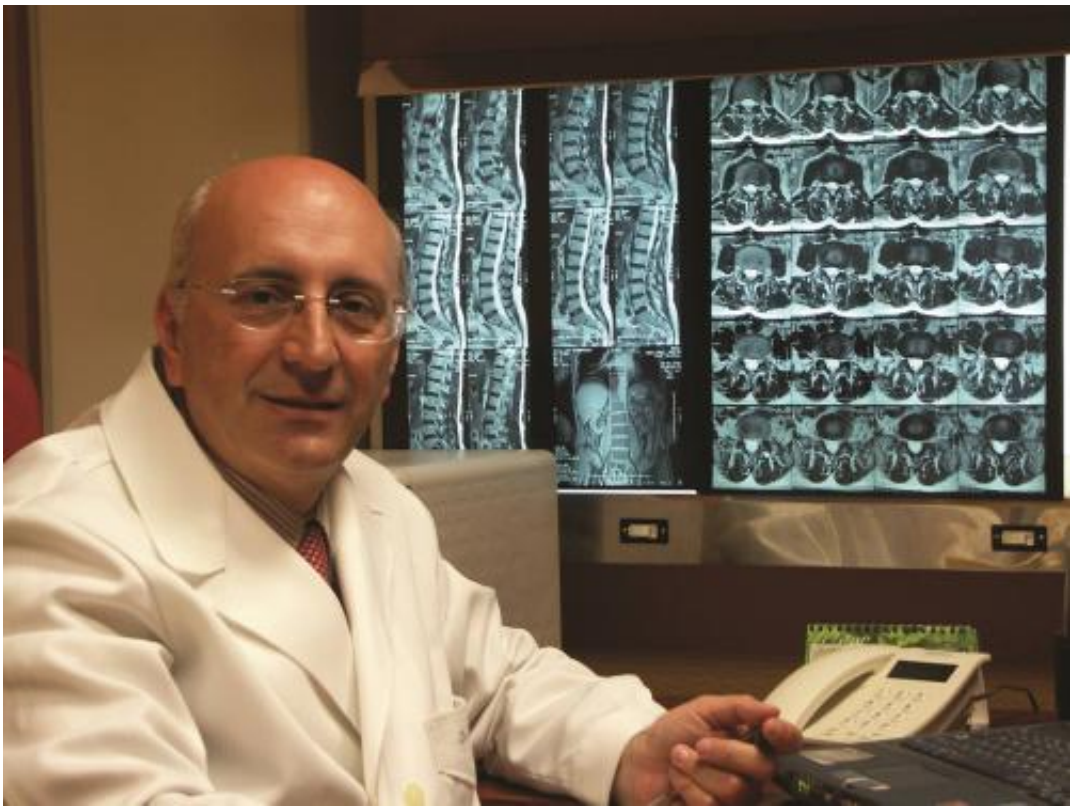
between 10 and 16. It is more common in girls than in boys (with a ratio of 10-1). Besides the obvious physical signs derived from the visible spinal deformity, AIS can cause psychological and emotional problems (low self-esteem, poor body image, etc.) that significantly reduce patients' quality of life.

Although bracing has been basic in non-surgical treatments for AIS for almost fifty years, some studies suggest that this technique is able only to stop the curve progression, but cannot reduce the deformity. Furthermore, bracing often conditions or boosts psychological disorders in patients wearing the brace for a long period of time.

Patients developing high-magnitude spinal curves or those who show a rapid and significant curve progression, often require a very aggressive surgery. More than 4,000 European adolescents undergo this procedure each year with the risk of long-term side effects.

"Surgery corrects the curve deformity, but fuses the spine, eliminating its function. The long-term consequences of spinal fusion cause several complications," says Professor Carlos Barrios, director of the Institute for Research on Musculoskeletal Disorders of the Universidad Católica de Valencia, Spain. "Efforts are currently being made to find techniques that do not involve extensive spinal fusion to correct the scoliotic deformity, preserving the physiological range of motion of the spine.

A high proportion of diagnosed patients are normally subject to mere observation, without receiving specific therapy. However, if the disease is diagnosed late or develops faster than anticipated, current medical practice only has treatments with brace or surgery, each one with its drawbacks".



Recent studies provide evidence that suggest possibilities for alternative treatments. "Recent findings show that AIS is a musculoskeletal expression of a central nervous system disorder, in other words a neurological disease," explains Professor Barrios, awarded twice for his publications in the EuroSpine Annual Meetings.

StimulAIS project

"Neurological dysfunction affects deep paraspinal muscles inducing an imbalance of forces acting on the vertebral segments." The StimulAIS Project is based on this research. The initiative is supported by an international consortium of businesses, research institutes and

universities and aims at introducing alternative AIS treatments based on electrical muscle stimulation of deep paraspinal rotator muscles - a technique known as functional electrical stimulation (FES).

The consortium consists of three SMEs: the Project coordinator Tequir S.L. (Spain), Synergie Ingeniere Medicale SARL (SYNIMED, France) and Bentronic Gesellschaft Für Medizintechnik GMBH (BENTRONIC, Germany), as well as three reference research centres: the Instituto de Biomecánica de Valencia (IBV, Spain), the Universidad Católica de Valencia (UCV, Spain) and Fraunhofer-Gesellschaft zur Förderung der Angewandten Forschung E.V. – IPMS (IPMS, Germany). Uniting their expertise, the project has developed the first prototypes of the device that provides the FES treatment.

As a spokesperson of Tequir, a Spanish company that specialises in innovative medical technologies in the fields of spinal medicine, orthopaedics and traumatology, explains, "The unit should provide personalized treatments. It is primarily aimed at not only inhibiting the curve progression, but also potentially correcting it significantly."

To achieve this, the project has developed an implantable device to sense and stimulate the key muscles as well as the integrated stimulation control software to modulate it into safety thresholds. To implement the device subcutaneously, the team has developed minimally invasive surgical instruments.

The findings obtained in the research phase have been incorporated into a stimulation protocol which allows real-time adaptation to the data received and therefore the treatments are more effective.

As indicated by the project partners, "We have met the initial objectives and our proposal is significantly closer to commercialisation. The next aim of the consortium to continue the project is to produce a fully

operational prototype in terms of greater efficiency-cost ratio" explains Professor Barrios. "After reaching collaboration with specialised suppliers, this version of the product will take part in Phase II and III clinical trials in order to validate the device."

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