TREATING SCOLIOSIS WITH A 3D PRINTed TLSO
A Prospective, Controlled Study of an Alternative Bracing Option

At the Academy Annual Meeting, Dr. James Policy proposes to present his case study in alternative bracing options for scoliosis patients. Dr. Policy will discuss how 3D printing has enabled more individualized care for scoliosis, the approach to the case study and preliminary feedback from the participants, as well as, ongoing avenues for continued research in scoliosis treatment.

Study Design
Report of a new bracing technique.

Objective
A new means of producing a TLSO brace is described and assessed for compliance and clinical effectiveness in adolescent idiopathic scoliosis (AIS).

Background
Adolescent idiopathic scoliosis (AIS) is a complex 3-dimensional spinal deformity. AIS primarily affects adolescent girls. It has a high risk of progression to the point where surgical intervention is required during any period of rapid growth, such as the adolescent growth spurt from ages 11-14. Brace treatment using a TLSO is the only treatment modality which has been objectively shown to reduce the risk of progression of AIS, and therefor reduce the rate of surgical intervention[1]. In the population of adolescents with scoliosis curves greater than 25 degrees, and with significant skeletal growth remaining, a TLSO can change the risk of progression to the point of needing surgery from 70% to 30%. Bracing is, however dose dependent, and only works if patients can be compliant with brace wear guidelines. optimal brace wear is 18 hours a day, with 12 hours being the minimum time needed to see positive results. Therefor, any alteration of the standard brace which leads to improved compliance while maintaining efficacy should improve patient outcomes.

Bracing Technology

We utilized advanced 3-D scanning, and printing technology to produce a TLSO that is lighter, easier to don, has holes for ventilation, and a superior aesthetic to the current models. These are all things that patients that patients, and parents have complained about in the traditional TLSO. The UNYQ brace provides a solution to many of the common complaints we receive from patients, and families. If our patients are more physically and emotionally comfortable in the brace, then they are more likely to wear it.

Study

We performed a clinical trial of the UNYQ brace to determine if it was safe, and if could effectively treat scoliosis. This was a pilot study to determine wether the UNYQ brace could

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[1] http://www.nejm.org/doi/full/10.1056/NEJMoa1307337

provide clinical outcomes on par with a traditional Boston brace. IRB approval was obtained. 60 adolescents with AIS who had curves between 25, and 40 degrees were enrolled in the study. None had received prior treatment. 30 were treated with a UNYQ brace, and a control group of 30 patients were treated with a standard Boston TLSO. All patients had pre-brace, and final x-rays. X-rays were also taken in brace. All patients filled out a questionnaire asking about compliance, level of satisfaction with the brace, and ease of use. Patients were followed until skeletal maturity, brace failure (surgery), or until they outgrew the brace. Some children required more than one brace, so for the second brace they received a standard Boston brace. This study only covered one UNYQ brace per patient.

There was no significant difference in the clinical outcomes between the two groups. There was no significant difference in the degree of correction of the curve while wearing the brace, or at the end of bracing. Three children in each group failed brace treatment and went on to require surgery.

The Patients in the UNYQ brace group found the brace to be more comfortable, and easier to get on/off. The patients who outgrew the UNYQ brace and were given a traditional Boston brace all said they preferred the UNYQ brace.

This study suggests that the UNYQ brace has identical capacity for in-brace curve reduction, and prevention of curve progression when compared to a standard Boston brace. The UNYQ brace has the advantage of greater patient satisfaction. We therefor conclude that the UNYQ brace is a viable option for the treatment of AIS. Further studies are planned utilizing in-brace heat sensors to evaluate patient compliance.

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