

## Study: Bracing Really Works for Scoliosis

### Beneficial effect was clear enough to halt clinical trial early

Terry Stanton

Bracing has been prescribed for scoliosis since the 1940s, but the actual benefits of wearing a brace were frequently called into question by concerns about compliance and time.

Now those doubts have been put largely to rest by the BrAIST (Bracing in Adolescents with Idiopathic Scoliosis Trial) study, a prospective randomized clinical trial. According to results published in *The New England Journal of Medicine* (Oct. 17, 2013), in 75 percent of patients randomly assigned to wearing a brace, curves did not progress to the 50° threshold for surgery at skeletal maturity; among those who did not wear a brace, just 42 percent did not progress to the surgical threshold.

The study began with 1,086 eligible patients at 25 sites in the United States and Canada ([Table 1](#)). Because fewer patients and parents than anticipated agreed to the randomization, the National Institutes of Health (NIH) approved the addition of a preference arm of patients and parents who chose whether to be treated with brace wear or observation.

Of the original group, 383 patients and parents consented to participate, either in randomization or treatment by preference. By the time 242 patients had reached the defined end point (skeletal maturity or curve progression reaching the indication for surgery), the effectiveness of bracing was so evident that the NIH called a halt to the study, which had run for more than 5 years. Of the 242 patients, 116 were in the randomized cohort and 126 were in the preference cohort. Their ages ranged from 10 to 15 years, and initial spinal curves ranged from 20° to 40°. The only significant difference between the groups was the degree of lordosis; in the bracing group it was  $62.8^\circ \pm 10.8^\circ$  versus  $57.3^\circ \pm 12.9^\circ$  in the observation group ( $P = 0.02$ ).

“Statistical analysis based on the numbers we had showed that patients who were using the brace had a significantly decreased chance of curve progression,” said coauthor **Matthew B. Dobbs, MD**, of Washington University.

When the study was stopped, patients who were still eligible but had not been prescribed braces were given the option to begin brace wear.

### The dose effect

The braces had temperature sensors that allowed investigators to confirm and monitor brace wear. They found that efficacy of brace wear is dose-dependent; children who wore the brace for less than 6 of the prescribed 18 hours a day had about the same success rate as those who were merely observed, while those who wore the brace more than 13 hours a day had a success rate of 90 percent or higher. “The more the child wore the brace, the better the chance of success,” said lead investigator **Stuart L. Weinstein, MD**, of the University of Iowa.

“When I originally proposed this study, the effectiveness of braces, the most common treatment for high-risk patients with adolescent idiopathic scoliosis, was unknown,” Dr. Weinstein said. “We wanted proof one way or the other, because if braces are not effective, physicians should stop prescribing them, and if they are effective, society needs to do a better job of detecting scoliosis early and getting children at high risk into treatment.”

Once routine, screening for scoliosis in schools has largely diminished. “The cost-effectiveness of screening is an issue,” Dr. Weinstein said. “The study does show that early detection is key. Now that we know we have an effective treatment, primary care physicians need to be better educated so they can make early referrals when they see children for their school physicals so that children can get treatment.”

### Compliance conversations

The study’s findings are heartening for orthopaedic surgeons and patients, and the confirmation of a dose-effect should be helpful to

the physician counseling a patient about brace wear, Dr. Dobbs said.

"The brace temperature sensor has a lot of potential clinical utility to open up conversations with both patients and their families, in terms of the importance of wearing the brace," he said. "Having sensors in braces as a standard of care will allow that conversation at every clinic visit.

"It doesn't mitigate the difficulties of adolescents who have to wear a brace and be different than their peers, but it does empower physicians to be more confident in the presentation of the treatment than before," he continued. "Without this information, physicians couldn't really tell a patient what the real chances of success would be."

Dr. Weinstein agreed. "Anyone who treats children with scoliosis knows that they don't like wearing the brace," he said. "Having compelling evidence that braces do work and that the longer they're worn, the greater the chance of avoiding surgery is pretty persuasive to youngsters who are facing a difficult situation in their lives."

### **Lessons learned**

The challenges of conducting randomized, controlled trials in orthopaedics have often been noted, and this study did raise the ethical quandary of assigning some patients to observation and potentially to surgery that might have been avoided with brace wear. In 2007, a study by Dr. Weinstein and BRAIST co-investigator Lori A. Dolan, PhD, found a high degree of variability among clinicians concerning the effectiveness of bracing, suggesting that a randomized trial of bracing would be ethical.

Dr. Dobbs said the BRAIST study not only yielded valuable findings but also provided some useful lessons.

"Understanding the infrastructure and processes of putting together a trial of this magnitude across 26 centers sets the stage for other investigators to follow suit with other trials that deliver a high level of evidence. It's groundbreaking in that realm."

Dr. Weinstein hopes the study will encourage more similar investigations. "This trial showed that orthopaedic surgeons—in our case, pediatric orthopaedic surgeons—could participate in good-quality clinic research. I hope that this will stimulate other members of the orthopaedic community to do clinical trials and that our successful track record will encourage the NIH and other funding agencies to support orthopaedic research and clinical trials."

He and his colleagues are continuing to review the data from the study. "We only analyzed whether braces work and whether a dose response exists," Dr. Weinstein said. "We still need to analyze the data to find out who is the ideal candidate for bracing."

In the patients studied, the number needed to treat to prevent one case of curve progression requiring surgery was three. "That means we are unnecessarily bracing two children to get that one success," he said. "That's pretty good, but we want to be able to identify the exact person who would most benefit from a brace. We hope to develop a predictive model that will be helpful. We still have many unanswered questions."

For instance, all patients in the study wore a thoracolumbar sacral orthosis (TLSO) (Fig. 1). "An obvious question is to look at the efficacy of different bracing types," Dr. Dobbs said. "We also can look in more detail at the issue of dose dependence, focusing on how much is enough in terms of hours in a brace.



"We also want to determine which curves don't respond to bracing from an etiologic and genetic standpoint," he continued. "The study shows that wearing a brace for the prescribed number of hours doesn't stop all curves from progressing. It will be important to determine the genetic factors and differences among that group of patients whose curves don't respond as well."

**Fig. 1** TLSO brace of the kind used in the BRAIST study.  
Courtesy of Stuart L. Weinstein, MD

Dr. Weinstein hopes the trial has an inspirational value. "I am extremely proud of my orthopaedic colleagues who participated," he said. "These trials can change clinical practice, ensuring that patients get the right treatment at the right time and don't get unnecessary treatment, and that treatments are cost-effective."

The other authors of the study are Lori A. Dolan, PhD, and **James G. Wright, MD, MPH**.

*Disclosure information: Dr. Weinstein—Wolters Kluwer Health—Lippincott Williams & Wilkins, Journal of Bone and Joint Surgery—American; Dr. Dolan—Scoliosis Research Society; Dr. Wright—Journal of Bone and Joint Surgery—American, Saunders/Mosby—Elsevier; Dr. Dobbs—D-Bar Enterprises, Pfizer, Clinical Orthopaedics and Related Research, AAOS, American Orthopaedic Association, Association of Bone and Joint Surgeons, Missouri State Orthopaedic Association, Orthopaedic Research and Education Foundation, and Pediatric Orthopaedic Society of North America.*

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### Bottom Line

- In the first conclusive controlled, randomized clinical trial to evaluate the effect of brace wear on AIS, bracing was found to be effective in preventing curve progression to the threshold for surgery (Cobb angle  $\geq 50^\circ$ ) at skeletal maturity.
- In patients randomized to brace wear, 75 percent did not exhibit curve progression to the surgical threshold versus 42 percent in the observation group.
- The trial was halted early when the effectiveness of bracing became conclusively evident; eligible patients who had not worn braces were given the option to wear them.
- Data from temperature sensors that indicated wear time demonstrated that the brace effect has a dose correlation.

### References:

1. Weinstein SL, Dolan LA, Wright JG, Dobbs MB: Effects of Bracing in Adolescents with Idiopathic Scoliosis. *N Engl J Med* 2013; 369:1512-1521. <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1307337>. Accessed Nov. 7, 2013.
2. Dolan LA, Donnelly MJ, Spratt KF, Weinstein SL: Professional Opinion Concerning the Effectiveness of Bracing Relative to Observation in Adolescent Idiopathic Scoliosis. *J Ped Ortho* 2007 Apr-May;27(3):270-6. [http://journals.lww.com/pedorthopaedics/Abstract/2007/04000/Professional\\_Opinion\\_Concerning\\_the\\_Effectiveness.4.aspx](http://journals.lww.com/pedorthopaedics/Abstract/2007/04000/Professional_Opinion_Concerning_the_Effectiveness.4.aspx). Accessed Nov. 7, 2013.

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