



Adolescent idiopathic bracing success rates influenced by time in brace: Comparative effectiveness analysis of the BrAIST and ISICO cohorts

Fabio Zaina (1), Sabrina Donzelli (1), Lori A. Dolan (2), Stuart L. Weinstein (2), Francesca Di Felice (1), Stefano Negrini (3,4)

- (1) ISICO (Italian Scientific Spine Institute), Milan, Italy
- (2) University of Iowa, Department of Orthopaedics and Rehabilitation, Iowa City, Iowa
- (3) Department of Clinical and Experimental Sciences, University of Brescia, Italy
- (4) IRCCS Fondazione Don Gnocchi, Milan, Italy

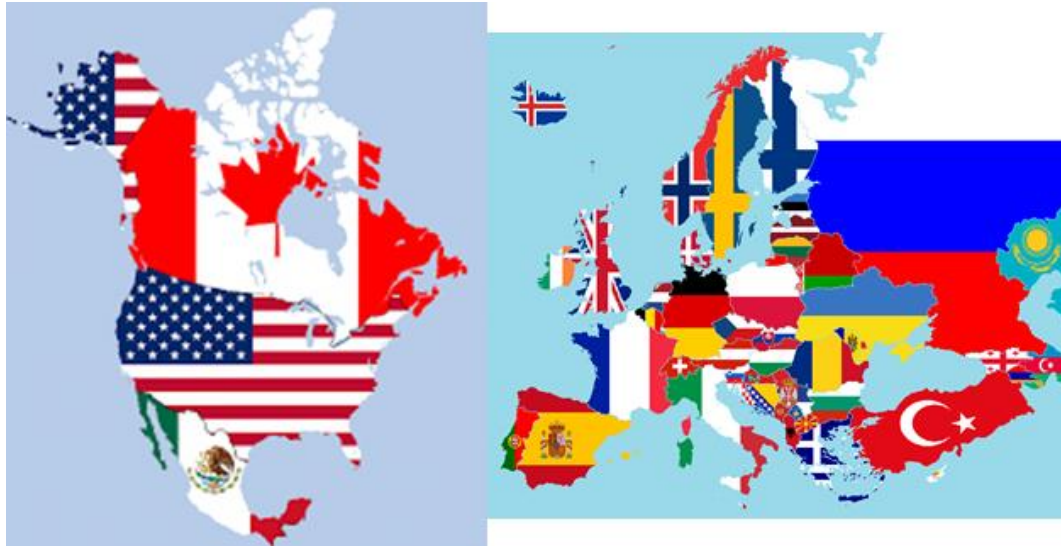
<http://www.isico.it>

francesca.difelice@isico.it



High variability in results for brace effectiveness

Studies of bracing in North America have not demonstrated the success reported by many studies from European centers, where progression to surgery often is less than 15%.



Differences could be due to:

- **Sample characteristics**
- **brace design**
- **Scoliosis specific exercises**
- **standard treatment protocols and weaning protocols**
- **Adherence to treatment**

Danielsson et al. "A prospective study of brace treatment versus observation alone in adolescent idiopathic scoliosis: a follow-up mean of 16 years after maturity". *Spine (Phila Pa 1976)*. 2007 Sep 15;32(20):2198-207.

Zaborowska-Sapeta et al. "Effectiveness of Cheneau brace treatment for idiopathic scoliosis: Prospective study in 79 patients followed to skeletal maturity." *Scoliosis*. 2011;6(2).

Negrini S, et Al. "The effectiveness of combined bracing and exercise in adolescent idiopathic scoliosis based on SRS and SOSORT criteria: a prospective study." *BMC Musculoskelet Disord*. 2014 Aug 06;15:263.





Objective

The aim of this study is to compare the effectiveness of the BrAIST and the ISICO programs in preventing curve progression to surgical indications



The word "DESIGN" is written in a colorful, stylized font. Each letter is composed of multiple overlapping shapes in various colors including red, orange, yellow, green, blue, and purple. The letters are arranged in a slightly staggered, modern layout.

DESIGN

Comparative effectiveness study using a subset of patients from two prospectively-collected datasets

A red, rectangular stamp with a distressed, ink-like texture. The word "SAMPLE" is written in bold, white, uppercase letters across the center of the stamp. The stamp is tilted slightly to the right.

SAMPLE

- Braced patients
- age 10-15
- Risser < 3
- Cobb angle 20 - 40°
- observed to Cobb angle of $\geq 40^\circ$ and/or \geq Risser 4.



Methods

Comparators: Bracing per BrAIST (TLSO) and ISICO protocol (SPoRT braces with or without SEAS exercises and cognitive-behavioral support).

Baseline characteristics -**sex, age, BMI, Risser, Cobb, curve type-** and **average hrs of brace wear/day.**

Differences in programs (e.g. SEAS, type of brace, weaning protocol) were captured by a variable named "SITE"

We were not able to evaluate the contribution of any given brace type to the outcome due to the large number of different designs used.

ISICO



BrAIST

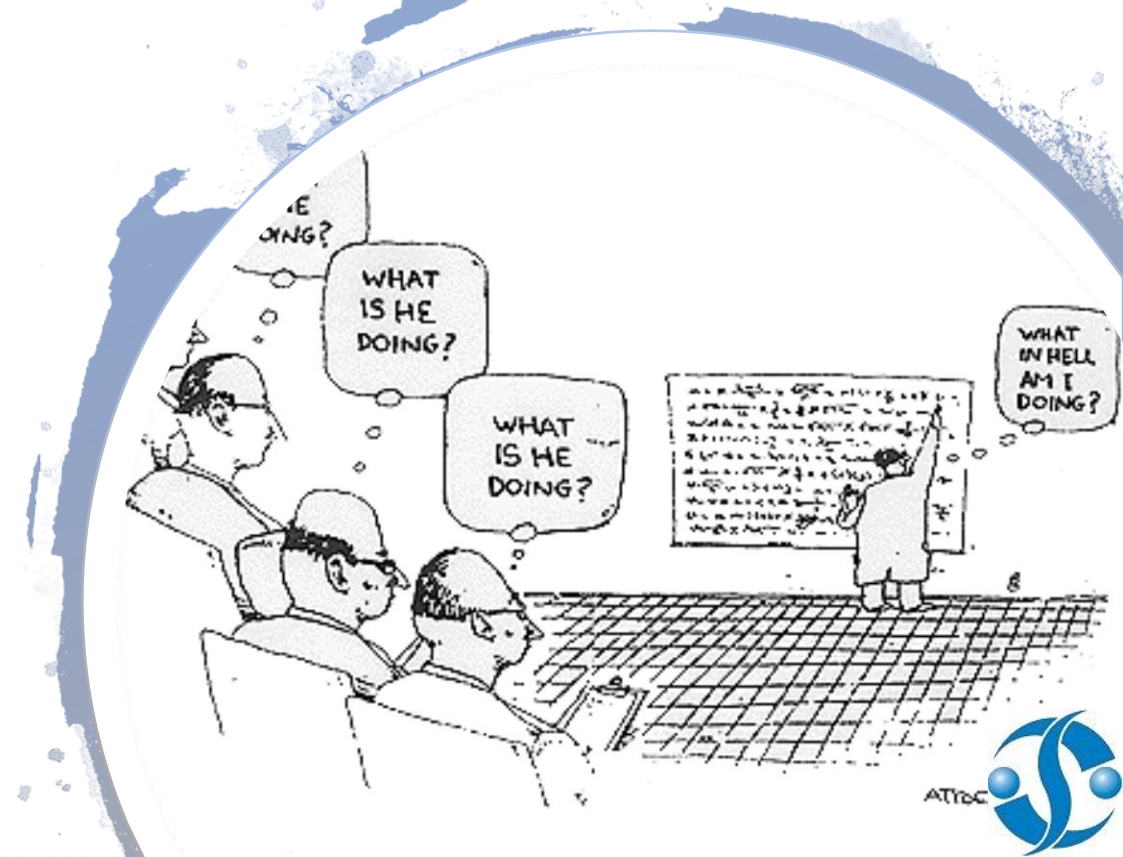


OUTCOME

Treatment failure = Cobb \geq 40 before
Risser 4

STATISTICS

- Descriptive and inferential statistics were calculated to describe and compare the samples.
- Univariable and multivariable logistic regression models estimated the relationship between risk factors, the site, and the outcome



| ISICO | BrAIST |
|-------------------------|-------------------------|
| Boys 17% | Boys 8% |
| Mean age 12.86 | Mean age 12.47 |
| % Risser 2 19% | % Risser 2 10% |
| Average wear time 18.31 | Average wear time 11.76 |
| 31% SEAS exercises | No exercises |
| Treatment failure 12% | Treatment failure 39% |
| %Low BMI = 6% | %Low BMI = 6% |

Results

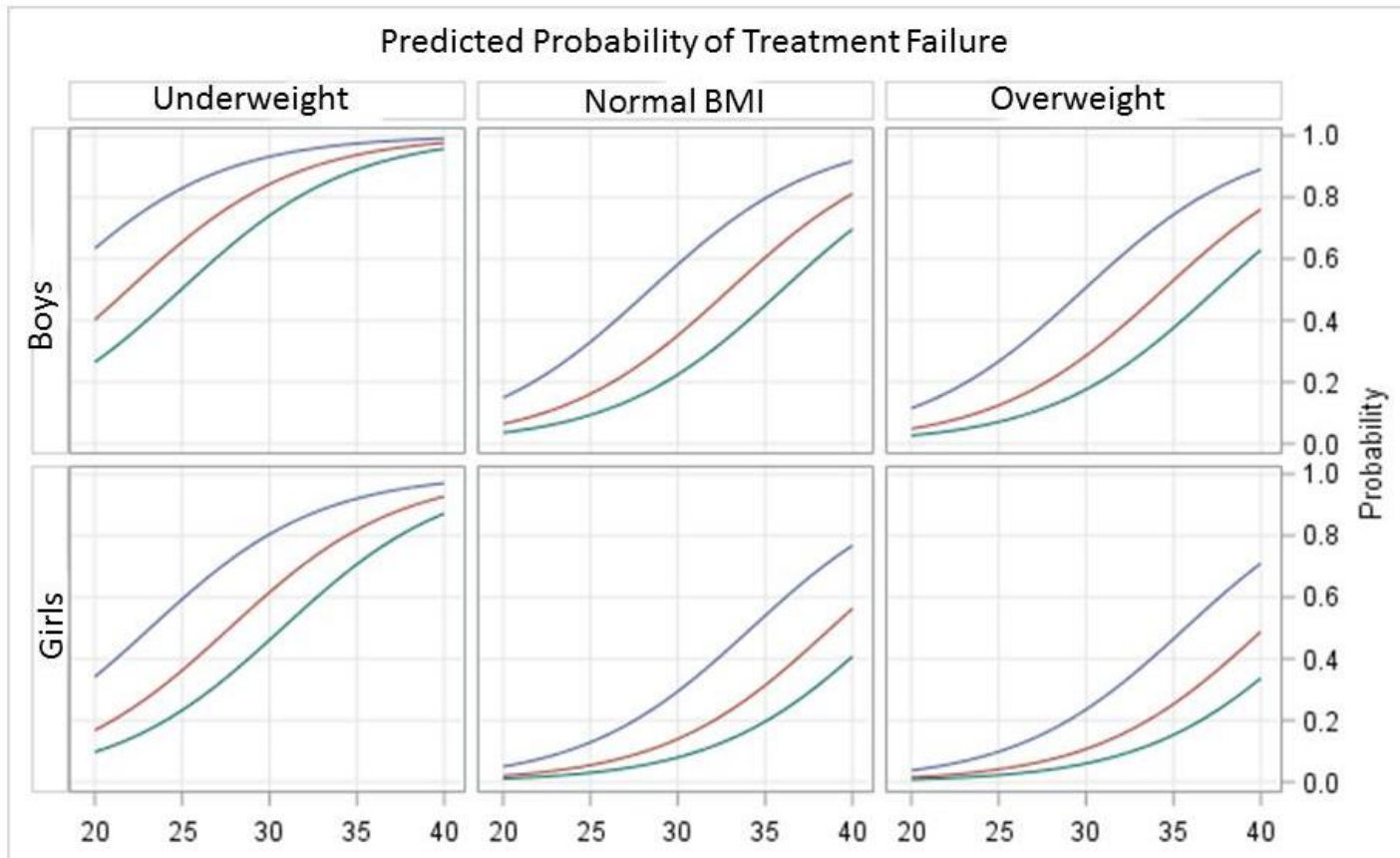
- 157 BrAIST and 81 ISICO subjects were included
- Cohorts were similar at baseline but differed significantly in terms of average hrs of brace wear: 18.31 in the ISICO vs. 11.76 in the BrAIST cohort. 12% of the ISICO and 39% of the BrAIST cohort had failed treatment
- the ISICO sample had more boys (17 vs 8%) and was slightly older (12.86 vs. 12.47 years) with a higher percentage at Risser 2 (19 vs. 10%)
- SITE was related to failure (OR=0.19), indicating lower odds of failure with ISICO vs BrAIST approach. With both SITE and wear time in the model, SITE was no longer a significant predictor

| Variable | B Coef. | Std Error | Adjusted OR (95% CI*) | p value |
|---------------------------|---------|-----------|-----------------------|---------|
| Intercept | 5.6896 | 2.2652 | | 0.01 |
| Age | -0.8900 | 0.1869 | 0.41 (0.29, 0.59) | <0.0001 |
| Gender | | | | |
| Females | Ref. | | | |
| Males | 1.2048 | 0.6938 | 3.34 (0.86, 13.00) | 0.08 |
| Maximum Cobb Angle | 0.2072 | 0.0416 | 1.23 (1.13, 1.34) | <0.0001 |
| Mean Brace Wear | -0.1571 | 0.0300 | 0.86 (0.81, 0.91) | <0.0001 |

Results

The odds ratios (adjusted for all other variables in the model) indicate that those with a larger maximum Cobb angle had higher odds of failure

As the average hours of brace wear per day increased, the odds of failure decreased



The plot show the probability of brace failure given the variables in the model.

To simplify the illustration, age was set at the mean value of 12.6, and the average hours of wear per day were set at 10, 16 and 20.

Overall, the highest probability of failure is seen in underweight boys and girls with larger Cobb angles.

When the baseline Cobb angle approached 40 degrees in underweight subjects, the risk of failure was near 100% regardless of the hours of brace wear.

At smaller Cobb angles, the effect of wear time is more apparent.

Final Model

Failure = WearTime+Cobb+Age+BMI+Age

Discussion

• ISICO

- The ISICO approach emphasizes the role of bracing in promoting good outcomes
- Treatment is provided by a strong team of physicians, orthotists and physiotherapists

• BrAIST

- Pts were aware of the low quality of research at the time supporting bracing
- At many centers, the orthopaedic and orthotic teams were not highly integrated

Treatment at the ISICO resulted in a lower failure rate, which was primarily explained by longer average hours of brace wear

Conclusion

- The results of this study suggest that the **effectiveness of bracing is determined by multiple variables**, specifically the **Cobb angle, sex, age, BMI and the average hours of brace wear per day**.
- *Lower rates of failure were seen in the ISICO sample where time in brace averaged 18 hours per day, compared to 12 hours in the BrAIST sample.*
- We were not able to evaluate the role that any specific brace type or other treatment factors had on the outcomes, either directly through curve correction or indirectly as a promotor of adherence. They will be investigated in future studies

Disclosure

None of the authors has any potential conflict of interest

