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ORIGINAL CLINICAL ARTICLE

Scoliosis in-brace curve correction and patient preference of CAD/CAM versus plaster molded TLSOs

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Abstract

Purpose CAD/CAM technology is a newer technique for creating spinal orthoses than standard plaster molded methods. To our knowledge there has been only one previous study of CAD/CAM braces. The purpose of our study was to compare patient preference and in-brace correction of Cobb angle between plaster molded thoracolumbosacral orthoses (TLSO) and CAD/CAM designed TLSOs in a series of patients with scoliosis.

Methods Ten patients with an average initial Cobb angle of 30.8° (range 18°–46°) had both a plaster molded TLSO and a CAD/CAM TLSO fabricated for them. In each case, the decision to brace was made by the treating surgeon based on curve magnitude and skeletal maturity. After 3 weeks of 23 h a day wear, in-brace correction of the Cobb angle was measured for each brace based on standard PA spine radiographs. After 3 months of use, patients were asked which brace they preferred.

Results For the CAD/CAM brace, the mean curve correction after 3 months was 51% compared to 44% in the plaster molded TLSO cohort. ($p = 0.46$). Seven out of nine patients preferred the CAD/CAM TLSO over the plaster molded TLSO. There were no brace complications in either group.

Conclusion In our matched cohort study, CAD/CAM TLSOs had at least equivalent if not superior correction of the Cobb angle compared to standard plaster molded TLSOs; 78% of our patients preferred the CAD/CAM brace over the standard TLSO.

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Introduction

Bracing, as a treatment for scoliosis, remains controversial. Although the US preventive task force has concluded that bracing is not effective based on the lack of level-one data, several reports have concluded that bracing can be successful in halting curve progression in compliant patients [1–14]. To help settle this controversy, the Scoliosis Research Society has recently developed guidelines for future brace studies to standardize the inclusion and exclusion criteria to determine exactly how effective braces are in the treatment of scoliosis [15].

The effectiveness of bracing depends on both patient compliance and the degree of in-brace curve correction. Studies have shown that bracing is more effective in controlling the curve the longer the orthosis is worn [2, 9, 14]. Improved patient comfort and acceptance of a spinal orthoses can increase brace compliance thereby improving the wear time of the brace. In addition, Emans et al [3] showed that the greater the initial correction in the brace, the greater the incidence of actual curve control at follow up.

Although several spinal orthoses are widely available including the Milwaukee Brace, the Wilmington Brace, and the Charleston night-time bending brace, custom-made thoracolumbarsacral orthoses (TLSOs) are commonly used to treat scoliosis. TLSOs have historically been made using negative casts of the body and hand forming of the braces. Computer-aided design/computer-aided manufacturing (CAD/CAM) has been used in the prosthetic and orthotic fields since the 1970s [16]. Recent advances in CAD/CAM technology and decreases in costs have allowed some orthotists to use this technology in the field of spinal braces. To date, there has only been one study examining the effectiveness of these CAD/CAM braces [17].

The purpose of our study was to compare patient preference and in-brace correction of Cobb angle between plaster molded TLSOs and CAD/CAM designed TLSOs in a series of patients with scoliosis.

Materials and methods

Ten patients with scoliosis of varying etiologies including idiopathic scoliosis (4), juvenile scoliosis (3), Prader Willi syndrome (1), neurofibromatosis (1), and microcephaly requiring growth hormone (1) formed the study group. The average age of the patients in our series was 8.9 years. All of the patients except two had a Risser score of zero, with one patient having a Risser score of one and another having a score of two.

In each case, the decision to brace was made by the treating surgeon based on curve magnitude and skeletal maturity. To create a perfectly matched cohort study, each patient had both a plaster molded TLSO and a CAD/CAM TLSO made for them. (Fig. 1) To minimize bias, patients were not told any specific information about each brace with regard to the fabrication techniques nor were they told which brace was the "newer" design. Patients were instructed to wear the braces for 23 h a day. After 3 weeks of wear, standing PA radiographs were taken in both braces, and compared to the most recent radiographs out of brace to determine the degree of in-brace curve correction. We considered a 5° difference in Cobb angle between radiographs to be significant. The degree of curve correction in both braces was compared using Student's *t* tests. After 3 months of use, patients were interviewed as to which brace they preferred.

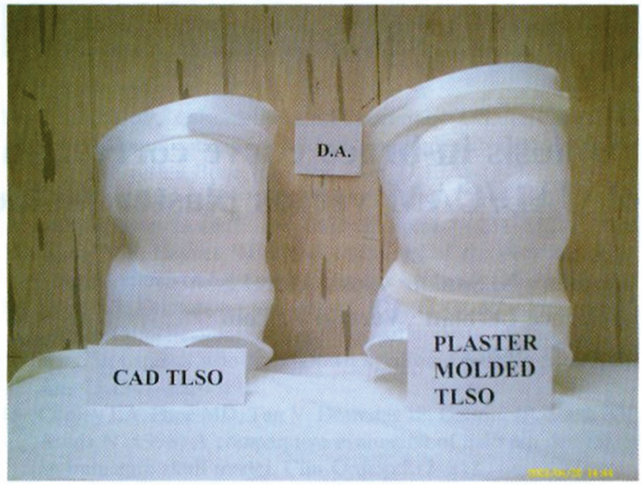

Fig. 1 An example of a standard TLSO and a CAD/CAM TLSO

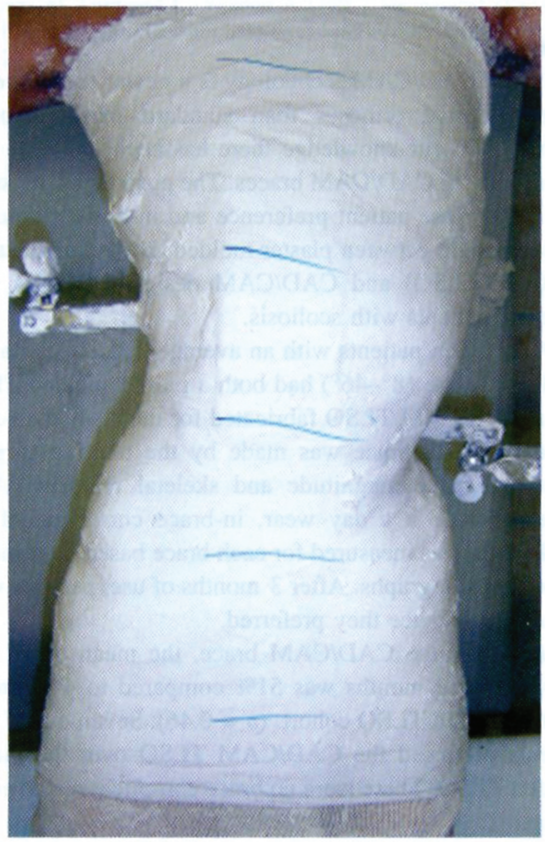

Fig. 2 The standard TLSO is molded on a modified Risser frame using Risser type push pads to correct the deformity

Technique of brace fabrication

The plaster molded TLSO (Fig. 2) is molded on a modified Risser frame. The patient is placed on the frame in a body stocking and an elastic waist strap is applied. Risser-type push pads (Fig. 2) are then placed, correcting the curve while maintaining alignment symmetry. Plaster rolls are applied to the patient over the push pads and the patient is held in the aligned position until the plaster is set. The cast is later filled with plaster and the TLSO vacuum molded with polypropylene.

The CAD/CAM TLSO (Fig. 3) is molded on a modified glass Risser table. The patient is placed on the Risser table in a body stocking and an elastic waist strap is applied. Translucent corrective pads (Fig. 3) are placed, correcting the curve, along with translucent pull straps. Reference positions are indexed with the laser and the patient is scanned in the aligned position. The digital mold is then modified on screen and a model of the torso is manufactured according to the computerized data. The TLSO is vacuum molded with polypropylene in a fashion similar to the regular TLSO.

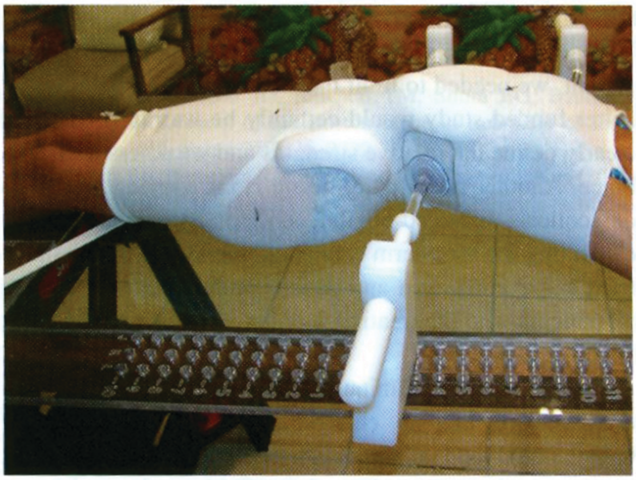

Fig. 3 The CAD/CAM TLSO is molded on a modified glass Risser table. Translucent corrective pads are placed, correcting the curve, along with translucent pull straps

Results

The ten patients in our series had a total of 14 curves (six single surves and four double curves) (Table 1). The average Cobb angle of the initial curves was 30.8° (range 18°–46°). In six patients there was no significance difference between the plaster molded TLSO and the CAD/CAM TLSO. Three patients showed a significant improvement in correction in the CAD/CAM TLSO over the plaster molded TLSO, and one patient had significant improvement of correction in the plaster molded TLSO over the CAD/CAM TLSO. Overall, the CAD/CAM brace demonstrated an average curve correction of 51%, compared to 44% by the plaster molded TLSO. ($p = 0.46$).

One patient was unable to convey his preference between braces due to mental retardation. Of the remaining nine patients, seven of the nine preferred wearing the CAD/CAM brace because they found it more comfortable. Patients two and three, who happened to be twin sisters, both preferred the plaster molded TLSO to the CAD/CAM TLSO. No patient stated that the braces were equally comfortable. There were no complications of brace treatment from either spinal orthosis.

Discussion

Although the use of spinal orthoses is controversial in the treatment of scoliosis, studies have shown that patient compliance, wear time of the brace, and the degree of in-brace correction can all influence the overall effectiveness of a bracing program [1–14]. Although CAD/CAM technology has recently been used to fabricate TLSOs for scoliosis, we are aware of only one previous study which directly compares CAD/CAM and standard plaster molded TLSOs in terms of some of these factors.

Wong et al [17] compared two cohorts of 20 patients with adolescent idiopathic scoliosis with average initial Cobb angles of 30.6° and 30.5°, respectively. In their series, the average curve correction by the CAD/CAM brace was 41.9% compared to 32.1% by the standard brace although these results were not statistically significant. Our study showed that three out of ten patients had a higher correction in CAD/CAM braces than in plaster molded braces, while one out of ten had worse correction. While we found no statistically significant improvement in curve correction between the two braces (51% vs. 44%, $p = 0.46$)

Table 1 Curve correction for standard TLSO vs. CAD/CAM TLSO

Patient number	Initial curve	Std TLSO correction of R curve	Std TLSO correction of L curve	CAD TLSO correction of R curve	CAD TLSO correction of L curve
1	R T4-L1 33 deg (apex T7–8)	8		10	
2	L T8-L2 46 deg (apex T10)		23		23
3	L T6-L1 44 deg (apex T9–10)		19		21
4	R T4-T11 32 deg (apex T8), L T10-L3 38 deg (apex L1–2)	16	27	21	12
5	R T10-L2 34 deg (apex T11–12)	11		12	
6	L T9-L2 25 deg (apex T11–12), R L1-L5 18 deg (apex L3–4)	12	10	6	13
7	R T5-T9 19 deg (apex T6), L T11-L3 30 deg (apex T12)	21	23	17	20
8	R T9-L3 25 deg (apex T12-L1)	15		0	
9	LT11-L4 25 deg (apex L2)		3		3
10	LT4-T12 29 deg (apex T8), R T12-L5 33 deg (apex L2–3)	12	32	23	30

the possibility exists that a study with more power may detect a difference.

Of the patients who were able to make their own choice of which brace was more comfortable to wear, seven out of nine chose the CAD/CAM TLSO braces. Some speculation is warranted to explain this preference. In the method of creating the plaster molded TLSO, there are uneven surface variations secondary to required manual manipulation. In the making of the CAD/CAM TLSO, the manufacturing device appears to leave less uneven surfaces on the brace. The increased brace comfort from this smoother surface may be associated with greater compliance. It is possible that an improved finishing process for standard plaster molded TLSOs could achieve comparable results to the CAD/CAM brace.

There are three main components needed to produce a CAD/CAM TLSO; a digitizer, a computer with design software, and a milling/carving machine. The cost of these machines can be as low as $1,400 for the digitizer and computer software and $47,000–$250,000 for the milling/carving machine [18]. Orthotists may have the digitizer and software in their office, and electronically send the collected patient data to off-site computer automated manufacturing (CAM) laboratories with the milling device where the brace can be produced.

There are similarities in the methods used to create a TLSO by the plaster molded and CAD/CAM techniques. Both involve fabrication of a mold of the outside of the patients body, filling this with plaster to make a positive mold, vacuum molding of a polypropylene brace over the plaster mold, and final finishing of the brace. There are two main differences between the two processes. To produce the first outer mold of the body the CAD/CAM method uses digitization while the plaster method requires the placement of plaster on the patient's body. The other difference is fabrication of the brace from the plaster mold. The standard method of fabrication requires 8–10 man hours compared to the CAD/CAM method which may be done in 1–2 h at the manufacturing laboratory. While the overall cost of making each brace at our institution is quite similar ($1,800–$2,500 each), the improved efficiency of the CAD/CAM method can allow for more braces to be made per day. Another advantage of the CAD/CAM method is the data storage. Should a patient lose or damage a plaster molded brace, a new mold is usually necessary as space prohibits keeping every mold made on every patient. In contrast, the CAD/CAM technology enables the stored digital information to be resent to the manufacturing laboratory so that a second (and identical) brace can be made.

One shortcoming of our study is the small sample size of patients. To minimize bias and decrease variability, we chose to create a perfectly matched cohort study by allowing each patient to wear both braces. Because of the large costs associated with making multiple braces per patient, we needed to limit the size of the cohort. A larger, better funded study would certainly be warranted to more clearly define the relative strengths and weaknesses of each brace. Another potential criticism is the varying etiologies of scoliosis included in the cohort. Since we were not evaluating the long-term results of bracing but rather short-term curve correction and patient preference we included all patients who the treating surgeon thought would benefit from bracing.

Regardless of its limitations, our matched cohort study demonstrated that in children receiving both a CAD/CAM TLSO and a plaster molded TLSO, there was at least equivalent correction of the Cobb angle, and better patient acceptance of the CAD/CAM brace. It is important to note that use of CAD/CAM technology, while associated with higher initial costs, may enable improved efficiency, because of the reduced time necessary for brace fabrication.

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