Augmented Feedback Spinal Orthosis
An Introduction and Preliminary Report

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INTRODUCTION

The Milwaukee* cervical-thoracic-lum bar-sacral orthosis has been the standard non-operative treatment for scoliosis in growing children since 1945 (Fig. 1). End result studies of the use of the Milwaukee orthosis have shown that it prevents curve progression in the majority of curves between 20 and 45 degrees.[1] The thoracolumbar-spinal orthosis originating in Boston and adapted elsewhere has shown similar results to those with the Milwaukee orthosis.[2 3] The efficacy of the Milwaukee orthosis was thought to be due to an active shift of the trunk away from the thoracic pad within a restricted space where the occiput was aligned over the sacrum.[4]

In order to help enforce the lateral trunk shift exercise within the orthosis, a tactile stimulator of the trunk with a plastic CTLSO was designed. The stimulator signals at preset intervals when the patient is to shift the trunk away from it and shut off the stimulator by the shift. In this way, exercise is enforced while the patient is erect and awake. By incorporating the major features of the Milwaukee orthosis with the all-important active voluntary exercise of lateral trunk shift, it is hoped to improve the results of treatment by achieving reduction of the spinal curvature. The mechanisms of reinforcing the active exercise in the orthosis is termed "augmented feedback."

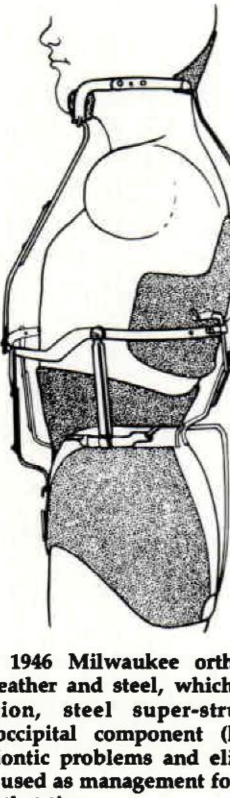

Fig. 1—The 1946 Milwaukee orthosis was constructed of leather and steel, which consisted of a pelvic portion, steel super-structure and a mandibular-occipital component (later found to cause orthodontic problems and eliminated). This orthosis was used as management for post operative protection at that time.

*An orthotic system which was conceived in Milwaukee, WI in 1945 by Walter P. Blount, M.D., John H. Moe, M.D. and through the technical pioneering efforts of Mr. Richard Bidwell, C.O. This orthotic approach has evolved technically through the years, but the biomechanical principles are very sound to this date.

The project goals were as follows:

- redesigning, formulating and fabricating an orthotic system incorporating a TLSO plastic component with a modified Milwaukee superstructure.
- using a refined negative casting procedure and positive model modification.
- determining the practicality of a refined orthosis in terms of correction, spinal realignment, comfort and cosmesis.
- determining the effect of the augmented feedback in improving and maintaining correction of the scoliosis during the spinal growth spurt in children.
- interfacing an electronic mechanism to maximize a lateral trunk shift exercise with an orthosis.
- inducing the patient to apply a corrective musculoskeletal action, thereby obtaining optimal therpeutic function in maintaining and limiting curvature of the spine through a dynamic force system.

PATIENT SELECTION

Twenty patients were selected for fitting of the augmented feedback spinal orthosis (AFSO); all had idiopathic scoliosis and growth potential with a Risser* sign (Iliac crest apophysis ossification) of three or less. All curvatures (except in two patients) were greater than 20 degrees. Patients 6 and 13 had curvatures of 19 and 14 degrees respectively. Both had been followed by observation; only one had demonstrated curve progression.

All patients had curvatures measured by the Cobb method† on standing anterior-posterior and initial standing lateral radiographs of the spine. Moire† polaroid photographs were made of the trunk as additional documentation. Radiographic examinations and Moire photographs were used in follow-up examinations.

Flexibility was determined by a posterior-anterior radiographic projection of the spine when manual pressure was applied to the apex of the curve and counter pressure against the opposite lateral aspect of the pelvis.[5] Active correction of the major curve was documented with a radiograph of the spine taken when the patient actively shifted the trunk away from the apex of the major curve. (Figs. 2a, 2b, and 3a x-ray; 3b, 3b x-ray).

Growth was assessed by interpretation of Iliac crest apophyseal ossification according to the Risser method, Tanner† stages of growth and serial measurements of the patient's height. Radiographic examinations to determine skeletal ages were performed in some patients but were of no value in most patients because all

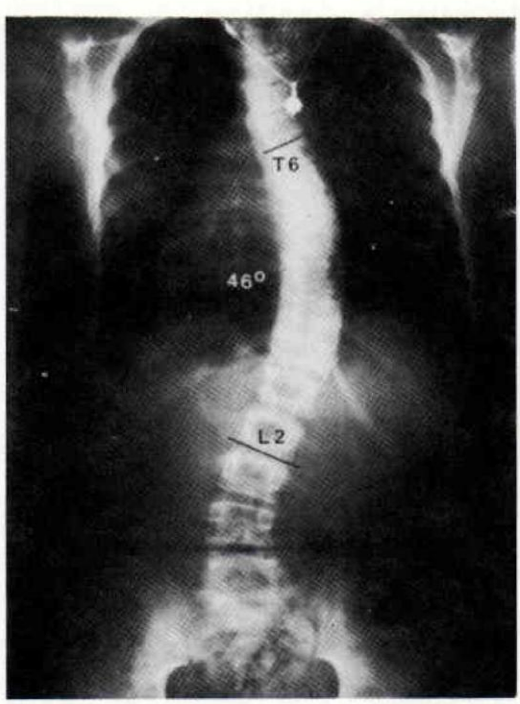

Fig. 2a—Anterior-posterior films are taken to determine curve patterns and degree of curvature. Also taken as a follow up to determine whether the patterns are progressional.

This radiographic film follow up indicated a progressional curve.

*Risser sign: is used to determine bone growth potential; a radiographic film is used to determine Iliac crest apophysis ossification.

+Cobb Method: a method to determine the length of a curve and to denote degree value of that curve.

‡Moire topography is a non-radiographic approach using a photographic method, and instrumentation, for scoliosis screening.

‡Tanner stages of secondary sexual characteristic: a clinical method to be used to determine growth potential related to osteo-maturation.

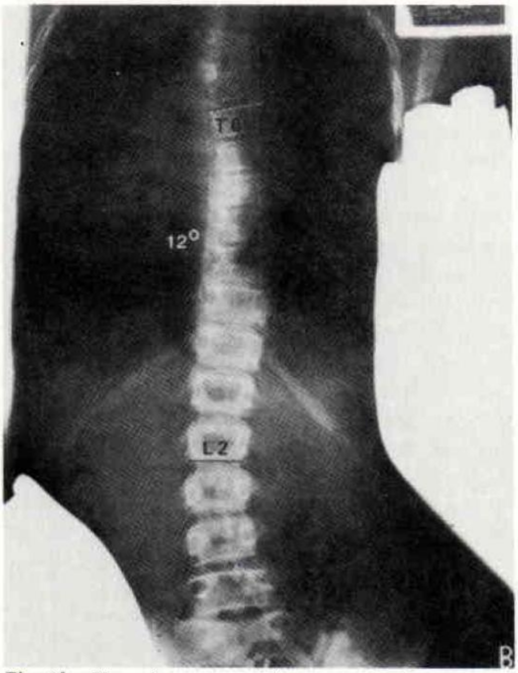

Fig. 2b—Use of a prone push posteroanterior film of the spine, in which manual pressure is applied, determines spinal flexibility in patients with scoliosis.

Fig. 3a x-ray—Anteriorposterior radiographic projection of the spine of patient indicating right thoracic curve from T-5 to T-11 with a degree value of 36 degrees and a left lumbar curve from T-12 to L-4 of 29 degrees.

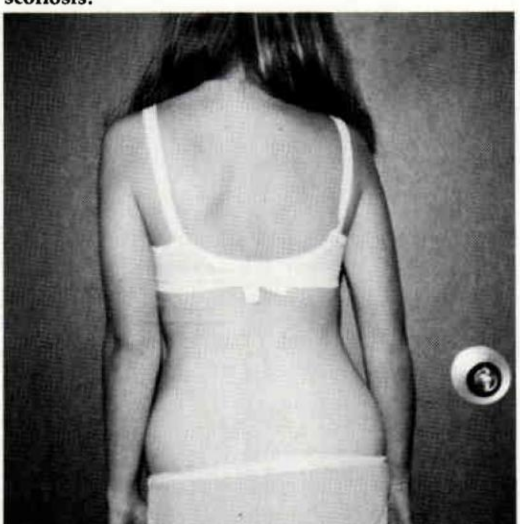

Fig. 3b—Patient demonstrating lateral musculoskeletal movement away from the apex of the right thoracic curve to the concave side of that curve.

Fig. 3b, x-ray—A radiographic film denoting shift movement indicating flexibility and muscular correctional control patient can exhibit. Note; right thoracic now 7 degrees and left lumbar, now 4 degrees.

had obvious growth potential in consideration of their mean chronological age of 11.6 years (range 8.6 to 15 years), and the Risser sign less than three. In addition, growth was demonstrated during the follow-up by measurements of their height (Table I).

Following these examinations, the patient was scheduled for an orthotic evaluation and casting procedure at the Rehabilitation Engineering Center (REC). Medical records and radiographs were reviewed to formulate the approach, modifications to the casting procedure and orthotist-patient communications.

An integral part of our orthotic treatment is to have open communication between orthotist, patient and parent(s), as well as developing the patient's psychological aspect of a positive attitude in relation to acceptance of any type of orthosis, stressing the importance of body awareness and presenting a positive image through posture. There is, naturally, an initial difficult adjustment period.[6]

NEGATIVE IMPRESSION PROCEDURE

A Risser casting frame is used for all of our spinal casting procedures (Fig. 4). The patient lies supine on the belt of the frame to reduce gravitational effects on the spine, thus allowing external manipulation of the trunk by applying pressure to the negative plaster impression to create a realignment effect based upon the apex of the curve.

Surface anatomy is used to determine hand positioning on the plaster impression. For example, if the patient we evaluate has an S-shaped curve, consisting of a right thoracic curve from T-5 to T-12 with an apex of T-9 and a left lumbar curve from T-12 to L-4 with an apex of L-3, surface anatomy can be more specific in relation to placement of external force (Fig. 5). The thoracic pressure area will be positioned laterally on the negative impression at a right angle to the xyphoid process (which indicates position of T-9 vertebra) so hand

Table I
FOLLOW-UP AFSO AFTER 12 MONTHS

Patient #	Age Mos.	Risser Sign	Curve Location	Degrees	AFSO Use Mos.	Growth Cms.	Degrees at follow-up	Increase or decrease degrees	Result
01. BF	161	161	0	T5-11	34	27	17.5	29	– 5
2. LD	150	1	T6-10 T11-L4	31 34	12	14.0	37	+ 8	–
3. EJ	155	0	T5-L2	24	22	13.0	38	–14	+
4. AS	157	3	T12-L4 L2-3	27 27	13	12.5	26 26	0	0
5. AQ	174	0	T7-12 L1-4	20 18	27	4.0	25 25	+ 5	–
6. AW	114	0	T6-9 T10-L3	19 24	18	22.5	17 21	0	0
7. KK	167	1	T6-11 T12-L4	36 22	14	14.5	35 25	0	0
8. SW	127	0	T7-L2	29	20	19.5	20	– 9	+
9. CL	150	0	T4-9 T10-L3	30 27	12	16.0	23 25	– 7	+
10. MM	192	1	T5-11 T12-L5	35 24	18	11.0	21 16	–14	+
11. KB	132	0	T5-11 T12-L4	40 40	19	6.0	50 50	+10	–

—Increase or decrease in curve of less than 5 degrees not significant.
—Result grading: + = improvement, – = worse, 0 = unchanged.

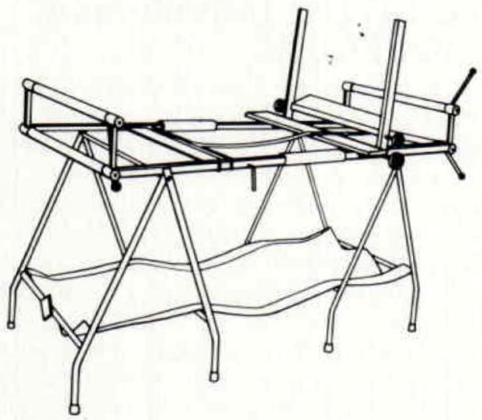

Fig. 4—Risser casting frame used for all our spinal casting procedures. Patient lies supine on the belt in the middle of the frame. This method allows us to limit gravitational forces acting on the spine.

position can be related to the apex of the curve on the convex side. This pressure is a lateral to medial force for realignment of the spine with somewhat of an anterior lift reducing the rotational aspect of that curve (Fig. 6). The hand placement for the left lumbar curve would be on the convex side of the curve at a right angle to the position of the umbilicus, which would indicate the apex of the third lumbar vertebra. The hand is placed posteriorly and laterally to the para-spinal muscles with a lateral-medial pressure realigning the lumbar spinal segment.

The casting procedure requires three people. Upon determination of the hand placement, the patient is positioned on the casting frame. Plaster bandage is applied, and the following steps are taken until hardening of the impression:

- One person controls pelvic rotation and lateral movement of the pelvis in relation to the transverse and frontal planes (Fig. 7). This person places his hands underneath the buttocks and a person from the opposite end, near the head, instructs that member to lift either the left or right hand, insuring that the buttocks are parallel to a horizontal surface. This allows us to maintain a symmetrical positioning of the pelvis within the cast.
- Then, as described, pressures are applied to the curve(s) until the plaster impression is dried to a point where

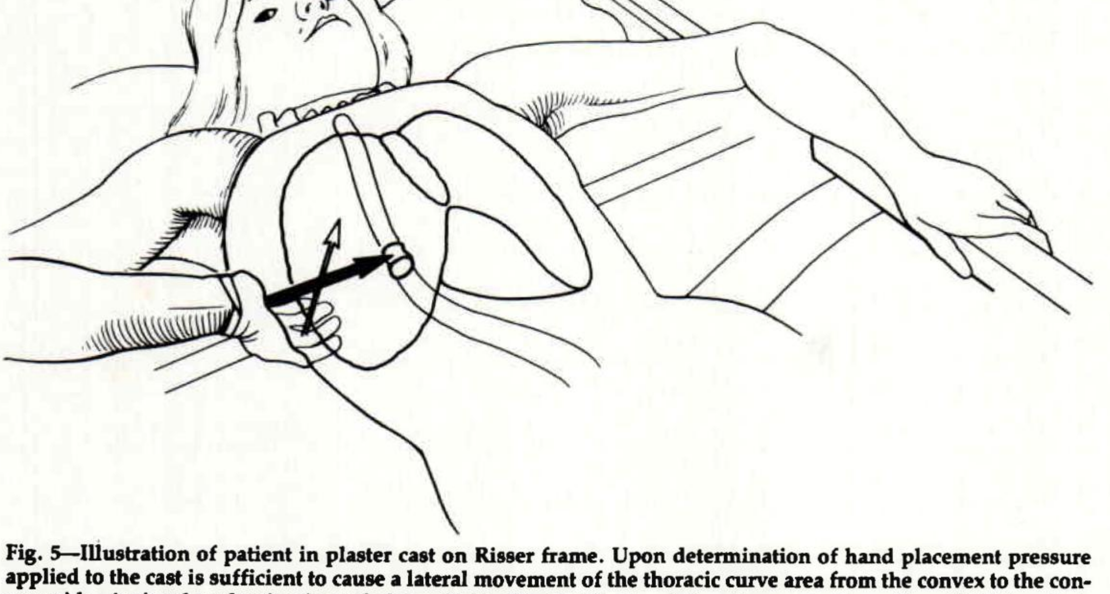

Fig. 5—Illustration of patient in plaster cast on Risser frame. Upon determination of hand placement pressure applied to the cast is sufficient to cause a lateral movement of the thoracic curve area from the convex to the concave side. A visual evaluation is made by a slight off set of the trunk in reference to the mid-sagittal line. This pressure is maintained until the plaster hardens.

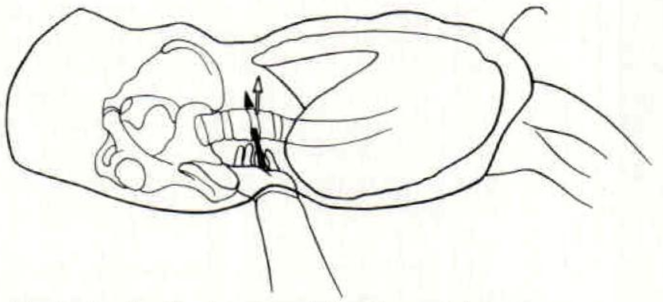

Fig. 6—Lumbar hand position. The palmer surface of the hand is placed near the paraspinal muscles in the lumbar area exerting a medial-lateral pressure from the convex to the concave side of that curve on the plaster cast as in Fig. 5, thoracic curve.

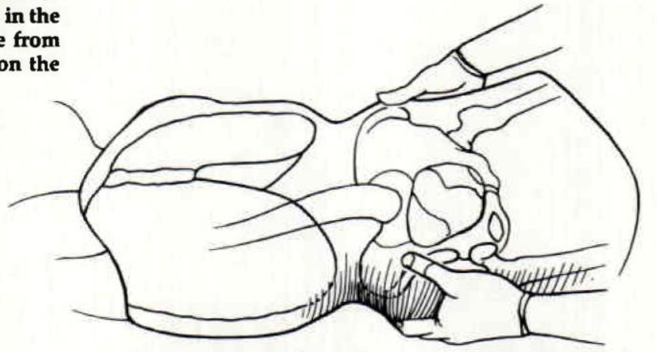

Fig. 7—Maintaining a firm grasp of the pelvis, as a stabilizing function, during the casting procedure establishes a symmetrical positioning of the pelvis in the cast where manipulative realignment pressures can be applied superiorly.

the patient can be lifted and stood erect on the floor.

- Metal washers are plastered near the apex of the external hand impressions on the plaster cast so they appear flat on the radiograph.
- A radiograph is taken of the patient in in the plaster impression for evaluation of the casting procedure to determine the amount of flexibility of the curve(s) and the amount of correction or realignment attained through the casting procedure.

The washer on the radiograph denotes the distance to the lateral aspect of vertebral bodies, the apex of the pressure of the negative hand impression in reference to the apex of the curve, whether the apex of that pressure needs to be moved superiorly or inferiorly, and the position and the angle of the ribs in regards to the apex of the curve in the thoracic area.

The lumbar washer placement gives the same indications as in the thoracic pressure area: the distance from the apex of washer to the lateral aspect of the vertebral bodies and the distance from the washer to para-spinal muscles in relation to the transverse processes in the lumbar area.

ORTHOTIC DESIGN BLUEPRINT

By drawing a horizontal line across the iliac crests on the film, a vertical ninety degree line can be drawn through the apex of each metal washer from the iliac crest line. By drawing right angle (reference to vertical line) horizontal lines on the radiograph through the apex of each metal washer to the lateral aspect of the lumbar (Fig. 8) and thoracic vertebrae, measurements are taken to determine positive model modification.

Lumbar Blueprint Layout

- From the horizontal line, we can determine the distance from the apex of the washer to transverse processes and the lateral edge of the lumbar vertebral bodies.

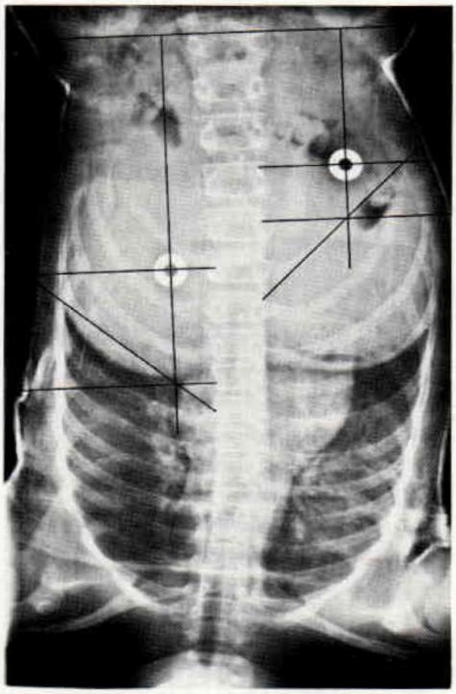

Fig. 8—Illustration of radiographic "blueprint" layout; a radiographic projection of patient in the negative plaster cast.

- From the vertical line, a vertical superior measurement is taken to identify the location and angle of the eleventh and twelfth ribs and an inferior measurement indicates location of the iliac crest of the pelvis. When modifying the positive model, a pressure relief can be built up, thus maintaining applied forces to the apex and transverse processes of the lumbar vertebrae. This reduces the amount of pressure being exerted on the ribcage (eleventh and twelfth ribs superiorly) and Iliac crest inferiorly.

Thoracic Blueprint Layout

The distance from the apex of the washer to the thoracic vertebral bodies is determined. The horizontal line is used as a reference to measure the angle of the ribs to the apex of the thoracic curve in relation to the apex of the pressure being applied.

Upon completion of the evaluation of the radiograph, the washer location is transferred to the positive model as a point of reference for positive model modifications.

The positive model basically reflects what is determined by the casting procedure, using the radiograph as a blueprint. That radiograph gives indications of maintaining what is achieved through the casting procedure. This method of positive model modification takes an asymmetrical positive model and realigns specific areas, which creates a symmetrical model maintaining asymmetrical pressure areas.

FABRICATION

The feedback orthosis consists of a TLSO component, vacuum-formed from a thermoplastic called Surlyn.* Surlyn was the plastic of choice because of its clarity, which enhances the cosmetic appeal of the device (Fig. 9). Due to the flexure of the material, it was necessary to provide more structural support to the plastic orthosis. Incorporating polypropylene rod crest components† into the vacuum-forming process reinforced the unity of the orthosis. The crest components are used for suspension and the foundation for forces can be applied.

The trimlines of the TLSO are similar to that of the Boston module† and Milwaukee orthosis. The inferior-anterior trimlines are cut to allow for hip flexion and sitting comfort. Superior-anterior trimlines are contoured along the base of the breast (Fig. 9a). On the convex side of the orthosis (right thoracic curve pressure area), the trim lines are high, allowing maximum distribution of pressure over a wider area (Fig. 10). The pressure pad area is concave or elliptical in shape to provide a fulcrum at the apex of the curve (Fig. 9a). This will promote a slight lateral spinal adjustment superior to the apex. The superior concave trimlines are similar to the convex side, left higher to place a counter pressure superior

*"Surlyn": trade name used by E. I. Du Pont de Nemours and Company (1007 Market Street, Wilmington, DE 19898), which is an Inomer resin produced by Du Pont Company. The plastic that is used in the drape forming process is Surlyn™, which is purchased from the United States Manufacturing Company under their trade name "Thermo-Vac Clear Plastic."

†The polypropylene "model #9493 Crest Pieces," which are used in the fabrication process, are purchased from Orthomedics, Inc. They are reheated to a pliable state and recontoured to each positive model.

†The Boston modular system: developed at Children's Hospital Medical Center, Boston, Mass., by Bill Miller, C.O., et. al.

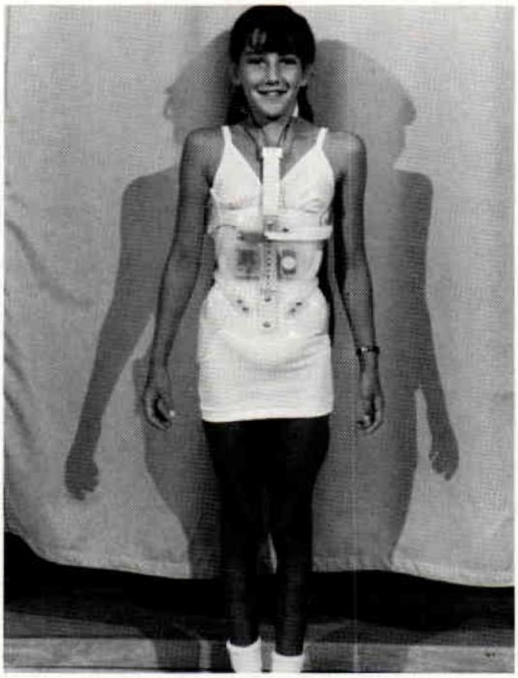

Fig 9—Anterior view of patient wearing Augmented Feedback Spinal Orthosis (A.F.S.O.).

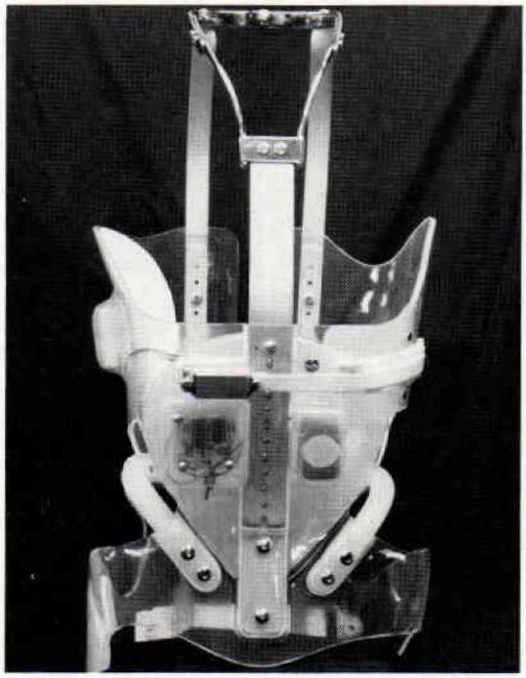

Fig. 9a—Anterior view of the A.F.S.O.

Fig 10—Right lateral view.

to the apex of the convex pressure (Fig. 11 and 11a). On the concave side, the posterior-superior trimline is cut out the permit movement of the scapula (Fig. 12 and 12a). The posterior inferior trimlines are trimmed approximately 2.5 cm above a hard surface to aid sitting comfort (Fig. 12a). The lateral inferior trimlines on the convex side of the thoracic curve are left low, approximately 2.5 cm to 3 cm. below the apex of the greater trochanter. This extends the lever arm of the thoracic pressure and incorporates another firm point of pressure in the force system (Fig. 10). On the lateral inferior concave side, the trimlines are high above the trochanter to allow lateral and pelvic motion (rotation). Large fenestrated areas are trimmed away to provide sufficient ventilation and heat adjustment to plastic for a growing patient (Fig. 11 and 11a).

Attached to the TLSO are standard and para-spinal bars. Superiorly attached to the superstructure is a redesigned cervical component* modified to remove the mandibular portion (Fig. 9 and 9a).

Fig. 11—Left lateral view.

Fig. 11a—Left lateral view of A.F.S.O. on the patient.

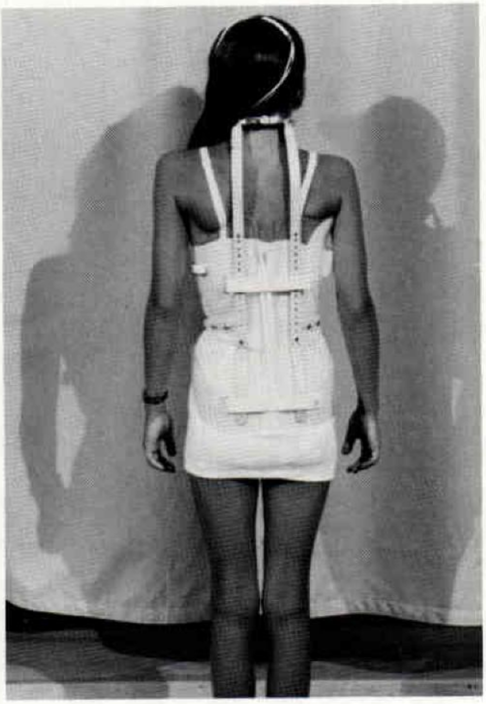

Fig. 12—Posterior view.

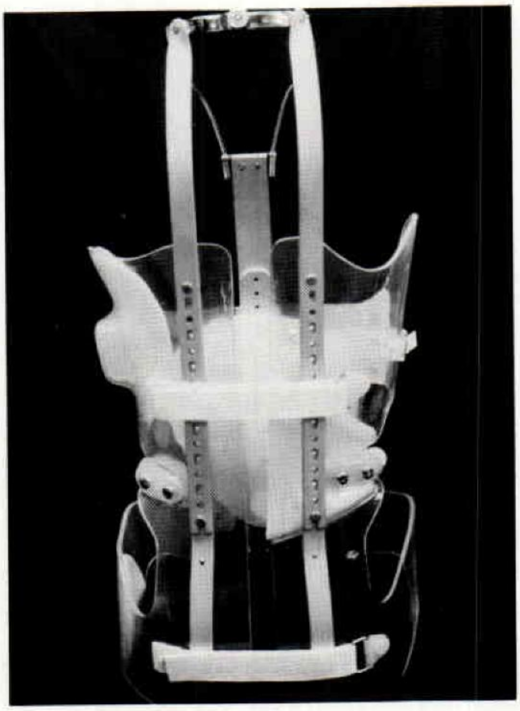

Fig. 12a—Posterior view of A.F.S.O. on the patient.

The purpose of the cervical component in this orthotic design is to control lateral movement of the head and cervical vertebrae, and maintain vertical alignment over the pelvis. The cervical ring is positioned low on the neck to make it more cosmetically appealing.

The TLSO has minimal foam interface. To areas having an extreme amount of correctional pressure, five millimeter medium density foam pads are glued in place to absorb some of the pressure being applied (Fig. 10 and 12). A large oval pad is placed laterally in the thoracic area, a triangular shaped pad is placed in the lumbar area and a circular pad is glued in place at the apex of the greater trochanter. Using a minimal amount of interfacing reduces the bulkiness of the orthosis, maintaining a more intimate fit.

On the abdominal portion—to the right side of the anterior bar—is the location of the electronic mechanism, which is a sophisticated timer (Fig. 13). This timer will activate the tactile stimulator every 45 minutes. The stimulator is a small electric motor with an offset flywheel that provides a vibratory tactile sensation. The stimulator is laterally located on or near the apex of the curve. Above the electronic unit is the pull switch*; its function through the strap attachment to the left side will discontinue the stimulator when the patient holds the lateral movement away from the convex side (Fig. 13a). The strap and strap attachment to the concave side of the curve are adjustable to minimize the exursion of the pull switch.

AUGMENTED FEEDBACK MECHANISM USAGE

The augmented feedback mechanism is interfaced into the orthosis to encourage lateral musculoskeletal movement away from the tactile vibratory stimulus on the convex side to the concave (Fig. 14).

*The headpiece, which includes the occipital brackets and throat frame mandible brakcets and superstructure are purchased from Fillaeur Orthopedic. The cervical component is modified by removing the mandible portion and the tangs on the occipital brackets.

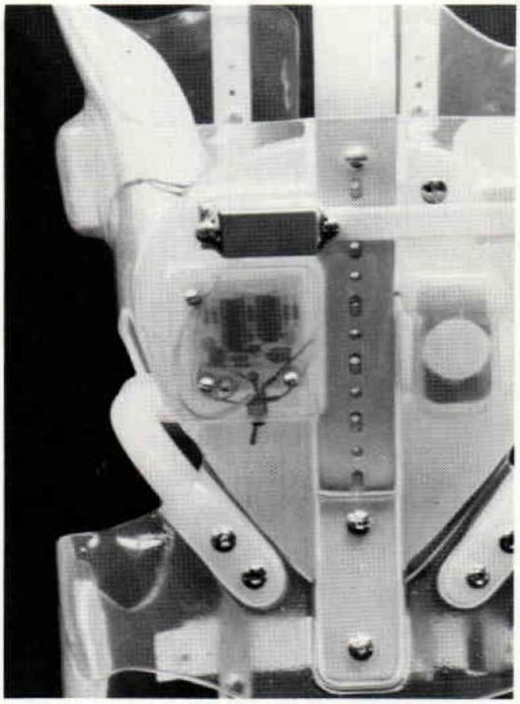

Fig. 13—Anterior abdominal view of the electronic section of the orthosis.

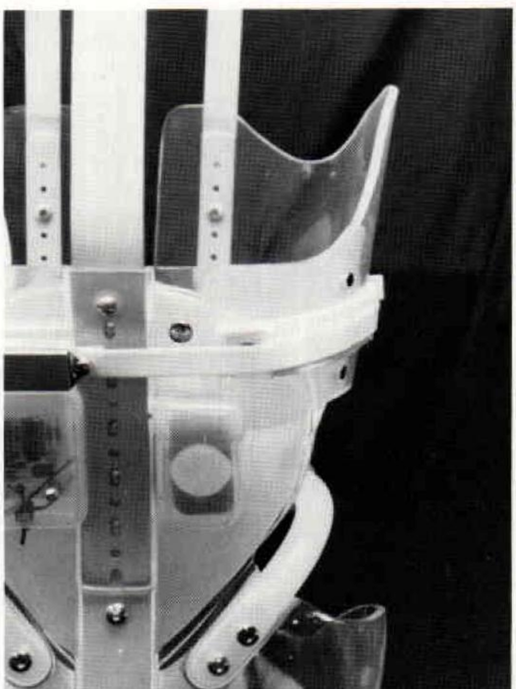

Fig. 13a—Anterior abdominal view of the electronic section.

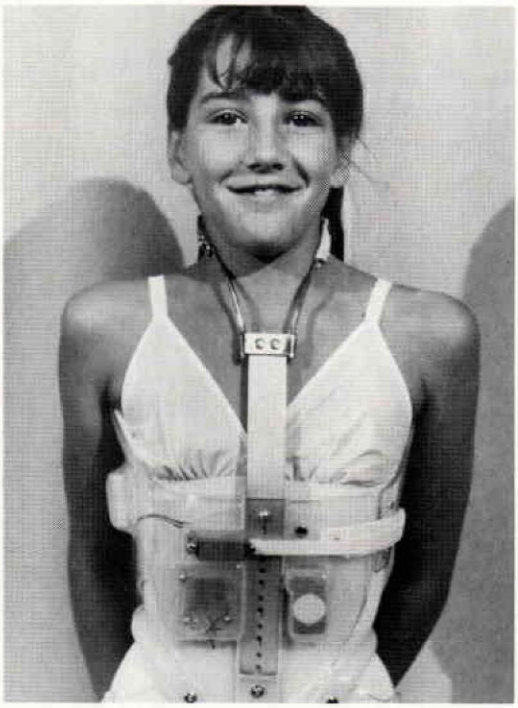

Fig. 14—Anterior close-up of the orthosis on the patient.

Through this mechanism, the paraspinal muscles on the convex side of the curve can be conditioned by performing an isotonic (or dynamic) exercise that occurs within the orthosis during the day hours. This conditioning and conscious effort by the patient to comply with the exercise program and regimentative wearing of the orthosis will, hopefully, have a beneficial effect upon the curve(s) by limiting further progression.

EXERCISE EVENT

Patients are instructed to wear their orthosis for 22 out of 24 hours. When donning their device, they secure the cervical component and then the velcro straps sufficiently enough to feel pressure within the orthosis. The two posteriorly-placed straps should have an equal amount of tension without incurring discomfort. A torso liner is worn beneath the orthosis.

The operation of the electronic system has two functions: the daily timed exercise event and the ten minute daily exercise.

The timed exercise event occurs approximately every 45 minutes. The patient is instructed as follows:

- When the stimulator's vibratory action is felt, you must keep your head and neck directly aligned over the pelvis, keeping your shoulders level (highly stressed when you are fitted with a TLSO not involving superstructure).
- Stand erect or, if sitting, make yourself taller.
- Move away from the sensation and hold that position for six seconds; this will discontinue the stimulator.

The ten-minute exercise is done in front of a mirror. The parents are involved in this segment of the exercise program to reinforce the child's efforts.

- Placing a magnet over an area on the electronic unit opens a switch and overrides the fixed time event, activating the stimulator.
- The patient would perform the same movement as instructed, relaxing for a few seconds and repeating for ten minutes.

Follow-up visits are made approximately every three months. All activities are encouarged in the orthosis with the exception of contact sports.

This report has described the protocol, casting, design and use of the Augmented Feedback Orthosis. This design has evolved over the last three years. In the past, more of our patients were fitted with TLSO's that with CTLSO's. Recently, we began using more CTLSO's (with superstructure), as the cervical component restricts occipital motion in relation to shifting exercise localizing the shift within the curve area exhibiting a more finite shifting pattern.

RESULTS

Eleven patients who were fitted with AFSO have been followed 12 months or longer. Of these 11, four major curves have decreased five degrees or more, four were unchanged, and three have progressed more than 5 degrees (8.5 and 10 degrees) (Table I).

Table II
FOLLOW-UP AFSO BEFORE 12 MONTHS

Patient #	Age Mos.	Risser Sign	Curve Location	Degrees	AFSO Use Mos.	Growth Cms.	Degrees at follow-up	Increase or decrease degrees	Result
12. BQ	130	0	T6-12 L1-4	24 22	3	0	19 13	− 5 − 9	
13. LW	150	0	L1-4	14	3	0	13	− 1	+
14. KT	180	1	T5-10 T11-L4	27 31	8	5.5	21 31	− 6	+
15. DK	153	2	T7-12 T11-L3	26 16	6	2.5	3 23	−23 − 7	+
16. KO	169	2	T5-11 T12-L4	27 27	6	7.0	24 22	− 3 − 5	+

—Increase or decrease in curve of less than 5 degrees not significant.
—Result grading: + = improvement, − = worse, 0 = unchanged.

Five patients have been followed less than 12 months. In all, the curvatures have decreased. One patient, age 14, was treated because of demonstrable progression of scoliosis during a period of observation (Table II). Four patients were eliminated from the study, four because they did not return after the orthosis was applied and one because indicated surgical treatment was delayed. When she was first seen, her curvature from the sixth thoracic to the first lumbar vertebrae was 52 degrees. She had severe congenital heart disease and her parents thought her to be a poor operative risk. Her curve increased to 57 degrees in six months. At this time, she was deemed a reasonable operative risk.

Of the 16 patients included in this report, only one eventually refused to wear the AFSO (Patient DK). Her reasons were interference with her social life, even though her major curve decreased 23 degrees in seven months.

Table III
AFSO HOURS OF WEAR PER DAY, RISSER SIGN, RESULT

Patient #	Hourse Wear Per Day	Risser Sign	Result
1. BF	23 22 12	0 1 3	+
2. LD	22 12	2 3	−
3. EJ	22 12	2 4	−
4. AS	16	3	0
5. AQ	18 8	0 4	−
6. AW	22	0	0
7. KK	22	1	0
8. SW	22	0	+
9. CL	22	0	+
10. MM	22 8 5	1 2 4	+
11. KB	12	2	−

DISCUSSION

Does duration of wear in 24 hours affect the outcome? Table III delineates the duration of daily use of the orthosis and the result to date. From this preliminary data, it appears that the duration of use to 20 hours per day or less adversely affects the correction.

We are sufficiently encouraged by the addition of augmented feedback to the principles of the Milwaukee brace in obtaining more than mere holding of a curve to possible correction that we have continued to offer it as a correcting device. It is likely that the best results will be obtained in idiopathic scoliosis when the major

Table 4
ASFO PATIENTS FOLLOWED AFTER
12 MONTHS (12-27 MONTHS)
RESULT RELATED TO GROWTH
(total cms. during treatment)

Patient #	Height Gained Cms.	Result
1. BF	17.5	+
2. LD	14.0	−
3. EJ	13.0	−
4. AS	12.5	0
5. AQ	4.0	−
6. AW	22.5	0
7. KK	14.5	0
8. SW	19.5	+
9. CL	16.0	+
10. MM	11.0	+
11. KB	6.0	−

—+ = curve decreased 5 degrees or more; − = increased 5 degrees or more; 0 = no change in curve.

—The above data on growth shows that most patients had rapid skeletal growth while in the orthosis. Patients 5 and 11 who had negative results had the least amount of gain in height recorded. The number of patients is too small to obtain statistically significant values; however, 50% of the patients who grew in height in a range of 11 to 19.5 cms. during the period followed had decreases of 5 degrees or greater in their spinal curves.

curve is 30 degrees or less. To date, no orthotic or electrical spinal stimulation has demonstrated significant decrease in scoliosis in the growing children on whom these methods were used.*

The etiology of idiopathic scoliosis remains an enigma and, furthermore, we do not know which cases will progress and which will not. Some current evidence suggests that scoliosis is a defect of the postural righting mechanisms under central nervous system control. If so, methods to bring improved postural control by feedback mechanisms seem logical if the spinal curve can be treated early enough. This poses a problem, however, because of the large number of minor curvatures 5-20 degrees that may not progress at all.

Application of orthotics to all such minor curves would result in massive over treatment and illusionary good results.* We hope that our research program on the postural mechanisms in scoliosis will define at an early age those children whose curves less than 20 degrees are likely to progress.

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