

## EVALUATION OF TWO EXPERIMENTAL SPINAL ORTHOSES<sup>1</sup>

Michael J. Quigley, C.P.O.<sup>2</sup>

The first metal spinal orthosis is said to have been designed by Lorenz Heister in the Eighteenth Century (1), and consisted of a flat metal piece extending from the pelvis to the occiput, with a crosspiece just below the shoulders.

The present design of the majority of spinal orthoses dates back to 1863, when Dr. C. F. Taylor (1) published an article in the *Transactions of the New York State Medical Society* entitled, "On the Mechanical Treatment of Pott's Disease of the Spine." Taylor's article described the function, use, and placement of paraspinal uprights, axillary straps, pelvic bands and abdominal aprons (Fig. 1). James Knight described a new design in 1884 claiming that it differed from Taylor's orthosis in that it "gives lateral support, and not extension" (1).

During the era of Taylor and Knight, work was being done by Goldthwait and his co-workers on body mechanics and its importance in postural deformities. Goldthwait designed his own spinal orthosis, but the three-point pressure system described by Taylor was still the basic principle behind its function. Goldthwait, however, stressed the fact that spinal orthoses should be used only as an aid or adjunct to the development of muscular strength and body balance by exercises (1).

The "Williams Lordosis Orthosis," a lumbosacral posterior and lateral control spinal orthosis, was the only significant development in metal orthotic designs since the late Nineteenth Century. According to Williams, the orthosis is designed "to exert a constant corrective force" on

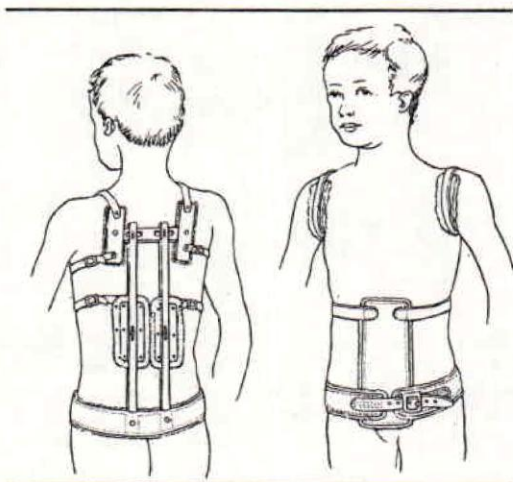


Fig. 1. Redrawn from the original illustrated description by Charles Fayette Taylor in 1863. This Taylor spinal brace was alluded to as "The Spinal Assistant."

the lumbar spine, lumbosacral joint, and pelvis in order to overcome excessive lordotic curves (1).

### "BODY JACKET" ORTHOSES

Paralleling the development of the metal spinal orthotic designs was the development of rigid body jackets. These supports typically extend from the mid-thoracic level to the sacral level and are designed as rigid or semirigid cylinders completely encircling the trunk.

One of the earliest examples of a body jacket was one made of tree bark, and discovered in the pre-Columbian Indians' cliff dwellings in Mesa Verde Park, Colorado (Fig. 2). It is estimated that it dates from about 900 A.D.

It is obvious that man has intuitively applied intra-abdominal pressure to relieve low back pain. Most present-day designs of body jackets can be traced back to the spinal orthotics renaissance in the late nineteenth century. During the 1940's Hauser (2) used a flexion body cast to produce flexion of the lumbar spine. The cast technique

<sup>1</sup> Prepared for the Subcommittee on Evaluation, Committee on Prosthetics Research and Development, National Academy of Sciences. The work was performed under the provisions of Contract SRS-72-7 between the Social and Rehabilitation Service and the National Academy of Sciences and Contract V101(134)P-75 between the Veterans Administration and the National Academy of Sciences.

<sup>2</sup> Staff Prosthetist-Orthotist, Committee on Prosthetics Research and Development.

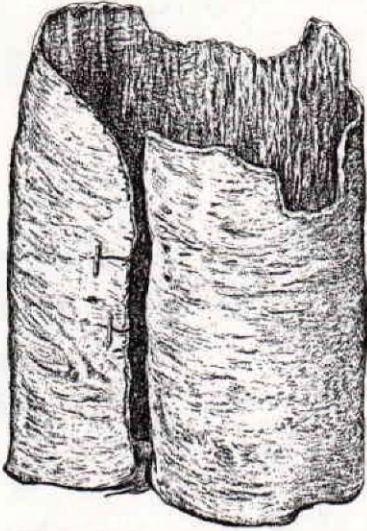


Fig. 2. Drawing of orthopaedic corset of tree bark, from the pre-Columbian Indians' cliff dwellings, circa 900 A.D., found in Mesa Verde Park, Colorado. (From the Colorado State Historical Museum, Denver) (*Orthopaedic Atlas*, Volume 1, 1952).

was modified by Raney who fabricated a thermo-plastic (Royalite) orthosis that included an indented front to provide intra-abdominal pressure. Raney stated that the factors "contributing to the back pain predominantly are the increased lordosis, the tight posterior structures (hamstrings), the poor anterior support, and nerve root compressions or irritation" (8). This orthosis has been termed the Royalite flexion jacket and is presently being widely used in the United States.

### SCOLIOSIS CONTROL ORTHOSES

The classic example of the evolution of present orthotic principles is the development of orthoses to control scoliosis, which is often accompanied by back pain. In 1841, an orthosis designed by Tavernier of Paris consisted of a pelvic band to which a thoracic sling was attached on one side and an axillary crutch-like extension on the other. In 1868, an "oblique and spiral bandage" that extended from the shoulder to the thoracic convexity and then across and down to the opposite thigh was used by Richard Barwell of London (1).

Dynamic scoliosis control was attempted in the Barr-Buschenfeldt orthotic design as reported in

the *Journal of Bone and Joint Surgery* in 1936 (1). This design incorporated an ingenious adjustable lever system that could apply the various pressures needed in the three-point pressure system. Dynamic correction was also attempted by Steindler in his design, which included elastic straps to provide corrective forces over the thoracic convexity and a thigh extension for additional stability when treating low thoracic and lumbar curves.

All of these former designs are rarely used at this time owing to the development by Drs. Blount and Schmidt of the "Milwaukee" design of scoliosis control orthoses (2). Although this orthosis originally was intended and considered to use dynamic forces to provide traction, it has been shown to act by stimulating the patient to do this by providing pressure points at selected areas. When the patient assumes poor postural alignment, he hits a pressure point which stimulates him to withdraw his body from the pressure thereby correcting his posture. This principle has proven effective and is widely accepted by authorities on scoliosis. This orthosis therefore provides a static stop against increasing deformity and a dynamic force using the musculature to correct the deformity.

### POPULATION OF PERSONS WITH IMPAIRMENT OF THE BACK AND SPINE

In 1966, the Social Security Administration conducted a survey among the civilian, noninstitutional population, 18-64 years of age, to determine the extent of work-limiting disability in this group (6). As part of the study each disabled person was asked to select from a list of 39 chronic disabling conditions the major one causing his limitation to work. Back or spine impairment (except paralysis) was the third leading chronic major disability in this group being responsible for 11.4 percent of all major disabilities. In the age group between 17 and 44 years, back and spine impairments ranked as the leading cause of chronic major disability.

In 1967, chronic disabling back and spine impairment affected an estimated 1,756,000 people 17 years of age and over (6). Forty-one percent (720,000) of this population were unemployed because of their impairment.

During 1971 there were in the United States an estimated 12.5 million impairments due to injury (7), the most frequently reported type being im-

pairment of the back or spine (except paralysis) with an estimated prevalence of 3.1 million cases.

#### THE PRESENT USE OF SPINAL ORTHOSES

Many types of spinal orthoses are presently used to treat low back pain. The factors influencing the type prescribed by the physician include geographical location, treatment philosophy, duration of pathology, type of pathology, availability, and effectiveness of the orthosis.

In a survey (8) of over 5,000 orthopedic surgeons, conducted by the Committee on Prosthetic-Orthotic Education (CPOE) of the National Research Council (NRC) in 1970, over 99 percent of responding orthopedic surgeons used external support for low back problems and over 90 percent of these indicated they used two or three different types of supports, the most common being the corset (Table 1).

Table 2 points out some interesting facts about orthotic usage in clinical situations. At the top of the "Frequency of Use" column, external support is usually used by 84 percent of physicians, by 51 percent of physicians in the middle of the column, and by only 17 percent at the bottom. The "Support Preference" column shows a similar situa-

tion. This reversal of the usage figures relates directly to the clinical situation (etiology).

It can generally be stated that external support is rarely used for low back problems of short duration (6-8 weeks) and usually used for problems of long duration (over 6-8 weeks). This is due to the variable effectiveness of spinal orthoses for short-term problems and the usual lack of prompt availability of the orthoses. Spinal orthoses have proven to be effective in many long-term cases where prompt availability is not such a deciding factor. However, one clinical situation, listed as "Chronic" in Table 2, did not follow this pattern.

#### CHRONIC LOW BACK PAIN

Chronic low back problems can be caused by a number of pathologies and either are of long duration or recur often. Problems in this category include herniated discs, arthritis, and spondylolistheses. It is apparent in the practices of orthopedics, physical therapy, and orthotics that there are many thousands of patients with chronic low back pain that obtain only minimal relief from pain by using medication, exercises, and spinal orthoses. Surgical stabilization of the spine is of-

TABLE 1. SUPPORT PREFERENCE [FROM (8)]

Support	By Individual Physicians (percent response)	For All Clinical Indications (percent)
Lumbosacral (LS) Corset	28.5	44.2
LS Orthosis/A-P Control (Knight)	21.11	22.4
LS Orthosis/P-L Control (Williams)	9.9	8.3
Body Cast	9.2	6.3
Flexion Cast	8.4	5.0
Body Cast and One Leg	6.0	2.6
Other Orthoses	11.6	8.3
Other Corsets	3.9	2.5
Other Casts	1.2	0.5
TOTAL	99.81	100.1

TABLE 2. EXTERNAL SUPPORT PREFERENCE BY CLINICAL ENTITY [FROM (8)]

Clinical Situation	Total Listing (Percent)	Frequency of Use		Support Preference		
		Rarely (Percent)	Usually (Percent)	Brace (Percent)	Corset (Percent)	Cast (Percent)
Postop. Fusion	100	16	84	51	20	29
Spondylolisthesis	100	30	70	59	33	28 [sic]
Pseudarthrosis	100	34	66	57	28	15
Preop. Trial	100	46	54	37	25	38
Disc Syndrome	100	49	51	34	51	15
Chronic	100	52	48	29	67	4 [sic]
Postop. Disc	100	72	28	31	65	4
Obesity and Pain	100	81	19	13	84	2 [sic]
Acute Strain	100	83	17	14	77	9

ten necessary, but it does not always guarantee freedom from pain.

Patients with chronic low back pain rely on corsets for external support the majority of the time, mainly because corsets seem to provide the same amount of pain relief as rigid orthoses, but are less restrictive, less expensive, and more readily available.

The need for an orthosis that will provide more pain relief than corsets and conventional rigid spinal orthoses, to the patient, is apparent.

#### DESCRIPTION AND USE OF THE EXPERIMENTAL ORTHOSES

##### THE LUMBOSACRAL A-P AND L CONTROL ORTHOSIS WITH INFLATABLE PADS (LSO/INFLATABLE PADS)

The LSO/Inflatable Pads, developed at the University of California Biomechanics Laboratory under the direction of James Morris, M.D., is a plastic trunk and spine support. The inflatable pads are used optionally to provide additional intra-abdominal pressure. The orthosis encompasses the trunk posteriorly from about the T9-10 vertebral level to the sacral and gluteal area and anteriorly from just inferior to the xiphoid process to the symphysis pubis (Fig. 3). One opening provided at the anterolateral aspect of the orthosis

is fastened by Velcro closures. The anterior aspect of the orthosis contains an oval inflatable pad (football or ptosis bladder) on the anterior aspect and a tubular inflatable pad (24-in. above-knee tourniquet) attached to the posterior inferior wall of the orthosis. An inflation valve protrudes through the plastic wall of the orthosis where the pads are placed. The bladders are attached to the plastic wall by Velcro, thereby allowing easy adjustment and removal.

##### Fabrication and Fitting

A plaster mold of the patient is taken in a standing position with the patient's knees flexed and the trunk inclined forward to decrease or eliminate lumbar lordosis. The mold extends from the mid-thoracic level to the gluteal fold. Before the plaster sets, an oval convex plate is pressed very firmly against the abdomen to form the indentation needed to increase intra-abdominal pressure in the area. Superior to the iliac crests, the cast is also indented to identify the iliac crests.

The negative mold is filled with plaster and the positive mold modified to relieve bony prominences and provide pressure over the abdomen. Plastic is then applied to the mold by either laminating or thermoplastic forming techniques. The plastic is trimmed and the closures and pads are attached when they are to be used.

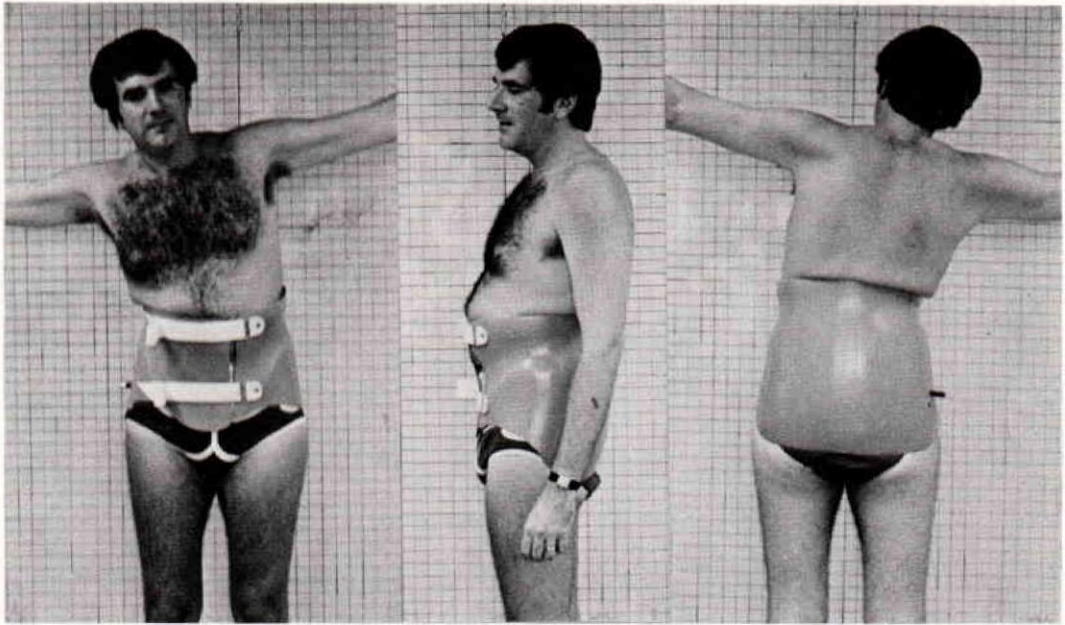


Fig. 3. The Lumbosacral Orthosis with Inflatable Pads.

To don the LSO/Inflatable Pads, the patient tightens the closures and then inflates the bladders (using an inflation bulb) to provide intra-abdominal pressure until he feels he has adequate support. The patient may not need the additional pressure supplied by the inflatable pads for relief of pain, so the pads are used as an option.

#### THE LUMBOSACRAL A-P AND L CONTROL ORTHOSIS INCORPORATING A STIMULUS TO WITHDRAWAL (LSO/STIMULUS TO WITHDRAWAL)

The LSO/Stimulus to Withdrawal, developed by Gustav Rubin, M.D., and Werner Greenbaum, C.P.O., Veterans Administration Prosthetics Center, consists of a molded thermoplastic pelvic section and a molded thermoplastic thoracic section that are separated by two threaded rods, one on the right lateral side and one on the left lateral side. Each rod is attached to the pelvic section by means of a ball joint riveted to a metal attachment plate. A nut on the threaded rod makes it possible to easily adjust the distance between the pelvic and thoracic sections (Fig. 4).

The pelvic and thoracic sections both consist of separate right and left halves that are attached

posteriorly, with an anterior opening that is fastened by adjustable Velcro straps. The thermoplastic sections are prefabricated and premolded to fit superior to the iliac crests and inferior to the inferior costal margin.

#### Fabrication and Fitting

The orthosis is fitted by placing the right and left pelvic sections firmly on the patient, or on a plaster mold of the patient, and trimming away the excess material. Modifications of flares and reliefs may be made in the thermoplastic by heating and recontouring. The two halves are riveted together posteriorly and a Velcro closure is placed anteriorly. The thoracic section is then fitted in approximately the same manner. The metal attachment plates and the tubing in which the threaded rods will be held are then aligned vertically and parallel to each other, and riveted to the right and left lateral aspects of the thoracic section. The threaded rods are aligned to match the tubing placement and riveted to the pelvic section. Final rod adjustments and trimming complete the fitting.

The patient can adjust the pressure against his costal margin by increasing or decreasing the

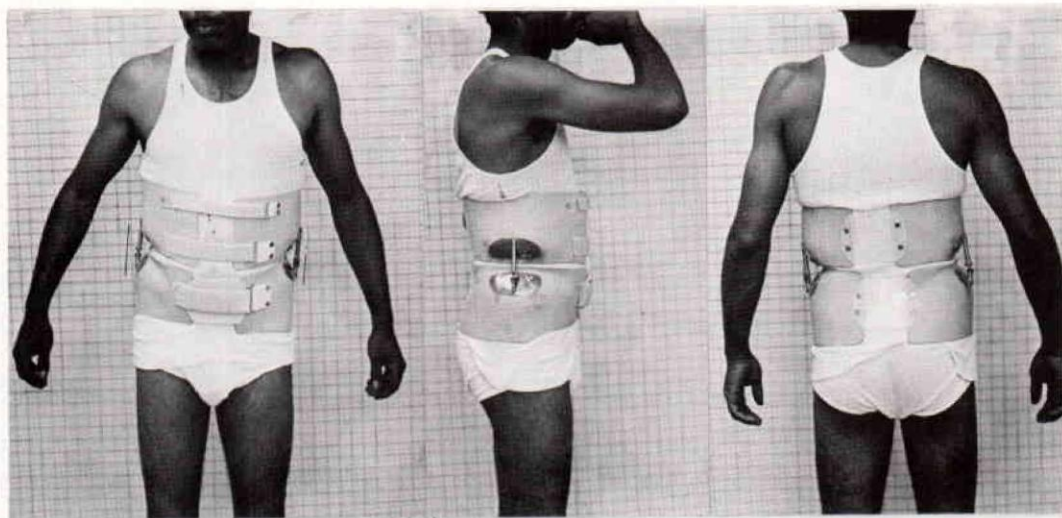


Fig. 4. The Lumbar Orthosis Incorporating a Stimulus to Withdrawal.

distance between the pelvic and thoracic sections. This is accomplished by raising or lowering the adjustment nut on the threaded rods. The amount of intra-abdominal pressure can be adjusted by varying the tension of the Velcro closures.

#### BIOMECHANICAL PRINCIPLES

The three-point pressure-system principle is inherent in both orthoses. Intra-abdominal pressure is also inherent in both orthoses, but to a greater degree in the LSO/Inflatable Pads. The "stimulus to withdrawal" principle is utilized in the VAPC design.

Because these biomechanical principles are the foundation of the orthoses that were evaluated, a review of these principles is presented in this section.

#### THE THREE-POINT PRESSURE SYSTEM

This well-known biomechanical force system has been the basic principle of orthotics for over a century.

In Figure 5, the patient is attempting right lateral flexion of the spine while wearing the LSO/Inflatable Pads. This motion is resisted by a counterforce of the orthosis at points A, B, and C. The force at point A causes the tissue bulge superior to the orthosis, and the force at point C causes the tissue bulge inferior to the orthosis. It is then

evident that these two forces are directed towards the patient because they resist the patient's lateral motion. Forces A and B must be equalled by a force in the opposite direction or the force system would not be in equilibrium. Force C provides this equal and opposite force. Thus when the patient attempts right lateral flexion he is also resisted by force C, which is located at and superior to the iliac crests.

Figure 6 demonstrates the same force system on a patient attempting right lateral flexion while wearing the LSO/Stimulus to Withdrawal. The system may be in effect to resist flexion and extension of the spine as long as there is a mechanical force resisting these motions.

#### INTRA-ABDOMINAL PRESSURE

The biomechanical principle of intra-abdominal pressure cannot be observed on the patient as in the previous case and, therefore, will be presented graphically. The explanation and diagrams of the biomechanics of intra-abdominal pressure presented here are based entirely upon the work of Morris, Lucas, and Bressler (5).

When a 170-lb. man lifts a 200-lb. barbell, forces acting upon the spine may be computed (Fig. 7) by multiplying the weights of the body parts, and the weight of the barbell times the perpendicular distance to the fulcrum. When the disc between the fifth lumbar vertebra and the

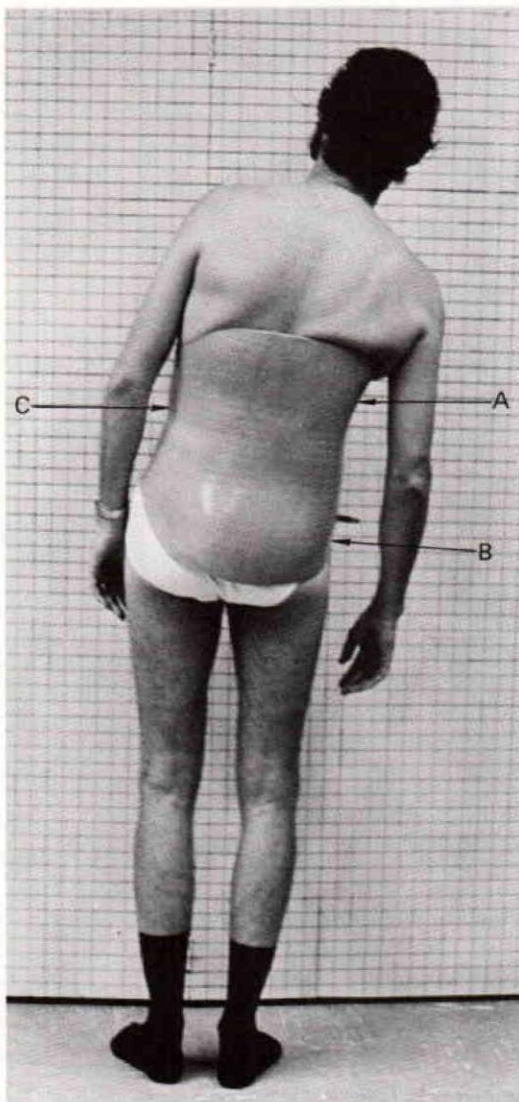


Fig. 5. The three pressure points preventing right lateral flexion of the spine on the LSO/Inflatable Pads.

first sacral vertebra (lumbosacral disc) is considered to be the fulcrum, the force on the lumbosacral disc will be 2,071 lb. However, experimental studies of the isolated ligamentous spine have demonstrated structural failure (fracturing) of the vertebrae under compressive loads ranging from 1,000 to 1,710 lb. and as little as 300 lb. in older people. The question arises as to how the lumbar vertebrae and discs are able to withstand the

amount of force that can be imposed in this example.

One possible explanation is to consider the spinal column as a segmented elastic column supported by the paraspinous muscles and attached to the thoracic and abdominal cavities. These cavities are filled, respectively, with air and a semi-fluid mass. The action of the trunk muscles converts these chambers into nearly rigid-walled cylinders which can resist a part of the force generated in loading the trunk and thereby relieve the load on the spine itself.

When large forces are applied to the spine—for example, lifting weights of 100 to 200 lb.—there is generalized contraction of the trunk muscles, including the intercostals, the muscles of the abdominal wall, and the diaphragm. The muscles about the shoulder girdle and those of the back are, of course, also active during lifting, just as the muscles of the thighs help maintain body balance and the erect position.

The action of the intercostals and of the muscles

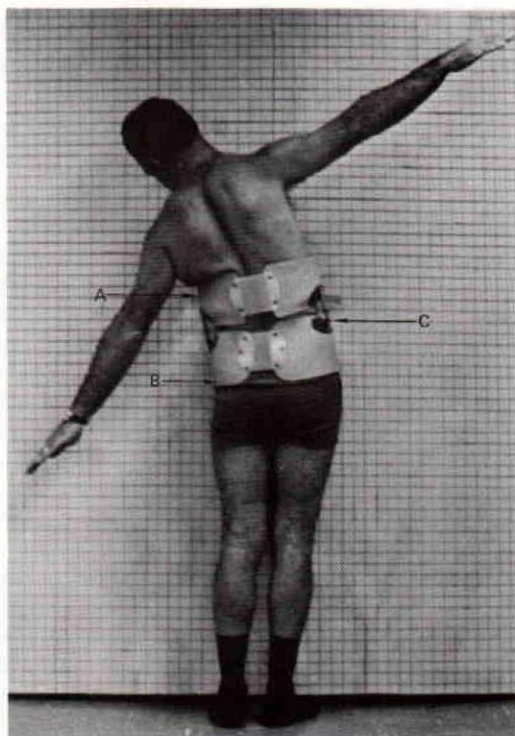


Fig. 6. The three pressure points preventing left lateral flexion of the spine on the LSO/Stimulus to Withdrawal.

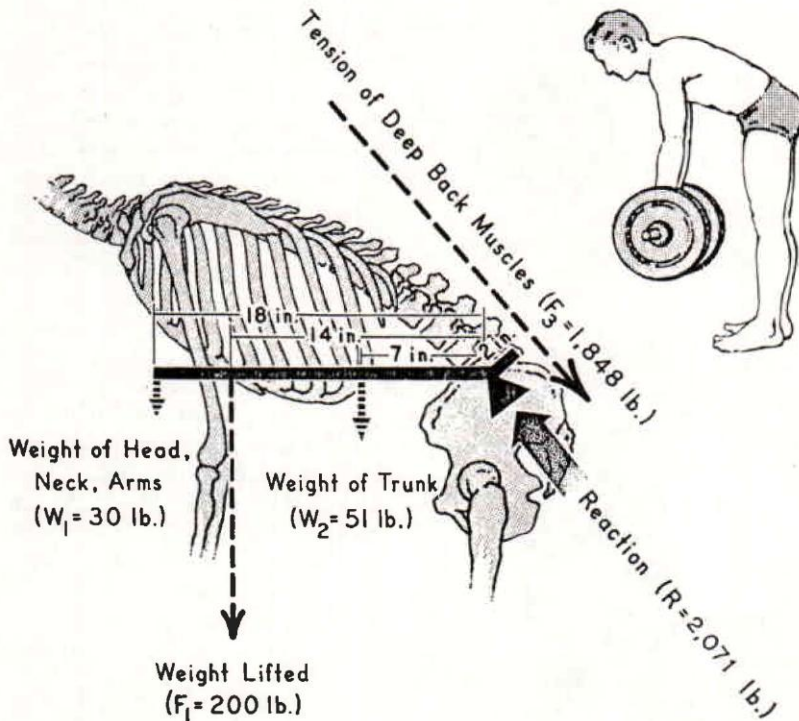


Fig. 7. Forces applied to the spine of a 170-lb. man lifting a 200-lb. weight, the tension of the deep back muscles, and the lever arms that transfer 2,071 lb. of force to the lumbosacral disc. (*Journal of Bone and Joint Surgery*)

of the shoulder girdle renders the thoracic cage a quite rigid structure firmly bound to the thoracic part of the spine. When inspiration and the action of the intercostal muscles which stabilize the rib cage increase intrathoracic pressure, the thoracic cage and spine become a solid, sturdy unit capable of transmitting large forces. By the contraction of the diaphragm, attached at the lower margin of the thorax and overlying the abdominal viscera, and of the muscles of the abdominal wall, especially the transversus abdominis, the abdominal contents are compressed into a semirigid cylinder.

The force of weights lifted by the arms is thus transmitted to the spinal column by the shoulder-girdle muscles, principally the trapezius, and then to the abdominal cylinder and to the pelvis, partly through the spinal column but also through the rigid rib cage.

When larger forces are involved, there is need for increased rigidity of the rib cage and com-

pression of the abdominal contents. This accounts for the increased activity of the trunk muscles and the increase in intra-abdominal pressure due to the contraction of the abdominal muscles and to the compression of the abdomen by the force which is transmitted through the trunk (Fig. 8).

This view is well substantiated by the fact that when an air-pressure corset is worn, although the resting abdominal pressure is considerably elevated (by approximately twenty millimeters of mercury), the pressures recorded during loading of the spine are similar to those recorded without the corset (Figs. 9 and 10). However, the activity of the abdominal muscles is markedly decreased when the inflatable corset is worn. It appears, therefore, that the contracted muscles of the abdominal wall or the rigid external-pressure apparatus act to contain the abdominal contents in a compressed state capable of transmitting force. When the compression or restraint is accomplished by an external apparatus, there is little



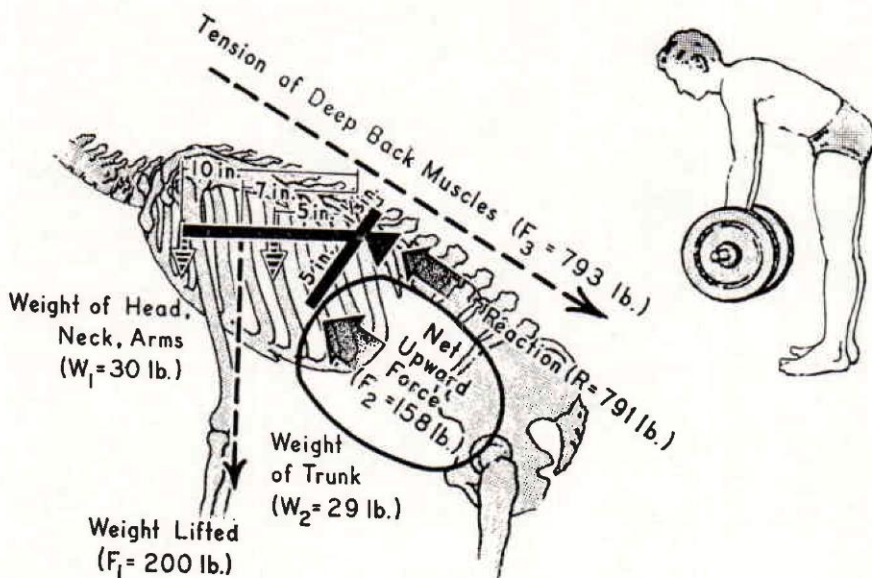


Fig. 8. Effect of intra-abdominal pressure. The force on the lower thoracic and upper lumbar vertebrae is reduced to 791 lb.

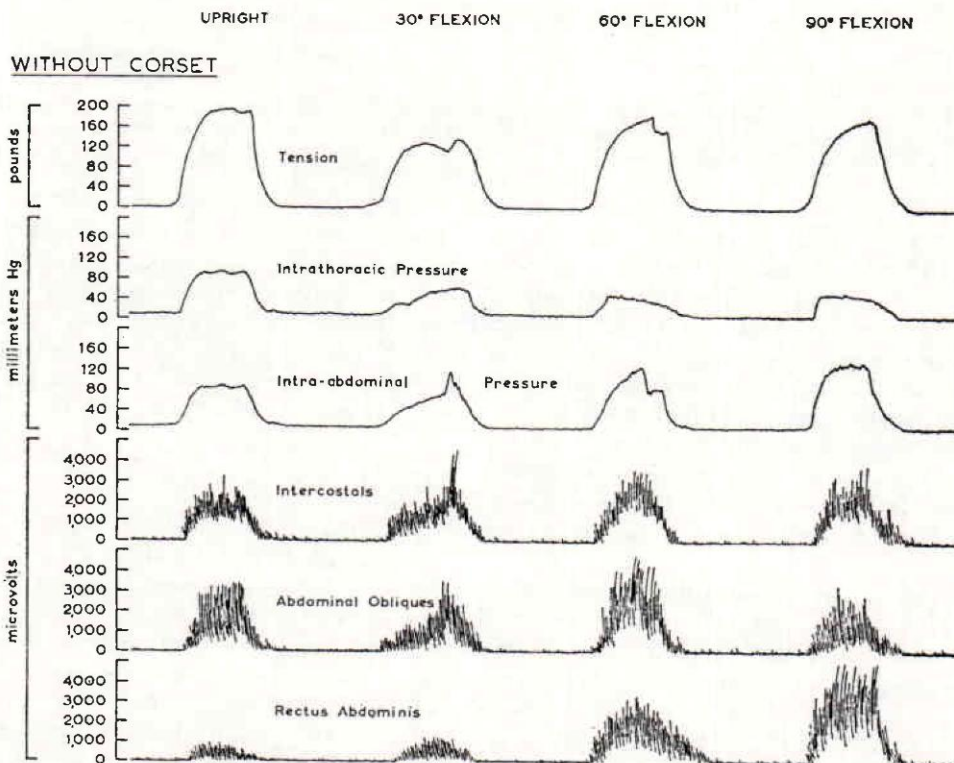


Fig. 9. Without corset, during static loading of the spine, intra-abdominal and intrathoracic pressure increase as abdominal muscle contraction increases. (*Journal of Bone and Joint Surgery*)

## WITH CORSET

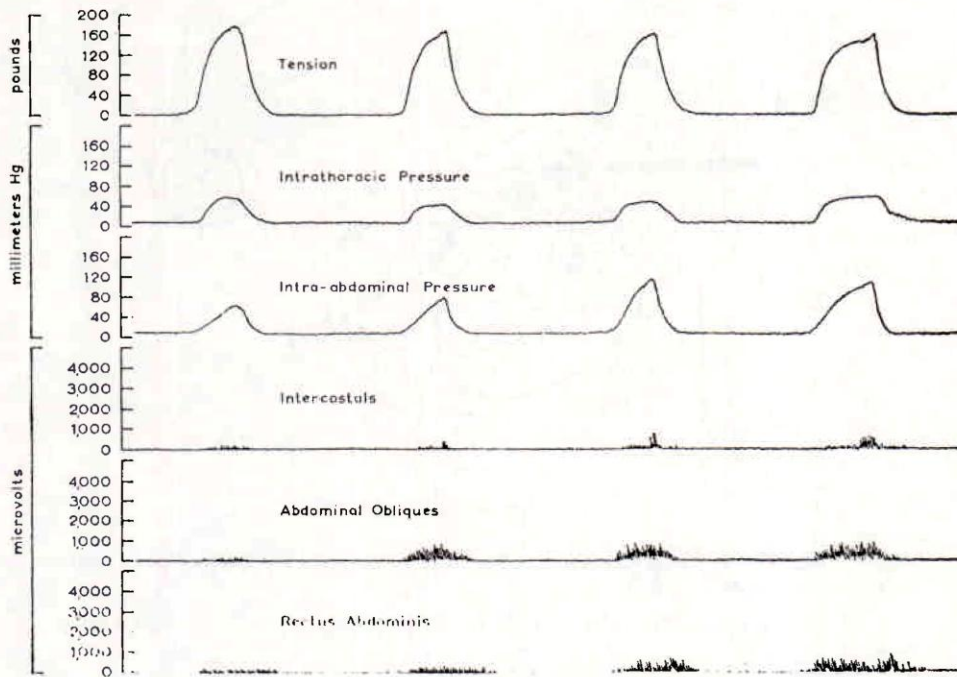


Fig. 10. While wearing a corset, during static loading of the spine, intrathoracic and intra-abdominal pressures increase, but less contraction of the abdominal muscles is necessary due to the supportive effect of the corset. (*Journal of Bone and Joint Surgery*)

need for contraction of the abdominal muscles. However, a small amount of activity is noted in the abdominal muscles even when the corset is worn, especially when greater forces or heavier loads are applied. The amount of compression of the viscera necessary to transmit these great forces can be tolerated briefly but not for prolonged periods. Since, in this study, the apparatus was inflated to the limit of comfort for extended periods, the abdomen was not compressed enough to obviate entirely the need for muscle activity with the larger forces.

It should be emphasized that the mechanism discussed here is a reflex mechanism. When a load is placed on the spine, the trunk muscles are involuntarily called into action to fix the rib cage and to restrain or compress the abdominal contents. The intracavity pressures are thereby increased, aiding in the support of the spine.

It may be concluded, from this calculation of the contribution of the trunk compartments to the support of the spine, that the actual force on the

spine is much less than that considered to be present when support by the trunk, or the effect of the intracavity pressures, is omitted. The calculated force on the lumbosacral disc is about 30 percent less, and that on the lower thoracic portion of the spine is about 50 percent less than would be present without support by the trunk.

#### STIMULUS TO WITHDRAWAL

The effect of the stimulus to withdrawal has also been called "inductive pressure" or the stimulus to "voluntary distraction." Jordan used the term "active correcting" to describe stimulus to withdrawal and defined it for spinal orthoses by stating, "the corrective forces of this appliance (CTLS "Milwaukee" orthosis) bring the trunk and the spine into such a position that the patient has to use his active muscle power for the correction of the deformity" (4).

The stimulus to withdrawal is caused by small pressures over prominent body areas. The pres-

sure is *not* continuous, and the patient can at any time withdraw himself from the pressure (10). An example of this is found in the throat mold on the anterior neck ring of the CTLS "Milwaukee" orthosis. When the patient slumps forward, his neck presses against the throat mold, and he withdraws his neck from this pressure by extending his spine.

The pressures causing the stimulus in the LSO/ Stimulus to Withdrawal are caused by the undercut contour of the pelvic and thoracic bands. When the patient slumps in the orthosis, the weight of the thorax rests on the inferior costal margin and the iliac crests. The pressure stimulates the patient to withdraw his weight by extending the spine and inspiring. This system, in effect, reminds the patient to maintain correct spinal alignment (Figs. 11 and 12).

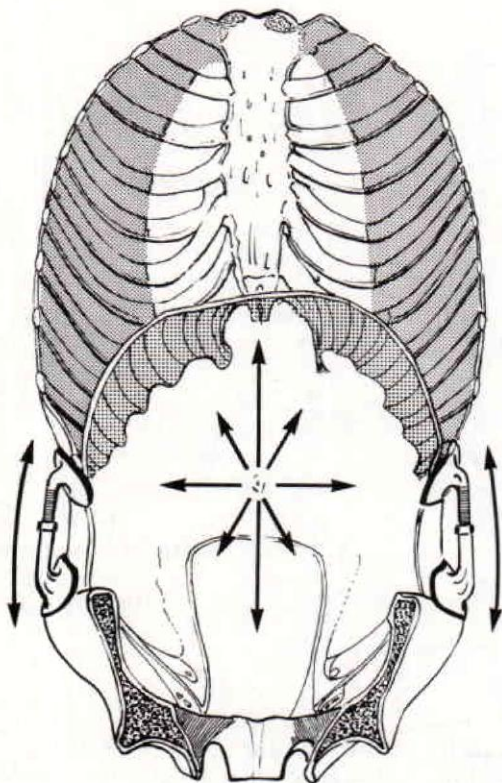


Fig. 11. View of trunk sectioned in frontal plane. The posterior section has been removed and viewer is looking toward the sternum. Note the curve of the diaphragm, the upper distribution of pressure, and the lateral supporting struts.

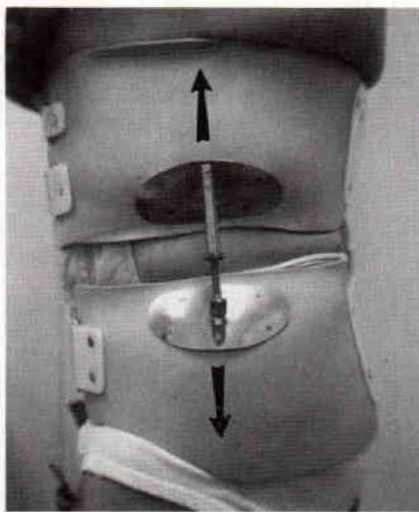


Fig. 12. Sagittal view of patient wearing the Lumbo-sacral Orthosis Incorporating a Stimulus to Withdrawal. Arrows depict the direction of forces applied by the pelvic and thoracic sections.

#### THE PURPOSE AND ORGANIZATION OF THE EVALUATION

The primary purpose of the clinical evaluation was to determine whether or not these orthoses could benefit patients with low back pain by providing relief from this pain. Also of importance was an attempt to determine if the orthoses utilized the principles stated by the developers, and to detect characteristics of design and materials. The results of the study are to be used by the Veterans Administration and by the Department of Health, Education, and Welfare to determine policy, by educational institutions as instructional material, and by medical and paramedical personnel as a guide for patient management. A schematic presentation of the major steps in the program is made in Figure 13.

The evaluation was initiated as a result of a request by the Veterans Administration.

At the fifteenth meeting of the Subcommittee on Evaluation the assignment was accepted, the members and staff were made familiar with the orthoses, and guidelines for the study were developed.

A steering committee was formed which met later in New York at which time the evaluation centers were chosen, the protocol was formed, and the timetable was set.



## EVALUATION CENTERS

The evaluation centers and members of the respective clinic teams were:

New York University  
George Hartman, C.P.O.  
Susan Bergholtz, R.P.T.  
Ralph Lusskin, M.D.

Columbus Orthopedic Appliance Company  
Herman B. Ording, C.O.  
Edward Weis, M.D.

Northwestern University  
James Russ, C.O.  
Robert Keagy, M.D.

Rancho Los Amigos Hospital  
Roy Snelson, C.P.O.  
Vert Mooney, M.D.

## PROTOCOL

The patient protocol was determined as follows:

1. *The patient must have a six-month history of low back pain.* This would eliminate the many patients who recover from back pains naturally within this period of time.

2. *There must have been history of previous use of conventional spinal orthoses.* Both orthoses are intended only for patients who cannot obtain relief using a less restrictive type of support.

3. *Appropriate trunk sensation and musculature must be present.* Both orthoses depend upon patient sensory feedback as both of them have pressure adjustment mechanisms. Muscle control is needed to withdraw from pressure areas when necessary. Sensation is also necessary if the patient is to provide valid opinions of the fit of the orthoses.

4. *There was to be no history of recent postoperative spinal fusion or other complicating problems.* This restriction was made in order to limit variables which might arise from postsurgical complications or additional pathologies.

5. *Patients were to be male adults.* The LSO/Stimulus to Withdrawal was developed by VA and had only been fitted on male patients. This rule was also applied to the LSO/Inflatable Pads to eliminate variables.

6. *There should be no underlying financial or emotional factors present which might unduly influence the patient's assessment of the orthoses.* Low back pain often originates from accidents in-

volving lawsuits, or is the primary reason a patient receives disability compensation, and therefore a financial factor enters the picture. Emotional problems, often family-related, often accompany recurrence of back pain, and may cause a further bias in the patient's opinions.

## NUMBER OF CLINICAL TRIALS

It was planned that each evaluation center would fit eight patients with each type of spinal orthosis, for a total of 16 fittings. In addition, each center would fit one of each type of orthosis as a practice fitting, not to be included in the results. A total of 64 patients, 32 with each type of orthosis, would be fitted by the end of the evaluation. A trial wear period of three months would be necessary to determine the success of each orthosis. It was estimated that all patients could be fitted during the first three months of the evaluation, and wear the orthoses the final three months.

## TIMETABLE

The evaluation timetable was set as follows:

June 1973	Orientation session
July	Site visits after practice session
August	
September	Completion of all fittings
October	
November	Conclusion of study and submission of
December	evaluation forms to the Committee on
January 1974	Prosthetics Research and Development

## ORIENTATION SESSION

Clinic teams from the four centers met at the VA Prosthetics Center in New York June 4-7, 1973. An explanation of the orthoses was given by the developers, Drs. Rubin and Morris, on the first day. The evaluation protocol was explained, as well as instructions on filling out the seven evaluation forms.

Two additional forms were included in the evaluation to record supplementary information. These were the "Technical Analysis Form for the Spine," and the "Subjective Pain Picture" form used at Rancho Los Amigos Hospital to record the location and type of pain a patient experiences.

The second and third days of the orientation

session were laboratory sessions for the orthotists. Measurements, casting, modifications, and fitting were demonstrated for the LSO/Inflatable Pads, and each orthotist fitted the LSO/Stimulus to Withdrawal.

## RELATED STUDY

A related study of the orthoses was to be undertaken as part of a larger study by Robert Tooms, M.D., and Ralph Snell, C.P.O. The purpose of the study was to determine roentgenographically the amount of spinal immobilization that spinal orthoses provide.

## EVALUATION

Each of the evaluation centers received the components needed for the casting and fabrication of the orthoses. They also received a folder of instructions and evaluation forms for each patient. All problems concerning the materials were reported to CPRD directly, and then the developers were notified. This system allowed CPRD to record any complications that would arise.

### Site Visits

Clinical trials began in late June and July and site visits to the four clinics were made in August. By August, three of the centers fitted one LSO/Stimulus to Withdrawal, each with no apparent problems. The fourth center, Rancho Los Amigos Hospital, had fitted ten of the same orthoses by this time, including two additional fittings on females.

At this point in the evaluation it was obvious that all centers preferred fitting the LSO/Stimulus to Withdrawal because of the ease of fabrication. The fittings began slowly due to vacation schedules.

Another site visit was made in October by a CPRD staff member and Werner Greenbaum. The status of the evaluation at this time was:

*New York University*—Not visited. One patient had been fitted. Local treatment philosophy and a lack of physician cooperation apparently restricted patient recruitment.

*Columbus Orthopedic Appliance Company*—Six patients wearing the LSO/Stimulus to With-

drawal were reviewed. Four of the six patients obtained more relief in the orthosis. One patient wearing the LSO/Inflatable Pads was reviewed, and he also stated he had additional relief.

*Northwestern University*—Two patients using the LSO/Stimulus to Withdrawal had favorable results.

*Rancho Los Amigos Hospital*—Of the ten patients fitted, three using the LSO/Stimulus to Withdrawal were seen. Two had good results. One patient fitted with the LSO/Inflatable Pads rejected it due to an unsatisfactory fit.

Of the 64 orthoses to be fitted in the evaluation, 23 were on patients at this time. However, 21 of these were the LSO/Stimulus to Withdrawal. At this point, the major thrust of the evaluation was placed on fitting the vast majority of future patients with the LSO/Inflatable Pads. It was also apparent at this time that physician cooperation was lacking at three of the four centers.

## DATA ANALYSIS

In December 1973, all centers were requested to complete the evaluation forms, take photographs of their patients, and forward this information to the Committee on Prosthetics Research and Development for tabulation by January.

The data were tabulated by the CPRD staff and by a member of the Subcommittee on Evaluation, Dr. G. E. Sharples. Dr. Sharples helped design the forms in a manner that made it easy for the clinics to record information, and simplified the task of tabulation and data comparison.

### Lumbosacral Orthosis Incorporating a Stimulus to Withdrawal

The following section presents the results obtained from evaluation forms.

#### *Clinical Trials*

Total patient fittings	21
*Patients meeting protocol	14
Average age (years)	49
Age range (years)	30-69

\*The most common breach of protocol concerned recent surgery and complicating conditions; four patients did not meet this standard. Two patients were female.

**Pathologies**

Herniated disc	5
Chronic low back pain	4
Facet arthropathy	3
Spondylolisthesis	2
Degenerative disc	2
Osteoporosis and scoliosis	1
Unstable fusion	1
Marfan's syndrome	1
	<hr/>
	19
Not given	2
	<hr/>
	21

**Pain Levels**

Prior to fitting of their previous orthoses (not evaluated orthoses), pain level ranged from moderate to severe for all 21 patients.

**Pain Relief from Previous Orthoses**

Some relief	13 patients
No change	5 patients
No response	3 patients

**Previous Orthotics Experience**

Previous orthoses were utilized by 18 of the patients. The orthoses in order of frequency were:

Lumbosacral corsets	9
Lumbosacral A-P control	5
Thoracolumbosacral A control (hyperextension)	1
Sacroiliac belt	1
Lumbosacral P-ML control (flexion)	1
Flexion body jacket	1
No previous orthosis	2
No response	1
	<hr/>
	21

The length of time the patients had used their previous orthoses ranged from two weeks to five years. *The average time was 16 months, the mean time was 12 months.*

**Experience with the LSO/Stimulus to Withdrawal**

Patients provided information after a 3-month trial-wear period by comparing the new orthosis to previous orthoses.

Increased relief of pain	7 patients
Decreased relief of pain	3 patients
No change	9 patients
No response	2 patients
Rejected	0

**Amount of Pain Relief with Medication**

The change in amount of medication used for pain relief was noted in order to further evaluate the effectiveness of the orthoses.

Increase in medication	1 patient
Decrease in medication	5 patients
Does not use medication	2 patients
No change	9 patients
No response	4 patients

**Activity Levels**

Increase in activity	5 patients
Decrease in activity	3 patients
No change	13 patients

**Physicians' Comments**

In 15 instances the physicians thought the orthoses performed as stated by the developer, but in five they did not think so. However, 19 of the 20 physician responses indicated that they planned to prescribe the LSO/Stimulus to Withdrawal for other patients when it became available.

An average physician response was that 30 percent of chronic low-back-pain patients might benefit from the orthosis.

**Orthotist Time Requirements**

Average evaluation and measurement time	1 hour 20 min.
Average fabrication time	1 hour 15 min.
Average fitting time	<hr/> 2 hours 20 min.
Average total time	4 hours 55 min.

**Lumbosacral Orthosis with Inflatable Pads****Clinical Trials**

Total patient fittings	13
*Patients meeting protocol	10
Average age (years)	44
Age range (years)	22-70

\*Three patients were female.

**Pathologies**

Herniated disc	3
Chronic low back pain	2
Arthritis	2
Laminectomy L <sub>34</sub> S <sub>1</sub>	1
Low back strain	1
Trauma	1
	<hr/>
	10
Not given	3
	<hr/>
	13

**Pain Levels**

Ten patients reported having severe pain prior to their previous orthotic fitting (not the evaluated orthosis); two reported moderate pain.

**Pain Relief from Previous Orthoses**

Much relief	3 patients
Some relief	7 patients
No change	2 patients
Worse	1 patient

**Previous Orthotics Experience**

Lumbosacral A-P control	7
Lumbosacral corsets	4
Lumbosacral P-ML control (flexion)	<u>1</u>
	12
Not given	<u>1</u>
	13

These orthoses were used from 3 months to 40 years. One patient wore a lumbosacral A-P control 40 years, one wore one 15 years, and one for 5 years. Another patient had worn a corset for 6 years. The average length of time that previous orthoses were worn was 6 years 5 months, although the mean time was only 2 years.

**Experience with the LSO/Inflatable Pads**

Patients provided information after a 3-month trial-wear period by comparing the new orthosis to their previous orthoses.

Increased relief of pain	6 patients
No change	3 patients
Orthosis rejected	4 patients

**Amount of Pain Relief with Medication**

Decrease in medication	1 patient
No change	8 patients
No response	4 patients

**Activity Levels**

Increase in activity	4 patients
Decrease in activity	2 patients
No change	3 patients
No response	4 patients

**Physicians' Comments**

Eight of the patients' physicians thought the orthosis was a suitable prescription, one did not. Seven patients' physicians thought the orthosis performed as indicated by the developer, four did not respond to the questions.

Four physicians thought the LSO/Inflatable Pads would benefit 10 percent of chronic low-

back-pain patients, one stated 20 percent, and seven did not respond. Seven patients' physicians stated they would prescribe the orthosis again; three were unsure.

**Orthotist Time Requirements**

Average evaluation and measurement time	1 hour 15 min.
Average fabrication time	6 hours
Average fitting time	<u>1 hour 20 min.</u>
Average total time	8 hours 35 min.

**FINAL MEETING**

A final meeting was held on March 6 to interpret the results and to make recommendations for further use. The orthotist from each clinic, the developers, members of the CPRD Subcommittee on Evaluation and staff, and representatives from the Veterans Administration and the Department of Health, Education, and Welfare attended.

Each clinic reviewed their results, and the developers reported their experiences with the orthoses.

**RECOMMENDATIONS****GENERAL**

Due to the increased activity levels of the patients, the 10 to 1 preference by patients to keep the orthoses, and the additional pain relief obtained by approximately 50 percent of the patients, it was recommended that both the LSO/Stimulus to Withdrawal and the LSO/Inflatable Pads be included among those utilized by the Veterans Administration physicians and all other physicians when patients meet the indications.

**THE LSO/STIMULUS TO WITHDRAWAL****Prescription Considerations**

The following prescription considerations were recommended:

1. Patients with low back pain should use conservative measures such as bed rest, analgesics, lumbosacral corsets and orthoses, etc., before utilizing this orthosis, which should be used mainly for chronic persistence of pain.

2. Contraindications include front herniated disc with sciatica and neurological deficit, throm-



bophlebitis, cardiac problems, emphysema, severe varicose veins, obesity, etc.

3. Patients should have adequate trunk sensation and musculature in order to effectively adjust the distraction rods.

#### Orthotic Recommendations

1. Different types of plastics, such as polyethylene and polypropylene, should be tried to replace the present material (Prenyl).

2. The prefabricated pelvic and thoracic sections should be more symmetrical and possibly flared over pressure areas.

3. The draft instruction manual should be updated to include the indications for the orthosis, the principles employed, and contemporary terminology.

The developers and manufacturer indicated that they would comply with the recommendations.

### THE LSO/INFLATABLE PADS

#### Prescription Considerations

The following prescription considerations were recommended:

1. Patients with low back pain should use conservative measures such as bed rest, analgesics, lumbosacral corsets and orthoses, etc., before utilizing this orthosis, which should be used mainly for chronic persistence of pain.

2. Contraindications include front herniated disc with sciatica and neurological deficit, thrombophlebitis, cardiac problems, emphysema, severe varicose veins, obesity, etc.

3. Patients should have adequate trunk sensation and musculature in order to adjust the inflatable pads effectively when they are used.

4. Prospective patients should wear a plaster flexion body cast (Hauser type) for three days, as the effectiveness of this cast for pain relief will generally indicate the effectiveness of the orthosis.

5. When using the orthosis for postsurgical stabilization, apply it after the sutures are removed (7-8 days postoperative) and request the patient to wear it all day for 6 months, preferably being removed only for bathing.

#### Orthotic Recommendations

1. The inflatable pads should be used *optionally*, and are not needed in many cases. The pads can be placed in the orthosis at a later date, although they will fit in the orthosis better if allowed for during fabrication.

2. Although a thermoset (polyester resin) was used throughout the evaluation for fabrication, it is recommended that a thermoplastic material be used to decrease fabrication time.

3. The draft instruction manual used throughout the evaluation needs rewriting, specifically to clarify and augment the design principles, casting and cast modification procedures, to state fitting procedures, and to explain the proper use of the orthosis.

4. The inflation system of the air bags and the valves need improvement.

The developer agreed with the recommendations and indicated that future work would follow along these lines.

### EVALUATION ASSESSMENT

The evaluation provided results that can be applied to redesign and use of the two orthoses. However, a number of problems occurred during the evaluation that might have been avoided. Each of the evaluation steps will be reviewed briefly in this section in order to assess where problems arose.

#### INITIATION

The LSO/Stimulus to Withdrawal had been used successfully by the developers on over 20 patients before it was evaluated. Prefabricated components had been made and the limitations of the orthosis were well defined.

The LSO/Inflatable Pads was still in the development stage when it was evaluated, and the measurement, casting, fabrication and fitting procedures had not been well defined.

Thus, at the initiation of the evaluation both orthoses were designed to relieve chronic low back pain, but were at different stages of development. This fact partially accounts for the greater patient acceptance the LSO/Stimulus to Withdrawal received in the evaluation.

## PLANNING

Three of the evaluation centers did not fit their quota of patients. One of the centers only reported two fittings prior to the final meeting. This problem could probably have been avoided had the centers been screened more thoroughly before their participation was requested. Two physicians in each area could have given estimates of the probability of recruiting 16 chronic low-back-pain patients within a three-month period who fitted the protocol. However, a patient-recruitment problem was not foreseen because of the large population of chronic low-back-pain patients. Had a screening taken place, possibly two of the four evaluation centers would have been changed.

The protocol was very practical. Despite the fact that 30 percent of the patients did not fit all six protocol requirements, the results were successful. A protocol should be used to define the type of patient, but should allow a small amount of flexibility during the evaluation if it is to be realistic.

The seven evaluation forms were designed as checklists, with each of the seven forms covering slightly different areas. Some areas overlapped in order to cross-check and compare information. The small amount of time required to complete these forms accounted for the large amount of feedback received from such a small number of patients. Long, complicated forms that require written answers often are left incomplete.

The "Technical Analysis Form for the Spine" was generally found to be confusing to use, and of little clinical use to the participants of the evaluation. It was recommended that this form be utilized as a teaching aid rather than a clinical tool.

The "Subjective Pain Picture" was found to be a useful method of recording the patterns and types of pain experienced by chronic low-back-pain patients.

The orientation session went well for the major part of the presentations, but the lack of a defined system of casting, measurement, fabrication and fitting of the LSO/Inflatable Pads resulted in a disorganized laboratory session with the orthotists. This lack of organization and understanding followed the LSO/Inflatable Pads throughout the

entire evaluation. The orthotists were also disenchanted with the great amount of time needed to fabricate this orthosis, and it was apparent in the evaluation results that they did not have the time.

## EVALUATION

The lack of available patients, mentioned earlier, was the only complication throughout the evaluation.

The related study of the limitation of motion provided by spinal orthoses (Tooms, Snell) did not produce well-defined results for these orthoses, and therefore the results have not been included in this report.

## COMMENTS

The amount of feedback from evaluation centers and the acceptance of the evaluation by the centers directly relate to the planning of the evaluation. Uncomplicated and brief evaluation forms, advance screening of the centers, and open lines of communication will undoubtedly result in a successful evaluation.

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