

"Initial Clinical Experience" - reflects prophylactic aspects of the Air Belt™ on a group of individuals who previously suffered back pain, and were therefore, considered as a high risk group in terms of re-injury and lost time.

PREVENTION IN HIGH RISK GROUP

TITLE: "Air Belt, Initial Clinical Experience." Prevention of Recurrence of Back Injury in High Risk Group

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SUMMARY: This study was conducted on a "high risk" group of 30 individuals. Sixteen out of 30 subjects (53%) were absent from their workplace 1 to 14 more days during the 3 months prior to Air Belt™ use. The implementation of the Air Belt™ back support was introduced for the next 3 months. During this time none of the individuals experienced lost time due to back pain and or injury.

AIR BELT

Initial Clinical Experience

By

Peter R. Sebastian, D.O.

An effective solution to management of low back problems - and returning victims to meaningful, productive lives.

INTRODUCTION

One million workers, 93 million lost work days, \$14 billion in cost.

These devastating figures represent the tremendous impact in just one year of low back pain on American workers in their most productive years.^{1,2,3} Despite our best efforts to contain this mounting problem, the toll rises higher each year. A long-awaited solution to this difficult problem may be finally available in a promising new air-filled lumbar support device - The Air Belt.

Developed by an individual with an engineering background, - himself a victim of low back pain, this pneumatic device is designed to support the lumbar spine and relax the painful muscular spasms commonly encountered by these patients.

This report examines the clinical experience with the Air Belt in the type of challenging individuals who have frustrated health care and safety professionals in the past.

The subjects studied experienced continued problems with low back pain for periods exceeding at least three months, and 28 of the 30 for greater than one year. Several reports^{4,5,6} document that individuals with symptoms of this duration are typically refractory to the most available therapeutic modalities. An impressive majority of such patients now wearing the Air Belt are working full-time, pain-free and without restrictions.

METHODS

The method of assessment utilized in this study provides important historical data of the workers' low back pain, and evaluates the effects of the Air Belt in the immediate pre- and post-treatment period by studying the relation of pain in producing functional impairment. Functional impairment questionnaires have been found to be a reliable and reproducible method of studying patients with low back pain.^{5,7}

While formal study of physical findings are useful in certain situations such as neurologic deficits (changes in motor strength, sensation, reflexes) in patients with nerve root compression, there are a few "objective" findings that can be reliably used for patients whose major source of pain is muscle strain and spasm.^{5,7,8} The same may be said of radiographic assessment to prognosticate risk of injury.⁹

Exquisite techniques of range of motion measurement have been employed; however, the end point of measurement is still governed by the subjective pain the individual subject experiences.^{1,10} Such measurements are taken in laboratory settings that do not truly replicate the worker's daily activity.

The functional impairment method, on the contrary, evaluates how the patients feel while actually trying to perform their routine tasks at home and on the job. The bottom line for success or failure of treatment really depends on a person's ability to resume normal lifestyle.

Thirty workers from a variety of occupations are included in the study group. Ages ranged from 19 to 64, and included 25 males and 5 females. Assessment was made utilizing a questionnaire in a personal interview conducted by the author and associates. Evaluation included the history, character of pain, subjective severity and prior methods of therapy.

A functional impairment scale, modified from that of Roland *et al*,⁷ was felt to represent a valuable and practical guide to improvement and therapeutic efficacy. Subjects were evaluated for the three months preceding and following treatment with the Air Belt.

CASE REPORTS

1 D.S., a 38-year-old hookup man, whose job involved attaching chains weighing up to 100 lbs. to cranes, incurred chronic recurrent low back strain which plagued him for two years. The intensity of pain gradually increased until he could no longer tolerate it.

In a two-year period, he missed 4^{1/2} months of work. His medical costs were significant (\$10,000) in addition to financial hardship from lost wages. A variety of treatments, including ultrasound, manipulation, TENS therapy, muscle relaxants and analgesics, exercise programs, bed rest and corset brace, provided partial or only temporary relief.

Functionally, he could not walk more than one block, ascend stairs, arise from a chair, or bend over without significant pain. He was unable to ride in a car for more than an hour, and always had difficulty getting a good night's sleep. When working, he almost always did so in pain, and at approximately half his usual efficiency with lifting limits imposed.

Eventually, the chronicity of his discomfort affected his personality. He became irritable, short-tempered and neglected his household duties. His wife, children and co-workers avoided him because of his behavior.

His interview was conducted eight months after acquiring the Air Belt, without a single further day lost from work. He has been essentially pain free without functional limitations on the job. He wears the Air Belt at home and for work, inflating it for 20-30 minutes at the first sign of discomfort. Co-workers have found him outgoing and friendly again. He even recently took up skiing.

2 P.R. is a 52-year-old nurse who initially injured her back in 1979 while pruning trees. She experienced considerable low back discomfort with occasional radiation of pain to the left lower extremity.

Neurosurgical evaluation disclosed a disc protrusion without herniation, and she improved over time with conservative therapy. Three years later, she began to experience recurrent strain injuries precipitated by lifting of patients, eventually developing continuous low back pain that persisted despite cessation of lifting duties.

During the two years prior to consultation with the author, she missed 25 days of work secondary to her low back pain, recently resulting in the loss of her job. She described herself as a "basket case", felt depressed with crying spells and avoided many routine activities such as social affairs and shopping.

When first evaluated by the author, she exhibited tenderness and spasms of the lumbar paraspinal muscles with significant limitation of flexion and side bending with essentially full rotation. Motor, reflex and sensory examination was normal, suggesting the absence of nerve root impingement.

Previous treatment with chiropractic manipulation, heat therapy, TENS, analgesics, muscle relaxants and stretching exercises were marginally helpful. Treatment was then initiated with the Air Belt. Improvement was noticed within 24 hours. With continued use of the Air Belt, she had considerably less pain and muscle spasm.

She is now able to ride comfortably in a car, and do her shopping without pain. Simple movements - such as climbing stairs, bending over and getting up from a chair - are performed with little or no discomfort. Emotionally she feels, "I have a handle on things now". She is starting a new job.

RESULTS

The jobs held by workers participating in the study are shown in **Table 1**. (See Appendix)

Twelve (40%) employees felt that their back pain was related to a specific injury [eight (27% lifting; four 13%) falls] while 60% could not blame a single precipitating event. Many of these felt their pain resulted from recurrent back stress and fatigue from repetitive bending and lifting or prolonged uncomfortable postures required by jobs.

The duration of back pain varied from four months to 30 years - with most of the subjects ranging between one and five years. The discomfort was continuous for most with fluctuations in severity. Back pain was primarily in the lumbosacral area in all subjects, while seven (23%) experienced additional pain in some area of the lower extremities. Only one of these had an actual disc herniation documented and underwent surgical treatment in the past, yet continued to have low back pain that interfered with activity.

The character of pain was variably described as sharp, aching tightness or fatigue. Subjective severity was graded on a scale of 0-10 (0 pain free; 10 excruciating) with 13.3% 0-3, 43.3% 4-7; and 43.3% 8-10 in the three months prior to the use of the Air Belt. The amount of time in pain during a typical day ranged from 0-6 hours in 30%; 6-12 hours in 26.6%; and "all day" in 43.3%.

Of the 30 subjects interviewed, medical diagnosis of medical strain was made in 13; disc bulge in 2; disc herniation in 1; and degenerative joint disease in 4, by the physician who initially evaluated them. Ten workers did not know their specific diagnoses, although most of them gave a history compatible with muscle strain. Prior attempts at treatment which were unsuccessful, or only partially helped are summarized in **Table 2**. (See Appendix)

Studies regarding the natural history of low back pain indicate that 80% of patients will improve within six weeks with or without treatment, while the remaining 20% are likely to have chronic pain difficulties. All of the patients in our study group would thus fall into this latter category where improvement is not expected.

The improvement in these workers, seemingly doomed to chronic low back pain, is borne out comparing functional impairment before and after use of the Air Belt. **Table 3** summarizes the results of the functional impairment questionnaire.

It is obvious that as a group, these workers made significant gains while wearing the Air Belt. No workers became worse. Almost all subjects were now able to perform their duties pain-free or with only mild discomfort, and no further time was lost from work because of back pain. Significant limitations were not imposed on any worker, and the three who mentioned minor limitations did not wish to discontinue use of the Air Belt.

DISCUSSION

The Air Belt is a uniquely designed lumbar support which can be comfortably worn without restricting mobility, while alleviating and preventing muscular low back discomfort, using two mechanisms. The inflated air pockets which line the inner posterior surface of the belt provide a static stretch to the longitudinally-oriented erector spinae muscles while supporting the osseous and ligamentous structures of the lumbar spine.

The vast majority of low back pain results from spasm and fatigue of the supporting lumbar musculature.^{3,11, 12 13, 14.} This may be seen as the primary pathology or as a secondary reflex phenomenon from derangement or injury to other pain-sensitive structures of the lumbar region.^{11.}

The static stretch of muscle has long been proven to be an effective means to both prevent injury and to alleviate myogenic pain with less danger of muscle or connective tissue injury.^{15,16,17,18 19, 20, 21.}

Muscles in spasm become painful as a result of ischemia to associated pain-sensitive structures with irritation of unmyelinated nerve fibers within the adventitial sheaths of intra-muscular blood vessels.^{11.} This is the result of increased concentrations of lactic acid and potassium ions in the interstitial fluid from abnormal metabolic activity of overactive muscle fibers.^{11.} If allowed to persist, shortening and contractures develop, further altering spinal mechanics and perpetuating the pain-spasm-pain cycle.

Faithful performance of stretching exercises is crucial to restoring normal muscle flexibility and strength. Unfortunately, compliance is usually poor on a long-term basis and cannot be readily done on the job when muscle fatigue and spasm develop. The Air Belt, on the other hand, is already in place while working, and can be conveniently inflated to stretch the muscles and provide relief in minutes.

This effect can be demonstrated electromyographically by recording muscle activity with surface electrodes. In normal individuals without muscle spasm, the lumbar erector spinae group is electrically silent or show only minimal activity when recorded in a relaxed standing position. **Fig. 1.** (See Appendix) As expected, inflation of the Air Belt produces no significant change in this situation.

A clear contrast is seen comparing the abundant muscle activity of patients with low back muscular spasm standing in the same "relaxed" position.

In **Fig. 2** (See Appendix), examples of two patients from our study group with muscular low back pain are shown demonstrating such activity. The effect of the Air Belt in relaxing muscular spasm is seen in the recordings obtained five minutes after inflation. The significant decrease in muscular activity correlated clinically with relief or reduction of the patients discomfort.

Much attention has been focused on lumbar spine loads in the various positions assumed during the course of task performance, particularly forward flexion or working in the erect position while manipulating objects held away from the body.^{10,22,23,24,25.} Flexion in the sagittal plane takes place initially in the lumbar region guided by the sagittal orientation of the articular facets. Further flexion is a combined movement in the lumbar spine and hips.^{1.}

Electrical silence occurs in the erector spinae muscles at approximately 80°.^{26.} Final trunk flexion limits are imposed by the articular facets and posteriorly placed ligaments.^{27.} When resuming the upright posture, muscle strain may develop as the erector muscles act to extend the spine to the upright posture. Support for these muscles and ligaments is thus important during movement of this type. Such support is provided by the Air Belt without limiting the motion needed to perform these routine and frequently repeated motions.

A comparison of the Air Belt to other currently-available modes of therapy already attempted by many employees in this study demonstrates significant differences. The functional impairments prior to use of the Air Belt existed despite the multiple treatment methods listed in **Table 2.** (See Appendix).

While other devices may be useful in the comprehensive management of low back pain, limitations and suboptimal effects often result.^{28.}

Analgesic and muscle relaxant medications are sometimes beneficial in the acute phase of injury, however, they are less effective in chronic conditions. Use is complicated by a number of side effects when given in adequate doses to alter pain. Sedation poses a significant hazard for many workers and must be avoided.

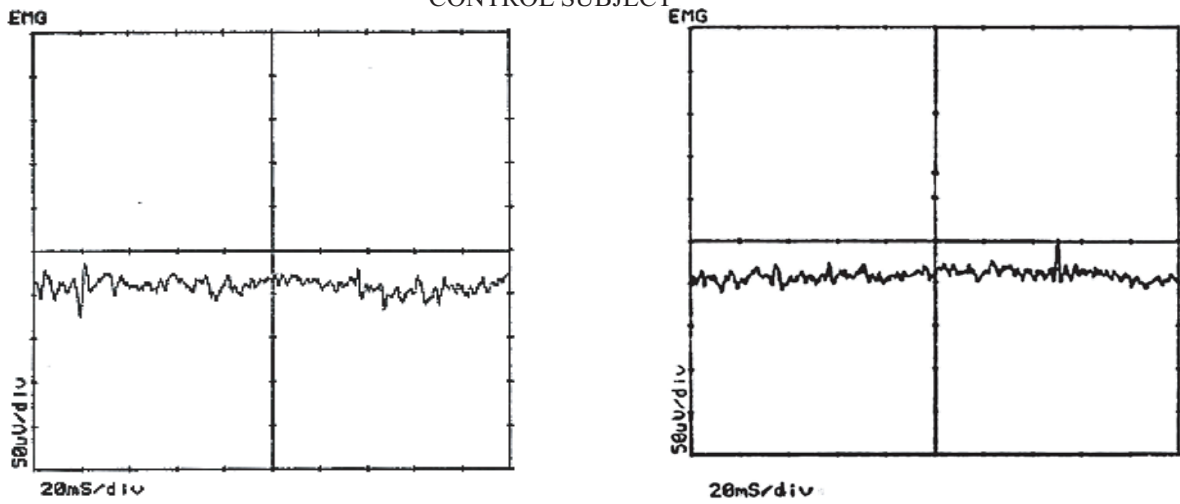
Conventional corsets are frequently too restrictive for most jobs that require mobility. Although tightly applied devices reduce compression loads on the lumbar spine by increasing intra-abdominal pressure.^{29.} they can not directly relieve muscular spasms.

While many unanswered questions remain regarding the genesis of low back pain, most surveys indicate that muscle spasm and strain are common denominators. The role of degenerative joint and disc disease remains unsettled in the mechanism of pain production. Disc herniation, with nerve root compression, is a more clearly defined low back syndrome which is often correctable by either conservative therapy or surgical decompression - but is relatively rare - representing only about nine (9) per cent of workers with low back pain.^{3.}

CONCLUSION

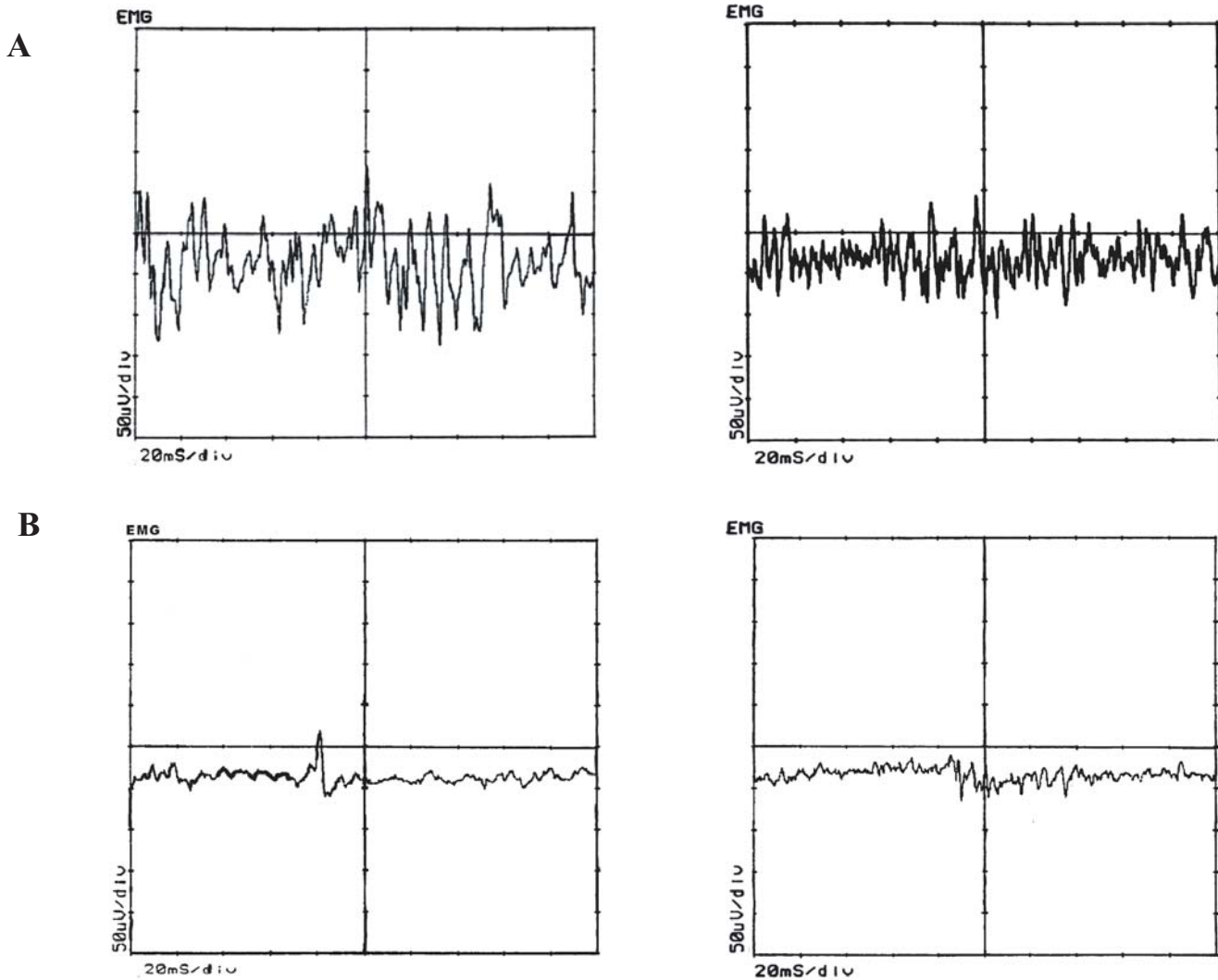
The devastating effect of low back pain on the American worker and industry has continued to grow each year. We may be seeing only the tip of the iceberg as many individuals continue to work in pain below their best efficiency. The 30 individuals studied who suffered from chronic back pain, have established the Air Belt as a promising new approach to this difficult problem. Further confirmation of these results continues to accumulate as progressive safety and health programs incorporate the Air Belt into their comprehensive management of low back pain.

APPENDIX
Figure 1
CONTROL SUBJECT



Subject in top recording, the erector spinae muscle group shows only minimal activity when recorded in relaxed standing position. Inflation of the Air Belt produces no significant change in this situation, as shown in lower recording.

Figure 2
CONTROL SUBJECT



Two subjects with low back pain and palpable spasm. A. Recording obtained in standing position, Air Belt deflated. B. Same subjects five minutes after Air Belt inflated demonstrates significant reduction in muscle activity.

APPENDIX

Table 1 Job Description			Table 2 Prior Therapy		
Welder - 5	Secretary/Clerk - 3	Fork Lift Operator - 2	Medication 24	Exercise Program 14	Corset 10
Truck driver - 4	Salesman - 3	Nurse - 1	Physical Therapy 17	Bed Rest 12	Surgery 1
Machine operator - 3	Hookup man - 2	Housewife - 1			
Supervisor - 3	Maintenance - 2				

Table 3 Functional Impairment Questionnaire					
"Because of my back pain"		Pre-Air Belt		Post-Air Belt	
		# pts.	%	# pts.	%
Walking distance	< 1 block	10	33%	0	0%
	3 blocks	8	27%	2	7%
	1/2 mile	5	17%	2	7%
	1 mile	2	7%	9	30%
	> 1 mile	5	17%	17	57%
Walking speed (% of normal)	25	6	20%	0	0%
	50	14	47%	0	0%
	75	4	13%	10	33%
	100	6	20%	20	67%
Walking upstairs	unable	0	0%	0	0%
	significant pain	12	40%	0	0%
	mild pain	12	40%	8	27%
	pain-free	6	20%	22	73%
Bending over	unable	4	13%	0	0%
	significant pain	21	70%	0	0%
	mild pain	4	13%	18	60%
	pain-free	1	3%	12	40%
Arise from chair	unable	0	0%	0	0%
	significant pain	18	60%	1	3%
	mild pain	7	23%	11	37%
	pain-free	5	17%	18	60%
Ride in car (time before pain)	unable	3	10%	0	0%
	1/2 hour	16	53%	0	0%
	1 hour	3	10%	5	17%
	> 1 hour	8	27%	25	83%
Sleep hindered	always	7	23%	0	0%
	frequently	8	27%	0	0%
	seldom	10	33%	12	40%
	never	5	17%	18	60%
Time at work with pain (%)	100%	10	33%	0	0%
	75%	8	27%	0	0%
	50%	10	33%	3	10%
	25%	2	7%	10	33%
	0%	0	0%	17	57%
Work efficiency (% of normal)	0-25%	6	20%	0	0%
	25-50%	12	40%	0	0%
	50-75%	8	27%	6	20%
	75-100%	4	13%	24	80%
Missed days of work	0	14	47%	30	100%
	1-6	5	17%	0	0%
	7-13	6	20%	0	0%
	14 or more	5	17%	0	0%

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