

CLINICAL EVALUATION OF THE CETRONE BELT

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INTRODUCTION

The Cetrone Contoured Support Belt developed by the Westchester Belt Company was submitted to the Prosthetic and Sensory Aids Service for evaluation and possible inclusion on the list of approved devices for issuance to veteran beneficiaries. As a first step, the belt was examined by the Bioengineering Research Service of the Veterans Administration Prosthetics Center (BPR 10-5, p. 146; BPR 10-6, pp. 266-269). They then fitted the device to a group of five patients. Based on the finding of their limited trials, the BRS stated that . . . "The Cetrone Belt seems to offer significant advantages over corsets and braces in the treatment of acute symptoms of low back syndrome, particularly where the pain is referred to the sacroiliac area. While the Cetrone Belt does not seem to offer any clear-cut therapeutic superiority, its potential advantages relate to increased comfort, reduction of inactivity and lost time, and economy." A clinical evaluation study was recommended. This was undertaken by the Research and Development Division, Prosthetic and Sensory Aids Service.

DESCRIPTION OF DEVICE

The originally submitted belt, the one tested by BRS, was constructed of 1¾-in.-wide top grain cowhide leather with a two-pronged metal buckle. Based on the recommendations of the Bioengineering Research Service the belt was redesigned and fabricated of a double layer of 1-in.-wide Dacron webbing. Two reinforcing pads, sandwiched between the layers, fit under the iliac crests and serve as anti-slipping pads to prevent the belt from riding up. Closure and adjustment were by means of Velcro fasteners. Three sizes of belts were considered adequate for the majority of individuals. Each size

belt was adjustable over a hip size range of 6 in. The redesigned belt was used in the clinical evaluation study.

EVALUATION PROCEDURE

Eight stations were invited to participate in the study and each was requested to select three patients who had a history of low back pain syndromes but were otherwise in good health. Their low back syndromes did not have to be in an acute stage at the time of selection, although this situation was preferred. The participating stations were:

- VAH, Atlanta, Ga.
- VAOPC, Boston, Mass.
- VAH, Houston, Texas
- VAH, Kansas City, Mo.
- VAOPC, Los Angeles, Calif.
- VAH, New Orleans, La.
- VAH, San Antonio, Texas
- VAH, Seattle, Wash.

Two of the stations (Kansas City and Los Angeles) were not able to select any candidates for the study, who, they felt, could benefit from the Cetrone Belt.

Three test instruments were prepared for the study and were to be completed and submitted as indicated below (see appendices):

Form CB-1 provided background information concerning the subject and was completed at the time of his selection.

Form CB-2 was the follow-up report and was completed after the subject had worn the belt long enough to determine whether or not it had been effective.

Form CB-3 was completed by the participating physicians at the conclusion of the study (i.e., when all CB-2 forms had been completed).

MEDICAL BACKGROUND DATA

Participating stations were able to select only eleven patients who for medical reasons might possibly have benefitted from wearing the Cetrone Belt. Table 1 presents basic data relating to age, height, weight, and condition and type of appliance worn by these 11 patients at time of selection. Seven of the patients were in an acute stage at the time of selection. All of them had had back problems for at least 5 years and during the prior 12 months had suffered from 3-6 attacks, except for one patient (#6) who indicated that he suffered from back pain almost continuously. Seven of the patients indicated that they wore a support routinely. Six of the seven indicated that their support was effective in relieving back pain; the seventh felt that the corset limited motion excessively. Five of the seven considered their routinely worn support comfortable. One said that it was comfortable

TABLE 1.—Background Data

Case No.	Age	Height (In.)	Weight (Lb.)	Condition	Orthopedic appliance used previously
1	43	68	190	L5 disc involvement	Lumbosacral corset
2	47	69	170	Chronic lumbosacral and left sacroiliac joint strain	Lumbosacral corset
3	50	68	186	Acute lumbosacral sprain with limitation of flexion	Lumbosacral corset
4	48	71	170	Low back pain (post fusion)	Walter Reed spinal brace
5	43	68	165	Low back and right hip pain (sacroiliac instability) Post op disc L4-L5	Lumbosacral support with steel stays
6	47	71	147	Ankylosis—sacroiliac joint	None
7	54	73	180	Chronic lumbosacral strain, possible HNP L4-L5 on right	None now, patient wore a lumbosacral corset but because of inguinal hernia discontinued wearing it
8	49	68	156	Low back strain	Lumbosacral corset
9	32	69	210	Chronic sacroiliac strain	None
10	68	62	117	Degenerative arthritis of cervical and lumbar spine	None
11	62	70½	192	Degenerative joint disease of entire spine	Has used a chair-type back brace and also lumbosacral belt, but not for past few years

except when sitting or driving an automobile. The seventh stated that the brace was too rigid and therefore uncomfortable.

RESULTS AND DISCUSSION

Each of the patients was provided with an appropriately sized Cetrone Belt. Patient #6 who had never worn any type of support in the past was also issued a more conventional sacroiliac support. One patient (#10) required a small size belt, two (#1 and #9) required large-size belts, while the remaining eight used the medium size belt. No set time was established for submission of a follow-up report. The patient was to wear the support until such time as he and the medical staff were able to judge if wearing the support had been of value or not. Patient reactions as to effectiveness, comfort, adjustability, comparison with other devices worn, and any other comments which were considered significant were collected during the follow-up interview. These data are presented in Table 2. Six of the eleven patients (#1, 2, 6, 7, 9, 11) reported that the support was ineffective, one patient (#10) indicated that he found it beneficial when lifting objects, while four patients (#3, 4, 5, 8) considered the belt generally effective.

Except for three of the patients (#1, 2, 10) who had some slight reservations, all rated the belt as comfortable. Adjustability was considered satisfactory by all of the wearers. Several of the patients indicated that they believed the belt would have been more effective and more comfortable if it were wider.

From this relatively small sample, no clear cut pattern of acceptance or indication can be drawn. Patients with the "same" diagnosis differed in their opinion of the device's effectiveness, some reporting favorably, others unfavorably. Those who found the device effective also found the device more comfortable than other devices. Patients who did not benefit from the belt usually indicated that their previously worn support was more comfortable. All of this obviously reflects the individuality of people and their medical problems.

SUMMARY

Two significant conclusions can be drawn from the study. It has been demonstrated that for a few patients the Cetrone Belt is at least as effective as the more conventional type of support. When medically effective its small size and low cost enhance its overall desirability. It probably, therefore, should be considered by physicians when prescribing supports.

On the other hand the total number of patients for whom this type of support is indicated is probably small. The eight VA stations selected to participate in this evaluation were able to prescribe the support in no more than eleven cases over a 6-month period. Several of the prescribing physi-

TABLE 2.—*Patients' Opinions of Cetrone Belt*

Case No.	Effectiveness	Comfort	Adjustability	Comparison with other devices worn	Other
1	Not effective	Fair—except developed rash in hot weather	Good	Not as effective	
2	Not effective, does not relieve pain—increased pain over sensitive area	Comfortable except for tender area in back	Excellent	Prefer lumbosacral corset which gives more support and is more comfortable	Could not tolerate for over one week at a time due to increase in pain over sensitive area of back
3	Relieves pain	Good	Very good, would like greater adjustment range for weight fluctuations	More comfortable	
4	Relieves leg pain	Good	Good	Much better	
5	Very effective	Very good	No problems	Prefer it to lumbosacral corset and spinal brace	
6	Not effective	Comfortable	Adequate	Does not give relief afforded by regular sacroiliac support issued at same time	

7	Not effective. Gives only minor support, does not relieve acute attack or prevent recurrence	Comfortable	Very easy to adjust	Prefer regular lumbosacral support which affords more relief and is more comfortable	
8	Good support for the back while working	Comfortable	Very satisfactory	More comfortable, can move about more freely	May not be as effective if he has a severe back strain
9	Not effective	Satisfactory	Satisfactory	Not as effective as a standard sacroiliac belt	
10	Hard to determine because of overall arthritic problem. Helps ease pain when lifting objects. Otherwise, about the same	Very comfortable (see column headed Other)	Very easy to adjust	No experience	Slips up and down if he doesn't get it tight enough. If tightened so doesn't slip, it gets uncomfortable. Patient wants to continue wearing it
11	Not effective	Comfortable	Good	More comfortable than other devices	Does not stay in place

cians commented that they saw very few cases during the course of a year requiring this type of support.

The following quotations are from the summaries completed by the participating medical staffs at the conclusion of the study.

"A pelvic belt of limited utility. I have seen very few indications for a belt of this type in my 17 years at the VA clinic. It is not intended (nor can it be used) for any sort of immobilization of the lumbosacral joint or any of the segments above it. The belt that was used was absolutely ineffective, although quite comfortable and adjustable. Its wear life was less than 6 months. It will probably not be often prescribed in this clinic."

"Of the three cases (#9, 10, 11), it seems highly questionable regarding the effectiveness with respect to therapeutic benefit. The simplicity and adjustability are appreciated by all, but very little relief has been obtained."

"From this limited study, the Cetrone Belt was not effective in relieving lumbosacral or sacroiliac pain or discomfort. In fact, it was reported to aggravate the symptoms, and it was uncomfortable to wear for over an hour or two."

"The adjustability of the belt is good, but in order for it to be effective, it must be drawn tight. This, in turn, binds the abdomen over a narrow area and is uncomfortable to the wearer."

"In my opinion, the belt is not indicated for these conditions since a lumbosacral corset gives more support and is much more comfortable to the patient."

Patient "experienced rather dramatic relief from his sciatica after fitting with a Cetrone Belt. . . . however, he also experienced improvement of his low back pain while performing prescribed exercises and reducing his job demands. (#1) . . . he (patient attributes this (relief) to his sacroiliac (Cetrone) belt."

"I think the feeling of well being is secondary to decreased lordosis resulting from use of the Cetrone Belt (#5)."

CONCLUSIONS AND RECOMMENDATIONS

Based on our rather limited evaluation of this device, due to the difficulty in finding patients for whom the device was felt to be indicated by prescribing physicians and the limited success where prescribed, we recommend that the device not be placed on contract. Although generally negative our findings were not conclusively so and we, therefore, propose the following:

Stations should be advised of the nature of the device and noncontract procurement be permitted with follow-up reports submitted to the Research and Development Division in order for us to gather further data. VA Prosthetics Center currently has on hand some 30 belts remaining from the study and these belts should be used for this purpose. These belts will probably be adequate for at least one year if our present experience is typical. It is not known at this time whether the developer will continue to produce these belts. In any event, we do not believe that there would be sufficient demand to justify stocking this item. Any savings in initial cost from quantity purchase of this low cost item would be offset by predicted long-term storage, handling, and shipping costs.

Lewis and Bernstock: Cetrone Belt Evaluation

APPENDIX A

VETERANS ADMINISTRATION
Department of Medicine and Surgery
Prosthetic and Sensory Aids Service

Clinical Evaluation Study: Cetrone Belt

Medical Background

Date_____

Patient_____ C#_____

Station _____

Age_____ Ht._____ Wt. _____ Occupation_____

Inpatient Outpatient Date of admission_____

Diagnosis:

Is patient now in an acute stage?_____

When was last acute attack?_____ Duration_____

How many attacks has patient had in the last year?_____

Last five years?_____

If back support is worn routinely, describe support:

Does patient find back support effective? Yes No Explain:

Does patient consider the back support comfortable? Yes No Explain:

If patient is in an acute stage at this time, describe treatment program:

Does patient receive Physical Therapy when *not* in an acute stage? Yes No

If yes, describe program:

What size Cetrone Belt is desired? (adjustment range 6"-8"):

Hip size to 34"_____

Hip size to 40"_____

Hip size to 48"_____

Signature

Title

APPENDIX B

VETERANS ADMINISTRATION
Department of Medicine and Surgery
Prosthetic and Sensory Aids Service

Clinical Evaluation Study: Cetrone Belt

Follow-Up Report

Patient _____ Date _____

Station _____

Inpatient Outpatient Date of admission _____

How long has patient been wearing a Cetrone Belt? _____

Hours per day _____ Days per week _____

What are the patient's reactions to the Cetrone Belt? (Consider relief from acute attacks and prevention of recurrences.)

- A. Effectiveness:
- B. Comfort:
- C. Adjustability:
- D. Comparison with other devices worn:
- E. Other:

Signature

Title

Lewis and Bernstock: Cetrone Belt Evaluation

APPENDIX C

VETERANS ADMINISTRATION
Department of Medicine and Surgery
Prosthetic and Sensory Aids Service

Clinical Evaluation Study: Cetrone Belt

Medical Staff Summary

What are your opinions regarding the prescription indications and contraindications for this device? Include comments on its effectiveness, comfort, adjustability, and durability. Any suggestions for improvement?

Signature—Title

Signature—Title

Signature—Title

Signature—Title