The Efficacy of Air Lumbar Brace* to Lumbago Patients

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(Air Lumbar Brace* is marketed in the United States under the brand name DDS by Disc Disease Solutions, Inc.)

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This clinical study was carried out by a medical research team led by professors Kim, Byung Jik and Park, Sin Woo at the Orthopedic Laboratory of Inje Medical College and Seoul Pail Hospital.

1. Introduction

This report evaluates the efficacy of the air brace by measuring 1. changes of pain levels 2. radiographic changes and 3. strength of the flexor and the extensor muscles at the lumbar vertebrae after having lumbago patients wear the air brace (air decompression brace).

2. The Subject and Methods of study

1) Subject of the study

22 patients with acute or chronic lumbago; Age range covers from 19 to 58. Average Age:44, 8 patients with slipped disks, 9 patients with acute lumbago and 4 patients with

Age	Male	Female	Total
20-29	2	1	3
30-39	1	3	4
40-49	2	4	6
50-59	3	5	8
60-69	1	0	1
Total	9	13	22

In order to evaluate the efficacy after wearing the air brace, Macnab's criteria was first used to examine changes in pain levels. Secondly, radiographic images were used to analyze the side views of the lumbar vertebrae. It compares pre and post application of the air brace. Finally, the Cybex 6000 Trunk Extension Flexion(TEF) machine was used to measure and analyze the strength of the flexor and the extensor muscles at the lumbar vertebrae.

3. Result of the study

1) Changes in pain levels

Macnab's criteria was used to evaluate the pain. 'Excellent' grade is a state without pain, without any restrictions on movements and that makes it possible to get back to normal activities. The 'Good' grade is a state with occurring pain, but possible to get back to normal activities. 'Fair' grade means slight progress and 'Poor' is no change. As a result, 85% of the patients that were tested showed Excellent or Good grades within 3 days. 3 showed 'Excellent' grades and 15 showed 'Good' grades among the total 22 patients.





11 mm

BRACE

Table 2. Pain relief before and after application of Air brace.

	Pre-Application	Post-Application
Excellent	-	3
Good	1	15
Fair	17	3
Poor	4	1

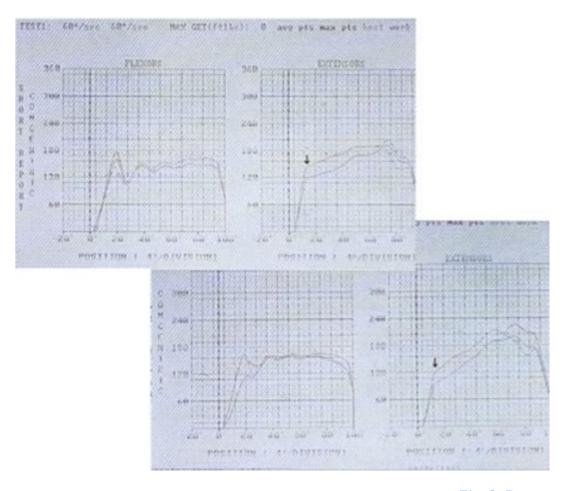
2) Changes in Radiographic images

12 patients participated in the x-ray evaluation comparing pre and post application of the air brace. Results show the anterior curvature of the lumbar vertebrae has increased at

3)Changes in muscular strength

3 out of 12 patients were randomly selected to test changes in muscular strength using the Cybex 6000 TEF machine. Results were measured by total joule at 60 angular velocity, maximum couple, maximum couple to weight and average power levels. The results demonstrated an increase in the extensor and flexor muscle strength shown in Fig 2-A and 2-B. The graphs illustrates that while wearing the air brace, the avg sustained torque of the flexor muscle is approx 180 torque compared to the 130 torque without wearing the air brace. While wearing the air brace, the lumbar extensor muscles reach maximum torque faster and sustains maximum torque 3 times longer.

Fig. 2-A



4. Condition Fig. 2-B

The air-injected lumbar brace widens the space between the forth and fifth lumbar vertebrae through distraction. Therefore, it can provide immobilization and stability to the spine to some degree and protect the lumbar vertebrae and the disc from damage. Although it does not reduce the load on the spinal muscles, it strengthens the extensor and flexor muscles. The research by Nachcmoson and Morris, after an isometric test of the myoelectric level of the erector spinal and the oblique abdominal muscles, claimed that the inflated brace can reduce the pressure on the spinal disc by 25%.

5. Efficacy and Effect

Based on these results obtained from the different studies, we believe that the air brace can play an auxiliary role in the treatment for chronic and acute lumbago.

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