

Impact of Prefabricated Versus Customized Lumbo-Sacral Orthoses on Pain and Functional Activities

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ABSTRACT

Background: The purpose of this study is to assess the impact of pre-fabricated and customized lumbo-sacral orthoses on patients with spinal problems in terms of activities of daily living as well as pain, and to ascertain the patient's preference of lumbo-sacral orthoses.

Method: Thirty subjects with spinal problems were studied. All subjects had previously been prescribed and were using lumbo-sacral orthoses to prevent the extent of pain. The impact of the brace on pain was assessed by using VAS (visual analog scale) and functional independence was assessed by using Katz ADL scale.

Result: Higher functional activity scores and higher pain scores were recorded with prefabricated lumbo-sacral orthoses when compared to customized lumbo-sacral orthoses.

Conclusion: Wearing a prefabricated as well as customized lumbo-sacral orthoses affected the independence level, but when compared, customized lumbo-sacral orthoses showed more restrictions on the functional activities of the patient and more relief in pain than prefabricated lumbo-sacral orthoses. Future studies with larger sample size should explore the relationship between pain and functioning with either brace.

Keywords: Lumbo-sacral orthoses, pain, functional activities

INTRODUCTION

Lumbo-sacral orthoses is a class I medical device used in the conservative and post-operative treatment of low back pain and to increase the likelihood of development of solid fusion by means of decreased lumbar force of motion. ⁽¹⁾ It is also used for pain management and motion or posture stability as abdominal support, lumbar support, and abdominal belt. ⁽²⁾ This form of orthoses is widely used to alleviate low back pain, but little scientific evidence of its clinical efficacy is available. ⁽³⁾ Nevertheless, the use of lumbo-sacral orthoses increases due to a high rate of satisfaction among patients with low back pain who were convinced that it would restrict movement, minimize disc pressure and improve posture. ^(4,5) Low back pain has

been correlated with anthropometric, postural, muscular and mobility features and etiological features caused by obesity, increased lumbar lordosis, low abdominal muscle power, inconsistency between flexor and extensor strength of the spine, reduced mobility of the spinal cord, tight hamstrings and disparity in the leg length. ⁽⁶⁾ The function of these devices in enhancing lumbar back pain symptoms, however, is yet uncertain. Specific hypotheses were suggested to explain the therapeutic effectiveness of orthoses and their respective mechanism of action. For example, these devices were found to limit the movement of the gross trunk. Inhibition of lumbar spine movements near the limits of the motion range is effective in pain relief. ⁽⁷⁾ On the other hand, some

researchers believe that an orthoses does not physically restrict the movement of the trunk. They believe that this device enhances the patient sense of lumbar position and avoids vigorous movements and thus helps to relieve back pain. (8) Many studies have examined different types of lumbo-sacral orthoses in terms of therapeutic (e.g. pain relief and disability and improved quality of life) (9-12) and mechanical efficacy (e.g. alteration of muscle activity, intra-abdominal pressure, muscle strength, and spinal load moment). (7,13) Nonetheless, few studies have evaluated the effectiveness of customized and prefabricated lumbo-sacral orthoses which are usually prescribed according to the facility available at the organization as well as the choice of the physician. Therefore this study focused on the effectiveness of customized versus prefabricated orthoses with respect to pain and functional independence.

MATERIALS AND METHODS

Study population: This preliminary study was conducted 30 patients with non-specific lumbar back pain. The participants consisted of 12 males and 18 females with the mean age of 47.47 ± 5.70 years, mean weight of 68.90 ± 13.19 kg, and mean height of 172.29 ± 10.14 cm. The subjects were collected from Indian Spinal Injuries Centre, Vasant Kunj, New Delhi, India.

The inclusion criteria were: 1) age of 30-50 years, 2) pain of a semi-continuous nature and various severities depending on the situation, and 3) a minimum score of 3 in VAS.

On the other hand, the exclusion criteria were: 1) non- musculoskeletal back pain, 2) neurological symptoms due to nerve root compression, 3) a history of vestibular disorders, diabetes, and an observable spinal deformity as confirmed by the Adam's Forward Bend Test, 4) lower limb length discrepancy, and 5) consumption of sedatives or substances affecting the central nervous system 24 prior to the test.

Lumbo-sacral orthoses

Two types of lumbo-sacral orthoses were used in the study. The orthoses were prescribed by the physician to the patients. Prefabricated lumbo-sacral were made of polyester and nylon, and had a posterior hard metallic panel. Customized lumbo-sacral orthoses were made of low temperature thermoplastic (LTTP) sheet that can be heat molded and shaped according to the anatomy of the patient's lumbar region to accurately match the patient's lordosis. The lumbo-sacral orthoses was fitted at an identical tension in all patients by an experienced licensed Orthotist following the manufacturer's instructions.

Equipment and Methodology

The parameters used in the study were VAS (visual analog scale) for pain and Katz index of independence in activities of daily living for functional independence. Two groups were formulated under prefabricated and customized lumbo-sacral orthoses and the subjects were grouped according to the orthoses prescribed. Each group consisted of 15 patients. The VAS and Katz score were recorded after 12 weeks of the prescription of orthoses from each patient of the group.

Visual analog scale is a measuring instrument which attempts to measure a characteristics or attitude which is believed to extend across a continuum of values and cannot be easily measured directly. For example, the amount of pain of pain a patient experiences varies from none to a severe amount of pain across a continuum. (14)

The Katz scale of Independence in Daily Living Activities, commonly referred to as the Katz ADL shown in table 1, is the most appropriate instrument for determining functional status as an indicator of the capacity of the person to carry out daily living activities independently. (15)

Statistical analysis

The mean score of the parameters for each group were used for statistical analysis. A paired sample t-test was used for the pair-wise comparison. Data analysis was performed in SPSS software, version 25. A

p-value less than 0.05 was considered statistically significant for all analyses.

RESULT

Analysis using the paired sample t-test showed that customized lumbo-sacral orthoses are better in reducing pain where as restricts the functional independence of the patient. The comparison in the value of pain reduction showed a significant difference, with prefabricated the value was 4.73 ± 0.96 and for customized it was 3.53 ± 0.18 (table 1). The comparison in the value of functional activities score showed a non-significant difference, with prefabricated the value obtained for functional independence were 0.53 ± 0.51 for customized and 0.66 ± 0.48 for prefabricated lumbo-sacral orthoses (table 2).

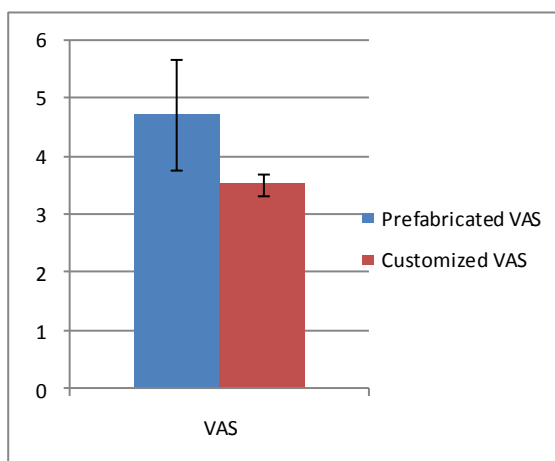


Table 1

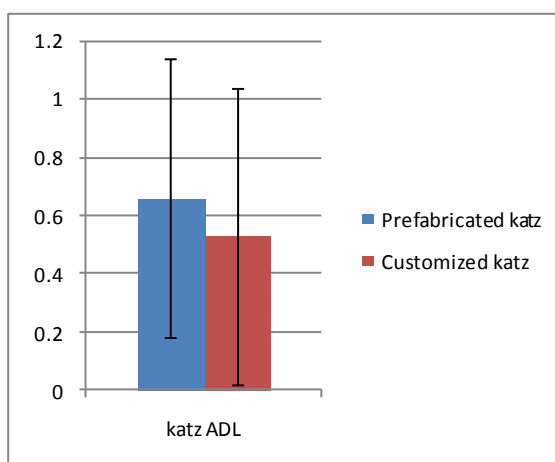


Table 2

DISCUSSION

This study was targeted towards investigating the effect of two types of lumbo-sacral orthoses on pain as well as functional independence. The conclusion extracted from the result shows that the customized lumbo-sacral orthoses are better in respect to relief of pain where as prefabricated orthoses were better in respect to functional independence. The prefabricated lumbo-sacral orthoses are made of stretchable material; hence the patient has an enlarged range of motion leading to functional independence. But the flexibility of the brace leads to less offloading of the lumbar spine and ultimately some amount of discomfort, leading to enhanced pain the activities. The more conformances and contouring of the customized lumbo-sacral orthoses to the lumbar spine shape of the patient prove to be more effective in the performance. This study might be helpful for the practitioner as well as the physician before the prescription of the choice of brace. A knowledge based counseling of the patient as well as the practitioner is necessary for effective result of the orthoses performance. Another advantage of the customized lumbo-sacral orthoses would be the options for re-molding according to the changes in the lumbo-sacral structure of the patient. The lumbo-sacral orthoses are commonly used for the treatment of back pain. Accordingly, the clinical and mechanical effects of these devices have been repeatedly investigated in different studies. (7,9,10,11,13) But there are no studies evaluating the effectiveness of the prefabricated and customized braces in context to clinical and mechanical effect as well. The reason for the less effective performance might be less conformance to the lumbar lordosis and hence less offloading of the area, and as the material consist of polyester and nylon, the rigidity is less, therefore more motion is expected in these type of orthoses. Whereas, since the customized lumbo-sacral orthoses is precisely matched to the shape of each individual differently, it performs better.

This study involved the Indian population and as the sample size was small, therefore the hypothesis extracted might change with different population group as well as ample size. Future studies with greater sample size and more types of orthoses would be better for more precise view on the choice of the orthoses.

CONCLUSION

The overall conclusion would be that the patients should be prescribed more of customized lumbo-sacral orthoses as they match the patient's anatomy more than prefabricated lumbo-sacral orthoses.

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