

Research Paper

Outcomes of Customized and Prefabricated Thoraco-Lumbo-Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

Praveen Kumar Shukla^{1*}, Shivani Sharma², Amit Kumar Vimal³

ABSTRACT

Spinal Cord Injury (SCI) leaves an impact on the patient's psychological and social well-being and overall quality of life. Various studies on the biomechanical comparison of different design of Thoraco-Lumbo-Sacral Orthosis (TLSO) in SCI patients have been done in the past, but no study has been done on the psychosocial impacts of the customized and prefabricated designs of TLSOs as a parameter of Quality of Life (QoL) in such patients. The psychosocial impacts of customized and prefabricated TLSO in spinal cord injuries patients helps to identify the reasons for acceptance or rejection of TLSO and thus gives an insight for a more rational TLSO prescription. This study is aimed at exploring if a custom-made TLSO provides better psychosocial impacts on SCI patients as a measure of QoL than a prefabricated TLSO. This cross-sectional observational study done on 30 SCI patients selected through a convenient sampling method using either a customized or prefabricated TLSO (15 in each group) and were given a self-reporting questionnaire to compare the measures of Quality of Life on the 3 sub-scales of PIADS (Psychosocial Impacts of Assistive Devices Scale)- Competence, Self-esteem and Adaptability. On comparing the data of customized and prefabricated TLSO users, we concluded as per our established hypothesis that the average PIAD score for customized TLSO on all the three subscales of competence, adaptability and self-esteem which are the measures for QoL is higher than the prefabricated TLSO irrespective to age and gender. As the customized TLSO provides better fit, comfort and compliance in comparison to the prefabricated design it was concluded that the psychosocial impacts as a measure of QoL in spinal cord injury patients is better in customized TLSO than the prefabricated one.

Keywords: *TLSO, spinal cord injury, PIAD scale, psychosocial, quality of life*

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The primary purpose of providing a Thoraco-Lumbo-Sacral Orthosis (TLSO) as an assistive device in spinal cord injury (SCI) post surgically is to maintain the surgical fixation and improve an individual's functions and independence, facilitate participation and enhance overall well-being and quality of life. It is very necessary to understand patient's psychology after the trauma to design and fabricate an orthosis (TLSO) which fulfils the patient's requirement without any social stigma associated while using the orthosis. The physical (biomechanical) aspects of orthoses have been studied a lot in past but the non-physical (psychosocial) aspects of orthoses needs have been largely ignored. By analysing these aspects one can optimize the prescription process of these assistive devices and hence identify the reasons behind acceptance or rejection of assistive devices. As a TLSO promotes quality of life of a user to the degree to which it makes the user feel competent, self-esteemed(confident), and adapted (motivated to exploit life's possibilities), this study will throw some light on the design aspects of a TLSO-customized and prefabricated to in SCI patients based on psychosocial dimensions when compared and analysed by using a valid and reliable scale like PIAD.

In this study the psychosocial impacts of customized and prefabricated TLSO have been measured and compared by using Psychosocial Impacts of Assistive Devices (PIAD) scale on the basis of patient's response through a self-reporting questionnaire which ultimately helps to identify the reasons for acceptance or rejection of TLSO and thus gives an insight for a more rational TLSO prescription and design based on patient's psychological adjustment and quality of life after using the TSLO on three subscales of competence, adaptability and self-esteem.

Psychological and social factors responsible for the successful orthotic compliance in the patients suffering from SCI are a major concern for the clinicians these days. Often patient's reaction towards an orthosis is neglected and is forced to wear it; this may sometimes result in abandonment of the orthosis and negligence of the post traumatic rehabilitation. Knowing the psychosocial impacts of orthosis on the quality of life (Competence, Self-esteem and Adaptability) of a SCI patient makes it easy for the orthotist to deal with the patient and motivate him to use orthosis without any possible discontinuation and social stigma associated with the use of the given orthosis. Socio-demographic factors (age, gender, ethnicity, socio-economic status, working status), condition specific factors (functional status, severity of condition, diagnosis, age of onset, duration of problem) and device specific factors (prescription rationale, waiting period, device training and instructions on its usages, affordability, funding, device usage frequency) are other factors that impact the assistive device's outcomes through their acceptance or rejection and are beyond the area of this study. Where acceptance of the orthosis enhances patient's life, its abandonment may lead to a dependent life of the individual. A TLSO can provide psychological(emotional) and social impacts on its users as well as some negative side effects in the form of anger, frustration, confusion and embarrassment. These negative side effects may cause TLSO abandonment and non-use. Possible reasons for abandonment include lack of consideration of device user's opinion, change in the device user's need or poor device performance.

Hence the ultimate purpose of this study is to study and compare between a customized and a prefabricated Thoraco-Lumbo-Sacral Orthosis on their psychosocial impacts in terms of Competence, Self-esteem and Adaptability which are the three subscales of Psychosocial Impacts of Assistive Devices Scale (PIADS) developed by Jutai J. in 2002. PIAD scale which is a 26-items, self-reporting questionnaire designed to assess the effects of an assistive

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

device on functional independence, well-being and quality of life. It is a missing link between the assessment of an assistive device and its acceptance or abandonment. When assistive device is successful in helping people to maintain or regain control, important results are increased self-efficacy and decreased negative emotional reactions to disability. These effects in turn are hypothesized to enhance subjective well-being. They are forms of psychosocial impact that are measured in the PIAD Scale. Utilizing PIAD scale helps in identifying the patients who are likely to comply with the TLSO as an aid that not only treats the body's structures or improves the user's abilities in activities, but also provides a psychosocial impact on the user's daily life, and to find meaningful goals for the user from a psychosocial perspective. The custom-made TLSO provides superior fit and support compare to the prefabricated design and induces better compliance among its users because of its simplicity. Role of an orthotist is not merely designing and developing assistive devices but prescribing the same as per the patient's functional requirements, environmental conditions and psychosocial status for a successful orthotic compliance. Patients sometime reject or abandon what seems to be well designed and functional device. The possible consequences of non-use of prescribed assistive device can be very serious. For these reasons an orthotist needs to better understand the psychosocial factors that might determine device's adoption, retention and abandonment (discontinuation).

Gallagher (2003) observed that majority of time spent in an orthotist's office deals with the mechanical issues related to assistive devices and hence is little opportunity to deal with the psychosocial issues that the patient might be experiencing. Through the application of PIAD scale it will lead to an increased patient's education, involvement of patient in their orthosis evaluation and decision making which will ultimately help the orthotist to determine patient's preferences and priorities.

Martins AC et al. (2016) noted that while acceptance of the orthosis improves the patient's quality of life, its abandonment could result in the person becoming reliant. A TLSO can have negative side effects like rage, annoyance, perplexity, and embarrassment as well as psychological (emotional) and social repercussions on its users. The adoption, abandonment, and non-use of TLSO may result from these adverse side effects. Lack of regard for the device user's perspective, a change in the device user's needs, or subpar gadget performance are a few potential grounds for abandonment.

In a 2006 study, Bernardoni GP and Gavin TM discovered that, despite being more affordable than custom-molded TLSO, over-the-shelf, or prefabricated TLSO, can and should be used under specific conditions to achieve carefully described treatment goals. Because of its simplicity, the custom-molded TLSO encourages higher compliance among its wearers and offers superior fit and support compared to prefabricated design.

In future the impacts of other factors like co-morbidities, pre-injury personality and use of other valid and reliable scale with a larger sample size of SCI population with distinct level and extent of injury may be studied and concluded for a deeper insight in TLSO design and its prescription.

Hypothesis:

- Customized TLSO provide better psychosocial impacts in terms of Competence, Self-esteem and Adaptability than a prefabricated TLSO in spinal cord injuries patients.

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

METHODOLOGY

Study Setting: Department of Prosthetics and Orthotics, Pt. Deendayal Upadhyaya National Institute for Person with Physical Disabilities (PDUNIPPD), New Delhi.

Study Design: Cross Sectional Observational Study.

Sample Size: 30 subjects (15 from each group-customized and prefabricated TLSO user) were selected as per the inclusion and exclusion criteria.

Table 1: Demographics of subjects in sample size of 30 patients.

Patient ID	Gender	Age in Years	TLSO	Level of Injury	Cause of Injury
SCI 01	Male	38	Customized	T11-T12	Traumatic
SCI 02	Male	34	Customized	L3-L4	Traumatic
SCI 03	Male	30	Customized	T12-L1	Traumatic
SCI 04	Male	41	Prefabricated	L1-L2	Traumatic
SCI 05	Female	15	Prefabricated	L4-L5	Traumatic
SCI 06	Male	19	Prefabricated	T11-T12	Traumatic
SCI 07	Male	20	Prefabricated	T12-L1	Traumatic
SCI 08	Female	50	Customized	L1-L2	Traumatic
SCI 09	Female	48	Prefabricated	L4-L5	Pathological
SCI 10	Female	35	Prefabricated	L1	Pathological
SCI 11	Female	32	Prefabricated	T10-T11	Traumatic
SCI 12	Male	28	Prefabricated	T8-T10	Traumatic
SCI 13	Female	36	Prefabricated	T12-L1	Traumatic
SCI 14	Male	32	Prefabricated	T11-T12	Traumatic
SCI 15	Male	42	Customized	T10-T12	Traumatic
SCI 16	Male	50	Customized	T12-L1	Pathological
SCI 17	Female	60	Customized	T10-T11	Pathological
SCI 18	Male	40	Customized	L1-L2	Traumatic
SCI 19	Female	39	Customized	L4-L5	Traumatic
SCI 20	Male	25	Customized	T10-T11	Traumatic
SCI 21	Male	28	Customized	T7-T8	Traumatic
SCI 22	Male	40	Customized	L4-L5	Pathological
SCI 23	Male	40	Customized	T8-T10	Pathological
SCI 24	Male	56	Customized	T10-T11	Pathological
SCI 25	Female	52	Prefabricated	L1-L4	Traumatic
SCI 26	Male	29	Customized	T12-L1	Traumatic
SCI 27	Male	32	Prefabricated	T9-T10	Traumatic
SCI 28	Male	34	Prefabricated	L4-L5	Traumatic
SCI 29	Male	45	Prefabricated	T12-L1	Traumatic
SCI 30	Male	56	Prefabricated	L4-L5	Pathological

Inclusion Criteria

- Age range: 20-55 (± 5 years)
- Both male and female
- Incomplete SCI patients (below T6) with ASIA score Grade-B

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

- Patients using a customized or prefabricated TLSO.
- Patients should be able to understand the questionnaires, and communicate their responses in the chosen language (Hindi or English)

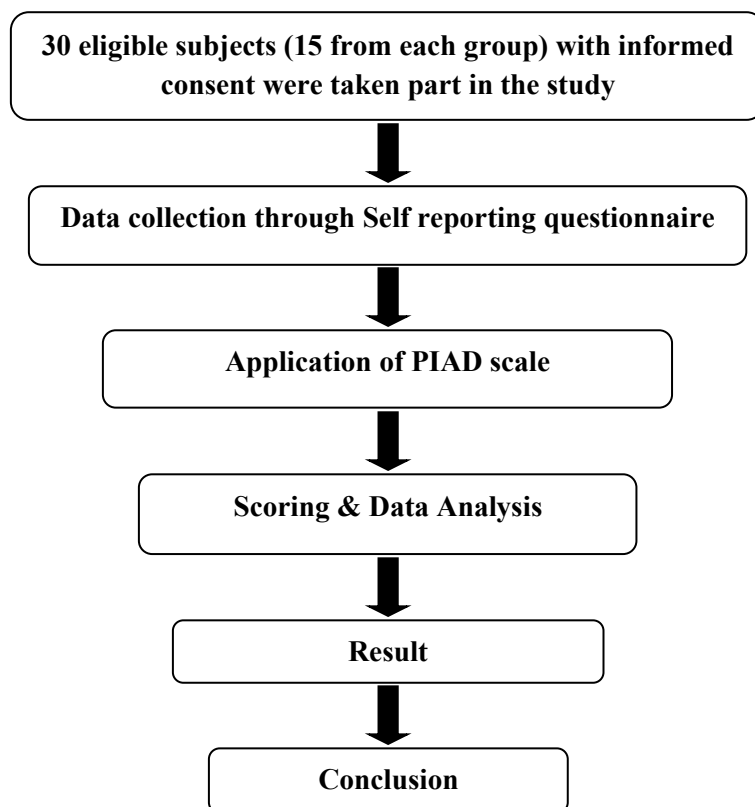
Exclusion Criteria

- Patient with poor or compromised cognitive or mental abilities.
- Visually impaired.
- Speech and hearing impaired.
- Patients contraindicated for TLSO.

Study Period: 9 months

- **Participants:** Patients (male or female) with incomplete below T6 level of SCI (ASIA score grade B) using either customized or prefabricated TLSO for a minimum period of three months.
- **Sampling method:** Convenient sampling method.
- **Dependent (outcomes) variables:** Competence, self-esteem, adaptability
- **Independent variables:** TLSO
- **Outcome measures:** To assess QoL quantitatively, the Psychosocial Impact of Assistive Devices Scale (PIADS) was used.

Procedure



Flow Chart for the procedure of the study

This cross-sectional observational study included 30 SCI patients (15 in each group) as per the inclusion and exclusion criteria using a customized or prefabricated TLSO after their informed consent. All the sample were administered through the PIAD scale via a self-report

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

questionnaire of 26 items on competence, self-esteem, and adaptability individually in the clinical setting of the PDUNIPPD, New Delhi through a convenient sampling method in the period of study. The necessary ethical approval was obtained from the IEC before starting the study. The total time to complete on questionnaire by one participant was around 20-25 minutes as patient just need to mark the relevant box against each item after understanding the meaning of the same. The respondents rate each item on a seven-point Likert scale ranging from -3 “maximum negative impact” to +3 “maximum positive impact” to indicate the extent to which they are affected by wearing or using their TLSO. The midpoint, 0, indicates “no impact” or no perceived change as a result of using the device. The impacts of each design of TLSO were observed distinctively on each patient through a self-reporting questionnaire to be filled out by the patient or caregiver with the inputs from the patient. The dependent variables, i.e., competence, self-esteem, and adaptability, were measured and compared according to their mean values by using an independent sample t-test, ($p < 0.05$) and represented graphically for users of customized and pre-fabricated TLSO. An independent sample t-test is used as a parametric test based on the normality of data tested through Shapiro–Wilk test. Quantitative data was entered and analyzed using SPSS version 25 for Windows.

RESULT

Table1: Comparison of PIAD score of Group A and Group B (p value < 0.001)

	TLSO (Gr. A & B)	N	Mean \pm SD	Min	Max	t value	p value
Competence	Customized	15	2.12 \pm 0.15	1.83	2.41	7.56	0.001*
	Prefabricated	15	1.21 \pm 0.43	.25	1.91		
Adaptability	Customized	15	2.47 \pm 0.31	2.16	2.83	10.18	0.001*
	Prefabricated	15	0.90 \pm 0.51	0	1.83		
Self esteem	Customized	15	1.31 \pm 0.21	.87	1.75	5.23	0.001*
	Prefabricated	15	0.71 \pm 0.39	0	1.37		

* Significant difference ($p < 0.05$)

Through the statistical analysis we can see in Table1 that: subjects with customized TLSO (**2.12 \pm 0.15**) are having significantly ($p < 0.005$) high competence as compare to the subjects with prefabricated TLSO (**1.21 \pm 0.43**). The average mean difference is shown in the Figure 1.

Subjects with customized TLSO (**2.47 \pm 0.31**) are having significantly ($p < 0.005$) high adaptability as compare to the subjects with prefabricated TLSO (**0.90 \pm 0.51**). The average mean difference is shown in the Figure 2.

Subjects with customized TLSO (**1.31 \pm 0.21**) are having significantly ($p < 0.005$) high self-esteem as compare to the subjects with prefabricated TLSO (**0.71 \pm 0.39**). The average mean difference is shown in the Figure 3.

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

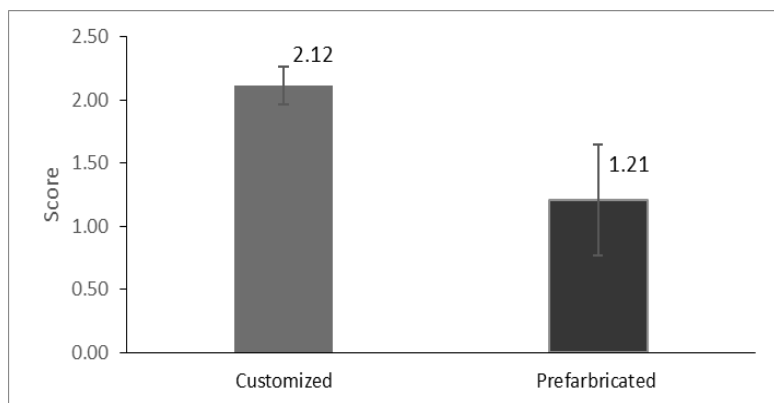


Figure 1: Average PIAD score for competence between two groups

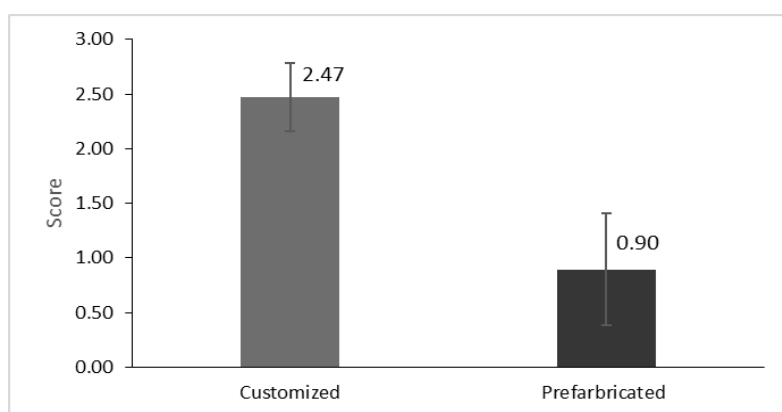


Figure 2: Average PIAD score for adaptability between two groups

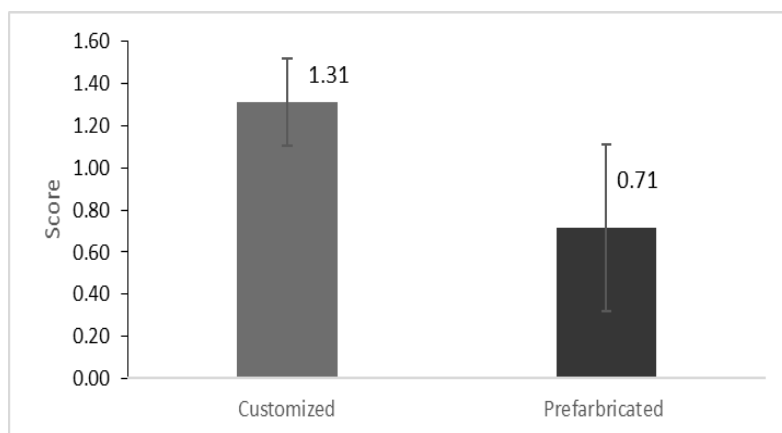


Figure 3: Average PIAD score for self-esteem between two groups

DISCUSSION

Psychosocial outcomes (competence, self-esteem, adaptability) in the context of assistive technology (TLSO) have been described as both factors within the person (psycho) and factors attributable to the environment (social) that affect the psychological adjustment to technology (TLSO) for the users. Though the stage of psychological adjustment of patient to spinal cord injury and patient's psychological response towards the orthosis are well considered.

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

This psychological conceptualization may hold the greatest promise for creating a patient-centred, environmentally conscious understanding of TLSO design which somehow affect its compliance and give better results. This study looked at how the PIAD scale can be used to advance the body of knowledge in this field and result in a rational TLSO prescription and design. The ability of the PIAD scale to predict acceptance or rejection of a specific design of TLSO in patients with SCI has prompted this study. The psychosocial impacts of customized and prefabricated TLSO helps to identify the reasons for acceptance or rejection of TLSO and thus gives an insight for a more rational TLSO prescription and design based on patient's psychological adjustment and quality of life after using the TSLO on three subscales of competence, adaptability and self-esteem.

The study demonstrates a correlation between the design of a TSLO and Quality of Life in patients with incomplete spinal cord injury leading to improved psychosocial outcomes during the process of rehabilitation which determine the factors responsible for TLSO acceptance or rejection and thus making the rehabilitation more meaningful. In customized design of TSLO adaptability subscale is highest and self-esteem subscale is the lowest whereas competence subscale is highest and self-esteem subscale is the lowest in prefabricated design of TSLO. The results indicate that patients have better adaptability which is a measure of desire to try out new things and take risks, ability to participate, and the ability to take advantage of opportunities which was quite evident in the user of customized TLSO. Whereas competence which demonstrate usefulness, performance, productivity, and independence with TLSO is higher in patients using a prefabricated TSLO. However, when we compare both the designs of TLSO, we conclude as per our established hypothesis that the average PIAD score for customized TLSO on all the three subscales of competence, adaptability and self-esteem which are the measures for Quality-of-Life is higher than the prefabricated TLSO irrespective to age and gender.

The custom-made TLSO provides superior fit and support relative to prefabricated design and induces better compliance among its users because of its simplicity in design and biomechanical features and thus high adaptability.

Competence scale which includes subscales such as usefulness, performance, productivity, and independence. This competence subscale measures the feelings of effective management of day-to-day tasks and ability to do well the important things one needs to do in life. An increase in this scale in Figure1 shows the increased efficiency of patient after using the customized TLSO and creates a sense of motivation to carry out daily living tasks more independently.

Adaptability has been seen the highest increase after the use of customized TLSO as shown in Figure 2. This scale specifies a desire to try out new things and take risks, ability to participate, and the ability to take advantage of opportunities which was quite evident in the user of customized TLSO.

Self-esteem includes impacts such as self-confidence, emotional well-being, security, sense of power and control which has relatively increased after the patients has started using the customized TLSO. This increment will help in greater acceptance of TLSO for their long-term rehabilitation process. However, the lowest increase in this subscale as shown in Figure 3 is due to various factors like age, gender, background of patients, preinjury personality, motivation level, follow up and training with the TLSO etc.

Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

Though a customized TLSO fabricated over the patient's body mould according to his/her body contours and size provide better biomechanical and psychosocial outcomes some patients find this design cumbersome. There are some associated challenges with a customized design of TLSO as accessibility, expertise, fabrication and deliver time, cost and maintenance. However, these perceived challenges may overcome with an improved accessibility and delivery system. Cost will always remain high compared the prefabricated design due to high level of expertise and supply system involved in the fabrication of this TLSO. On considering the apparent benefits of a customized TLSO over the prefabricated design other challenges associated with its delivery and cost may be overlooked but not at the cost of patient's compliance and immediate needs.

CONCLUSION

We conclude after this research study that the customized TLSO provide better psychosocial impacts based on competence, self-esteem and adaptability and thus a better Quality-of Life and lower rate of rejection as compared to the prefabricated TLSO in patients with SCI.

Study Limitations:

- This study has certain limitation like small sample size, subjective health condition (incomplete SCI below T6), not considering patient's preinjury behaviour and personality, existing use of lower limb orthoses and patients' sociodemographic factors.
- Reliable comparison could not be made with other studies due to lack of such similar studies in Indian context. It needed to be kept in mind that the psychosocial aspects constituted a wide range of factors and interacted in a very complex way, thus, was extremely difficult to measure or interpret in one exposure.

Future scope of the study:

- In future the impacts of other factors like co-morbidities, pre-injury personality and use of other valid and reliable scale with a larger sample size of SCI population with distinct level and extent of injury may be studied and concluded for a deeper insight in TLSO design and its prescription.

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Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

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Outcomes of Customized and Prefabricated Thoraco-Lumbo- Sacral Orthoses on the Psychosocial Impacts in Spinal Cord Injury: A Comparative Study

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Conflict of Interest

The author(s) declared no conflict of interest.

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