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- pressure ulcers, spinal cord injury,
- wheelchair, sitting posture, rehabilitation care,
- occupational therapy
- **Abbreviation:**
- ASIA american spinal injury association
- EPUAP european pressure ulcer advisory panel
- OT occupational therapy
- PTs patients
- PUs pressure ulcers
- SCI spinal cord injury

Info Authors :

¹ Master in Rehabilitation Science and Occupational Therapy
Unipolare ASST GOM Niguarda Spinal Unit, (Milan, Italy)

² Doctor in Orthopaedic Techniques
Ortopedia Pessina Annamaria, (Casatenovo, LC, Italy)

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NOVEL PLIANCE SYSTEM, interface pressure mapping system

Crivelli N. ¹, Cafueri G. ¹, Zucchiatti N. ²

THE OFF-LOADING POSTURE SYSTEM:

AN AID IN THE DEVELOPMENT OF TREATMENT FOR PRESSURE ULCERS IN PEOPLE WITH SCI? PROSPECTIVE OBSERVATIONAL STUDY

ABSTRACT

INTRODUCTION

The problem of pressure ulcers (PU) in the people with spinal cord injury is very common.

The specific preventive measures, first of all the trunk-pelvis posture system, have important relevance as regards the prevention and / or treatment of PUs, in people who use the wheelchair as the main device for their own mobility so these postural devices need specific study in terms of choice, identification and correct use in order to prevent more effectively one of the main causes of hospitalization.

For many wheelchair users, the risk of PUs can be reduced by choosing an optimal seat cushion.

OBJECTIVE

To measure the effectiveness of the off-loading posture system, as an aid for healing of stage I-II-III PUs in people with SCI.

DESIGN

Prospective observational study. This study is for exploratory purposes only.

SETTING

PTs were hospitalized at the spinal unit over 8 months in 2019.

PARTICIPANTS

15 people with SCI, from 14 to 72 years old without active movement under the lesion level.

INTERVENTION

Pressure sensor technology system was used to measure the pressures generated while sitting in the wheelchair.

Main outcome measures: the forces and pressures exerted by the patient in various situations were

MEASURED

Static sitting/dynamic sitting during the push phase both on the backrest and the wheelchair seat; EPUAP scale to evaluate the skin's state of health in the areas subject to PUs.

RESULTS

The posture system with the load-relieving cushion brought benefits for the treatment of ischial PUs: all of them healed by the end of the study and no recurrence occurred.

CONCLUSION

If we consider that a high lesion level leads to less postural stability and less trunk balance: the shape of the cushion combined with the support of a properly installed backrest had a positive effect both on posture and on the treatment of PUs.

The load-relieving cushion can promote the healing of stage I-II ischial PUs in less than 8 weeks, in people with SCI and at high risk of developing PUs.

Maybe the cushion is therefore a valid alternative to the traditional communicating air-cell cushion.

INTRODUCTION

Those using wheelchairs as their primary means of movement are at risk of developing pressure ulcers (PUs), which occur mainly in the ischial tuberosity, greater trochanteric and sacral regions. By definition, pressure ulcers are caused by external forces on tissue, often in the area of bony prominences.

Pressure ulcers are recognized as a significant secondary complication in wheelchair users and the prevalence of pressure ulcers in this type of user has been well documented ^{(1) (2)}.

It is clear that the problem of pressure ulcers in individuals with spinal cord injuries is very frequent, especially with regard to long-term hospitalization ^{(3) (4)} and furthermore, there is no single shared intervention method, which also involves occupational therapy, to address the problem both in terms of prevention and therapeutic treatment ⁽⁵⁾.

Specific prevention measures, primarily the trunk-pelvis posture system, are highly relevant with regard to the prevention and/or treatment of pressure ulcers ⁽⁵⁾ in people using a wheelchair as their main mobility aid.

Therefore, they deserve careful study in terms of choice, identification and correct use in order to better and more effectively prevent one of the main causes of hospitalization (and the related social-health cost).

Immobility due to spinal cord injury (SCI) impairs the vital functions and this occurs even more often when the patient's level of consciousness decreases ⁽⁶⁾.

Pressure ulcers (PU) are the result of excessive pressure applied by two hard surfaces (one of which is usually a protruding bone) on the tissue in-between them.

This situation can evolve towards major tissue loss, with complications such as septic infection, osteomyelitis, or enterocutaneous fistulas ⁽⁷⁾.

In the past, pressure ulcers were one of the causes of death in para-quadrilegics ⁽⁸⁾.

The pressure must be such as to close the capillaries or arterioles that moisten the tissue and the time must be sufficient to create thrombosis of the small arterial vessels followed by ischaemia and subsequent death of the tissue ⁽⁹⁾.

In the English-speaking world, various investigations studying skin lesions have been conducted in hospitals and regionally: the data relating to hospitals show approximate prevalence values between around 8% and 22%.

In particular, for certain population subgroups (quadriplegics, bedridden elderly people, patients admitted to ICU) the risk is higher and the prevalence can be very high (33-66%) ⁽¹⁰⁾.

PUs are one of the most frequent complications in patients with spinal cord injuries due to the total or partial loss of mobility and sensitivity, contributing significantly to increasing healthcare costs (for treatment and care; PUs complicated by osteomyelitis result in prolonged hospitalization with consequent delay in the implementation of rehabilitation programmes) and reduces these individuals' quality of life ⁽¹¹⁾.

To differentiate between the type and severity of ulcers, a European Pressure Ulcer Advisory Panel (EPUAP) classification system has been designed [EPUAP guidelines].

This classification divides the ulcers into 4 broad categories and can be used as an initial ulcer assessment scale, to identify its level of severity.

The scale identifies 4 levels of severity.

At present, we can confirm that the literature contains an abundance of programmes that describe in detail how to prevent PUs, but a total lack of data on the effectiveness of the proposed measures ⁽¹²⁾, and this study fits precisely within this framework.

Currently, the approach to initial recovery from bed confinement during hospitalization and the final supply of postural support involves the use and/or prescription of a 10 cm-deep interconnected air cell cushion, to be used on the seat of the wheelchair,

for all patients who have or have had a PU in the ischial, sacral and/or trochanteric area, since these cushioning technologies, based on a buoyancy principle, minimize the peak pressures under the bony prominences of the pelvis, in particular the ischial tuberosities, thus distributing the pressure as evenly as possible over as large a contact area as possible ⁽¹³⁾.

This approach is based on experience, but to date there are doubts about the appropriateness of always using this device for all patients due to the difficulty of managing the correct inflation of the cushion ⁽¹⁴⁾, and because of the limitations it presents for those who need more substantial postural stability.

Furthermore, although the interconnected air-cell cushions are useful for reducing the pressure under these bony prominences ⁽¹⁵⁾, the pressure observed in these areas can still remain unacceptably high ^{(16) (17)}.

Therefore, it may be useful and necessary to completely relieve these high-risk areas with a contoured off-loading posture system, to effectively reduce the risk of pressure ulcers in these critical areas.

The literature contains a study that considers, and seeks to measure, the effectiveness of the off-loading cushion for the prevention of PUs in people with spinal cord injuries and compares its effectiveness with the traditional interconnected air cell cushion ⁽¹⁸⁾.

For many wheelchair users, the risk of PUs can be substantially reduced thanks to the choice of an optimal seat cushion ^{(19) (20)}.

The choice of wheelchair cushion is particularly important, mainly for its effect on 2 factors: pressure of the tissue interface ⁽²¹⁾ and sitting position ^{(22) (23)}; in addition to the implications of body posture on musculoskeletal health and upper limb mobility.

OBJECTIVES

To measure the effectiveness of the RIDE-JAVA off-loading trunk-pelvis posture system as an aid for healing of stage I-II (III) pressure ulcers in hospitalized people with recent spinal cord injuries.

METHODS

The study can be defined, in accordance with current legislation, as a prospective observational study. The study was conducted according to the guidance given by Good Clinical Practices.

The study was approved by the Ethics Committee of the hospital.

POPULATION STUDIED

The project involved recruiting 15 people with spinal cord injuries, hospitalized at the spinal unit of ASST GOM Niguarda over 8 months in 2019.

INCLUSION CRITERIA

All subjects were required to meet the following criteria before being enrolled in the study:

- diagnosis of paraplegia or quadriplegia (ASIA¹ A or B)
- presence of existing I, II, or III stage PUs (without recommendation for surgery)
- absence of structured deformities greater than 2 cm scoliosis deviation and/or pelvic obliquities and/or hip paraosteopathy)
- low or zero risk assessment of the pressure zone on the ischiatic, trochanteric and sacral zones or spinous processes, as indicated by the Novel Pliance pressure measurement system
- signed, informed consent to collaborate in all the study procedures

¹ASIA/IMSOP (1992) *International Standards for Neurological and Functional Classification of spinal Cord Injury - revised 1992*. American Spinal Injury Association, Chicago U.S.A

EXCLUSION CRITERIA

- presence of existing III or IV stage PUs (with recommendation for surgery)
- presence of structured deformities greater than 2 cm scoliosis deviation and/or pelvic obliquities and/or hip paraosteoarthropathy)
- high risk assessment of the pressure zone on the ischiatic, trochanteric and sacral zones or spinous processes, as indicated by the Novel Pliance pressure measurement system.

MATERIALS USED

Off-loading posture system by Ride Designs composed of:

JAVA cushion and relative postural accessories.
JAVA Backrest and relative postural accessories.



FIGURA 1. The off-loading cushion JAVA



FIGURA 2. Java backrest

INSTRUMENTATION

The Novel Pliance technology system for wheelchairs was used to measure the pressures generated while sitting in the wheelchair.

This tool offers the most advanced technology for measuring static and dynamic pressure in wheelchairs, offering a dynamic quantification of pressure points in the wheelchair sitting position; this pressure-measuring mat includes both the mat for the cushion and for the back-support, and is currently a scientifically valid and internationally approved device for the research and publication of data in scientific articles ⁽²⁴⁾.

VARIABLES MEASURED

- amount of pressure in the support areas using the Novel Pliance technology system for wheelchairs
- skin status in the PU zone using special EPUAP and PUSH TOOL 3.0 (the latter where significant) dedicated assessment scales.

PROTOCOL

Day 1 (T0)

Explanation of the study and the written informed consent.
Checking of inclusion/exclusion criteria
Postural evaluation with regard to any deformities affecting the spine and/or limbs.
Collection of demographic data and medical history
Verification of previous and current treatments.
Evaluation of existing PUs using the EPUAP scale.

Day 7 (T1)

Evaluation of existing PUs using the EPUAP scale.
Provision of a JAVA cushion with appropriate measurements for both the user and his/her wheelchair. Provision of a JAVA postural backrest with appropriate measurements for the user and shaped according to the patient's comfort needs and properly installed on his/her wheelchair. Measurement of pressure in the wheelchair support areas using Novel Pliance System technology.

Day 14 (T2)

Evaluation of existing PUs using the EPUAP scale.

Day 21 (T3)

Evaluation of existing PUs using the EPUAP scale.

Day 28 (T4)

Evaluation of existing PUs using the EPUAP scale.

Day 35 (T5)

Evaluation of existing PUs using the EPUAP scale.

Day 42 (T6)

Evaluation of existing PUs using the EPUAP scale.

Day 49 (T7)

Evaluation of existing PUs using the EPUAP scale.

Day 56 (T8)

Evaluation of existing PUs using the EPUAP scale.

Measurement of pressure in the wheelchair support areas using Novel Pliance System technology.

OUTCOME MEASUREMENT

This study is for exploratory purposes only.

The forces and pressures exerted by the patient in various situations were measured:

- static sitting
- dynamic sitting during the push phase

both on the backrest and the wheelchair seat; the skin's state of health was also assessed in the areas subject to PUs, at time T1 (after 1 week), T2 (after 2 weeks), T3 (after 3 weeks), T4 (after 4 weeks), T5 (after 5 weeks), T6 (after 6 weeks), T7 (after 7 weeks) and T8 (after 8 weeks).

Descriptive statistics of the data collected were subsequently produced.

RESULTS**TABLE 1: AGE, TYPE OF LESION AND WEIGHT (KG) OF THE STUDY POPULATION**

TABLE 1 shows the study population.

The age, gender, weight (expressed in kg) and the level of spinal cord injury according to the ASIA scale are specified for each user.

The population includes 15 subjects between the ages of 14 and 72, 13 men and 2 women; 10 people with quadriplegia and 5 people with paraplegia.

13 users have a complete spinal cord injury (ASIA A) and 2 people have an incomplete spinal cord injury (ASIA B and C) with no active movement of the muscles under the lesion level.

TABLE 2: ZONE AND GRADE OF PU (EPUAP ASSESSMENT) OF EACH PATIENT

TABLE 2 shows the PU characteristics detected at time T0 (time of suitability assessment and enrolment in the study), in particular indicating the areas of affected skin and the grade of lesion according to the EPUAP assessment [bibliographical reference].

6 subjects have ischiatic PUs: 4 of them have PUs on both ischia, 2 subjects on just one ischium. 8 subjects have only sacral PUs; finally, 1 subject has lesions on both sacrum and one ischium.

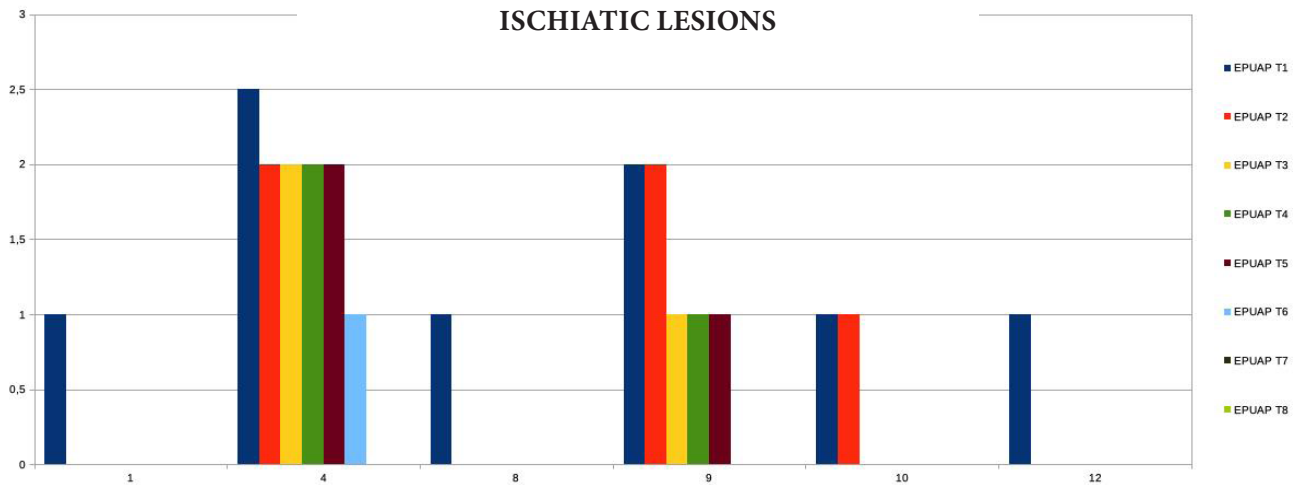
According to the EPUAP evaluation at T0, 5 subjects present grade 3 sacral PUs, 4 subjects present grade 2 PUs, 2 of these in the sacral area and the remaining two in the ischiatic areas. 6 subjects have a grade 1 lesion, of which 4 are ischiatic and 2 sacral.

TABLE 1 - AGE, TYPE OF LESION AND WEIGHT (KG) OF THE STUDY POPULATION

PATIENT	AGE	GENDER	WEIGHT (KG)	ASIA ASSESSMENT	DATE OF INJURY
1	15	M	38	T4 ASIA A	02/2019
2	62	M	65	T5 ASIA A	09/2018
3	20	M	66	T4 ASIA A	09/2018
4	45	F	51	C6 ASIA A	05/2014
5	23	M	45	C4 ASIA A	03/2019
6	72	M	70	D4 ASIA A	04/2019
7	22	M	75	C5 ASIA A	08/2015
8	23	M	55	C5 ASIA A	07/2019
9	47	F	50	C5 ASIA A	09/1993
10	48	M	70	C6 ASIA A	07/2019
11	40	M	82	D7 ASIA A	08/2019
12	28	M	50	C5 ASIA A	06/2019
13	14	M	42	C5 ASIA B	08/2019
14	54	M	77	C6 ASIA C	05/2019
15	16	M	67	C4 ASIA A	08/2019

TABLE 2 - ZONE AND GRADE OF PU (EPUAP ASSESSMENT) OF EACH PATIENT

PATIENT	PU ZONE	EPUAP T0
1	R/L ISCHIUM	1
2	SACRUM	3
3	SACRUM	3
4	R/L ISCHIUM	2
5	SACRUM	1
6	SACRUM	2
7	SACRUM and R. ISCHIUM	3
8	R/L ISCHIUM	1
9	R. ISCHIUM	2
10	R/L ISCHIUM	1
11	SACRUM	3
12	R. ISCHIUM	1
13	SACRUM	1
14	SACRUM	3
15	SACRUM	2



GRAPH 1. Progress of ischial PUs from T1 to T8

Graph 1 outlines PU progress in the ischiatic areas from T1 to T8, the subjects are reported on the abscissa, in order of grade of lesion according to the EPUAP evaluation over the weeks.

The ischial pressure lesions were completely healed in all cases. The EPUAP scale grade 1 lesions healed within 2 weeks and none of them recurred during the entire period using the cushion.

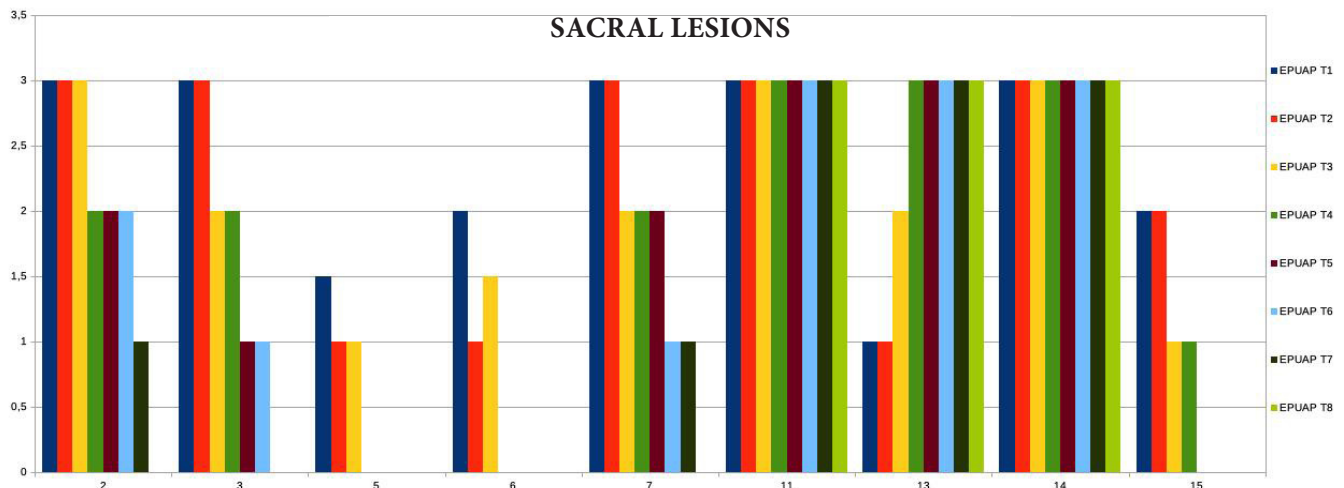
The EPUAP scale grade 2 or above lesions healed over a longer period, however less than 7 weeks and equally none of them recurred during the entire period using the cushion.

Graph 2 outlines the progress of sacral PUs from T1 to T8.

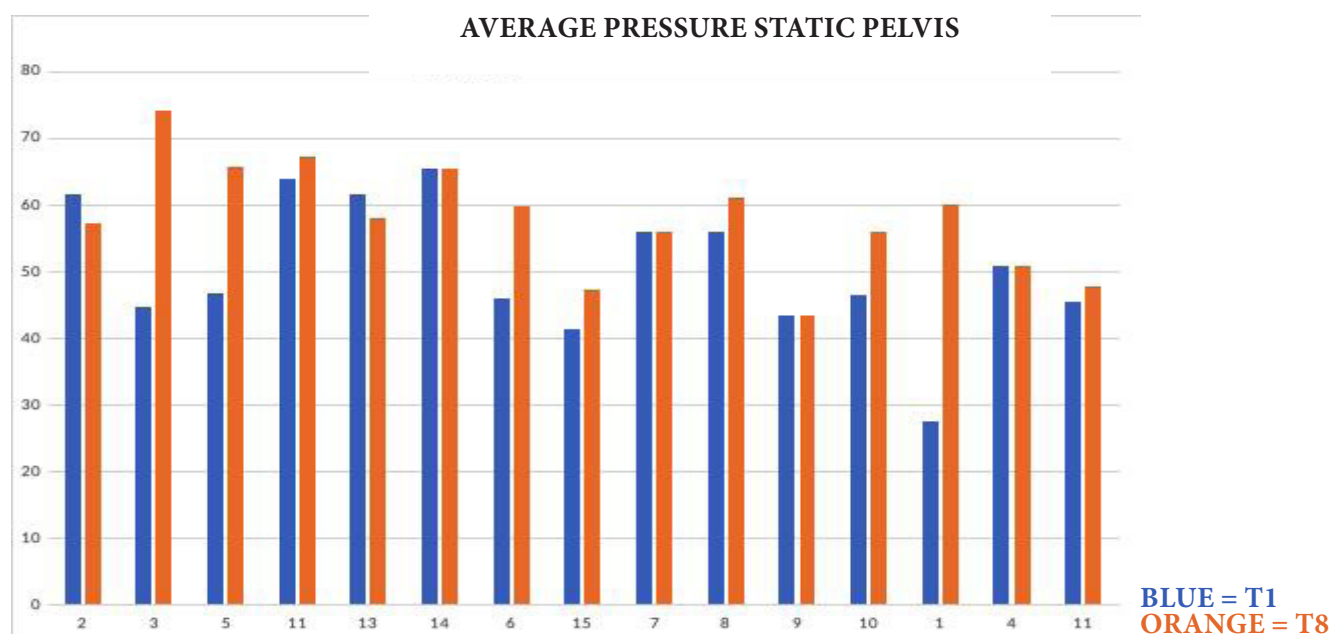
2 subjects with grade 2 PUs showed complete healing at time T8.

The 5 grade 3 sacral lesions did not deteriorate over the 8 weeks, but there was no progressive improvement process comparable to that of cases with grade 2 PUs.

A single case of grade 1 lesion at T1 has progressively deteriorated over the weeks.



GRAPH 2. Progress of sacral PUs from T1 to T8



GRAPH 3. Detection of static pressure of the pelvis on the cushion, at T1 and T8

As shown in **Graph 3**, pressure was measured in all patients using the NOVEL PLIANCE SYSTEM at T1 and T8.

In all patients the apparatus average pelvic pressure was always below the individual risk threshold, which means the device can be considered safe in terms of proper use; an essential requirement for definitively recruiting subjects to the study.

DISCUSSION

Principally, it is interesting to note the benefits that the posture system with the load-relieving cushion has brought for the treatment of ischial PUs: in fact, all of them healed by the end of the study and no recurrence occurred.

If we then consider that the individuals with ischial PUs are also subjects with body weight less than or equal to 60 kg, hence very thin, with hypotrophy of the lower limbs (**TABLE 1**) and therefore more at risk, we can say that the cushion effectively removed the load from bony prominences. Furthermore, if we consider that a high lesion level leads to less postural stability and less trunk balance: the shape of the cushion combined with the support of a properly installed postural backrest again has a positive effect both on posture and on the prevention and treatment of PU. It is to be remembered that grade 2 lesions healed in less than 6/7 weeks and grade 1 lesions healed in less than 2 weeks.

Intuitively we can understand why the progress of the sacral PUs cannot be compared to the ischiatic PU: in the case of sacral PU, maximum care and attention is required in the choice and use of both mattress and/or bed; aspects which we did not address.

Those with sacral PU enrolled in this study are however considered to be at high risk of developing PU and it is significant to note that none of them, using the load-relieving posture system, showed changes in their skin at the ischial level and at the same time the sacral PU never deteriorated.

This study did not make a comparison with other cushions (e.g. with communicating air-cell cushions), because it involves acute patients, many of them still did not have a personal cushion, let alone a personal wheelchair.

The sample included individuals at the onset of spinal cord injury and rehabilitation treatment, or those hospitalized due to complications and therefore undergoing a complete re-evaluation of both posture system and wheelchair, according to their particular PU.

STUDY LIMITS

Clearly it is a small sample, however there is variety in terms of gender, age, grade and type of lesion.

We believe that the load-relieving cushion's function would be extremely beneficial in a larger population than this study; however, further tests would be needed to support this hypothesis.

In this study, we made no effort to quantify or evaluate the characteristics of the sitting posture (e.g. pelvic inclination in the sagittal plane); however, this can also be helpful in researching the potential benefits of a customised load-relieving cushion.

Finally, the data obtained could be used to plan a prospective study to assess the statistical and clinical significance of the differences of the various measurements between patients.

CONCLUSION

It is reasonable to think that the load-relieving cushion is capable of promoting the healing of stage I, II and III ischial pressure lesions in less than 8 weeks, in people with spinal cord injury and at high risk of developing PU.

It is plausible to imagine that the same cushion is therefore a valid, preventative alternative to the traditional communicating air-cell cushion.

The load-relieving cushion also offers postural stability due to its shape, which is a valuable resource for people with complete cervical spinal cord injury, especially during the acute phase, in which they present weakness, hypotrophy, poor posture control and high risk of developing PU.

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