INPLASY PROTOCOL

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None declared.

Effects of limb exoskeleton gait orthosis and mechanical gait orthosis on rehabilitation of patients with spinal cord injury: a systematic review and future perspectives

Zhang, C[1]; Li, N[2]; Xue, X[3]; Lu, X[4].

Review question / Objective: **We aimed to systematically evaluate the gait improvement efficiency of limb exoskeleton gait orthoses and mechanical gait orthoses in patients with spinal cord injury.**
Condition being studied: **Spinal cord injury (SCI) is a major public health problem worldwide. In recent years, various orthotic training has been applied to the rehabilitation of SCI patients. Although many studies have reported the effect of orthoses on the walking function of patients, the comparison of two main types of orthoses, limb exoskeleton gait orthoses and mechanical gait orthoses, is still a vacancy. Therefore, an updated assessment of the impact of these two orthoses on the rehabilitation of SCI patients is needed.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2022 and was last updated on 17 April 2022 (registration number INPLASY202240104).

INTRODUCTION

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METHODS

Participant or population: This systematic review will consider studies of adults with complete and incomplete spinal cord injury with injury levels between C4 and L5.

Intervention: Patients can be trained with powered exoskeleton gait orthoses for a period of time.

Comparator: Patient trains with non-powered mechanical orthoses.

Study designs to be included: Including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case control studies.

Eligibility criteria: Inclusion Criteria: his review was a literature survey which considered all two types of orthotic devices that may have effects on gait performance, only studies involving people with spinal cord injuries were included. Types of Participants and Interventions: This review considered studies that included both complete and incomplete SCI adult patients with injury levels between C4 to L5, patients were able to be trained wearing either a powered exoskeleton gait orthoses or a non-powered mechanical gait orthoses. When a paper involved subject samples with other characteristics, only the findings from participants fulfilling the inclusion criteria were reviewed and reported.Types of orthotic devices This review categorized orthotic devices into two types: (1) Powered limb exoskeleton gait orthoses (Designed typically to utilize pneumatic actuators, hydraulic actuators or direct current electric motors to provide external power for the specific joints). (2) Mechanical gait orthoses (It provides both the intensity and the upright walking mode, but it is designed with no driven device). Types of Intervention Outcomes and Studies: This review considered studies that included the following intervention outcome measures: (1) instrumented measurements by three-dimensional motion analyzer system (2) non-instrumented measurements involved clinical functional tests such as Time up-and-go test (TUG), 10-Meter Walk Test (10MWT), 6-Minute Walk Test (6MWT), etc.This review considered experimental study designs, including randomized controlled trials, non-randomized controlled trials, quasi-experimental, before and after studies, prospective and retrospective cohort studies, case control studies.

Information sources: First, an initial search on PubMed will be performed, followed by an analysis of keywords used to describe the article's title and abstract . The second is to search all included databases such as Web of Science, Google Scholar, and Cochrane with all identified keywords . Finally, search the reference lists of all identified articles to add other relevant studies. This review will include studies published in English between 1970 and 2022.

Main outcome(s): This review considered studies that included the following intervention outcome measures: (1) instrumented measurements by three-dimensional motion analyzer system (2) non-instrumented measurements involved clinical functional tests such as Time up-and-go test (TUG), 10-Meter Walk Test (10MWT), 6-Minute Walk Test (6MWT).

Quality assessment / Risk of bias analysis: Our two evaluators will independently use the scoring protocol of the Oxford Centre for Evidence-based Medicine to evaluate the included studies on levels of evidence and grades of recommendation, then compared the results with each other. In case of disagreement, seek the opinion of the third evaluator. The reporting quality, external validity, internal validity-bias&

confounding and power of all included studies will be assessed using the Downs and Black quality list.

Strategy of data synthesis: Two authors will extract data independently and then compare results with each other. In case of disagreement, seek the opinion of the third evaluator. The following data will be extracted: author, year of publication, sample size, mean age, ASIA score, lesion level, course of disease, type of orthoses, outcome measures, and training period.

Subgroup analysis: We will compare and analyze the same type of powered exoskeleton gait orthoses as a subgroup, such as PGO, WPAL and WBCO.

Sensitivity analysis: Not applicable.

Country(ies) involved: China.

Keywords: limb exoskeleton gait orthoses; mechanical gait orthoses; orthotic devices; gait; spinal cord injury.

Contributions of each author:

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