Contributions of quantified movement analysis (QMA) in assessment of medical devices such as orthosis
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Opinion/Feedback QMA brings together the different measurement methods that can help the clinician in providing relevant evidence concerning orthosis effectiveness according to its functional purpose: immobilize, stabilize, fix, supply, and control.
The choice of sensors and variables which can be analyzed (kinetic, cinematic, energy, attention load) will be adapted to the objectives of the study with regard to measuring capacity and/or performance or use optimization of the medical device (biofeedback). While the patient is still ‘in fine’ the indirect beneficiary of a clinical study, the choice of the measuring tool will depend on the direct beneficiary of the results (patient, prescriber, prosthetist, rehabilitation team, manufacturer, Medicare…); this amounts to defining the main criterion of the study.
QMA provides such a substantial amount of data that it is always possible to find a significant variable, but is it relevant with regard to the framework used and the sponsor of the study, the environmental conditions, or coherent with the patient and his orthosis’s journey?
This presentation illustrates the relevance of QMA in medical device assessment using, as a common thread, examples of research hypotheses from various actors involved in orthosis choices.
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Role and limit of biomechanical modeling in the study of medical devices
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Objective Although it is only a part of their therapeutic effect, the mechanical effect of compression or contention medical devices (CCMD) is always claimed by the manufacturers. However, the mechanism between the pressure application zone and the targeted organ is complex. It involves a purely passive mechanical effect and mechanisms related to the tonic postural system. Various strategies can be implemented to show the effectiveness of a mechanical action; among them, biomechanical modeling is able to consider complex mechanical effects before any clinical trial.
Objectives This work aims to describe the contributions of a biomechanical modeling in understanding the action of CCMD using as an illustration the lumbar belt treatment of chronic and sub-chronic back pain.
Material and methods Three successive models are described: a finite elements model of the intervertebral discs, coupled with a low intensity X-ray imaging, a finite elements model of the entire trunk, including the spine but also the soft tissue of the abdomen and finally a purely analytical model based on external measurements of the trunk shape.
Results These three models correspond to different questioning: the first shows that the use of lumbar belts changes the pressure in the back of intervertebral discs and therefore pain. The second allows kriging the most important parameters on posture – trunk shape, belt properties – from the others – abdominal tissues. Finally, the third model specifies the mechanical efficiency of a given lumbar belt on a specific patient.