Introduction.– Knee conditions often lead to the prescription of knee orthoses for their “claimed” mechanical effects. The evaluation of these devices is currently based on biomechanical/pathophysiological studies or therapeutic trials [1,2]. However, data remain weak, highlighting methodological issues, a high variability of effects and arguable – controversial results. This work is placed within the context of developing assessment methods adapted to medical devices.

Objectives.–
1. Mechanical characterization thanks to a numerical finite element model. A model featuring a generic leg braced with an orthosis allows to quantify the mechanical reactions of knee braces against non-physiological movements and to relate these mechanical reactions to the pressure applied by the brace onto the skin.
2. Validation of the model based on physical (mechanical) measurements followed by a clinical validation.

Methods.–
Stage 1: development of a numerical model under Abaqus® featuring a deformable leg braced with an orthosis whose design and fitting characteristics may vary.
Stage 2: mechanical and clinical validation of the numerical model.

Results.– The developed numerical model will be presented; a leg kinematic is imposed in order to output the reaction forces/moments. First results about the comprehension and conceptual adjustments of orthoses will be discussed.

Discussion.– This evaluation method is going to be:
- adapted for different wearing conditions: tightening – skin adhesion;
- validated for “performance grading” of mass-produced orthoses (measurements with a metrology apparatus – instrumented simulator of knee movements);
- validated by clinical trials: anti-drawer effect with clinical analysis on functional scales and drawer measurements.

Thanks to this computational tool, novel brace designs can be tested and evaluated for an optimal mechanical efficiency of the devices and a better compliance of the patient to the treatment.

References

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The strain distribution for the natural and implanted hip joint articulation
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Efficacy and satisfaction of a lowered dynamical ankle-foot orthosis in chronic walking hemiparetic subjects
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Objectives.– To evaluate in chronic walking hemiparetic subjects the efficacy regarding the correction of the knee recurvatum and the walking performances of a lowered dynamical ankle-foot orthosis (D-AFO) in comparison with a prefabricated ankle-foot orthosis (P-AFO, Ottobock™) and shoes alone (SH). The secondary objective was to evaluate the satisfaction of the patients, with a focus on the putting of the orthosis and the shoes.

Methods.– The D-AFO is a carbon individually made orthosis, with a lowered articulation. Twenty chronic hemiparetic walking subjects were included in this single center comparative study. Gait quality was assessed on a GaitRite treadmill with a video recording performed with the D-AFO as compared to the P-AFO and shoes alone. The walking performances were assessed with a six minutes walking test and a Wade test with the D-AFO versus the P-AFO. The satisfaction was assessed with the ESAT-QUEST.

Results.– Walking with the D-AFO shows a significant improvement of the speed and quality of the gait as compare to shoes alone (walking time: 16.7 s ± 11 s versus 21.9 s ± 17 s, P = 0.04; FAP: 64 ± 18 versus 59 ± 16, P = 0.0018). The mean walking time and FAP are better with the D-AFO than with the P-AFO, but the statistical comparison doesn’t reach significance. The D-AFO allows a better quality and a better control of the knee recurvatum as compare to the P-AFO, and is also associated with a high level of patients ‘satisfaction (ESAT-QUEST 43 ± 6/50).

Conclusion.– In a population of chronic walking hemiparetic patients with a knee recurvatum problem, the lowered D-AFO improves the gait quality and walking performances comparatively to a P-AFO and shoes alone. It is also associated to a high level of patients’ satisfaction especially regarding the putting of the orthosis and the shoe.

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