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### ▶ To cite this version:

Léa Boillereaux, Simon Le Floc'h, Abderrahmane Kheddar, Franck Jourdan. Evaluation of knee unloader braces and brace designing challenges - A literature review. SB 2023 - 48e Congrès annuel de la Société de Biomécanique, Société de Biomécanique, Oct 2023, Grenoble, France. hal-04274876

### HAL Id: hal-04274876 https://hal.science/hal-04274876

Submitted on 8 Nov 2023

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### Evaluation of knee unloader braces and brace designing challenges – A literature review

L. Boillereaux<sup>a,b</sup>, S. Le Floc'h<sup>a</sup>, A. Kheddar<sup>b</sup>, F. Jourdan<sup>a</sup>

<sup>a</sup> Laboratoire de Mécanique et Génie Civil, Université de Montpellier, France; <sup>b</sup>Laboratoire d'Informatique, de Robotique et de Microélectronique de Montpellier, Université de Montpellier, France

#### 1. Introduction

In order to relieve patients suffering cartilage diseases and to facilitate the rehabilitation after an operation, it is necessary to unload the knee during daily living activities. Doctors used to prescribe knee orthosis to relieve their patients. These devices are based on various concepts to unload one or both knee's compartments by reducing or thresholding the tibiofemoral contact load or the abduction-adduction moment. Nevertheless, because it is difficult to measure articular forces *in vivo*, few studies evaluated such devices in terms of tibiofemoral contact force (TFCF) reduction. This leads us to question their effectiveness.

#### 2. Methods

This work highlights the methods of quantitative evaluations of the reduction of the contact effort by the knee unloading orthoses.

After listing the different methods to evaluate tibiofemoral contact force, we reviewed the studies that evaluate knee brace reduction of the tibiofemoral contact forces using these methods. We focused on passive or quasi-passive orthoses.

With respect to the results, we can conclude on the need to design more efficient unloader braces. We finally focus on the current issues and limiting points to design such orthotic devices.

#### 3. Results and discussion

# 3.1 Methods for quantitative evaluation of the tibiofemoral contact forces

Several methods for qualitative or quantitative evaluation of the effectiveness of knee braces have been developed and reviewed (perception based score, joint geometry modification, knee abduction moment modification) (Parween *et al.*, 2019).

The measure TFCF *in vivo* or *ex vivo* is quite new and developed by various laboratories all around the world. *In vivo*, the tibiofemoral contact force is estimated associating musculoskeletal models and measured electromyography (EMG) signals, associated to

Motion Capture (Mocap) measurements (Zeighami et al., 2018).

*Ex vivo*, cadaveric knees placed in a test rig are instrumented with pressure plates. Muscular forces are created with pneumatic cylinders. (Hale *et al.*, 2018)

# 3.2 Evaluation of knee braces tibiofemoral contact force reductions results

Various mechanical knee braces have been tested using the *in vivo* method presented above.

It shows that the reduction of the tibiofemoral contact force peak by knee braces is weak with orthosis that are just trying to create abduction-adduction moment (max 5% with the Unloader Brace provided by Ossür during gait (Hall *et al.*, 2019)).

Unloader braces are presenting better results in terms of contact force reduction (around 40 % for the prototype of Stoltze *et al.*, 2021 and 25% for the Levitation Brace commercialized by Spring Loaded ((Bishop *et al.*, 2023)). However, these braces are designed to unload the knee during one specific movement and sometimes are effective during one phase of this movement (e.g., first peak of the stance phase during gait).

# 3.3 Major issues and limiting points in knee brace design

It is necessary to design more efficient orthoses allowing the reduction of the tibiofemoral contact effort. However, it is necessary to take into account other parameters during the design of the device:

- The non-linearity of the contact force;
- The patient specific TFCF profile;
- Skin and soft tissue sensitivity to prolonged pressure (pressure sores);
- The complex fine 6 degrees of freedom (6dof) kinematics of the knee, patient specific.

Authors	Method (in/ex vivo)	Movement
Zhou et al.	MRI + fluoroscopy	Squat
Dreyer et al.	Instrumented implants + EMG + Mocap + Fluoroscopy	Downhill walking, squat, sit to stand, stair descent
Taylor et al.	Instrumented implants + fluoroscopy + EMG + Mocap + force plates	Downhill/level walking, squa sit to stand, stair descent
Li and al.	Dual fluoroscopy + CT scans	Box squat, seated knee extension
Kozanek and al.	MRI + Fluoroscopy + force plates (stance phase)	Treadmill walking
Zeighami and al.	Mocap + Force plates + musculoskeletal model	Treadmill walking
Thomeer and al.	MoBix system : Fluoroscopy Mocap + Forces plates	Open-chain flexion,standing, stair descent/ascent, sevel/sownhill walking,

Figure 1 : Methods used to determine knee kinematics and contact locations during daily living activities. The fine kinematic of the knee according to the 6 degrees of freedom can be determined experimentally, using complex medical imaging devices, recently developed, presented in the table above (Zhou *et al.*, 2021; Dreyer *et al.*, 2022; Taylor *et al.*, 2017; Li *et al.*, 2022; Kozanek *et al.*, 2009; Zeighami *et al.*, 2018; Thomeer *et al.*, 2021)

#### 4. Conclusions

Knee brace effectiveness is complex to evaluate in terms of tibiofemoral contact force reduction. New TFCF measurement methods (*in vivo*) are in development and few braces have been tested using it. Results of this studies are showing that the contact force reduction is generally weak. It seems that orthoses aiming to reduce muscular activity have the best results.

Several issues must be considered when designing an orthosis, such as the interaction of the device with the soft tissues or the kinematic constraints imposed by the system at the knee joint.

Finally, as methods for measuring contact forces and kinematics in vivo are still under development, much progress remains to be made both in the design of unloading orthoses and in the evaluation of their effectiveness. It is what we are working on.

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Keywords: unloader brace; contact force reduction; knee kinematics \*Corresponding author. lea.boillereaux@umontpellier.fr