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Evaluation of the mechanical efficiency of knee orthoses: a combined experimental-numerical approach

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Abstract

Knee orthotic devices are commonly prescribed by physicians and medical practitioners for preventive or therapeutic purposes with the aim of supporting, aligning, or immobilising the joint. However, the evaluation of these devices relies on few biomechanical studies or therapeutic trials and the level of their mechanical actions remain unclear. The objectives of this work are to develop and validate an experimental testing machine regarding its realism as compared to a standardised human limb by using a FE approach, and then use this machine to characterize the efficiency of different categories of orthoses under different pathological kinematics and investigate the influence of various design characteristics. It was found that the measured mechanical actions should be corrected to compensate for the rigid design of the test machine. Experimental results showed that the tested orthoses highly differed in their ability to restrain motions, and that the stiffening effects of these devices may be able to compensate for deficient internal structures only under low load. Although results remain to be confronted to clinical evidence, this approach paves the way to a standardised procedure for evaluating knee orthoses and developing new designs.

Keywords

Knee braces; Knee orthoses; Efficiency; Experimental; Finite element; Orthotics

1. Introduction

The knee is the largest joint in the body and is vulnerable to injury during athletic activities and to degenerative conditions such as osteoarthritis. Various syndromes are associated with an increased knee laxity, leading to a functional instability (i.e. a “wobbly” feeling). The wide and varied methods of treatment and prevention of knee injuries include the use of knee orthoses, or knee braces. More than 5 million knee braces and supports were sold in the US in 2011 and this market is expected to exceed \$1.2 billion by 2018 [1]. The general purpose of these devices is to support, align, or immobilise

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the knee [2]. Despite the fact that they are commonly prescribed by physicians and medical practitioners, their evaluation relies on few biomechanical studies or therapeutic trials [3, 4]. Their claimed effects are mainly proprioceptive input and joint stabilisation, but their action mechanisms are not fully understood. They are usually fitted into three main categories: prophylactic (prevent injury), functional (increase stability) and rehabilitative (control motion during rehabilitation) braces [5]. However this classification is based on expected clinical effects but there is no evidence that there is a difference in terms of mechanical response of the brace itself.

Assessment of the motion restraining of various braces of the US market has been experimentally investigated in the 1990s under different testing conditions. Some authors used cadaveric specimens [6–8], in which case substantial scatter were noted (anatomical, physiological and methodological variances) and the integrity of the joint was problematic to simulate non-physiological kinematics. Besides, this procedure is not adapted to standardised testing. Others have developed phantoms in the form of mechanical surrogates [8–13] consisting in mechanical parts mimicking the joint, thigh and leg on which a specific motion was simulated (drawer, pivot shift, lateral impact...), and instrumented with electronic strain gauges in order to quantify the mechanical effects of a brace. However, the mechanical realism of such surrogates is subject to caution as compared to a real human limb, as most of them were made of rigid materials. What is more, these studies are not recent and brace designs have evolved. Orthotic manufacturers have developed new brace design specificities (e.g. blocking hinge mechanisms, complex strapping systems...) and attribute specific effects to these features in relation with a given pathology without objective assessment.

As a consequence of these uncertainties, medical practitioners and manufacturers still lack a simple evaluation tool for knee orthoses. A French committee of experts highlighted this problem [14] and stated that orthoses must be evaluated by taking both the mechanisms of action and the desired therapeutic effects into account.

Finite Element (FE) analysis is a powerful tool when it comes to complex mechanical simulations and a combined experimental-numerical approach would definitely help to develop a standardised procedure for testing knee orthotic devices and validate the mechanical behaviour of a surrogate limb in relation to a real human limb model, as the one presented in a previous work [15].

For this purpose, a 3-axis instrumented surrogate limb was developed to test knee braces against different pathological kinematics. The objectives of this work are described in Figure 1. In a first step, a FE model of a generic brace was built and validated using this experimental device. Then, FE modelling was used to investigate the mechanical realism of the machine by confronting the numerical response of a FE generic brace:

1. on a model of the test machine limb,
2. on a model of a morphological, deformable limb.

Finally, the robotic limb was used to investigate the effect of different design factors on a generic brace and test a panel of commercially available knee orthoses and rank them based on their mechanical responses.

2. Materials and methods

2.1. Surrogate lower limb

Structure. The test machine depicted in Figure 2 consists of two cone-shaped steel parts mimicking the thigh and leg. The dimensions were chosen accordingly to the size of a median French male limb (circumference at the knee: 38 cm; +15 cm above the knee: 49.3 cm; -15 cm below the knee: 36.2 cm). They were linked by a silicon ring to maintain a continuum between the limbs. An artificial skin-like membrane (DawSkin™) was glued over the assembly. This material is similar to the skin in terms of texture and stiffness, and was assumed to have the same frictional behaviour.

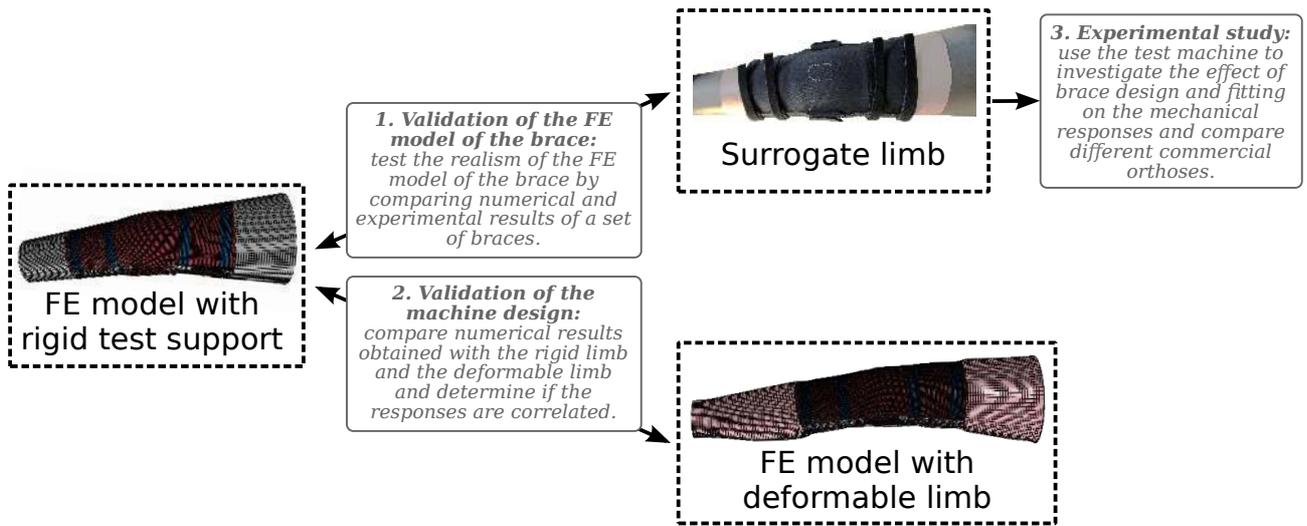


Fig. 1. Objectives of the present work with details on the cross-validation process.

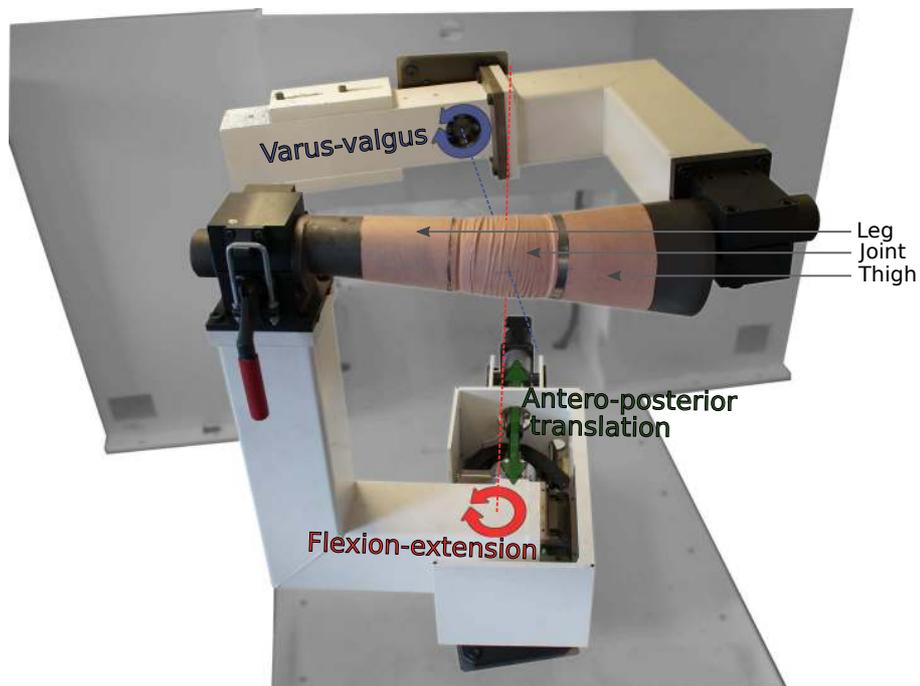


Fig. 2. Test machine for knee orthoses designed to simulate three kinematics of the lower limb: flexion-extension, varus-valgus and antero-posterior translation. Each motion is instrumented with either a torque sensor or a force sensor.

Kinematics and motorisation. This machine was used to simulate three joint movements: a flexion motion of a healthy knee and two pathological kinematics, a varus rotation and an anterior translation of the leg with respect to the thigh (drawer). The flexion and varus motions are driven by two brushless motors and two reducers, providing a nominal torque of 500 N-m. The motors are controlled by two resolvers (0.05° accuracy). The drawer axis is powered by a linear actuator providing a maximal force of 200 N and a position accuracy of 0.05 mm. In this study, three particular kinematics were tested:

- a 30° flexion; this amplitude is characteristic of a walking motion [16]. For splints, a flexion of only 10° was performed to avoid damage.
- a 15 mm translation of the leg with respect to the femur; this instability is normally prevented by the anterior cruciate ligament [17] and is increased by an injury to this ligament, as shown by the Lachman test.
- a 10° varus; this instability is associated to either a ligamentous injury of a lateral ligament [18] or to arthrosis [19].

These kinematics have also been chosen in a concern of comparing the results with existing studies, either on phantoms or cadaveric knees [8–13], and also to numerical simulations. This is also why it was chosen to work with a quasi-static loading rate (10°/min for flexion and varus and 10 mm/min for drawer). If considering only the mechanical aspects of orthopaedic treatment, the role of a knee orthosis is to replace a deficient body structure and restore the joint stiffness in the case of the two latter pathological laxities; however the flexion motion should remain unrestrained (except for knee splints).

Instrumentation. In order to measure the motion restraining ability of knee orthoses, each axis is instrumented to measure reaction forces and moments. Before doing the experiments, the three axes have been calibrated using a load cell and the repeatability of the sensor output has been checked. The flexion and varus axes include torque sensors with 0.1% accuracy. The drawer axis is instrumented with a load sensor with 1 N accuracy. Step by step motions were simulated: the three amplitudes were divided into 30 steps and 10 sensor values were recorded and averaged at each step with the motors stopped in order to minimise noise due to motor vibrations, and to remain in a quasi-static state. The acquisition sampling was 1° for the flexion, 0.5 mm for the drawer and 0.33° for the varus.

Testing protocol. The brace was positioned with the help of alignment marks to make sure that the axis of rotation of the hinge mechanism was aligned with the axis of rotation of the flexion movement. Each test consisted in a run without the brace to measure the response of the silicon ring only; then the brace was fitted and the response of the ring/brace assembly was measured. Finally, the response of the ring only was subtracted from the response of the assembly to obtain the response of the brace only. Five tests were performed for each brace, and each time the brace was re-fitted on the surrogate limb. Assuming a Gaussian distribution of the responses, a mean \pm 90% confidence interval was computed at each point.

2.2. Knee braces

Generic knee braces In a first step, generic knee braces were tested to validate a FE model of the same braces. These braces were designed to be mechanically representative of usual commercially available braces but with a simple design and known material characteristics. They feature a synthetic fabric body with a cylindrical, slightly conical geometry, bilateral hinged bars with a blocking system to prevent knee hyper-extension and tightening straps, as depicted in Figure 3. The position of the straps can be adjusted and the tightening tension was quantified using a loading cell.

This reference brace was declined in various sizes and lengths, and the influence of several parameters were tested on each response:

- Strap tightening level: no tightening (0 N tension), medium (30 N tension) and high (60 N tension) tightening (in preliminary tests, 30 N was qualified as ‘comfortable’ and 60 N as ‘slightly too tight’).

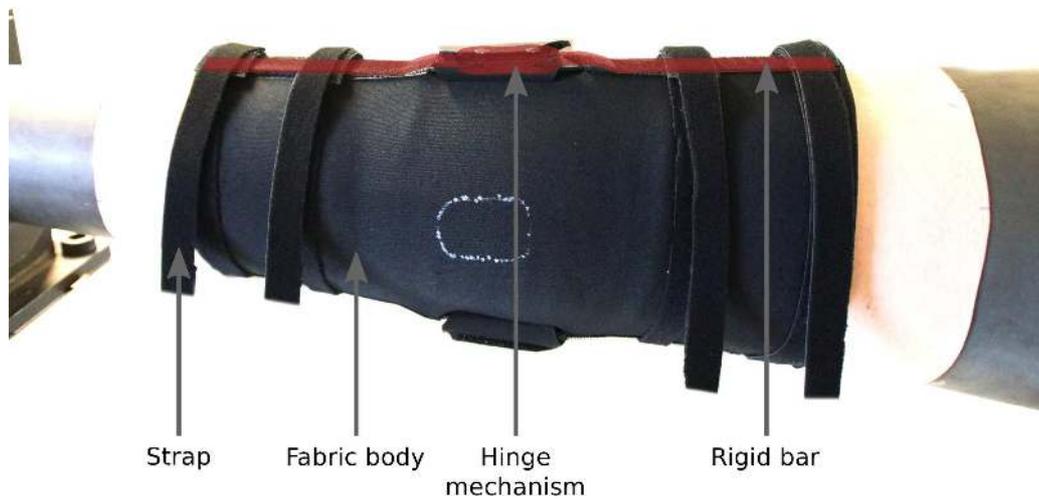


Fig. 3. Medium size generic brace with known geometry and mechanical characteristics.

- Brace size: standard reference size for the surrogate limb circumference, 2 sizes too small and 2 sizes too large (center circumferences: 36.8 cm, 32.4 cm and 45.2 cm respectively).
- Brace length: reference length (34 cm), a longer (51 cm) and a shorter (17 cm) brace.

The effect of varying these factors was compared to numerical models to validate the FE model of the brace and validate the design of the test machine. In a second time, other design factors were investigated experimentally only:

- Parallel/helical strap shape (two helical straps criss-crossing behind the thigh and in front of the tibia).
- Presence/absence of a patella opening surrounded by a silicon ring.
- Presence/absence of silicon pads inside the fabric body to prevent brace sliding.
- Presence/absence of fabric body (hinged bars and straps only).

Emphasized parameter values are those of the reference brace (centre point of the design of experiments).

Commercial knee orthoses In order to investigate the mechanical response of knee orthoses in various categories, different functional and rehabilitative braces have been tested. The product line of three orthotic manufacturers has been chosen (Gibaud[®], Lohmann & Rauscher[®] and Thuasne[®]). Although designs are slightly different among manufacturers, they all fit into four categories: compression sleeves, hinged braces with a fabric body (similar to the generic brace described in Section 2.2), rigid hinged orthoses and splints. The first two have a functional role whereas the two others are rehabilitative orthoses. It is noteworthy that none of these orthoses is aimed at correcting varus or valgus deformities, i.e. they do not apply a corrective torque to the joint in the rest position. Their primary claimed mechanical role is to prevent instabilities/laxities. An example of each category is depicted in Figure 4. 12 orthoses were tested (one of each category for each manufacturer). As this study is focused on the evaluation of the surrogate limb and its role in brace efficiency assessment, results were anonymized. A tightening of 30 N was applied to the straps.

2.3. Finite element models

A FE model of a generic brace was developed under Abaqus[®] v6.10. It was numerically tested on both a rigid support (FE model of the surrogate limb) and a morphological, deformable support (FE model of a human limb).



Fig. 4. Example of a knee orthosis in each category: (a) compression sleeve; (b) fabric hinged brace; (c) rigid hinged orthosis; (d) splint.

	E_1 (N/m)	E_2 (N/m)	G_{12} (N/m)	F_1 (N·m)	F_2 (N·m)	τ_{12} (N·m)	$\nu_{12}, \nu_{21}, \mu_1, \mu_2$
Body fabric	790	910	321	$1 \cdot 10^{-4}$	$2.8 \cdot 10^{-4}$	$8 \cdot 10^{-5}$	0
Strap fabric	15000	15000	7500	$1 \cdot 10^{-3}$	$1 \cdot 10^{-3}$	$5 \cdot 10^{-4}$	0

Table 1: Identified mechanical properties of brace and strap fabrics for the generic brace.

FE model of the brace. The generic brace described in Section 2.2 was modelled using shell elements. It features hinged rigid bars, a fabric material and fitting straps. The fabric material was defined as homogeneous, orthotropic and linear elastic. It was meshed with 14790 to 43690 S4R shell elements [20] depending on the length of the brace. The constitutive equations are:

$$\begin{pmatrix} N_{11} \\ N_{22} \\ N_{12} \end{pmatrix} = \begin{pmatrix} \frac{E_1}{1-\nu_{12}\nu_{21}} & \frac{\nu_{21}E_1}{1-\nu_{12}\nu_{21}} & 0 \\ \frac{\nu_{12}E_2}{1-\nu_{12}\nu_{21}} & \frac{E_2}{1-\nu_{12}\nu_{21}} & 0 \\ 0 & 0 & G_{12} \end{pmatrix} \begin{pmatrix} \epsilon_{11} \\ \epsilon_{22} \\ 2\epsilon_{12} \end{pmatrix} \quad (1)$$

and

$$\begin{pmatrix} M_{11} \\ M_{22} \\ M_{12} \end{pmatrix} = \begin{pmatrix} F_1 & \mu_2 F_1 & 0 \\ \mu_1 F_2 & F_2 & 0 \\ 0 & 0 & \tau_{12} \end{pmatrix} \begin{pmatrix} \kappa_{11} \\ \kappa_{22} \\ 2\kappa_{12} \end{pmatrix} \quad (2)$$

where N_{ij} and M_{ij} are the tensions and bending moments of the fabric, ϵ_{ij} and κ_{ij} the strains and bending strains, E_i the tensile rigidities, G_{12} the shear rigidity, ν_{ij} the Poisson's ratios, F_i the bending rigidities, τ_{12} the torsional rigidity and μ_i parameters analogous to Poisson's ratios. Subscripts 1 and 2 represent the longitudinal and circumferential directions of the brace cylinder and the directions along and across the straps respectively.

Tensile rigidities, shear rigidity and Poisson's ratios were obtained from unidirectional and off-axis tensile tests on an Instron[®] machine at speeds of 50 mm/min on 40×20 mm fabric samples. The linear elasticity assumption was judged reasonable from tensile tests for strains below 40%. Bending rigidities were measured using a KES-F (Kawabata Evaluation System for Fabrics) device [21, 22]. Identified properties are reported in Table 1.

Rigid bars were modelled as a shell with a thickness of 2 mm and an isotropic linear elastic behaviour ($E = 70$ GPa, $\nu = 0.3$).

FE model of the rigid support. The rigid support was modelled as an undeformable material with the geometry of the test machine. A Neo-Hookean strain energy function [20] was used to model the silicon ring: $C_{10} = 1 \cdot 10^6$ Pa and $D_1 = 1 \cdot 10^{-7}$ Pa⁻¹.

FE model of the morphological deformable limb. This model has already been described in a previous study [15] but a quick summary is given here. It features a deformable limb with a separate skin layer, able to glide over underlying tissues. The soft tissues material (homogenized muscles, fat, tendons...) was defined as homogeneous, isotropic, quasi-incompressible and hyper-elastic (Neo-Hookean strain energy function [23, 24]) and meshed with 60199 hexahedral elements. It is noteworthy that the mechanical properties ($C_{10} = 5$ kPa) were identified in a passive muscle state. The skin layer material was defined as homogeneous, isotropic, quasi-incompressible and hyper-elastic (Ogden strain energy function [25]), meshed with 22648 hexahedral elements and an initial strain of 20% was applied at the start of the analysis. Bones were considered as rigid bodies.

Brace/limb interface. A Coulomb friction [20] was used to model the brace/limb interactions. A friction coefficient of 0.4 has been chosen from literature [26, 27].

Analysis steps and post-treatment. A quasi-static analysis was performed using the Explicit solver [20] in order to solve significant discontinuities (fabric buckling, contacts). Time scale and material density were carefully chosen to prevent dynamic effects (kinetic energy was much inferior to external work) to remain in a quasi-static case. The simulation consisted in three steps:

1. A displacement field was applied to the brace to enlarge it and to make it fit at the right place on the limb.
2. Contacts were activated, previously applied displacements were released in order to let the brace come into contact with the limb and reach the mechanical equilibrium; the limb was fixed; the straps were pre-stressed to simulate a real fitting.
3. A joint kinematics was imposed to the lower limb (flexion, drawer or varus, as described in Section 2.1); the thigh part was fixed.

The main output of the simulations was the load vs. motion curve, similarly to what is given by the robotic limb. The response of the limb only (obtained from a simulation without brace) was subtracted from the simulated response to obtain the response of the brace only, as done for the test machine. Typical responses are reported in Figure 5. As the Explicit solver was used, a low-pass filter was applied to reject the noise due to residual dynamical effects of the solver, as seen in Figure 5.

2.4. Performance evaluation indexes

In order to compare the efficiency of different orthoses to prevent or allow a motion, three efficiency indexes have been developed. Most responses were found to have a transition behaviour for low displacements/rotations quickly followed by a rather linear curve, as seen in Figure 5.

Consequently, the chosen efficiency indexes were the slope of the load-displacement curves in the linear domain for each kinematics, calculated by a linear regression. These domains are reported in Table 2. The indexes may be interpreted as the average rigidity of the brace with respect to a rotation/displacement and were assumed to characterize its ability to restrain a motion.

The relative importance of each index needs to be confronted to the pathology of the patient; for instance, a torn ACL involving antero-posterior laxity will be treated with a brace with a high drawer efficiency index, whereas a brace with a high varus index will be preferred to treat lateral laxities caused by arthrosis.

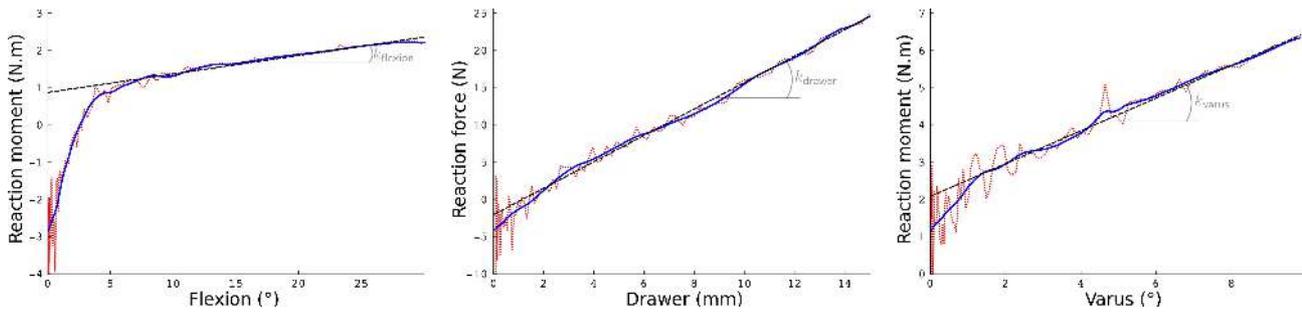


Fig. 5. Typical responses for the different kinematics (flexion, drawer, varus) as obtained by FE simulation of the rigid limb model. In dotted red, the raw response; in solid blue, the response after low-pass filtering; in dashed black, the linear regression line.

Motion	Linear regression domain	Efficiency index
Flexion	5–30°	k_{flexion}
Drawer	2–8 mm	k_{drawer}
Varus	1–10°	k_{varus}

Table 2: Details on linear regression domains for the calculation of the efficiency index for each motion.

3. Results

A single FE simulation completed in about 4 hours for the rigid limb and 8 hours for the deformable limb (12 CPUs at 2.4 Ghz). The mechanical equilibrium was checked by observing energy quantities to verify that dynamic effects had dampened out.

3.1. Validation of the FE model of the brace

Experimental and numerical curves of the mechanical responses of generic braces were compared. An example is given in Figure 6 where the effect of strap tightening was investigated. First it can be noted that strap tightening had an effect on the responses: increasing tightening increased reaction forces and moments of the brace, especially for drawer and varus motions. This parameter has a positive effect on the overall brace stiffening effect. Secondly, the FE results are in good agreement with actual experimental data even if some differences are noticeable. For the flexion kinematics, the responses are similar in the first part of the motion, then the FE simulation underestimates the reaction moments. For the drawer kinematics, the FE responses are slightly shifted below the experimental curves, but still in the confidence intervals. Experimental responses exhibit a slightly different behaviour at the end of this motion with a sudden change in the curve slope. This is why the regression domain for this motion (Table 2) was purposely reduced to avoid this non-linear part. The reasons and impacts of these errors will be discussed in Section 4.1. Finally, the varus motion curves are in very good agreement.

This comparison was then performed by varying three factors (brace tightening, brace length and brace size) from the reference brace (medium tightening, medium length, medium size), without taking the interactions between the factors into account (simple design of experiments with three levels, no interactions). The efficiency index was computed for each case and the main effects were plotted in Figure 7. It can be noticed that the responses varied rather linearly with the factors, meaning that the quadratic effects are low compared to the main effects.

As expected, the experimental and rigid FE efficiency indexes (red and green colours) were in good agreement as well, except for the flexion motion for which the responses are underestimated. The FE model successfully predicted efficiency

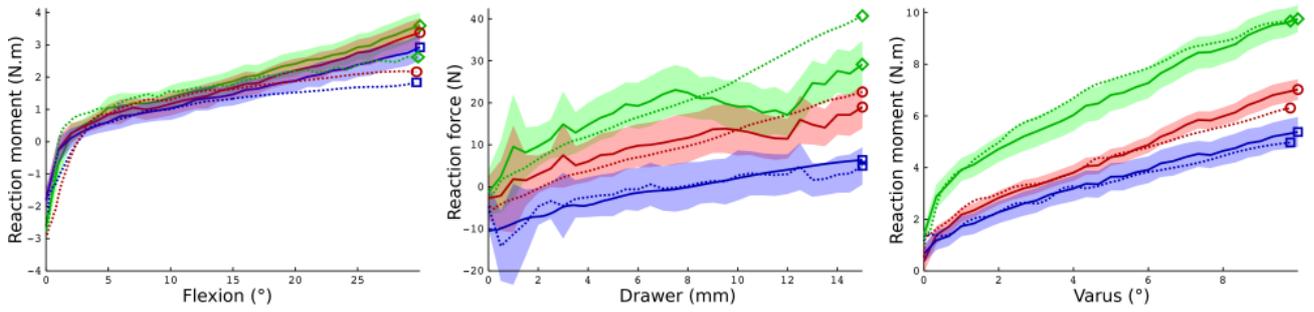


Fig. 6. Comparison of experimental results (solid lines with 90% confidence intervals computed from the Gaussian distribution of 5 repeated tests) and numerical results of the rigid limb model (dotted lines) for three strap tightening levels (blue squares: 0 N; red circles: 30 N; green diamonds: 60 N) for each motion.

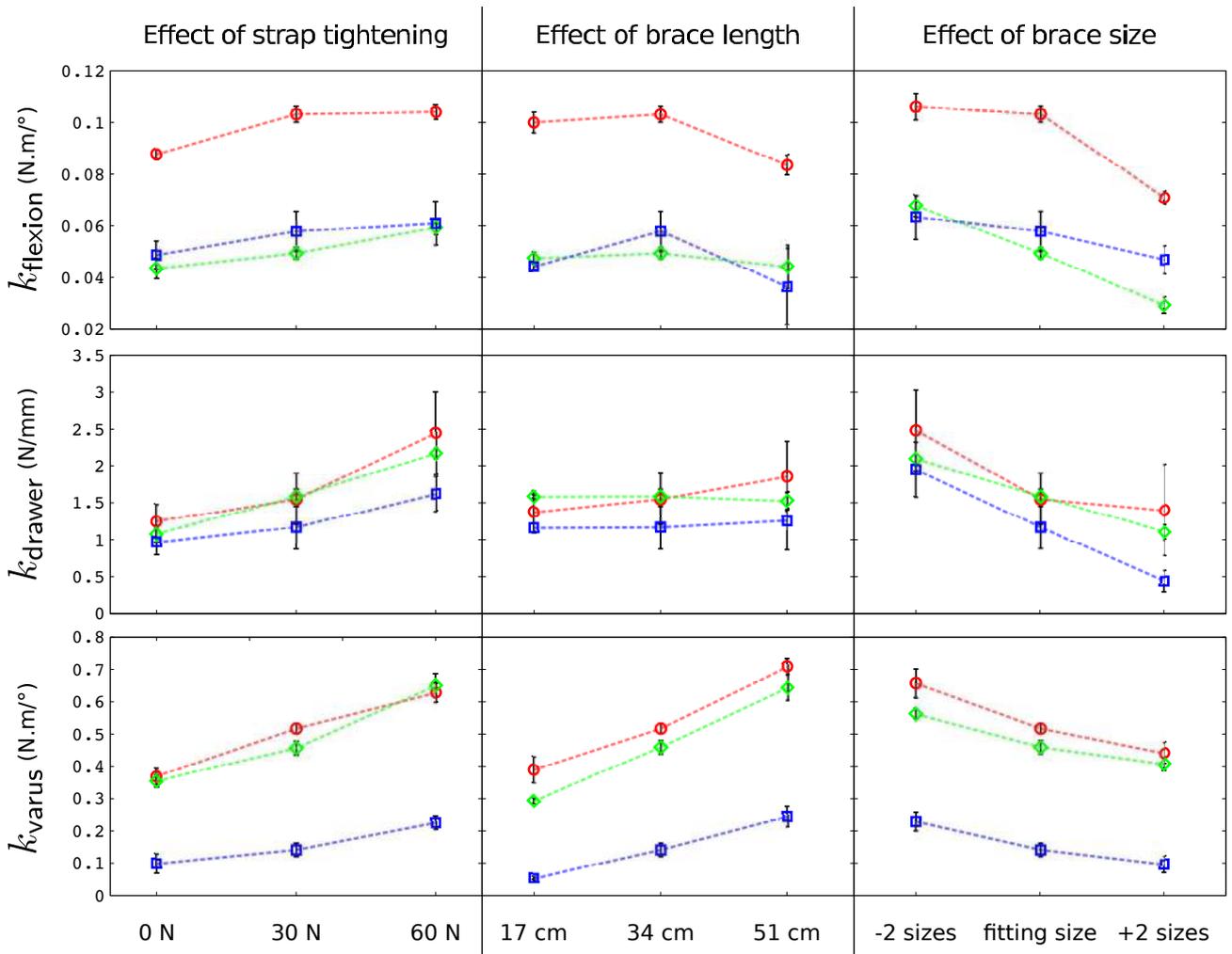


Fig. 7. Main effects for the three efficiency indexes. Red circles: experimental; green diamonds: rigid limb FE model; blue squares: deformable limb FE model. The 90% confidence intervals of the regression coefficients are shown.

Motion	Correction factor	Mean value \pm standard deviation
Drawer	f_{drawer}	0.75 ± 0.15
Varus	f_{varus}	0.31 ± 0.07

Table 3: Values of the two correction factors compensating for the rigid design of the machine. Mean values and standard deviations of these factors for all the different simulated braces.

indexes for varus and drawer motions, not only when varying strap tightening but also brace length and brace size. The mean prediction relative errors were 49% for the flexion, 11% for the drawer and 11% for the varus.

3.2. Validation of the machine design

As the FE model of the brace successfully reproduced experimental data for drawer and varus kinematics, responses of this brace were numerically simulated on the deformable, morphological leg and compared to the responses from the FE model of the machine. The corresponding efficiency indexes for different brace parameters are plotted in Figure 7 (blue colour). It can be noticed that the behaviour of the brace/limb system is different with a morphological, deformable limb: for the flexion kinematics, it is similar to the numerical responses obtained with a rigid limb, but any explanation would be meaningless as the model was not validated for this kinematic; for the drawer kinematics, the stiffening effect of the brace slightly decreases (mean relative difference of 25%); for the varus kinematics, this decrease is even more pronounced (mean relative difference of 69%). Supposing that the FE model of the morphological, deformable limb is closer to a real human limb than the FE model of the test machine in terms of mechanical response, the machine design would be validated if the same responses were obtained, but this is not the case. However, the efficiency indexes vary the same way for both models when changing brace parameters, as seen in Figure 7. Consequently, general correction factors may be introduced in order to compensate for the unrealistic rigid limbs of the machine. Correction factors f_{kin} were calculated as the ratio between $k_{\text{kin}}^{\text{FE_def}}$, the efficiency index computed from the deformable FE model response and $k_{\text{kin}}^{\text{FE_rig}}$, the efficiency index computed from the rigid FE model response:

$$f_{\text{kin}} = \frac{k_{\text{kin}}^{\text{FE_def}}}{k_{\text{kin}}^{\text{FE_rig}}} \quad (3)$$

where the subscript kin is either drawer or varus.

Looking at Figure 7, these ratios do not seem to depend much on the brace design, which is a good point since the goal is to use these factors for other kinds of braces, but they definitively depend on the kinematics. The mean values of these factors for all tested brace parameters are reported in Table 3. The low standard deviations confirm that these correction factors are valid for all the tested braces. As the correction factor is mainly related to the low stiffness of the limb soft tissues, it should be mostly independent on the brace itself. The correction is much more important for the varus motion because the rigid parts of the brace are pushed against the side of the limb and largely deform the soft tissues.

3.3. Experimental study

The test machine is a useful tool to quickly investigate the effect of brace design parameters and characterize and compare the mechanical response of commercial orthoses.

Effect of generic brace parameters on their mechanical efficiency. A design of experiment approach [28] was used to compare the effects of different factors on the mechanical responses of the generic brace. The following equation was used

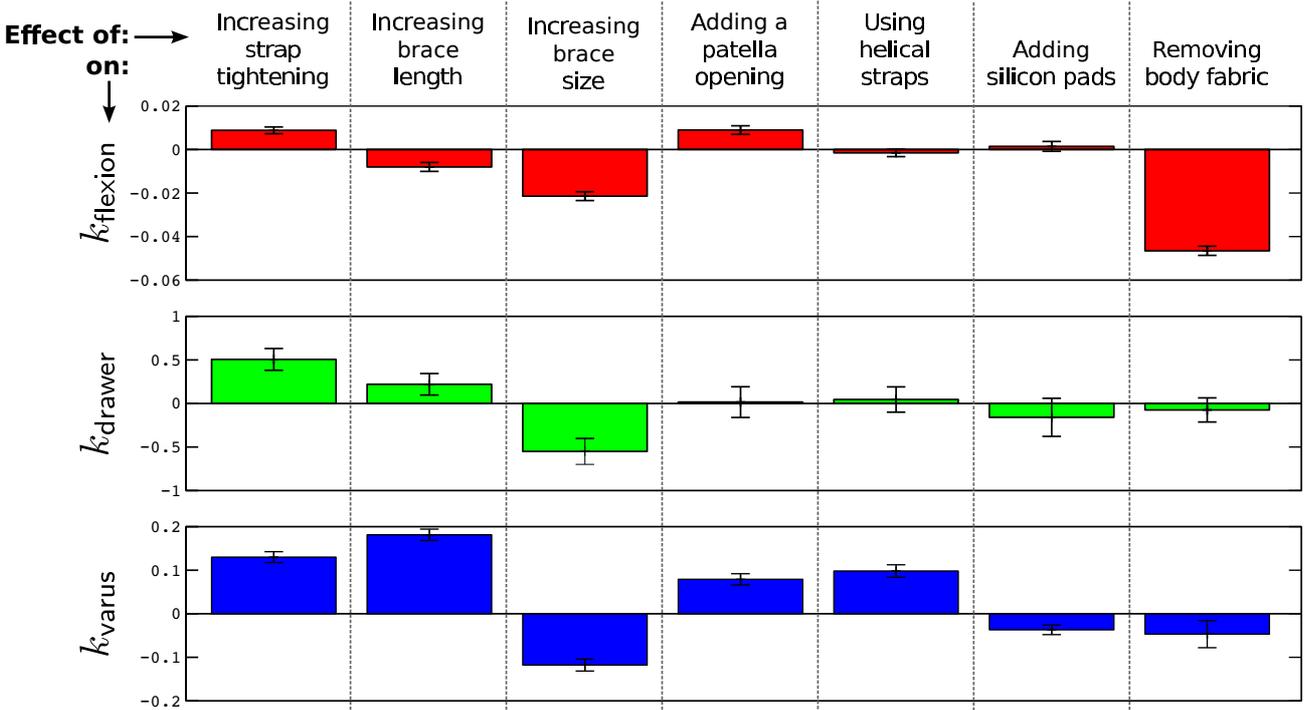


Fig. 8. Effect of different factors on the efficiency indexes. Confidence intervals are 90%.

to model the response variable k_{kin} as a function of n input factor values $[p_1, p_2, \dots, p_n]$:

$$k_{kin} = a_0 + a_1p_1 + a_2p_2 + \dots + a_np_n \quad (4)$$

where a_0 is the mean overall response and $[a_1, a_2, \dots, a_n]$ are the main effects of factors $[p_1, p_2, \dots, p_n]$ on the response. The input factors values were coded in a $[-1; +1]$ range. As two or three levels were chosen for each factor, $[a_0, a_1, a_2, \dots, a_n]$ were calculated using a linear regression. Graphically, the effect of a factor on a response is the slope of regression lines of the curves in Figure 7 (with coded units on the x-axis instead of original units).

The computed effects are depicted in Figure 8. It can be noticed that the levels of effects depend on the kinematics. For instance, increasing brace length has a strong positive effect on the efficiency of the brace to prevent varus kinematics, but is not so influential for the two other motions. A detailed interpretation of each effect will be discussed in Section 4.3.

Mechanical response of various commercial orthoses. Three commercial orthoses in each category (12 in total) were tested on the robotic limb. Their mechanical responses are depicted in Figure 9, and the corresponding efficiency indexes are reported in Table 4. First, it can be noticed that these responses allow to grade the different categories based on their mechanical responses, even if the domains slightly overlap: different designs lead to significantly different mechanical behaviours. Compression sleeves have a very low stiffness, which is negligible for drawer and varus motions compared to other orthoses. Rigid hinged orthoses allowed flexion better than fabric hinged braces, which makes them more efficient for knee bending, although they were better to restrain drawer and varus motions. This should make them globally more efficient and easier to walk with. Finally, knee splints were the stiffest orthoses: their mechanical action was significantly higher, especially for flexion and drawer motions.

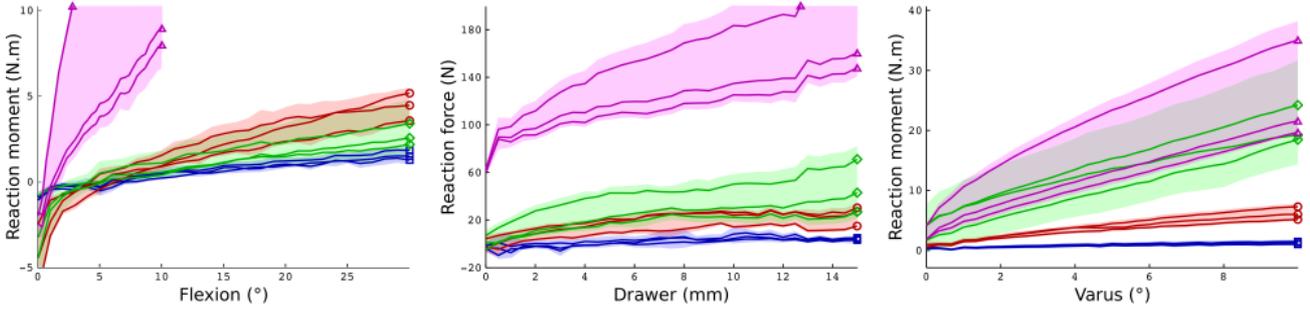


Fig. 9. Mechanical response of three commercial orthoses in each category: sleeves (blue squares), hinged braces (red circles), rigid hinged orthoses (green diamonds) and splints (magenta triangles).

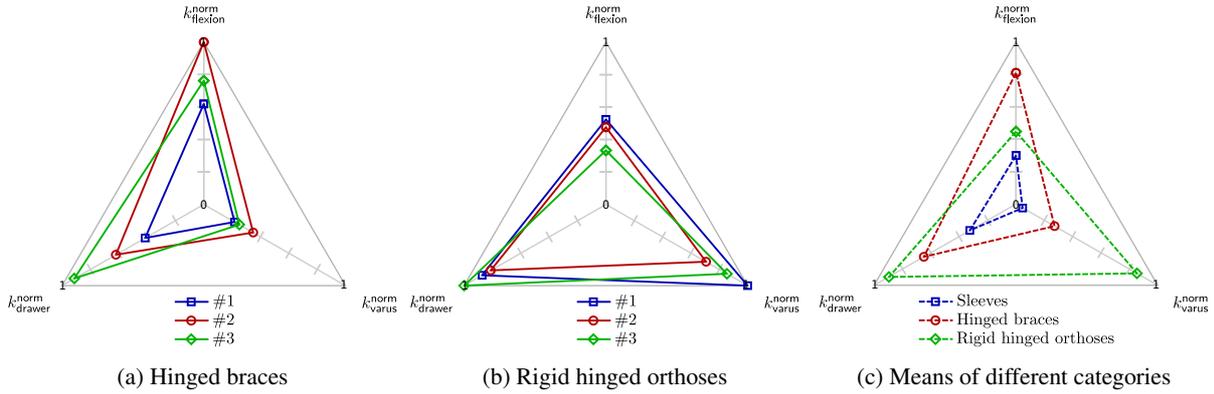


Fig. 10. Net charts of the mechanical effect of knee orthoses regarding their motion restriction in flexion, drawer and varus, showing discrepancies within categories – hinged braces (a) and rigid orthoses (b) – and between different categories (c).

In Figure 9 it can be noticed that an increasing stiffness is also accompanied by an increase in initial reaction force for drawer motions. This is due to the fact that the tested device has a zero-load position which is different from the initial fitted position. This behaviour is not characterized by the efficiency indexes but may have an impact on joint stabilisation.

It was convenient to represent the different effects of these orthoses in a net chart display with three axes, as shown in Figure 10. For this purpose, normalized variables of each index were defined as:

$$\begin{cases} k_{\text{flexion}}^{\text{norm}} &= \frac{k_{\text{flexion}}}{k_{\text{flexion}}^{\text{max}}} \\ k_{\text{drawer}}^{\text{norm}} &= \frac{k_{\text{drawer}}}{k_{\text{drawer}}^{\text{max}}} \\ k_{\text{varus}}^{\text{norm}} &= \frac{k_{\text{varus}}}{k_{\text{varus}}^{\text{max}}} \end{cases} \quad (5)$$

where $k_{\text{flexion}}^{\text{max}}$, $k_{\text{drawer}}^{\text{max}}$ and $k_{\text{varus}}^{\text{max}}$ are the maximum efficiency indexes of the compared set. In this case, the set comprised sleeves, hinged braces and rigid hinged orthoses; splints were not included because they aim at restraining all the degrees of freedom of the joint and their mechanical action is an order of magnitude higher.

Figure 10a shows some discrepancy within hinged braces; for instance, brace #3 is very efficient to prevent drawer while brace #1 is poorly efficient but has the advantage of not restraining flexion too much. Concerning rigid hinged orthoses (Figure 10b), the tested devices were relatively close to each other in terms of mechanical responses, although small differences may be noticed. Finally, Figure 10c highlights the specificities of each category. Sleeves did not restrict much the different motions. Hinged braces were efficient in restricting drawer but not varus and were stiffer to bend than rigid hinged orthoses. The latter were found to be the most efficient devices overall because they restricted drawer and varus motions while allowing flexion.

	Brace model	k_{flexion} (N·m/°)	k_{drawer} (N/mm)	k_{varus} (N·m/°)
Sleeves	#1	0.069 ± 0.003	1.78 ± 0.26	0.088 ± 0.004
	#2	0.051 ± 0.004	0.66 ± 0.20	0.069 ± 0.007
	#3	0.069 ± 0.002	0.94 ± 0.26	0.11 ± 0.01
	Mean	0.063 ± 0.009	1.13 ± 0.54	0.088 ± 0.017
Hinged braces	#1	0.13 ± 0.003	1.44 ± 0.24	0.40 ± 0.01
	#2	0.21 ± 0.005	2.16 ± 0.23	0.64 ± 0.02
	#3	0.16 ± 0.013	3.18 ± 0.36	0.46 ± 0.02
	Mean	0.17 ± 0.03	2.26 ± 0.77	0.50 ± 0.10
Rigid hinged orthoses	#1	0.11 ± 0.02	3.04 ± 0.64	1.84 ± 0.30
	#2	0.10 ± 0.01	2.83 ± 0.36	1.30 ± 0.12
	#3	0.07 ± 0.01	3.48 ± 0.83	1.57 ± 0.18
	Mean	0.094 ± 0.020	3.12 ± 0.69	1.57 ± 0.31
Splints	#1	2.58 ± 0.28	8.80 ± 1.41	2.63 ± 0.12
	#2	0.90 ± 0.13	4.45 ± 0.40	1.74 ± 0.06
	#3	0.93 ± 0.12	3.59 ± 0.49	1.64 ± 0.03
	Mean	1.47 ± 0.81	5.61 ± 2.45	2.00 ± 0.45

Table 4: Efficiency indexes of various commercial orthoses (values are reported as mean ± 90% confidence interval).

4. Discussion

4.1. FE modelling and model validation

The FE modelling approach developed within this study is an original attempt to investigate the link between a mechanical behaviour as measured on a surrogate testing device and the expected action in-vivo. Some limitations of this method have been identified and are discussed below, but they were taken into account and do not discredit the given results.

The predictions of the FE model of the brace were not perfectly accurate for flexion and drawer motions (Section 3.1). This was probably due to the formation of fabric creases that became apparent for flexion angles above 10° . These creases were not accurately reproduced numerically because no self-contact was defined on the fabric surfaces. This phenomenon can explain the higher experimental reaction moments in the second part of the flexion curves in Figure 6. Concerning the drawer motion, the discrepancy observed in the second part of the curves (Figure 6) was probably due to brace sliding at high displacements, and is characteristic of a stick-and-slip behaviour. It was not reproduced numerically; this is a very unstable and discontinuous phenomenon and even if it may be simulated with the Coulomb friction model by carefully adjusting the friction coefficient, it is complicated and not relevant.

The FE model of the deformable lower limb described in a previous study [15] was not strictly experimentally validated. Furthermore, it is morphologically accurate and representative of a median subject, but large morphological and mechanical discrepancies exist between individuals. Consequently, the computed responses may differ significantly from one subject to another. However, this model was not intended to be subject-specific, but to give a more realistic alternative to a rigid limb model with conical shapes in order to investigate the level of mechanical difference. It is presumably more representative of a real human limb than the machine developed for this study or other robotic devices presented in the literature. The comparison between this FE model and the rigid FE model of the test machine shows that the responses are correlated but not similar. Correction factors are not negligible, and mechanical responses previously identified with similar experimental devices may be overestimated. The difference in terms of mechanical behaviour may be explained by a more realistic mechanical representation (deformation of soft tissues, skin sliding) and an accurate morphology. These factors were characterised for hinged fabric braces, but as it was shown that they are independent of the tested brace design, they might be applied to responses of commercial orthoses as well.

4.2. Efficiency characterisation

The efficiency indexes were formulated in order to have a comparison tool to grade knee orthoses. Their values depend on the mechanical response of the brace and of the regression domains. Even if these domains were arbitrarily set to correspond to the linear parts of the curves, they are related to the mechanics of the knee joint. The rotation amplitude of a flexion motion during walking normally lies between 5 and 50° [16], the chosen domain (5 – 30°) is more limited but is still representative of this motion. It is worth noting that hinged orthoses or sleeves are not designed to modify the mechanical response of the flexion motion, but a stiffer flexion should cause discomfort and consequently influence the patient's compliance to the treatment.

Concerning the drawer motion, the domain 2 – 8 mm corresponds to the transition between low and high passive stiffness of the joint, as shown by Eagar et al. [29], explained by the tensioning of ligaments. A high rigidity is required from the orthotic device in this domain to compensate for deficient structures.

As for the varus motion, Markolf et al. [18] found that the transition between low and high passive stiffness was around 2.7° (at 20° knee flexion), and that sectioning the LCL increased this value to 3.6° . The selected domain (1 – 10°) is broader but the linear part starts at $\sim 1^\circ$, so the computed efficiency index is also valid for these domains. It is noteworthy that as most braces have a symmetric design and the test support is only slightly asymmetric, the characterized efficiency indexes for varus kinematics may also be valid for valgus kinematics.

One limitation of these indexes is that they do not take the initial forces/moments into account, yet these values are not negligible and may have an effect on joint stabilization. Large initial reaction forces applied by the orthoses were measured for the drawer motion (Figure 9), ranging from -5 to 5 N for hinged braces, -5 to 10 N for rigid hinged orthoses and 60 to 65 N for splints. Initial positive reaction forces would probably have the effect of decreasing strain in the ACL by displacing the lower limb with respect to the thigh at the cost of increasing strain in the PCL.

Another limitation of the efficiency indexes is that they account for pure passive mechanical stiffness of the orthoses, but do not take the active behaviour of the joint into account (joint stiffening by active muscular recruitment, as investigated by Wojtys et al. [30]), nor do they account for the comfort of these devices. This latter point is particularly important, as the therapeutic efficiency of knee orthoses strongly depends on the compliance to the treatment. For instance, rigid designs yielding high mechanical efficiency in varus-valgus (i.e. with a high varus efficiency index) are usually reported to apply medial/lateral compression forces to soft tissues, resulting in a poor compliance to the treatment. In that way, orthotic manufacturers should not rely only on the optimization of their designs in the unique goal of maximizing these indexes but should have a joined approach with clinical data and patients' overall feelings.

4.3. Recommendations for brace designs

A discussion on the different parameters and their effects is of interest. From Figure 8, some design recommendations may be given by observing the effect of different factors on the desired effect.

Optimized braces may be designed to prevent drawer laxity by increasing strap tightening and decreasing brace size (circumference), at the cost of possible tolerance issues for the patient; consequently, they must be adjusted with caution. On the other hand, it was found that the most influential factor to prevent varus-valgus laxity is increasing brace length. Helical straps also specifically help to prevent this motion. Adding silicon pads or a patella opening did not have a high influence, but once again they might have an effect on the brace comfort. Finally, an interesting result is the effect of removing the brace fabric, resulting in a brace composed of hinged bars and straps only. This brace allowed a much less constrained flexion movement, while having almost no impact on the drawer and varus stiffness. As it was reported that knee bracing may impair performance of athletes [31], such a design would yield better performances due to the lower flexion stiffness in cases where the compression effect of a fabric body is not required. Besides, most rigid hinged braces adopt this design.

Graphical representations of the measured motion restrictions as presented in Figure 10 are an efficient tool to objectively compare different braces and quickly select a device based on the desired therapeutic effects. Such charts could be completed by other kinematics such as the pivot shift test and updated by manufacturers with different products, providing a simple evaluation and selection tool for both orthotic clinicians and product designers.

4.4. Levels of mechanical actions

The characterised responses and indexes may be compared to previous studies. Liu et al. [12] experimentally tested 10 rigid hinged orthoses on a similar surrogate limb with a drawer motion. From their data, an average efficiency index of 11.3 N/mm (min: 5.1, max: 18.3) was found. Cawley et al. [10] did a similar study with the same type of orthoses but with a different surrogate limb design for drawer and valgus kinematics. For the drawer motions, their data lead to an average efficiency index of 5.6 N/mm (min: 3.0, max: 10.0); for the valgus motions, an average efficiency index of 1.07 N·m/° (min: 0.38, max: 2.05) was found. Even if the latter study exhibits results close to those found in the present work, they may hardly be compared because of the different set of orthoses and the different surrogate limbs; these values emphasize the fact that results depend on the testing apparatus. In this regard, the proposed approach consisting in a FE validation of the testing device with a standard reference limb is essential.

Secondly, the efficiency indexes may be compared to the stabilisation brought by internal structures of the knee joint under physiological loads with respect to the tested motions. Data provided by Eagar et al. [29] allowed to estimate the contribution of the ACL to the joint stiffness in response to a passive drawer. By comparing the mechanical response of intact and ACL-deficient knees, the equivalent efficiency index of the ACL was computed. It was found to be 3.8 ± 3.6 N/mm in the low stiffness region and 14.6 ± 6.0 N/mm in the high stiffness region. Applying the computed correction factor for this motion (0.75) on the most efficient orthosis in each category yield corrected indexes of 1.78 ± 0.33 ; 2.39 ± 0.55 ; 2.61 ± 0.82 ; 6.6 ± 1.5 N/mm respectively. Fabric hinged braces and rigid orthoses may effectively compensate for an ACL deficiency in the low stiffness region, i.e. before this structure is put in tension, but their contribution would be low in the high stiffness region. Similarly, Pierrat et al. [15] recommended an efficiency index of at least 8 N/mm to approach the stiffening effect of the ACL. Nevertheless, these devices may be effective to take the load off of the ligament for lower grade injuries (e.g. ACL partial tear). As for knee splints, they have a higher drawer efficiency index approaching the level of action of the ligament, meaning that they may then effectively compensate a complete ACL tear.

Concerning varus-valgus stability, Markolf et al. [18] found a varus stiffness of 1.1 ± 1.2 N·m/° in the low stiffness region and a terminal stiffness of 15 ± 5.7 N·m/° for intact joints. Once again, the characterised orthoses may bring a substantial stability to the joint for low torques, but they are largely outperformed by internal structures for high torques. The role of the surrogate limb could be extended to the testing of asymmetric corrective orthoses (such as off-loading braces for osteo-arthritis or corrective braces for genu varum or genu valgum) and provide objective gradings of their corrective ability based on measured torques for different varus-valgus positions.

5. Conclusion

An experimental surrogate lower limb has been developed in an attempt to standardise the evaluation of mechanical actions of knee orthoses. The motion restriction ability of the orthoses characterised by this phantom has been related to the corresponding expected in-vivo actions, showing that the levels of action that were previously measured using similar devices and reported in the literature may be overestimated. Objective efficiency evaluation indexes have been proposed and measured for various orthoses, giving useful directions to design devices targeted to particular pathologies. When comparing the stiffening effect of different categories of commercial orthoses to the structural role of internal stabilizing structures of the joint for physiological loads, it was found that current hinged orthoses may bring a substantial stability to the joint for low loads and help with lower grade injuries, but their contribution would be insufficient to effectively replace complete deficient structures in terms of passive stiffness. Finally, this mechanical characterization needs to be completed by understanding how other mechanisms such as proprioceptive action, localized structural unloading or muscle recruitment participate in the global stabilization effect and how they are affected by a brace.

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