Pneumatic Osteoarthritis Knee Brace

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Knee osteoarthritis is a chronic disease that necessitates long term therapeutic intervention. Biomechanical studies have demonstrated an improvement in the external adduction moment with application of a valgus knee brace. Despite being both efficacious and safe, due to their rigid frame and bulkiness, current designs of knee braces create discomfort and difficulties to patients during prolonged periods of application. Here we propose a novel design of a light osteoarthritis knee brace, which is made of soft conforming materials. Our design relies on a pneumatic leverage system, which, when pressurized, reduces the excessive loads predominantly affecting the medial compartment of the knee and eventually reverses the malalignment. Using a finite-element analysis, we show that with a moderate level of applied pressure, this pneumatic brace can, in theory, counterbalance a greater fraction of external adduction moment than the currently existing braces. [DOI: 10.1115/1.3072890]

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1 Introduction

Knee osteoarthritis (OA) is the most frequent cause of lower limb disability and affects approximately 30% of adults over 55 years of age, two-thirds of whom are women [1,2]. In the absence of a cure for the disease, current therapeutic modalities are primarily aimed at reducing pain and improving joint function by nonspecific symptomatic agents (such as non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesics), which are associated with high rates of adverse events [3–5]. In addition, these drugs rarely relieve symptoms completely [6]. Many individuals with knee OA will ultimately require total knee replacement, a procedure that is also not without inherent morbidity and cost [7]. Thus, there is the need to develop alternative, efficacious, nonpharmacologic, and nonsurgical treatment approaches that are capable of ameliorating the symptoms of OA.

The symptoms of knee OA are described as mechanical; that is, they occur with activity. Similarly, mechanical risk factors such as the external adduction moment and malalignment of the knee are the most potent risk factors for the disease progression. Attempts to ameliorate these factors in the knee with the use of braces have proven effective in relieving symptoms [8,9], and potentially may alter the course of the disease. Most OA unloader braces consist of a rigid design that increase the brace's bulk and potentially reduce comfort over more pliable materials. Giori [10] found that within 6 months, 20% of persons wearing braces had discontinued their use and further 29% stopped using them after 6 months. Of those who remained compliant, 73% wore the brace only intermittently. While OA is more common in women than in men, with a sex predisposition of 2:1 [11], brace prescription has, to date, been more frequent in men than in women. Most manufacturers suggest that sales of braces for knee OA are two times more frequent in men than in women. The return data from Generation II brace manufacturer demonstrates that even though fewer braces are sold for women (60% men, 40% women), the number of returns in women matches that in men. This may be due to concerns about style and the bulky nature of braces, which supports the theory that form (style of brace) may be as important as its function (efficacy) in determining adherence for braces in knee OA [12]. Our goal is to develop a novel knee brace that would overcome these fundamental limitations while still being effective at unloading the affected compartment of the knee.

1.1 Mechanical Causes of Knee OA and Valgus Bracing. The most influential factor affecting load distribution across the medial compartment is malalignment [13]. Any shift from the collinear alignment of the hip, knee, and ankle affects load distribution at the knee [14]. The loading axis is represented by a line that passes through the femoral head of the hip to the center of the ankle. In a varus deformed knee, this axis passes medially from the knee center, resulting in excessive adduction moments at the knee. This tends to force the leg into a "bow-legged" position, which increases medial compartment loading [13,15]. In a valgus deformed knee, the axis passes lateral to the knee center resulting in excessive abduction moments at the knee, which increase lateral compartment loading [15]. Varus and valgus misalignments have been shown to increase OA progression in the medial and lateral knee compartments [13].

The mean maximum magnitude of the adduction moment during normal gait is ~3.3% of bodyweight times height [16]. In patients with medial OA this moment increases to ~4.2% of bodyweight times height [16,17]. Thus, the excessive adduction moment is ~1% of bodyweight times height, which translates into 25% higher than normal values of the maximum reaction force on the medial compartment [17,18]. Prior studies suggest that the adduction moment and alignment of the lower extremity is linked to pain and functional decline [13,19]. A 20% increase in the peak adduction moment has been shown to increase the risk disease progression [20].

Valgus unloader braces, in theory, correct varus alignment by

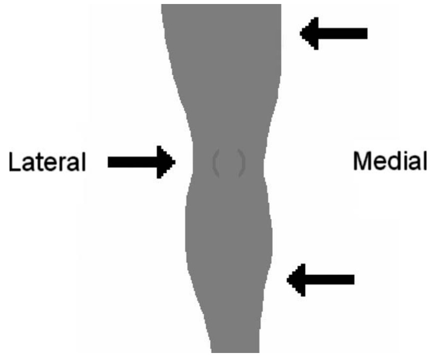

Fig. 1 A schematic depiction of the front view of the leg with a three-point-bending system of forces (arrows) applied by a brace to the knee. One of the forces acts at the lateral side and two at the medial side of the knee.

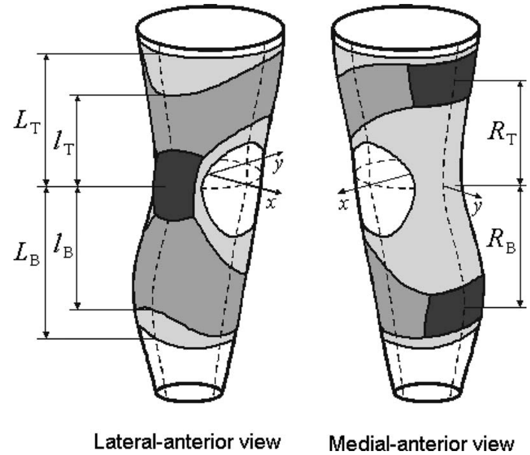

Fig. 2 The basic design of the pneumatic knee brace, which is comprised of a sock (light gray), a strap (medium gray), and three bladders (dark gray) attached to the strap. By inflating the bladders a three-point-bending system of forces is generated.

applying an opposing external valgus moment at the knee, which counteracts the adduction moment and attenuates medial compartment loading. Current brace designs consist of rigid upper and lower thermoplastic cuffs, hinged at the knee and fastened to the leg by straps. Medial unloading is provided by three-point leverage (Fig. 1), the upper and lower supports combined with the hinge account for two points of the leverage and an opposing force from a diagonal strap that crosses over the knee, which creates an abduction moment that "pushes" the knee into valgus [21]. A series of studies have demonstrated an improvement in many aspects of gait with valgus bracing in patients with varus knee OA. Lindenfeld et al. [22] demonstrated a 10% reduction in the external adduction moment with application of a valgus brace. Pollo et al. [23] demonstrated that valgus bracing reduced the net varus moment by an average of 13% and the estimated medial compartment load at the knee by an average of 11%.

The aim of this study is to develop a lightweight knee brace made of soft conforming materials. The three-point leverage is achieved using a novel pneumatic leverage system that, when pressurized, evokes a valgus correction, which reduces excessive medial compartment loading. Using a finite-element analysis, we hypothesize that with moderate amounts of pressure, the pneumatic brace can counterbalance a greater fraction of external adduction moment than the currently existing braces.

2 Materials and Methods

2.1 Design. The brace is conceptualized as a pneumatic device, similar to blood pressure cuffs, which, when inflated, would generate a system of forces at the knee that would counterbalance the excessive adduction moment (ΔM). ΔM is defined as the difference between the mean maximum magnitude of the adduction moment in subjects with medial OA and in normal subject. This difference equals $\sim 1\%$ of the bodyweight (W) times height (h), i.e., $\Delta M = 0.01 \; W \times h$.

The brace is comprised of three major components: a sock, three bladders, and a strap (Fig. 2). The sock is a tubelike component that conforms to the anatomy of the leg about the knee. It is made of a light elastic material (e.g., neoprene) and its purpose is to hold the brace in place via elasticity of the neoprene sock when worn over the knee. Three inflatable latex bladders are placed such that when inflated they create the three-point leverage system. The bladders are firmly attached to the inner side of the strap, and sandwiched between the neoprene sock and the strap, which goes around the knee (Fig. 2). For the model, it is assumed that all bladders are inflated to the same pressure. The strap is made of a light but sturdy fabric (e.g., nylon fabric). When the bladders are pressurized, they push against the leg and the strap. As a result, the strap becomes tensed. Together, tension in the strap and pressure in the bladders produce net force at each of the three strategic points of the knee, which create an abduction moment. Since the bladders are an integral part of the strap, and since the elastic modulus of the latex bladder is much smaller than that of the nylon fabric strap ($\sim 10^0$ MPa versus $\sim 10^3$ MPa) [24], we assume that the parts of the strap where the bladders are located have the same mechanical properties as the rest of the strap. In order to calculate a distribution of the applied stresses and the abduction moment at various levels of inflating pressure and to calculate stress and strain distributions within the brace, we use a finite-element analysis.

2.2 Finite Element Analysis. The leg-brace assemblage in Fig. 2 can be considered as a single mechanical system. For the model, it is assumed that brace materials and knee tissue have linearly elastic properties. However, strains of the brace (i.e., displacement gradients) due to inflation of the bladders are large and thus the whole assemblage represents a nonlinear mechanical system. The most common approach for solving complex nonlinear structural problems is to use a finite element analysis. Equilibrium configurations of the leg-brace assemblage when subjected to pressure loading due to bladder inflation can be calculated in an incremental-iterative scheme, as described below.

The pressure loading is increased incrementally. At equilibrium configurations, following discrete loading steps, finite element nodal forces generated by the stresses within the deformed material must balance external loading (i.e., pressure) of the structure. An incremental-iterative equilibrium equation for a finite element can be written as follows [25]:

$$({}^{n+1}\mathbf{K}_{\mathrm{L}} + {}^{n+1}\mathbf{K}_{\mathrm{NL}})^{(i-1)}\Delta\mathbf{U}^{(i)} = {}^{n+1}\mathbf{F}^{\mathrm{ext}} - {}^{n+1}\mathbf{F}_{\mathrm{int}}^{(i-1)} \tag{1}$$

where ${}^{n+1}\mathbf{K}_{\mathrm{L}}$ and ${}^{n+1}\mathbf{K}_{\mathrm{NL}}$ are linear and nonlinear element stiffness matrices, respectively; $\Delta\mathbf{U}^{(i)}$ is the incremental nodal displacements vector; and ${}^{n+1}\mathbf{F}^{\mathrm{ext}}$ and ${}^{n+1}\mathbf{F}_{\mathrm{int}}^{(i-1)}$ are the external and internal nodal forces, respectively; superscript $n+1$ denotes the end of a load step (n=step number) and superscript i is the iteration counter for the equilibrium iterations within the current time step. Iterations are terminated when the unbalanced forces on the right-hand side of Eq. (1), for the assemblage of the finite elements is small enough (within a numerical tolerance).

In general, the stiffness matrices can be expressed as follows:

$$ {}^{n+1}\mathbf{K}_{\mathrm{L}} = \int_{{}^{n+1}V} {}^{n+1}\mathbf{B}_{\mathrm{L}}^{T\,n+1}\mathbf{C}\; {}^{n+1}\mathbf{B}_{\mathrm{L}} dV \quad \text{and} \tag{2}$$

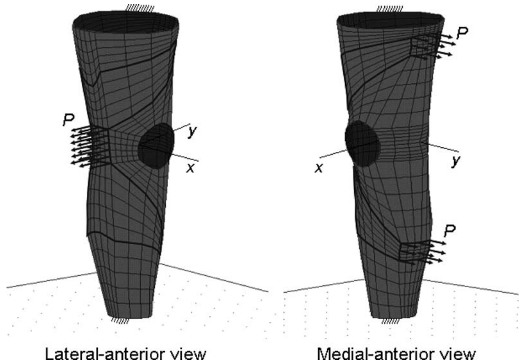

Fig. 3 Lateral-anterior view (left) and medial-anterior view (right) of the finite-element model of a leg-brace assemblage totally constrained at top and bottom. Lateral and medial bladders are loaded by pressure (*P*). Heavy black lines indicate contours of the strap and the bladders.

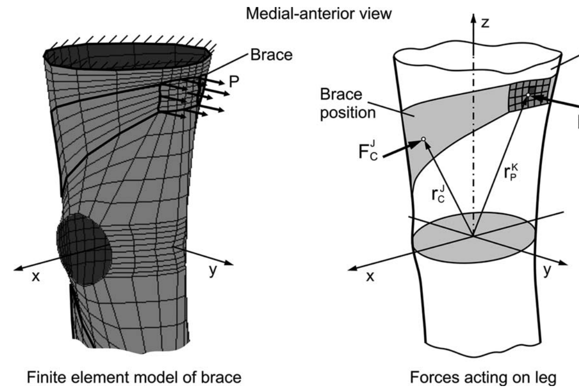

Fig. 4 Left: inflating pressure (*P*) produces abduction moment (*M*) around the *x*-axis. Right: The moment is calculated as a crossproduct between the radius vectors (r_P^K and r_C^J) and corresponding forces acting on the leg (Eq. (6)), including the proximal medial bladder nodal force F_P^K, calculated as the sum of the surface integrals of pressure *P* over the bladder area (Eq. (5)), and the brace-leg contact forces F_C^J, calculated at all contact nodes as forces in fictive trusses.

$$^{n+1}\mathbf{K}_{\mathrm{NL}} = \int_{^{n+1}V} {}^{n+1}\mathbf{B}_{\mathrm{NL}}^{T}\, {}^{n+1}\hat{\boldsymbol{\sigma}}\, {}^{n+1}\mathbf{B}_{\mathrm{NL}} dV$$

where $^{n+1}\mathbf{B}_{\mathrm{L}}$ and $^{n+1}\mathbf{B}_{\mathrm{NL}}$ are the linear and the nonlinear strain-displacement matrices, respectively, $^{n+1}\mathbf{C}$ is the constitutive matrix representing the stress-strain relationship, $^{n+1}\hat{\boldsymbol{\sigma}}$ is the stress matrix, and ^{n+1}V is the volume of the finite element. These matrices change over iterations.

The internal force vector can be expressed as follows:

$$^{n+1}\mathbf{F}_{\mathrm{int}}^{(i-1)} = \int_{^{n+1}V^{(i-1)}} {}^{n+1}\mathbf{B}^{(i-1)T}\, {}^{n+1}\boldsymbol{\sigma}^{(i-1)} dV \tag{3}$$

where $^{n+1}\boldsymbol{\sigma}^{(i-1)}$ is the vector of stresses (Cauchy stresses) corresponding to strains $^{n+1}\mathbf{e}^{(i-1)}$ at a material point.

The constitutive matrix is calculated as follows:

$$^{n+1}\mathbf{C}^{(i-1)} = \frac{\partial\ {}^{n+1}\boldsymbol{\sigma}^{(i-1)}}{\partial\ {}^{n+1}\mathbf{e}^{(i-1)}} \tag{4}$$

Since we assume linearly elastic materials, the constitutive matrix is represented by the elastic matrix $\mathbf{C}^E$ for each material component of the brace.

Using specially developed software (pre- and postprocessors for the solver PSA, Ref. [26]), the finite-element model of the OA brace is parametrically generated (Fig. 3). All three parts of the brace (sock, strap, and bladders) are modeled using four-node shell elements with linear material characteristics.

The boundary conditions for the computational model are as follows. It is assumed that the top and the bottom end of the brace do not move relative to the leg in order to maintain stability of the leg-brace system; hence the top and bottom nodes of the brace are constrained. Since the sock material is relatively soft in comparison with the other components of the assembly, these constraints do not affect overall brace stiffness and the mechanical response of the model. The contact between the leg and the brace is modeled using fictive trusses normal to the leg at all shell nodes. The boundary at the brace-leg interface is assumed to be rigid in order to prevent the brace to move perpendicularly toward the leg. The brace is allowed to slide relative to the leg surface and the contact between the brace and the leg is assumed to be frictionless. The mechanical action of the pressure within the bladder on the brace is modeled by applying distributed uniform surface loading to the inner wall of shell elements (Fig. 3).

A nonlinear finite-element analysis is performed using the PSA finite-element solver [26]. Forces acting on the leg are calculated as a part of the result postprocessing. These forces are separated into two groups: forces from inflating pressure (P) of the bladders and contact forces between the brace and the leg. The net pressure force $\mathbf{F}_P$ at one bladder is obtained as follows:

$$\mathbf{F}_P = P\sum_e \int_{A^e} \mathbf{n} dA = P\sum_e \sum_K \int_{A^e} N_K^e \mathbf{n} dA = \sum_K \mathbf{F}_P^K \tag{5}$$

where $\mathbf{n}$ is the normal vector to the shell surface, N_K^e and A^e are the interpolation functions and the surface area for the eth element, respectively, and $\mathbf{F}_P^K$ is the shell nodal force at the Kth node due to P; the summations over e and K are performed over all shell elements and shell nodes of the bladder, respectively. The contact forces represent the forces in the fictitious trusses ($\mathbf{F}_C^J$ for the Jth truss). The pressure and contact forces are evaluated for each loading step.

The abduction moment (M) due to action of the brace on the leg is determined by calculating moments of all forces from one side of the mid xy-plane of the knee, with respect to the x-axis (Fig. 4)

$$M = \sum_K (y_K F_{Pz}^K - z_K F_{Py}^K) + \sum_J (y_J F_{Cz}^J - z_J F_{Cy}^J) \tag{6}$$

where y_K and z_K are the coordinates of shell nodal points of the bladder finite-element model, and F_{Py}^K and F_{Pz}^K are components of the pressure nodal force $\mathbf{F}_P^K$; y_J and z_J are coordinates of the point of action of the contact force $\mathbf{F}_C^J$ (with components F_{Cy}^J and F_{Cz}^J); the position vectors of points where the forces $\mathbf{F}_P^K$ and $\mathbf{F}_C^J$ are acting are $\mathbf{r}_P^K$ and $\mathbf{r}_C^J$, respectively (see Fig. 4). The first sum includes all nodal points of the bladder model and the second sum is over trusses in the domain $z>0$.

We first calculate M that pushes the knee into valgus. Calculations are carried out for different levels of P, ranging from 0 kPa to 48 kPa, in ten equal increments of 4.8 kPa, for different values of geometrical parameters (L_B, l_T, l_B, R_T, and R_B—see Fig. 2, and medial bladder sizes), for different values of the elastic moduli of the strap (E_{strap}) and sock (E_{sock}), for fixed values of L_T=20 cm, for fixed dimension of the lateral bladder 6×6 cm^2, and for fixed values of Poisson's ratios of the strap ν_{strap}=0.3 and of the sock ν_{sock}=0.43. This range of P is chosen considering that pressures applied by the brace on the leg should not have a negative effect on the blood circulation through the leg nor should they produce pain and discomfort. Values of E_{strap}, E_{sock}, and ν_{sock} are selected based on the elastic properties of nylon and neoprene [24],

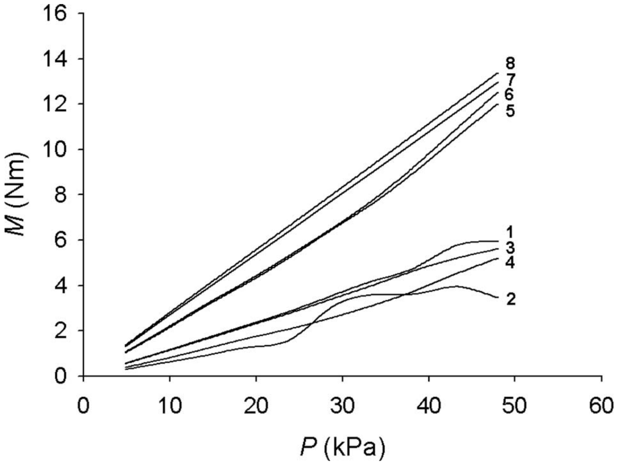

Fig. 5 Unloading abduction moment (*M*) versus bladder pressure (*P*) relationships predicted by the finite-element model for different sets of parameter values; numbers 1–8 correspond to the cases 1–8 given in Table 1.

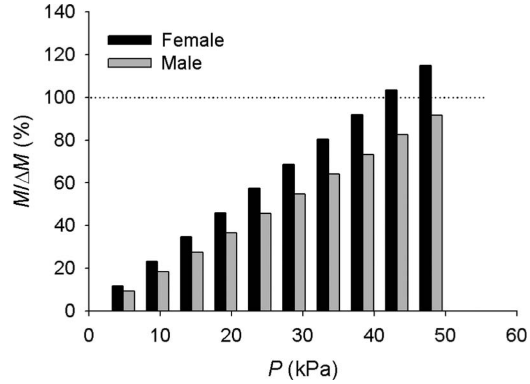

Fig. 6 Unloading moment of the brace (*M*) as a fraction of the excessive adduction moment (ΔM) for human female and male patients, for different levels of inflating bladder pressure (*P*). *M* corresponds to the curve No. 8 from Fig. 5. ΔM is calculated from the anatomical data from the literature: for females $\Delta M = 11.65$ N m, and for males $\Delta M = 14.61$ N m. In the case of female patients, the *M* can completely counterbalance ΔM within the given range of *P*.

whereas the value for ν_{strap} is selected ad hoc; numerical simulation show that M is little sensitive to changes in ν_{strap} and ν_{sock} in the given ranges of P and of the geometric parameters.

3 Results

We obtain that, in general, M increases with increasing P (Fig. 5). This relationship is primarily dependent on the size of the medial bladders and the distance between the bladders and to a lesser extent on the elastic properties of the brace materials (Fig. 5). The results obtained for different values of E_{strap} and E_{sock} and for different geometrical parameters are given in Table 1 for the maximal value of inflating pressure of $P=48$ kPa.

To show that the brace can counterbalance the excessive adduction moment ΔM, we calculate ΔM in female and male patients based on anatomical data from the literature [27]. For ~45 old women (average $W=72.4$ kg, $h=164.1$ cm), $\Delta M=11.65$ N m and for ~45 old men (average $W=84.6$ kg, $h=176$ cm), $\Delta M = 14.61$ N m. By normalizing M obtained from the finite-element model with these values of ΔM, we show that the brace can completely counterbalance ΔM in women and ~90% of ΔM in men (Fig. 6).

We also calculate displacement, strain, and shear stress distributions in the brace, as well as the pressure distribution that the brace exerts on the knee. By displacement we mean a change in position of different points on the brace at different steps of inflation relative to the uninflated state. We find that displacements and strains are largest near the top medial bladder, mainly due to deformation caused by inflation of the bladder. Strains are largest in the sock and smallest in the strap. Shear stress and pressure are largest in the bladder region and shear stresses are primarily carried by the strap. The difference in the strain and stress distributions between the sock and the strap reflects the difference in their material properties. The elastic modulus of the sock is three orders of magnitude smaller than that of the strap (10^0 versus 10^3 MPa). Thus, the sock easily deforms while the strap undergoes very little deformation. Consequently, the stresses generated in the sock are much smaller than the stresses generated in the strap. Importantly, calculated stresses are much smaller than the tensile strength limit of the proposed brace materials.

There are several "hot spots" located on the lateral side of the knee, at the borderline between the strap and the sock, where the pressure (P_{max}) exceeds the inflating pressure by nearly a factor of two (Table 1). This is a concern since those high pressure regions may inflict discomfort and hamper local blood circulation. A possible measure that could reduce the pressure at the hot spots is to change the elastic properties of the strap and the sock. For example, if the elastic modulus of the strap is reduced from 5000 MPa to 3000 MPa and the elastic modulus of the sock increases from 1 MPa to 3 MPa, the pressure at the hot spots is reduced by ~33%.

4 Discussion

The most significant result of this study is that the pneumatic knee brace design made of soft materials can counterbalance the

Table 1 Results obtained from testing the brace using different parameter values (left portion of the table): L_B, l_T, l_B, R_T, R_B (indicated in Fig. 2), medial bladder (Bl. med.) dimensions, and elastic modulus of the strap (E_{strap}) and of the sock (E_{sock}). Predicted values (right portion of the table) are given for inflating pressure of 0.048 MPa, including the unloading moment (*M*), maximal pressure (P_{max}) at the hot spots, maximal shear stress (τ_{max}), maximal strain (ε_{max}), and maximal displacement (d_{max}).

Test No.	L_B (cm)	l_T (cm)	l_B (cm)	R_T (cm)	R_B (cm)	Bl. med. (cm)	E_{strap} (MPa)	E_{sock} (MPa)	M (N m)	P_{max} (MPa)	τ_{max} (MPa)	ε_{max} (%)	d_{max} (cm)
1	30	10	15	16.5	18.5	6×3	5000	1	5.94	0.092	11	27	0.56
2	30	10	15	13	15	6×3	5000	1	3.46	0.08	11	12	0.8
3	25	10	15	16.5	18.5	6×3	5000	1	5.62	0.095	11	27	0.53
4	30	15	20	16.5	18.5	6×3	5000	1	5.21	0.076	10.2	14	0.39
5	30	10	15	16.5	18.5	6×6	5000	1	12.02	0.12	13	40	0.78
6	30	10	15	16.5	18.5	6×6	3000	1	12.54	0.11	11.2	47	0.94
7	30	10	15	16.5	18.5	6×6	3000	3	12.97	0.08	8	17	0.21
8	25	10	15	16.5	18.5	6×6	3000	3	13.39	0.1	8.8	15	0.21

negative influence of the adduction moment and thus alleviate its negative influence on the progression of OA. The finite-element analysis shows that brace is capable of unloading 90–100% of the excessive adduction moment. While this is a much greater fraction of the adduction moment than what is obtained from experimental testing of the existing rigid-frame braces (10–13%) [22,23], it should be taken into consideration that the modeling results are based on some crude approximations and assumptions that are addressed below.

In this study we use the mean peak adduction moment as a criterion for identifying whether adduction moment reductions are obtained with our brace design. The mean peak adduction moment was previously used as a measure of mechanical loading of the knee during gait [16]. However this measure does not reflect how the adduction moment changes during stance, where it normally exhibits a biphasic behavior [17,28], and further it is not clear what aspect of this behavior provides the best reflection of mechanical loading during gait.

A critical evaluation of key modeling assumptions is appropriate. We assume that the top and bottom ends of the brace do not move relative to the leg (i.e., the length of the brace remains constant during inflation). This implies that the contact forces at the brace-leg interface at the top and bottom are sufficiently large to prevent a motion of the brace relative to the leg. In reality, brace migration is common and patients must repeatedly adjust the straps and reposition the brace throughout the day. For example, the net force in the strap would tend to bring the medial bladders closer to each other, causing sliding of the brace relative to the knee and effectively shortening the brace. This, in turn, would reduce the moment arm and thereby M would decrease. One measure to offset this effect is to insert flexible bars along the medial part of the brace, as in prophylactic type braces, that would tend to keep the medial bladders equidistant. Another measure is to increase the contact forces at the top and the bottom of the brace by additional straps around the leg.

We also assume that during inflation the contact area between bladders and the leg remains unaltered. In reality, this is not the case since during inflation the bladders tend to round up, which would cause the contact area to decrease. This would cause the pressure on the knee to be transmitted over a smaller area, which would mean a smaller net force exerted by the bladders on the knee and thereby a smaller M.

Another assumption is that the leg surface is regarded as a rigid body. However, the tissue around the knee is deformable, which would affect stress and strain distributions in the brace as well as M. For example, during inflation bulging bladders will push into compliant leg tissue thereby increasing the contact area between the bladders and the leg surface. This would cause an increase in force that inflating pressure exerts on the knee and thereby an increase in M. On the other hand, the compliant tissue would offer less resistance to tension in the strap that would tend to pull the bladders closer together. As a result, the distance between the bladders and thereby the moment arm will decrease, which would cause M to decrease.

The brace finite-element model considers only static loading in a fully extended knee. However, the knee undergoes dynamic loading and flexing, which would certainly alter the load distribution and M. Experimental studies on a prototype of a pneumatic knee brace would be an ultimate test of the appropriateness of using this type of brace as a countermeasure against OA.

As a result of the progression of OA, the knee joint space becomes narrowed and more lax than normal [29–31]. Furthermore, mechanical properties of cartilage and ligaments of the joint become altered. Together, these factors influence mechanical resistance of the knee to adduction moment. However, these considerations are beyond the scope of this study.

In summary, our model has demonstrated the feasibility of developing a light pneumatic knee brace, made of soft materials, which could effectively replace the existing bulky rigid-frame knee braces. The finite-element analysis shows that with moderate inflating pressures, our pneumatic brace design can produce an unloading moment that could completely counterbalance the negative effect of the adduction moment in a fully extended varus knee.

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