Technical note

Preliminary study on a novel minimally invasive extra-articular implant for unicompartmental knee osteoarthritis

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ABSTRACT

The purpose of this research was to study the efficacy of a novel implant for osteoarthritic knees. This implant is designed to eliminate excessive loads through the knee and to provide suitable conditions for possible tibiofemoral cartilage repair. The implant was designed for the medial side of the knee joint. Finite Element Analysis (FEA) was performed for an extended knee position of the knee joint. Von Mises stress and contact pressure distributions on the medial and lateral compartments were investigated as well as stress distributions throughout the implant's plates. Comparison of FEA results with and without the implant showed that the maximum von Mises stress and contact pressure experienced by the femoral cartilage were reduced by 40% and 35%, respectively, after introducing the implant. Furthermore, after attaching the implant, the femur was slightly abducted and more stress and pressure were perceived in the lateral compartment compared to the model without implant. The maximum von Mises stress in the implant (96 MPa) was far lower than the yield strength of Ti–6Al–4V (∼900 MPa), the selected material for manufacturing the implant. According to the above points, this initial study shows promise for the new prosthesis.

1. Introduction

Osteoarthritis (OA) is the most common form of arthritis; it is one of the main causes of musculoskeletal impairments in elderly people [1,2]. Researchers at the World Health Organization (WHO) expected that OA will be the fourth most common reason for physical disability by 2020 [3]. There is no cure for this progressive degenerative disease; however, there are many different kinds of treatment for OA, which normally target symptom amelioration and knee performance improvement [4]. Therapies comprise conservative methods, such as medications, braces, exercises, physical therapy; and also invasive surgical methods, such as High Tibial Osteotomy (HTO), and the most frequent one: Total Knee Arthroplasty (TKA) [5]. Conservative treatments are recommended for mild to moderate stages of OA, and TKA is the general therapy for the latter, severe, stages of this disease [6]. Evidently, by increasing the number of TKA, the rate of implant-revision will also increase. Projections depict that in the US the overall number of TKAs and revisions will be around 1.5 million and 125 thousand, respectively, in 2020 [7].

Most patients with knee osteoarthritis undergo TKA eventually, and the main reason for use of other methods, specifically in young patients, is to postpone this last resort (an invasive TKA operation) [8]. It should be noted that TKA is largely recommended for elderly people (>65 years old); however, research shows that more than 40% of TKAs have been performed before this age [4,9]. One problem is that even patients with severe symptoms of OA are not willing to undergo a joint arthroplasty operation, and they prefer to wait as long as is possible before undergoing this invasive surgery [10]. Accordingly, there is a gap between conservative and invasive therapies, particularly in the case of younger patients and those with early-onset knee OA; despite the many conservative treatments, many young patients suffer years of pain until they become qualified (>65 years old) for a TKA operation, although some less invasive surgeries such as HTO or Unicompartmental Knee Arthroplasty (UKA) can be useful for such patients in the meantime, depending on the condition of their disease [11]. Moreover, the average lifespan of TKA implants is about 15 years and, after that, revision operation is very often required [12]. The higher cost, difficulty, and complexity of revision surgery should also be taken into account before any decision is made to proceed by the surgeon and patient [10,13–17].

A number of efforts have been made with the aim of introducing new techniques to fill the aforementioned gap between

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conservative and invasive therapies. One of these is the Kine-Spring® (Moximed), an extra-capsular implant, which acts as a joint-unloader for unicompartmental knee osteoarthritis [10,18]. The KineSpring attaches to the femur and tibia and utilises a mechanism similar to a shock absorber, and is capable of unloading 13 kg of knee joint load [19]. An in vitro study reported that all tested samples survived 10 million cycles of fatigue loading without any sign of plastic deformation or cracking [16]. The initial clinical studies for the KineSpring appeared promising. For instance, Miller et al. [2], after a 2-year pilot study, reported that according to the preliminary evidences, KineSpring could affect knee OA, in terms of pain reduction and joint performance improvement by increasing the joint space width. However, some patients treated with this implant have faced significant adverse events after treatment, leading to implant-removal and necessitating further therapies to solve the generated issues [8,9,20,21].

It should also be mentioned here that, in treating OA for young patients, much effort has been made to repair focal lesions in cartilage and the menisci, without addressing the underlying etiology. Therefore, it seems that those programs have not been successful in halting the progression of OA because of the existence of an aberrant environment or biomechanical heterogeneity [6,7,22]. Excessive loading results in cartilage degeneration in certain areas [6]. Hence, before making any attempt to repair or regenerate tissue, a first-line therapy would address the deleterious extra loading at the knee joint. In other words, abnormal loading and uneven stress distribution can be considered to be one of the major reasons for osteoarthritis progression [3,6,23,24]. The main treatment for eliminating extra joint loading in order to treat degenerative arthropathies such as osteoarthritis is joint distraction, an invasive surgical technique, enabling intrinsic joint tissue repair. In this treatment, two surfaces of the joint (knee, hip or ankle) are separated using an external frame for a specific period of time [25]. Note, however, that this treatment is not yet a widespread clinical practice as more evidence is still required to attest to its efficacy before it can be adopted as a mainstream treatment.

To the best of our knowledge, no intra-capsular load sharing implant for osteoarthritic knees has been proposed or developed to date, and the implant designed and examined in this initial study would serve as a bridge-treatment between noninvasive and invasive therapies. The implant targets early-to-moderate grades of OA and might specifically be appropriate for younger patients. In fact, the proposed implant operates as a partially unloading device and has been designed in such a way so as not to affect the natural movement of the knee. The main aim of this new implant would be to remove excessive load from the knee and so slow progression of OA, creating a suitable environment in which osteoarthritic lesions might be repaired. Moreover, it might be applied as an adjuvant treatment with other therapies. The current paper presents a preliminary structural analysis of this novel minimally invasive implant for unicompartmental knee osteoarthritis.

2. Materials and methods

The extra-articular implant discussed in this paper was designed to remove the excessive load in the medial compartment, because that side bears 60–80% of the overall load experienced by the knee joint during gait [26,27]. The main components of the implant are: a femoral plate which attaches to the medial side of the femur and a tibial plate which attaches to medial side of the tibia. These plates act as a load transmission medium between the distal femur and proximal tibia. The transmitted load distributes over the articulating surfaces between the plates, where the plate-surfaces slide over each other.

The knee model that was used for this study was developed by Wangerin [28], and is publicly available in the biomedical repository at Simtk.org. Wangerin's model is based on one of the most accurate publicly available knee models, from the Open Knee project [29]. Note that the stance phase only of this model is used here, and the boundary conditions and material properties have been altered. The knee model was imported into SolidWorks® (Dassault Systemes) and the curvature and contact surface profiles of the implant were designed to closely follow the curvature of the bone surfaces and edges. Several holes were incorporated into both parts of the implant to reduce overall weight and to help prevent the possibility of bone or tissue necrosis around the implant [30]. A larger hole in the femoral plate was also incorporated in order to accommodate the Medial Collateral Ligament (MCL). One of the most widely used materials for knee and hip implants is titanium alloy (Ti6Al4V), which was also selected for finite element analysis of this implant [12,31]. Other types of material are used for implants, such as cobalt chromium alloy. However, for this study, titanium was selected, as its Young's modulus is lower than that of cobalt chromium, so it reduces the possibility of bone resorption [32]. Although titanium alloy was selected, cobalt chromium is another option. Note that optimum material selection for the implant is not part of the scope of the particular research reported in this paper. Another, separate, large-scale parallel study into implant component tribological properties and material selection is underway. A change to the particular material chosen in this study (titanium), to some similar conventional implant bearing material, will not greatly affect the main outcomes reported here.

This implant can easily be designed on the surfaces of MRI-scanned bones, thus it can be considered to be a patient-specific implant. A prototype of the implant was produced by additive manufacturing (selective laser sintering), which may well be the best method of manufacture for this implant (ongoing research is investigating this aspect further). Other manufacturing techniques which could be used to produce this implant include machining, investment casting, and forging [33,34]. The assembled implant attached to the 3D-printed bones is illustrated in Fig. 1(a).

A static Finite Element Analysis (FEA) was conducted in Abaqus®/standard (Simulia) for the extended knee position, before and after attaching the implant, in order to evaluate the stress distribution on the tibiofemoral interfaces, particularly on the medial side. A homogeneous linear elastic material model was developed for cortical bone with a Young's modulus of 17 GPa and a Poisson's ratio of 0.33 as well as for cancellous bone with a Young's modulus of 0.4 GPa and a Poisson's ratio of 0.33 [36]. The cartilage was assumed to be an isotropic elastic material with a Young's modulus of 10 MPa and a Poisson's ratio of 0.45 [37]. The meniscus was modelled as a transversely isotropic, linear elastic material based on the collagen fibre directions of menisci.

For menisci, the Young's moduli in the circumferential (E_θ), radial (E_R), and axial (E_Z) directions were 125, 27.5, and 27.5 MPa, respectively [36]. The Poisson's ratios for menisci were 0.1 ($\nu_{\theta R}$), 0.1 ($\nu_{\theta Z}$), and 0.33 (ν_{RZ}), and the shear moduli ($G_{\theta R}$ and $G_{\theta Z}$) were 2.0 MPa [36]. All ligaments were assumed to be hyperelastic and their stress–strain relationship was obtained from Mesfar and Shirazi-Adl [38]. Hyperelastic model constants were automatically calculated by Abaqus using input uniaxial tensile test data [37]. For the implant material, a linear elastic model was developed for titanium with a Young's modulus of 110 GPa and a Poisson's ratio of 0.3 [31,32].

According to the study by Wan et al. [39], use of the 10-node quadratic tetrahedral element (i.e., C3D10 element type) is a proper element choice for the calculation of mechanical response and stress in this model. The comprehensive Finite Element knee model that was used in this study is shown in Fig. 2.

The number of elements for each part of the model is listed in Table 1. A mesh sensitivity analysis with finer mesh sizes was also conducted; this showed that finer meshes with more elements
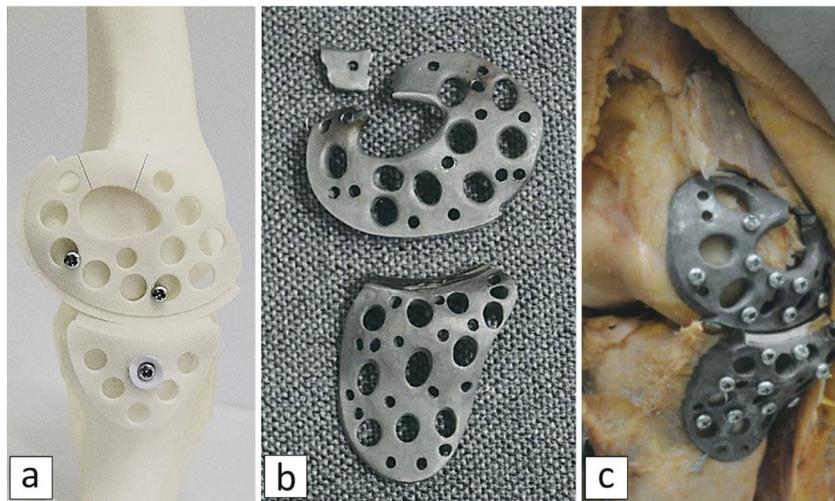
Fig. 1. (a) A prototype of the implant at the medial side of the knee, (b) prototype of the knee implant [35], (c) cadaver knee with attached implant [35].
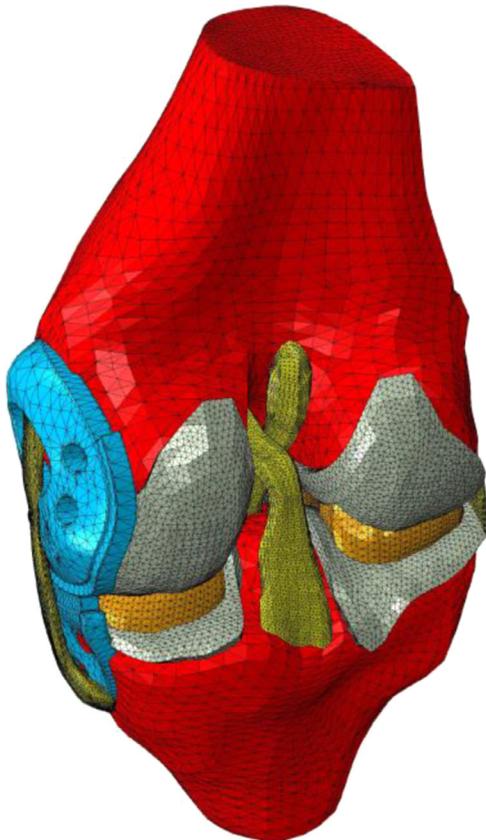

Fig. 2. Posterior view of the finite element knee model including the implant.

Table 1
Number of elements for the knee model.

Component	Number of elements
Femur	63,604
Tibia	54,584
Femoral cartilage	132,345
Tibial cartilages	44,034
Meniscus	30,328
ACL	38,604
PCL	48,794
MCL	72,908
LCL	21,094

than that listed in Table 1 increases the computation time significantly without improving the accuracy of the results.

The cross-sectional area of the femur was measured in Solid-Works and, based on that, a distributed force of 400 N (half of the body weight) was applied on top of the femur [40]. All degrees of freedom at the base of the tibia were constrained and, for the femur, transverse movements along the Y (sagittal plane) and Z (coronal plane) axes were constrained. The detailed mechanism by which the implant is fixated to the bones, e.g., with pins, screws, etc., is not a main aspect of the present study. As this is a novel implant, fixation techniques will be developed for it at a later stage. In order to keep the present model simple, both plates were tied to the bones (when surfaces or elements tie to each other, they connect together firmly to avoid any separation or sliding).

Model results were compared with those for the case of no-implant, in order to study the efficacy of the implant: stress and contact pressure distributions of femoral cartilage were investigated in the model with and without the implant. Results of this study were compared to the results of research conducted by Wang et al. [37] and Thambyah [41] for validation.

3. Results

Results for von Mises stress distributions on the cartilages (medial and lateral compartments) are illustrated in Fig. 3(a) (without implant) and 3b (with implant), respectively. As observed in Fig. 3(a), the maximum von Mises stresses at the medial and lateral compartments, in the absence of the implant, were 1.44e+00 MPa and 9.88e−01 MPa, respectively. After unloading the knee with the implant, the maximum stresses at the medial and lateral sides decreased to 8.58e−01 MPa and 1.02e+00 MPa, respectively, as shown in Fig. 3(b).

Contact pressure distributions on the surfaces of the femoral cartilage before and after attachment of the implant are depicted in Fig. 4(a) and (b), respectively. According to these pressure contours, the peak pressures without the implant at the medial and lateral sides were 2.36e+00 MPa and 2.48e+00 MPa, respectively. The peak pressures in the knee with implant at the medial and lateral compartments were 1.60e+00 MPa and 2.72e+00 MPa, respectively.

Von Mises stress distributions in the femoral and tibial implants are shown in Fig. 5. The maximum stress observed was approximately 9.58e+01 MPa at the contact surfaces between the two plates on the anterior side.
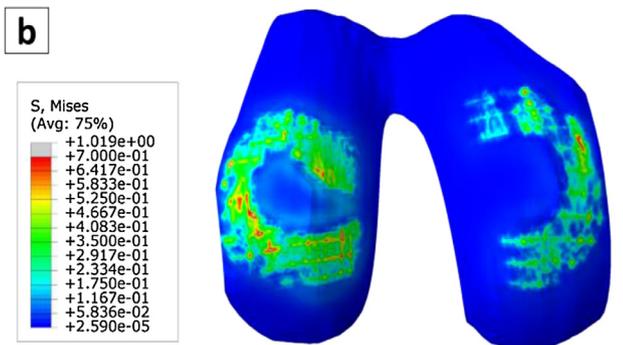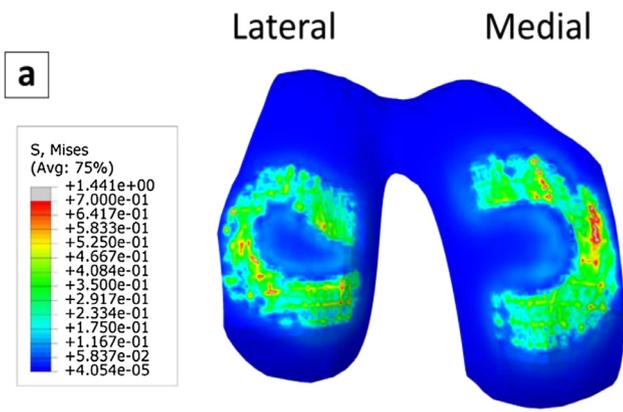
Fig. 5. Von Mises stress distributions of femoral and tibial implant-plates.

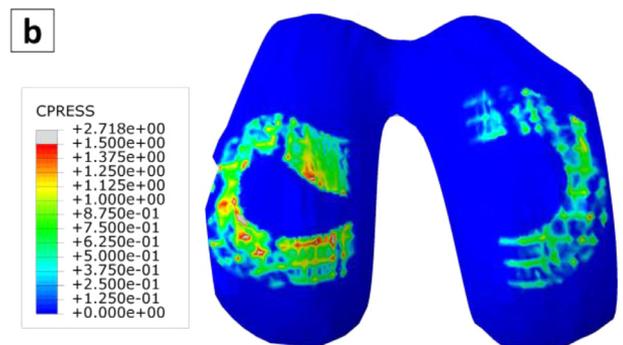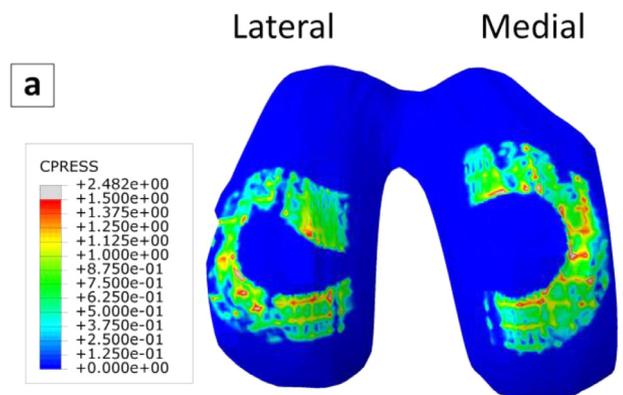**Fig. 3.** Stress distributions within femoral cartilage, (a) without implant, (b) with implant.

Fig. 4. Distributions of contact pressure on the surface of the femoral cartilage, (a) without implant, (b) with implant.
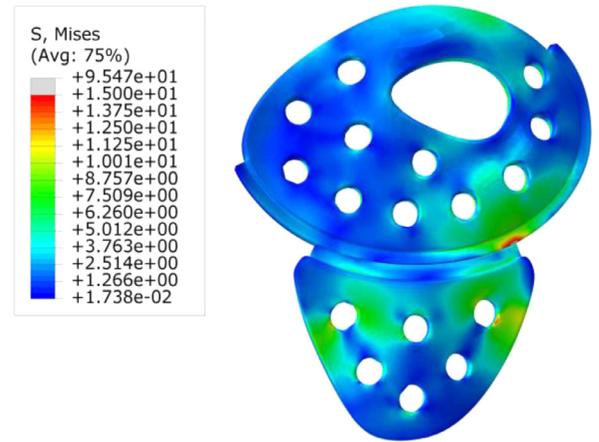
4. Discussion

The primary aim in any OA therapy is preventing its progression. Studies have confirmed the influence of mechanical unloading on prevention of osteoarthritis advancement [3]. Moreover, unloading osteoarthritic knee joints alleviates pain and provides a proper condition for tissue repair. The clinical benefits of cartilage repair were seen to remain in most patients even after a five-year follow-up [7]. Steadman et al. [22] studied the influence of unloading braces on knee OA, and reported that these braces were effective for treatment of unicompartmental knee OA. Cheong and Kelly [35] carried some basic experiments on cadaver knees in order to study the overall performances of the proposed implant, such as range of motion, attachment method, and simplicity of implant insertion. The prototype of the implant that was used in that research is reproduced here in Fig. 1(b).

After attachment of the implant by a knee surgeon, Cheong and Kelly reported that the implant did not appear to affect the soft tissue around the implant, the collateral ligament was left intact and the articular cartilage was not damaged [35]. In terms of motion, it was observed that the plates were able to slide over one another without any hindrance and that the implant does not affect the range of motion during flexion and extension. It was also reported that the articulating surfaces remained in contact even during complete flexion. Importantly, the articulating surfaces did not dislocate and they remained in contact during the knee movement [35]. This is a patient specific implant and its thickness would be different for each patient. In the case where there is an insufficient gap between the MCL and bones, a thin layer of the bone surface would be removed in order to prevent stretching of the MCL. However, further studies need to be performed to investigate the possibility of knee laxity upon removal of the implant. The implant as attached to the cadaver knee is depicted in Fig. 1(c).

By comparing the results of the extended knee position model of the current study, before and after implementing the implant, the von Mises stresses were clearly seen to decline in the medial compartment after applying the implant. Indeed, the maximum stress was reduced by 40% in the medial side, while stress in the lateral side increased slightly. Further, the maximum contact pressures on the distal femoral surface declined by 35% at the medial side, while contact pressure in the lateral side was slightly increased. Clearly, because of attaching the implant to the medial side, unloading the joint was observed at this compartment, for both von Mises stress and contact pressure. Accordingly, this implant could be considered for unicompartmental knee OA.

As mentioned, after implementing the implant the maximum stress and contact pressure in the lateral compartment was slightly higher compared to the model without implant. It appears that after attaching the implant to the medial side, the femur was slightly abducted towards the lateral compartment. In other words, the whole unloading process involves removing any excessive load from the medial side, by attaching the implant on that side, leading to a slight femur abduction. Further experimentation is required to study the effect of this abduction on the other compartment and on the knee kinematics.

Wang et al. [37] conducted research on a standing knee model under different compressive loads using various Poisson's ratios. The maximum von Mises stress was reported to be just under 1.5e+00 MPa, for a 400 N applied load and a Poisson ratio of 0.45 for cartilage. This stress is very close to the observed maximum stress (1.44e+00 MPa) at the femoral cartilage in the current model without implant, intimating the reliability of the results obtained in the current study.

To further check the accuracy of the results, model contact pressures were compared with findings in the research conducted by Thambyah [41] on a cadaver knee joint. In that research, the experimental setup was designed in such a way that a major part of the load was applied to the medial compartment, similar to the current study. Although the stress on the medial side was higher, the contact pressures in the medial and lateral compartments showed no significant differences, as was observed in this study, again pointing to the reliability of the current results.

It is worth mentioning that the design of the implant was not optimised in this preliminary research, and stress concentrations occurred at the interface between the femoral and tibial plates. Although this issue might be eliminated by modifying the design, at this stage the existing stress is not of any real concern, as it is far less than the yield strength of titanium (~900 MPa) [42]. In fact, there could be other sources of failure, such as failings due to the tribological properties of the implant, which need more experimental investigation; these will be studied on the produced parts after finalising development of the implant's design.

This method has some benefits compared to other surgical treatments. For instance, a HTO is not suitable if there is unicompartmental knee OA without deformity, and compared to the proposed implant in this study, HTO is relatively an invasive option [43]. In comparison with TKA, the surgery required for the implant introduced here can be categorised as a minimally invasive operation. Unlike in the case of TKA, such surgery does not require sacrificing the ligaments and also there is no need to cut bone from the surfaces of the distal femur and proximal tibia, hence normal knee kinematics will be retained [44]. Accordingly, the patient's recovery should be quicker and less painful. It should also be noted that this implant is not considered to be a permanent implant such as TKA. Thus, the risk of implant surgery is minimised, and younger patients would be more willing to undergo the surgery as soon as osteoarthritis is detected. In other words, a surgical option for early-onset knee osteoarthritis might well be suggested more often by surgeons, if the operation was reversible and the patient could recover relatively quickly [6]. In fact, instead of using various types of conservative methods to postpone invasive surgical therapies, the implant considered here unloads any excessive load on the knee, before degeneration worsens, and allows for the possibility for cartilaginous tissue to be repaired [7,8].

The reason for the above suggestion from most orthopaedic surgeons for patients with early-onset OA is that they believe this kind of implant, or any other viable treatment for the mentioned gap, might be suitable for patients who are young or not yet willing to undergo invasive surgical therapy [17]. It would also help the patient to avoid sedentary lifestyle morbidity and encourage them back to a normal life and exercise, which would lead to a decrease in the possibility of obesity and depression [17]. Moreover, by reducing the post-operation expenses and limiting the related costs of invasive surgeries and revisions, this novel implant could help produce savings to the large financial burden of the healthcare system [16,17].

Although the static analysis carried out here does not allow for investigating all possible aspects of the implant, such as implant kinematics and dynamic analyses, the preliminary results obtained from investigating the implant statically are very promising for removing excessive joint loading. After modifying the implant based on the obtained results, further studies will focus on dynamic analyses.

5. Conclusions

The effect of a novel extra-articular implant on stress and contact pressures distributions in femoral cartilage was investigated. The main results are as follows:

- After attaching the implant to the medial side of the knee, the von Mises stress within femoral cartilage and contact pressures over the femoral cartilage surface were reduced by 40% and 35%, respectively.
- After introducing the implant to the medial side of the knee joint, the maximum stress and contact pressure were slightly increased at the lateral compartment due to the slight abduction of femur.
- A static FEA of the extended knee position of the model showed that the maximum observed stress in both implant plates (femoral and tibial) was about 96 MPa, which is far lower than the yield strength of titanium (~900 MPa). Thus, no failure of the implant is expected due to plastic yielding; however, there is a possibility of failure due to other mechanisms, such as wear.

Most importantly, the studied implant is minimally invasive and it is not considered to be a permanent implant. Thus, patients would be encouraged to undergo surgery when the disease is at an early stage.

Conflicts of interest

None.

Funding

None.

Ethical approval

Not required.

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