Preliminary results on the effects of orthopedic implant stiffness fixed to the cut end of the femur on the stress at the stump-prosthetic interface

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ABSTRACT. People with trans-femoral amputation often experience skin breakdown due to the pressures and shear stresses in the stump-prosthesis interface. In this study, a finite element model was employed to investigate the stresses at the stump interface in the case of an orthopedic implant fixed to the cut end of the femur. By changing the stiffness of this implant, we aim to see how the stiffness of this implant affects the stresses in the interface between the amputated limb and the prosthesis. To find out the effects of implant stiffness, five values for the elastic modulus, ranging from 0.1 to 0.5 MPa, with an interval of 0.1 MPa were employed in the implant structure of the FE model.

Obtained results show that the implant played important role in reducing the stresses at the stump-prosthesis interface where the contact pressure did not exceed 53 kPa and 17.3 kPa for shear stress in the stiffer case of an implant, while the contact pressure in the case of femur without an implant exceeded 79 kPa and 42 kPa for shear stress. We also noted that the intensity of the contact pressure and the shear stress is proportional to the stiffness of the implant, as the greater the implant stiffness, the higher the peak of these stresses.

KEYWORDS. Prosthesis; Stump interface; Stiffness; Contacts stresses; Implant.

INTRODUCTION

Lower limb amputations are mainly due to traffic accidents, particularly motorcycle accidents [1], diabetes and cancer are also major causes of amputation [2, 3]. After lower limb amputation the patients need a prosthesis to retain upright mobility capabilities, unfortunately, many of them remain dissatisfied with the performance of this

prosthesis [4], some patients also suffer from deep problems with this prosthesis, like discomfort, redness, sores, and inability to stand for a long time [5]. The stresses at the stump-prosthetic interface are primarily responsible for these problems.

Several studies have discussed the stresses at the residual limb interface using the finite element method (FFM) [6-18]. The models developed in these studies can be divided into three types. The first type involves linear static analysis established under assumptions of linear material properties, the second type can be referred to as nonlinear analysis, taking into consideration the nonlinear material properties, and the third type involves dynamic models. Analyses of this type consider not only dynamic loads but also material inertial effects and time-dependent material properties [19, 20]. Jia et al (2004) [18] performed a (FE) study on the influence of inertial load on interface pressure and shear stress, the socket was modeled as rigid in the study, and all materials were assumed linear. Lacroix et al (2011) [14], developed five EF models from five different patients to study the effect of the socket donning process on the stress-strain state at the outer residual limb interface. The main goal of the study performed by Zhang et al (2013) [13] was to predict the stress distribution between the socket and the residual limb, in this study a prosthetic liner with 5 mm thickness has been used. Meng et al (2020) [7] investigated the residual limb stress of trans-femoral amputees Compression/release stabilized (CRS) socket by finite elemental modeling. Most of these studies applied a load equivalent to half or full body weight at the bone head or they apply forces equivalent to the reaction forces extracted from larger (FE) models.

Medical implants are devices that can place inside or on the surface of the body, these implants can replace body parts and function or provide support to organs and tissues. A soft implant under the cut end of the femur bone (fig. 1) could be one of the suggested solutions, as it helps the bone to increase the ability to carry weight and thus reduce stresses on the stump-prosthetic interface also help to cushion the end of the femur bone. 2D simulation of this type of orthopedic implant has previously been performed in Chillale's study [11].

In this study, an implant that is fixed to the cut end of the amputated femur bone (fig. 2) was simulated, we aim by employing a 3D finite element model to investigate the effect of this orthopedic implant stiffness on the stresses at the stump-prosthetic interface. To find out the effects of implant stiffness, five values for the elastic modulus, ranging from 0.1 to 0.5 MPa, with an interval of 0.1 MPa were employed in the implant structure of the FE model.
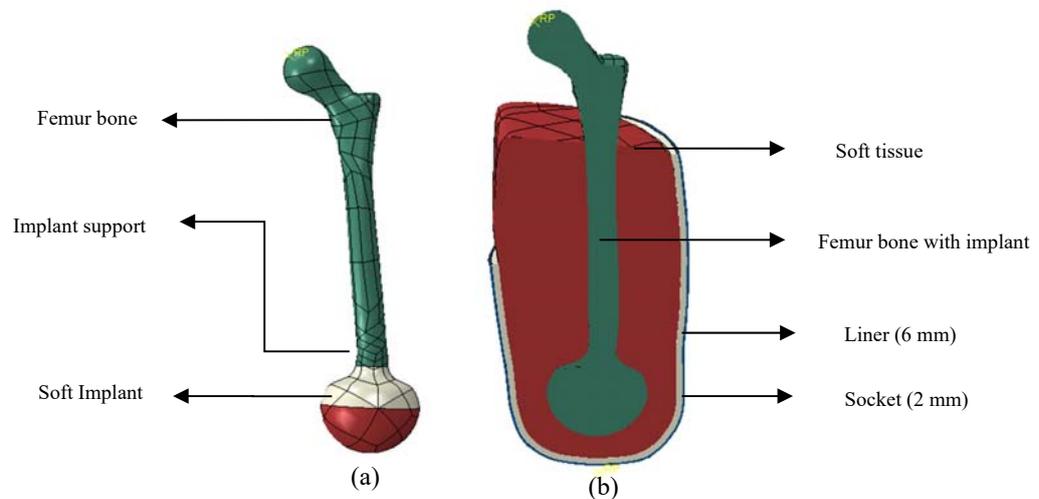

Figure 1: Schematic representation of the (EF) model, (a) bone with implant parts, (b) the different sections of the 3D (EF) model geometry (bone, soft tissues, implant, liner, and socket).

METHOD

Geometry

A finite element (FE) model for a virtual patient was developed to simulate an above-the-knee amputation, this model is composed of a limb (soft tissue, bone, implant, and implant support) and a prosthesis with a prosthetic liner and socket. The liner and the socket were designed using Autodesk Meshmixer this software allows to adapt

the prosthetic liner shape to the residual limp, the liner was considered to be **6** mm thick, as for the socket, it was **2** mm. The model has been converted from STL to IGS with MIMICS 3- MATIC software. The different parts are shown in fig 1.
The implant was developed in the (EF) model with two principal parts, the top was the support part for the soft implant with a height of 45.5 mm, and the diameter of the soft implant was 45 mm [11] as shown in Fig. 2.
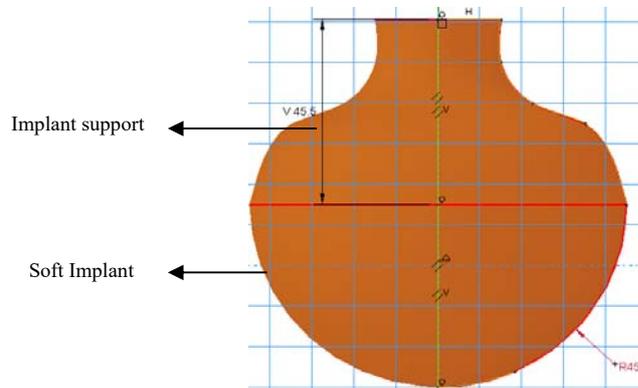

Figure 2: Schematic representation of implant geometry

Mechanical properties
The material properties of the femur bone, soft tissue, implant support, implant, liner, and socket were assumed to be linearly elastic, homogeneous, and isotropic. The list of the values of elastic modulus and Poisson's ratio used in the finite was shown in Tab. 1.
The Young's modulus of the implant was changed from 0.1 to 0.5 [17] to predict how the stiffness of the implant affected the stresses at the limb-prosthetic interface.

Material	Young's modulus	Poisson's ratio
Bone [16]	10 GPa	0.3
Soft tissue [18]	0.2 MPa	0.49
Implant support [11]	5.5 MPa	0.38
Implant [17]	0.1 to 0.5 MPa	0.49
Liner [18]	0.38 MPa	0.39
Socket [16]	1.5 GPa	0.3

Table 1: details material properties for the (FE) model [11, 16, 17, 18]

Boundary and loading condition
In this study, a non-linear finite element static analysis method was used. This analysis employed multiple finite element techniques, including geometric non-linearity due to large deflections, non-linear contacts due to friction between the contact surfaces of the stump and the prosthetic.
 The interfaces between the femur bone with the implant and soft tissue were tied; the physical contact between the stump and the liner and between the liner and the socket was represented by using surface-to-surface contact condition, which impede the residual limb nodes (slave nodes) to trespass or penetrate into the socket (master surface) during the displacement caused by the application of body weight. The coefficient of friction between the liner and soft tissue was assumed to be 0.5 [13, 20]. Although the bone is considered quasi-brittle material [21, 22], however, it is responsible for carrying human weight. In this study static vertical load equivalent to the half body weight [23] 350 N (two-leg stance) was applied on the femoral bone head, the distal end of the socket was fixed.
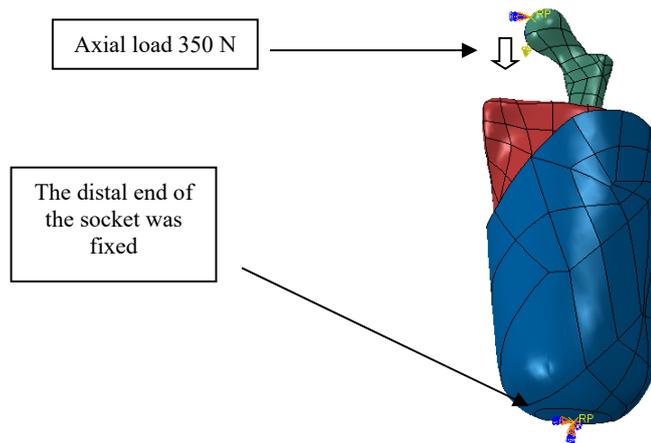
Figure 3: Schematic representation of load and boundary conditions

Mesh

The reliability of the results obtained requires a very refined mesh. The meshing was performed using C3D4 tetrahedral elements (C-continuum, 3D-three dimensional element, and 4- four noded element) for all components (bone, stump, liner, socket, and implant), tetrahedral meshes are generally preferred over hexahedral meshes for free-formed complex geometries as the former are computationally more cost-effective [24]. The total number of elements and element types for all components are specified in Tab. 2.

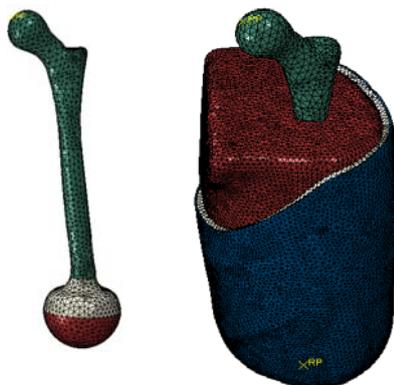| Parts	Elements number	Element type
Soft tissue	53214	C3D4
Liner	17933	C3D4
Socket	19413	C3D4
Bone with implant	12749	C3D4
Bone without implant	8984	C3D4

Table 2: Mesh properties used

Figure 4: Mesh of the analyzed (FE) model

RESULTS

Results represent the predictions of residual limb reaction after patient weight application in all cases in this simulation.

Distribution of Von Misess stress in the femur bone and the soft tissue with implant 0.1 and without implant was shown in fig 5. The maximum Von Mises in the femur in the case with the implant was 65.9 kPa almost double of Von Mises recorded in the case without an implant (36.3 kPa), this proves that the soft implant increases the weight carrying ability of the amputated femur.

The maximum Von Mises stress in the soft tissue in the case with implant 0.1 was 11.5 kPa this is less than that recorded in the case without implant that was 42 kPa. The stresses in the case of residual limb without implant recorded high concentration under the truncated femur bone region, this proves that the soft implant was played an important role in cushioning the end of the amputated bone and reducing the stresses on the soft tissue.

Bone with implant 0.1 MPa
(Young's modulus)

Bone without implant

Soft tissue in the case of implant 0.1
MPa (Young's modulus)
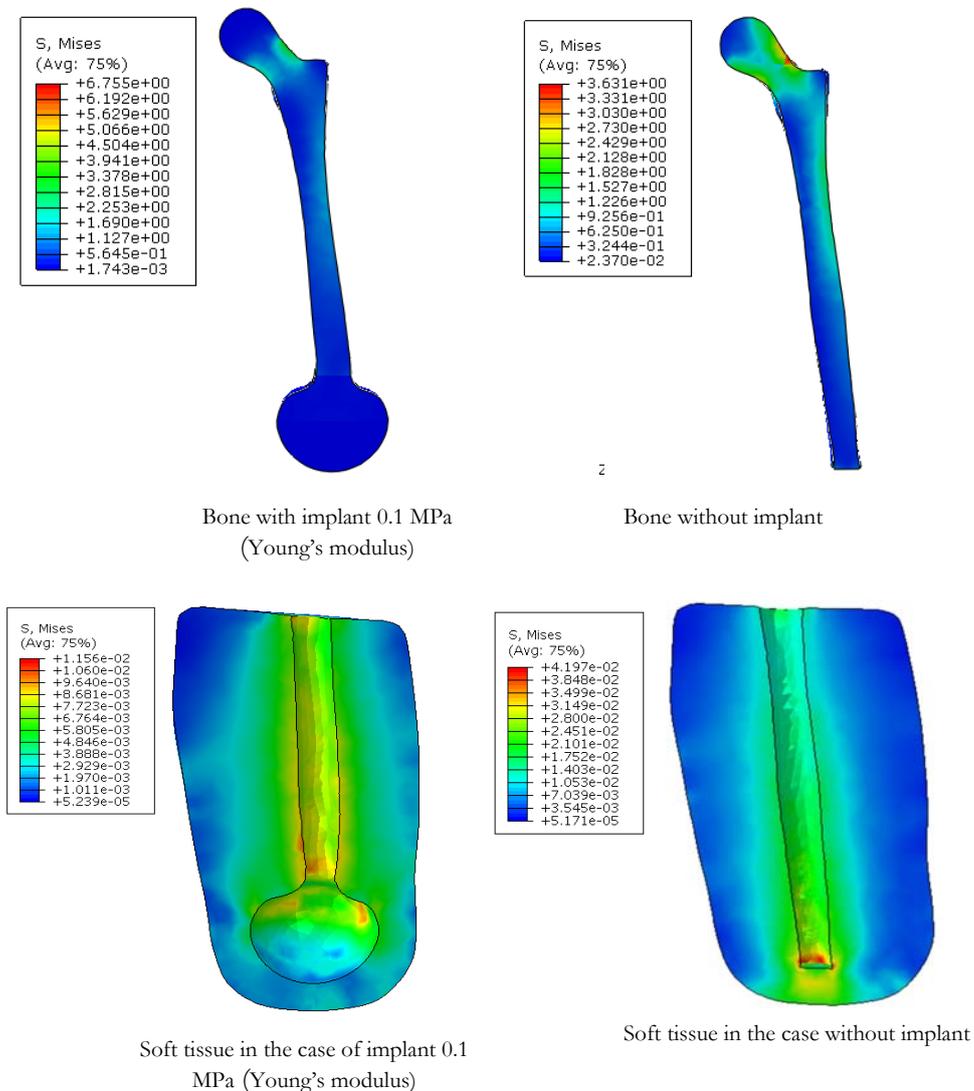
Soft tissue in the case without implant

Figure 5: Von Mises stress distribution (MPa) on the limb with and without implant

Fig 6 shows the distribution of contact pressure at the stump-prosthetic interface in all cases of implant stiffness and the case without an implant.

In the case without an implant, we get a high concentration of contact pressure under the truncated femur region; the peak pressure, in this case, was 79.7 KPa.

In the case of the implant below the amputated bone, we noticed that the intensity of the contact pressure at the outer stump interface rises with the increase of stiffness of this implant. The highest peak contact pressure between the implant cases was 53 KPa at the implant (0.5 MPa Young's modulus). The lowest peak contact pressure was recorded in the limb in the case of the least stiffness implant (0.1 MPa Young's modulus) up to 45 KPa.

The Stump at implant 0.1 MPa (Young's modulus)

The Stump at implant 0.2 MPa (Young's modulus)

The Stump at implant 0.3 MPa (Young's modulus)

The Stump at implant 0.4 MPa (Young's modulus)

The Stump at implant 0.5 MPa (Young's modulus)
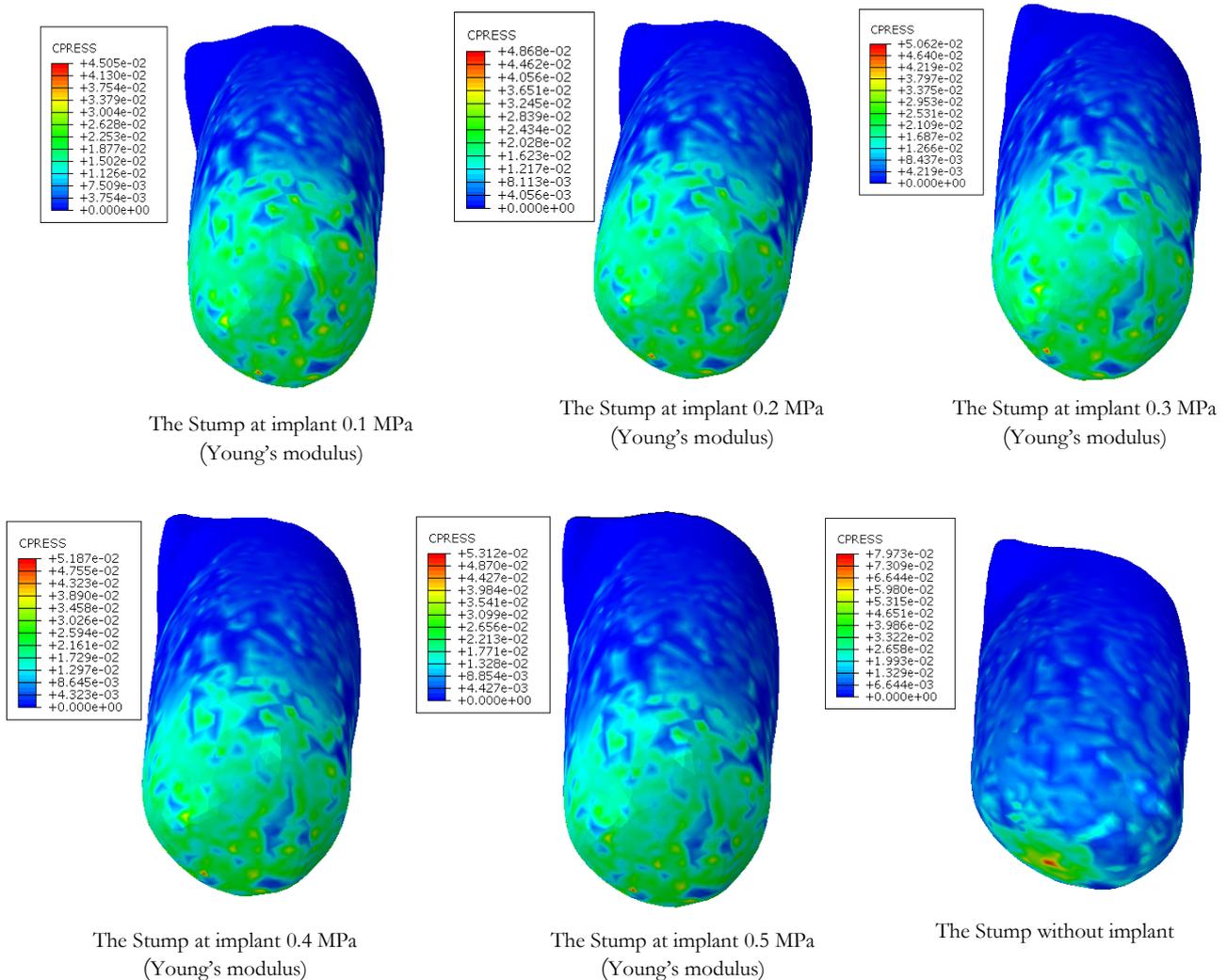
The Stump without implant

Figure 6: contact pressure distribution (MPa) on the stump-prosthetic interface for all implant stiffness cases and the case without implant.

Fig 7 shows the distribution of longitudinal shear stress at the stump-prosthetic interface in all cases of implant stiffness and the case without an implant. It can be noticed that the case of limb without implant was recorded the highest values of shear stresses up to18.4 kPa the lowest shear stress was recorded in the limb in case of the least stiffness implant (0.1 MPa Young's modulus) up to 6.8 kPa.

The Stump at implant 0.1 MPa
(Young's modulus)

The Stump at implant 0.2 MPa
(Young's modulus)

The Stump at implant 0.3 MPa
(Young's modulus)

The Stump at implant 0.4 MPa
(Young's modulus)

The Stump at implant 0.5 MPa
(Young's modulus)
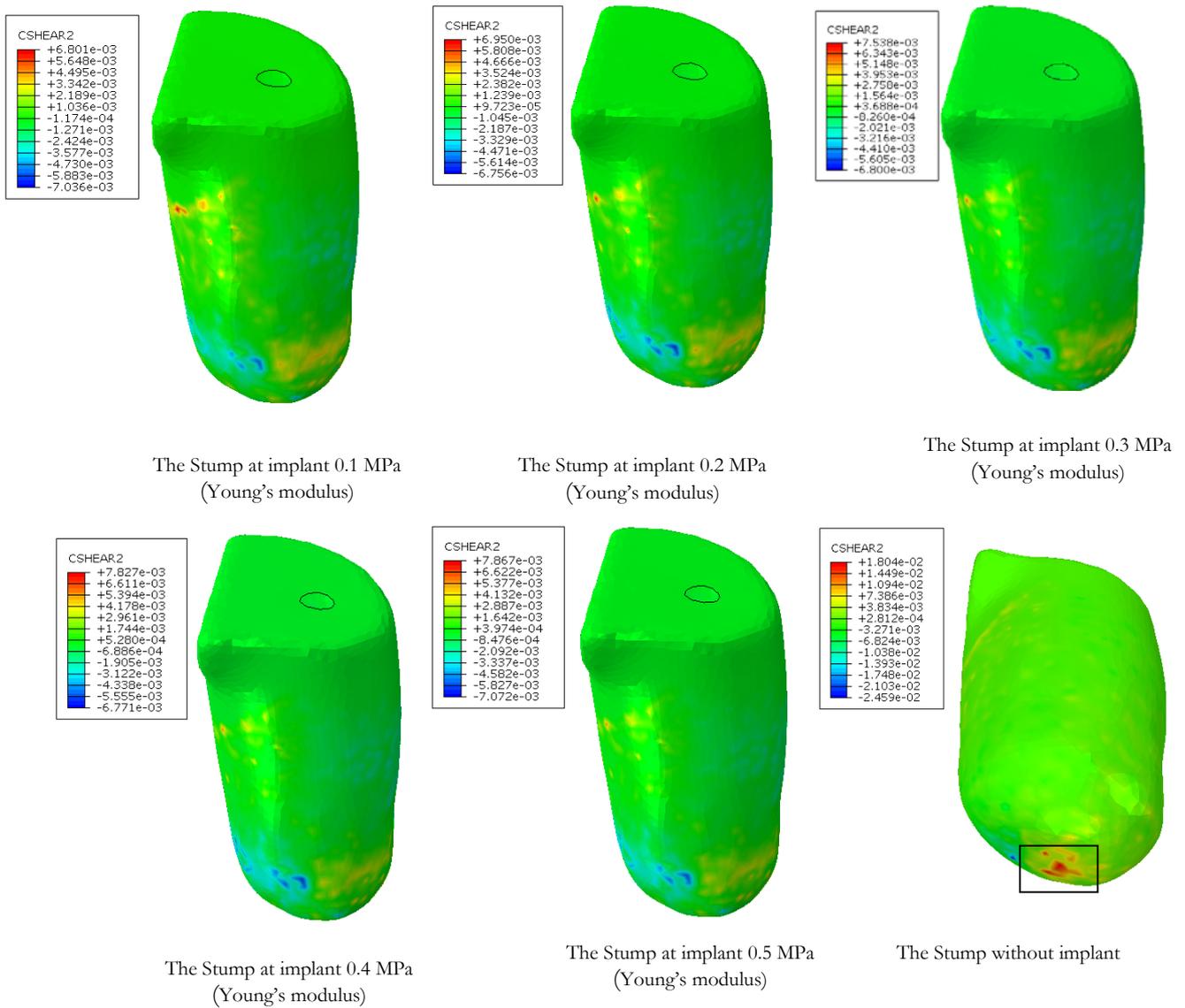
The Stump without implant

Figure 7: Longitudinal shear stress distributio (MPa) on the stump-prosthetic interface for all implant stiffness cases and the case without implant.
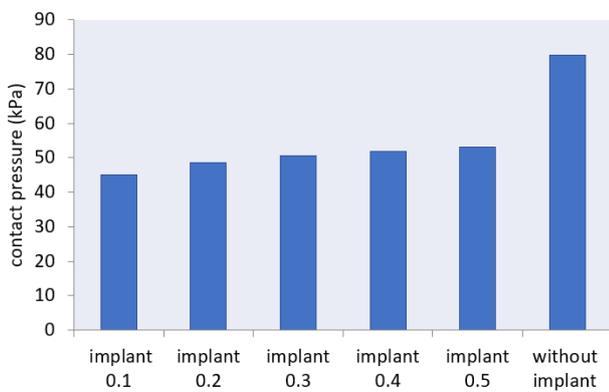
Figure 8: Peak contact pressure(kPa) on the stump-prosthetic interface for all implant stiffness cases and the case without implant.
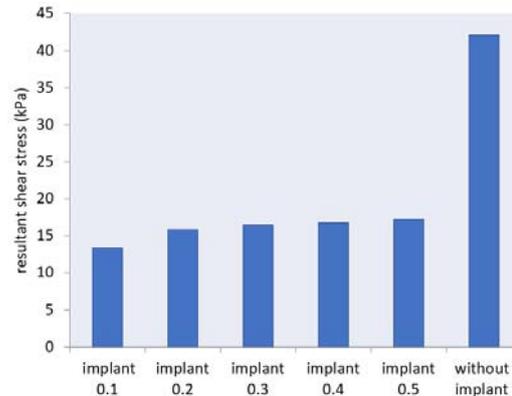
Figure 9: Resultant shear stress (kPa) on the stump-prosthetic interface for all implant stiffness cases and the case without implant.

Fig. 8 shows a histogram of the relationship between the peak contact pressure at the stump-prosthesis interface and the implant stiffness (elastic modulus, ranging from 0.1 to 0.5 MPa), The relationship between implant stiffness below the amputated bone and the contact pressure on the interface between the stump and the prosthesis was a direct relationship, as the higher the implant stiffness, the greater the stresses at the interface.

Fig. 9 shows a histogram of the relationship between the peak resultant shear stress at the stump-prosthesis interface and the implant stiffness. The resultant shear stress is the magnitude of the combination of longitudinal and circumferential components of shear stresses in the contact interface. The maximum resultant shear stress was recorded in the case of femur without implant up to 42.16 kPa. While the resultant shear stress increase from 13.3 KPa in the case of implant 0.1 to 17.3 KPa in the case of implant 0.5.

CONCLUSIONS

By employing a non-linear finite element method (EFM) to investigate the stresses after trans-femoral amputation in the case of a soft implant below the amputated bone. We came out with conclusions, including that the implant under the amputated bone had a very clear effect in reducing stresses caused by body weight, whether inside the muscle tissue in the area below the amputated bone or on the interface between the limb and the prosthetic, as the difference between the peak contact pressure in the case without an implant (79.7 KPa) and the case with implant 0.1(45 KPa) was 34.7KPa. We observed also that the relationship between implant stiffness below the amputated bone and the contact pressure on the interface between the stump and the prosthesis was a direct relationship, as the higher the implant stiffness, the greater the stresses at the interface.

This simulation predicted that the soft implant under an amputated bone is a very promising technique for relieving the patient's pain, problems of skin degradation, and even the inability to stand for a long time, as the contact pressures and the shear stress recorded were much less than those causing problems for the patient, according to Cagle study [6]. The results of this study reinforce the results of previous studies such Chillale's study [11] about the efficiency of this implant below the bone in reducing stresses at the stump-prosthetic interface. This implant may be a solution to the great problems suffered by amputee patients. These results remain hypothetical despite the efficiency of the finite element method further work is necessary to validate this result.

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