



## Effect of multi-layer prosthetic foam liner on the stresses at the stump–prosthetic interface

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**ABSTRACT.** The prosthetic liner plays a significant role in the redistribution of the pressure between the stump and the socket, as adds a cushioning layer between the stump and the socket which relieves pain and makes the prosthesis more comfortable.

This study employed nonlinear finite element analyses to investigate the peak pressure and shear stress at stump–prosthetic interface in the case of multi-layer prosthetic foam liner, this liner has an inner polymeric foam layer surrounded by another type of polymeric foam layer, we used three different types of foams in different order to define this liner (flexible polyurethane foam, polyurethane-shape memory polymer foam, and natural rubber latex foam). That allows comparing 6 different configurations of multi-layer prosthetic foam liner.

**KEYWORDS.** Prosthesis; Stump; Contacts stresses; Multi-layer liner; Trans-tibial amputation.



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### INTRODUCTION

Lower limb amputations are mainly due to arterial disease problems, often associated with diabetes, and to a lesser extent to trauma and cancer [1], after trans-tibial amputation (TTA) patients need prostheses to keep their mobility, this prosthesis should be comfortable and should not cause pain to the patient. Lower limb prostheses are generally developed with three principal parts: socket, pylon (leg section), and foot [2], most modern sockets are used with an intermediate liner, this liner helps to redistribute the stresses at the stump–prosthetic interface [3], the contact pressure at the stump–prosthetic interface is the most important parameter to evaluate the comfort of the prosthesis.

Sockets are customer products, designed to fit the unique geometry of the patient's residual limb [2]. Significant trauma can be caused by a poorly fitting socket. The manufacturing process of a socket is based on patient feedback and the

personal judgment of the prosthetics. This process is long and expensive requiring several prototypes to arrive at the final product. These lead to the high prices of the products [4], and they are built to withstand only three to five years. A low-cost efficient socket design and manufacturing process are required in order to reduce the high price of these products.

There are many advantages in using finite element analysis (FEA), including the ability to determine the stresses distribution at the whole stump-prosthetic interface. Also, these results can be used to design high-performance prosthesis by reducing the contact stresses, several studies have used the element finite method to investigate the pressures at the stump-prosthetic interface, and some model in these studies didn't include a prosthetic liner [4, 5], while others included liner. Lin et al (2004) [3] studied the Effects of liner stiffness in trans-tibial model, they used an axial load of 600 N (one-leg stance) with linear material properties for all components (bone, soft tissue, liner, socket). Jia et al (2004) [6] studied the influence of inertial load on interface pressure and shear stress in this study a prosthetic liner with 4 mm thickness has been used with patellar tendon bearing socket. Cagle et al (2018) [7] investigate the pressure distribution at the stump-prosthetic interface in three different limb shapes (short conical, long conical, and cylindrical) and they used elastomeric liner, the peak contact pressure across all simulations was 98 Kpa and the maximum resultant shear stress was 50 Kpa in Cagle's study.

In this study a trans-tibial element finite model was developed to investigate the effect of the multi-layer prosthetic foam liner on the stresses at the stump-prosthetic interface, this liner has an inner polymeric foam layer Surrounded by another type of polymeric foam layer, three different polymeric foams were chosen (flexible polyurethane foam, polyurethane-shape memory polymer foam, and natural rubber latex foam) to get different combinations of liners.

## METHOD

### *Geometries*

The development of the finite element (FE) model in this study was passed through several stages, the first was to create a 3D trans-tibial model with liner and socket, the limb was generated from Computed Tomography scans, the socket and the liner was designed using Autodesk meshmixer, this software allows to adapt the liner shape and socket with the residual limb and also allows to get rid of cavities in the contact surface between the residual limb and the liner and between the liner and the socket (Fig. 1), the model has been converted from STL to IGS with MIMICS 3-MATIC software.

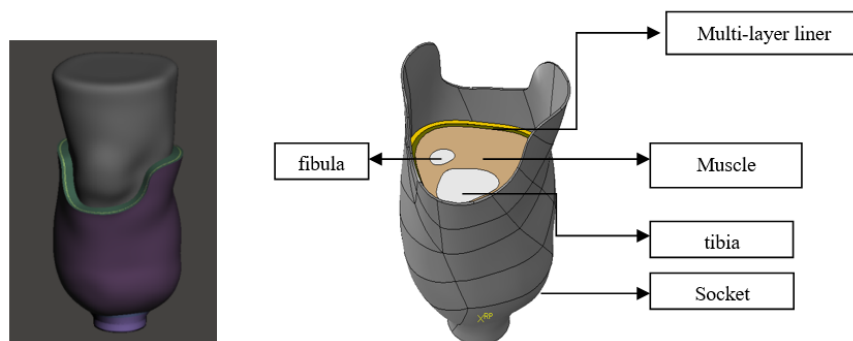


Figure 1: Schematic representation of the STL 3D model and the finite element (EF) model (bone, soft tissue, liner, and socket).

The liner was divided into two sections the thickness of each section was 5 mm as shown in Fig. 2, by giving each section different mechanical properties, it is possible to simulate different formations of the multi-layer liners as shown in Tab. 1.

### *Mechanical properties*

The material properties of the tibia bone, soft tissue, and socket were assumed to be linearly elastic, homogeneous, and isotropic. The bone was assigned with Young's modulus of 10 GPa and Poisson's ratio 0.3 [6], Young's modulus of the soft tissue was 200 kPa, and Poisson's ratio was assumed to be 0.49 [6], the socket was assigned with Young's modulus of 1.5Gpa and Poisson's ratio 0.3 [8].

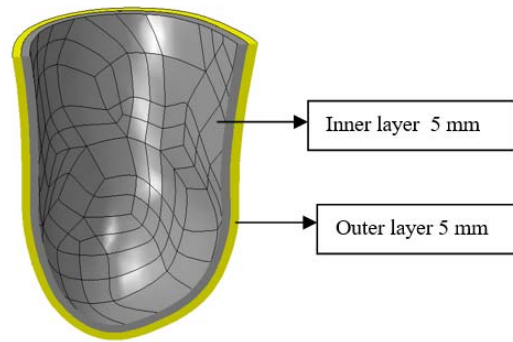


Figure 2: Schematic representation of prosthetic liner (EF).

Liner	Inner layer	Outer layer
Liner(a)	Flexible polyurethane foam	polyurethane-shape memory polymer foam
Liner(b)	polyurethane-shape memory polymer foam	Flexible polyurethane foam
Liner (c)	Flexible polyurethane foam	Natural rubber latex foam
Liner (d)	Natural rubber latex foam	Flexible polyurethane foam
Liner (e)	Natural rubber latex foam	polyurethane-shape memory polymer foam
Liner (f)	polyurethane-shape memory polymer foam	Natural rubber latex foam

Table 1: The different configurations of all six multi-layer foam liners Studied.

Structure	Young's modulus	Poisson's ratio
bone	10 GPa	0.3
soft tissue	200 kPa	0.49
socket	1.5 GPa	0.3

Table 2: Details material properties for the (FE) model.

For the liners the foam the flexible polyurethane foam, polyurethane-shape memory polymer foam, and natural rubber latex foam were assigned as hyper-elastic materials, the open-cell flexible polyurethane foam was assigned with hyper-elastic Ogden's model  $\mu_1=7.27\text{MPa}$ ,  $\alpha_1=1.63$ ,  $\mu_2 = -7.2 \text{ MPa}$ ,  $\alpha_2 =1.63$ ,  $\mu_3=8.5\text{E-}4\text{Mpa}$ ,  $\alpha_3= 45.75$  [9].

Fig. 3 shows the mechanical properties of polyurethane shape memory polymer foam [10] and natural rubber latex foam [11] used.

#### Boundary and loading conditions

The interfaces between the bone and soft tissue were tied, the physical contact between the stump and the liner was represented by using surface-to-surface contact. The coefficient of friction (COF) between the liner and soft tissue was assumed to be 0.5 [3, 6, 8].

A static vertical load equivalent to the half body weight [12] (350 N) was applied on top of the tibial bone, the distal end of the socket was fixed.

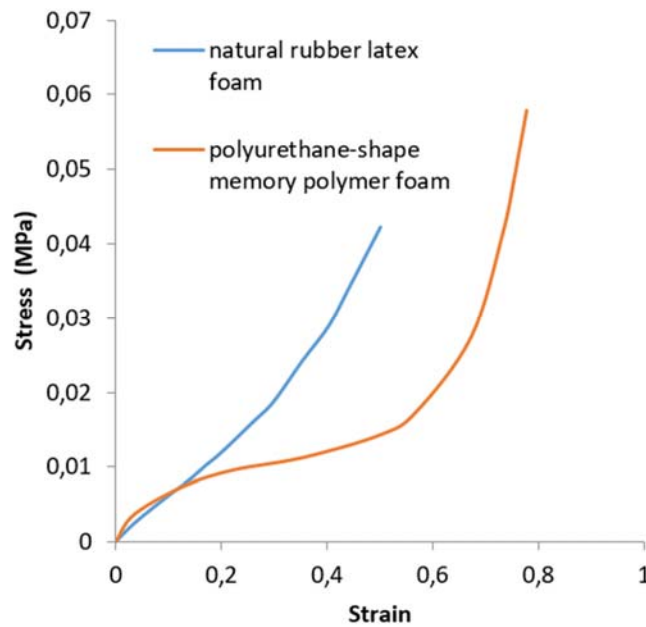


Figure 3: Compressive stress strain relationship of natural rubber latex foam and polyurethane-shape memory polymer foam.

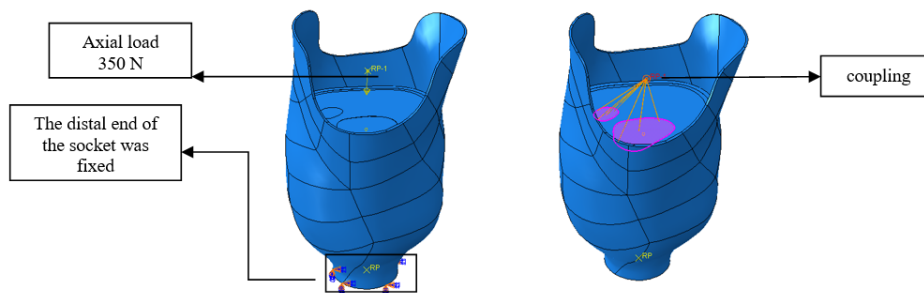


Figure 4: Schematic representation of load and boundary conditions.

*Mesh*

Tetrahedral meshes for all components (bone, soft tissue, socket, and liner), was chosen tetrahedral meshes are generally preferred over hexahedral meshes for free-formed complex geometries as the former is computationally more efficient [13].

Structure	Elements number	Element type
Bone	32539	C3D4
Soft tissue	6411	C3D4
Socket	26185	C3D4
Liner	33257	C3D4

Table 3: Mesh properties used

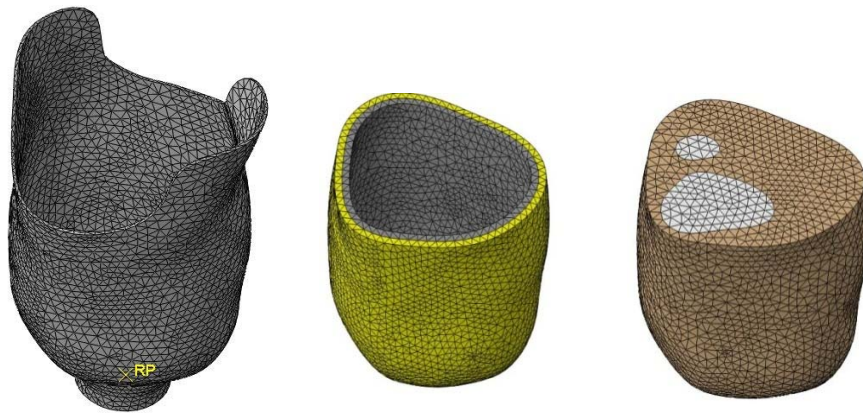


Figure 5: Mesh of the analyzed (FE) model.

## RESULTS

This section outlines the stresses obtained at the interference between the trans-tibial prosthesis and the stump due to the body weight application, this reflects the residual limb reaction with all six cases of multi-layer prosthetic foam liner shown in the Tab.1.

The results based on the peak contact pressure and peak longitudinal shear stress at the stump interface. The computed contact pressure and the shear stress will help determine which liner produces the least pressure on the stump-prosthetic interface. The vertical displacement recorded in the liners was used to compare their weight-bearing capacity in every case. Fig. 6 shows the distributions of contact pressure at the stump–prosthetic interface for all liners cases, the patellar tendon area, and the region under the amputated tibia bone were recorded the highest pressure distributions. The highest contact pressure recorded in the stump between all cases was in the liner (f) up to 52 kPa, the lowest contact pressure between all cases was in the cases of liners (a) and (c) up to 31 kPa and 30 kPa respectively as shown in the Fig. 8.

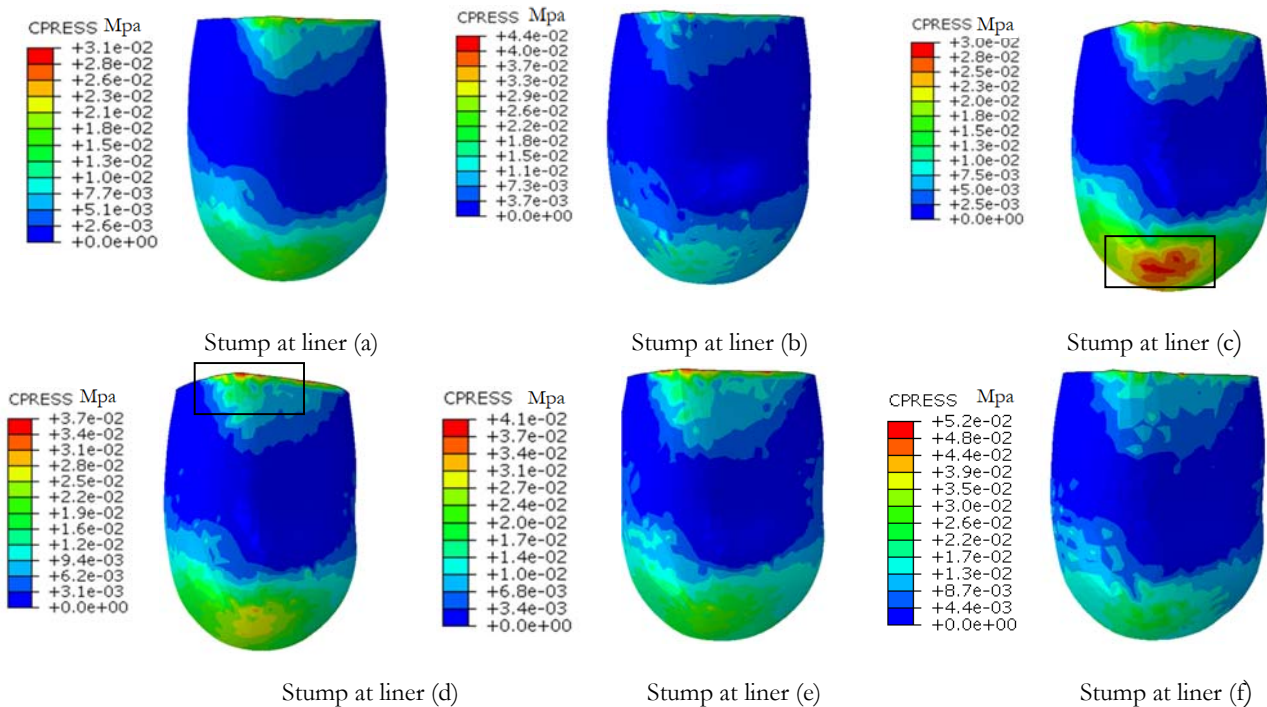


Figure 6: Distributions of contact pressure at the stump interface for all six types of multi-layer liners.

Fig. 7 shows the distributions of longitudinal shear stress at the stump–prosthetic interface for all liners cases, the patellar tendon area, and the region under the amputated tibia bone were recorded the highest longitudinal shear stress distributions. The highest longitudinal shear stresses recorded in the stump between all cases was in the cases of liners (b), (e), and (f) up to 22,20 and 26 Kpa respectively, the lows longitudinal shear stress between all cases was in the cases of liners (a) and (c) up to 15 Kpa as shown in the Fig. 8.

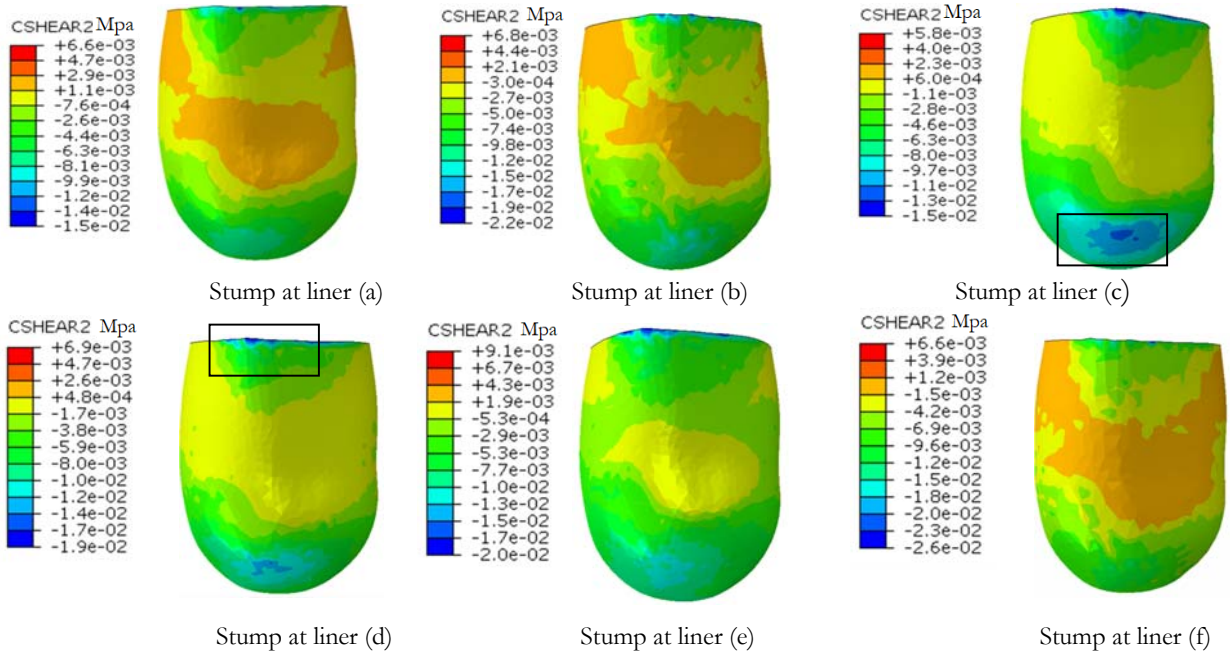


Figure 7: Distributions of longitudinal shear stress at the stump interface for all six types of multi-layerliners.

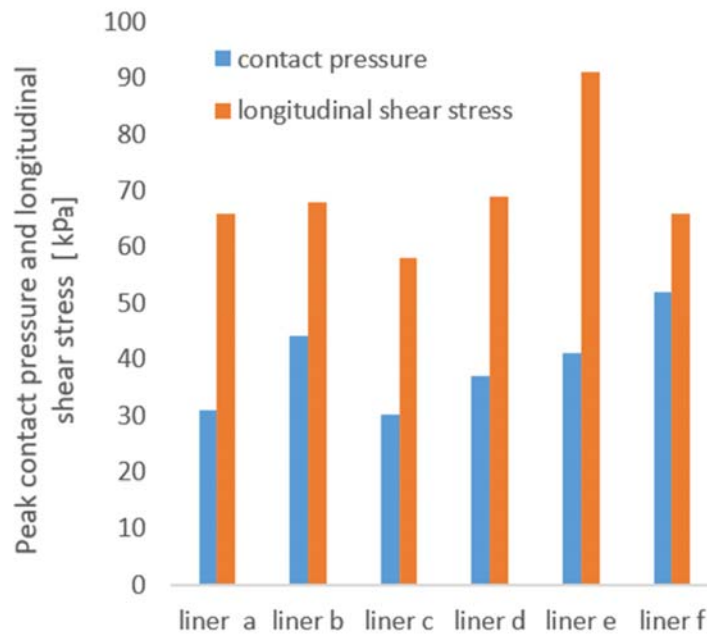


Figure 8: Peak contact pressure and longitudinal shear stress at the stump–liner interface for all multi-layer liners cases.

The distributions of displacement in all six cases of multi-layer prosthetic foam liner allow knowing the capacity of these liners to support the patient's weight. Fig. 9 shows the distributions of vertical displacement at all liners cases, the highest vertical displacement distributions in the liners was located in the area below the tibia end, the highest displacement

between all cases was recorded in the liner (a) up to 9.2 mm, the lows displacement between all cases was in the cases of liners (e) and (f) up to 5.5 and 5.4 mm respectively.

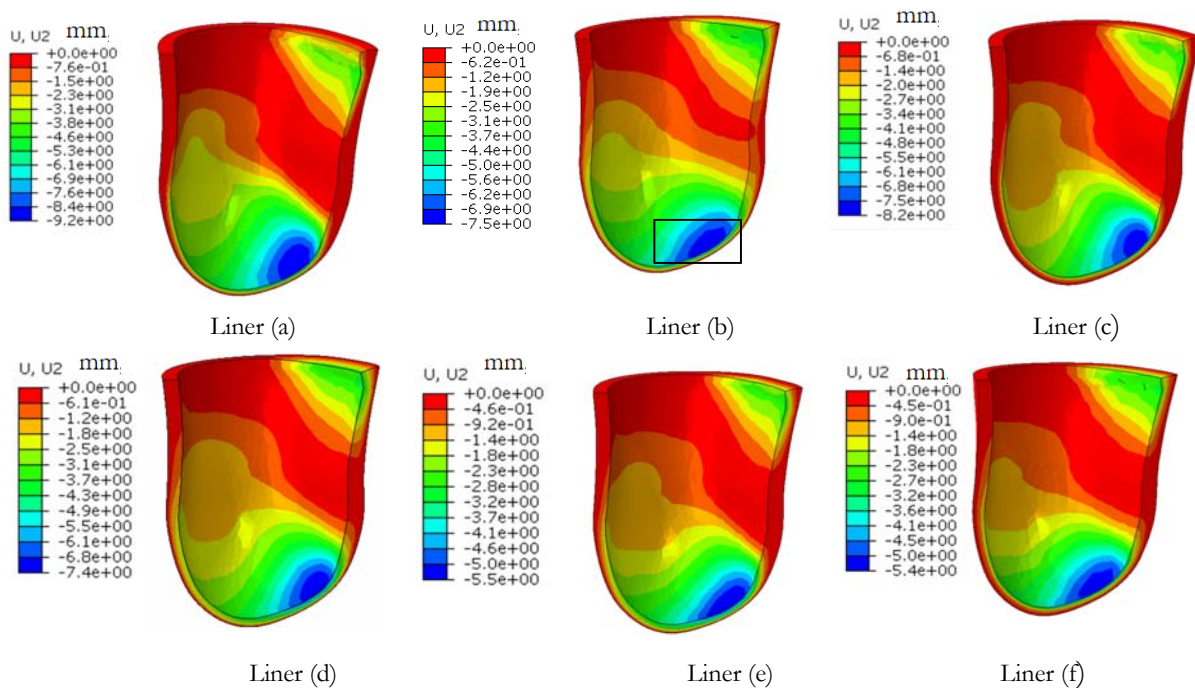


Figure 9: Distribution of displacement along the load axis (U2) in all liners cases.

## CONCLUSION

In this study, A 3D nonlinear FE model was established to predict contact pressure and longitudinal shear stress at the stump interface, a static force equivalent to the half-body weight was applied at the knee joint during a two-leg stance.

The effects of multi-layer prosthetic foam liner materials inertia during analysis were estimated by comparing the results of the stresses at the stump–prosthetic interface.

Based on the study of Cagle et al [7] it can be said that the stresses recorded on the prosthesis interface in all cases of multi-layer foam liners in this study were very suitable for patient's comfort, the peak contact pressure values did not exceed in the highest case 52 kpa, and 25 kpa for the longitudinal shear stress.

Through this simulation, the multi-layer prosthetic foam liners were showed High efficiency in reducing the stress at the stump–prosthetic interface. However, some cases of multi-layer prosthetic foam liners did not show adequate support for the patient's weight, it's recorded large displacement values (liner (a) and liner(c)).

The multi-layer foam liners that have achieved the best balance between low stress values at the stump–prosthetic interface and weight bearing capacity were the liners (b) and (d).

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