POLITECNICO MILANO 1863

SCUOLA DI INGEGNERIA INDUSTRIALE E DELL'INFORMAZIONE

EXECUTIVE SUMMARY OF THE THESIS

Safety of Port-a-cath implantation in everyday life: a finite element study

TESI MAGISTRALE IN BIOMEDICAL ENGINEERING – INGEGNERIA BIOMEDICA

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1. Introduction

Cancer is a major issue affecting 22 million people worldwide [1]. Nowadays, chemotherapy is the main therapeutic option chosen, but, since it is an intravenous treatment, it requires continuous venous access that becomes increasingly difficult to establish and harder to sustain over time. To overcome these problems, totally implantable central venous access devices (TIVAPs) have been recommended to enhance patient comfort and quality of life. Port-a-cath is the most used fully implanted, permanent central venous access device, composed of a silicone reservoir placed percutaneously under the clavicle and accessed using a Huber needle (Fig. 1) [2]. The device is connected to a biocompatible catheter that goes through a large vein (subclavian) and ends near the superior vena cava. It is visible through the skin raising concerns in patients about its safety during everyday activities. Finite element simulations were carried out to evaluate the safety of port-a-cath implantation during a common soccer ball impact. Since there are no studies in the literature, the present work aimed to provide physicians with more scientific evidence to support their responses to patients' concerns regarding the safety of port-a-cath in activities of daily living. For this purpose, a patient-specific human torso model, composed of the ribcage, costal cartilage, muscle, and skin, was obtained through the segmentation process of CT scans of a patient with port-a-cath, whereas internal organs were neglected.

Figure 1. Puncture with Huber's needle (left), Port structure (in the middle), and Port system implant (right).

2. State of the art

Before building the model, the focus was on defining the mechanical properties of different tissues that make up the human torso. Bone is a heterogeneous tissue, woven into cortical and spongy patterns, and the combination of these components determines the overall mechanical behavior of the bone itself [3]. Costal cartilage acts as a shock absorber to prevent rib fractures in case of blows to the anterior chest. Skeletal muscle, 40-50% of body mass, is essential for accurately representing the human torso [4]. Skin is the largest organ in the body, in contact with the external environment, and the first incised during the port-a-cath positioning procedure [5]. To understand how researchers handled the materials representing the tissues considered, a detailed literature research was conducted, to assess what are the mechanical parameters to assign to each tissue and to model their behavior as faithfully as possible. Soccer is the most popular ball sport in the world, but ball impacts can cause damage to the body with a severity that depends on the ball material type and its shooting velocity [6]. Researchers have attempted to develop finite element (FE) models of soccer balls to understand the mechanics of ball impacts, such as Prince et al., which developed a model of a manually stitched soccer ball inflated by a latex bladder within. Then, the ball velocity and the resultant force developed to impart speed to the sphere itself, depending on the football players' age and sport level, were studied by Cambiaso and Cambiaso [7] using the Valente test (Fig. 2).

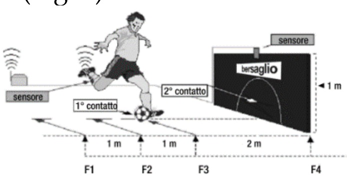


Figure 2. Valente test.

TEMPO DI CONTATTO (ms)	TEMPO DI VOLO (ms)	FORZA (kgp)	VELOCITÀ (m/s)	VELOCITÀ (km/h)	ETÀ ANNI
14,99	230,75	23,58	8,67	31,20	6
13,81	192,13	30,73	10,41	37,47	7
13,34	175,38	34,85	11,40	41,05	8
13,43	172,75	35,14	11,58	41,68	9
12,88	161,03	39,32	12,42	44,71	10
13,12	149,85	49,08	13,60	48,95	11
13,30	149,18	49,65	13,77	49,59	12
12,91	132,91	54,82	15,52	55,88	13
11,87	126,65	64,35	16,53	59,50	14
12,66	121,15	62,27	16,93	60,93	15
12,86	113,56	66\,63	18,46	66,45	16
12,93	105,42	70,34	19,42	69,94	17
13,11	106,89	68,44	19,23	68,04	18

Figure 3. Valente test values for teenagers from six to eighteen years old.

In the literature, several examples of impact simulations are performed using the explicit solver LS-DYNA R12 (Ansys Inc). Both impact simulations in sporting events, such as hits of a soccer ball during a match, or caused by bullets, are included in these works that were used to extract some guidelines to carry out the implementation of the present study [8]. Finally, the accurate segmentation of the human body is crucial for identifying the anatomical regions of interest. In the present work, the segmentation technique used is thresholding, which separates images based on their grey-level distribution, according to the Hounsfield values associated with each tissue. By changing the upper and lower threshold values on the Hounsfield scale, features from the CT image can be hidden.

3. Materials and methods

A port-a-cath model was created via CAD modeling using Autodesk's Fusion 360 software. The model was reconstructed in ANSA and meshed with tetrahedral elements 3 mm in size (see Figure 4a). A patient-specific model of the human torso was created from a patient's Computed Tomography (CT) scans provided by the Tumour Institute of Milan as anonymous data. The model includes bones (spine, ribs, sternum), costal cartilage, muscle, and skin. Bone and cartilage segmentation was performed by means of 3D Slicer (Brigham and Women's Hospital, Harvard University, NIH) using an automatic threshold algorithm, with the only difference in the threshold range. The bone and cartilage STL models were then individually imported into ANSA BETA CAE software (BETA CAE Systems, Switzerland) to eliminate segmentation artifacts and create a uniform triangular shell mesh with a target length of 5mm (see Figure 4b).

(a) (b)

Figure 4. a) CAD model of the Port-a-cath. b) Mesh of bones and cartilages, and Port-a-cath at its final location.

The skin was segmented with the software Vmtk (Orobix s.r.l.) and imported into ANSA where a surface triangular mesh (element size 5 mm) was created. Then, all parts were assembled into ANSA to create the final computational model: the costal cartilage was attached to the bone apparatus, and the skin was placed in the correct position with respect to the bones, taking the suprasternal notch as a reference. The empty space between skin and bone-cartilage was filled with a volumetric mesh representing the muscle component. The port-a-cath was positioned 1/3 outside the skin and 2/3 inside the subcutaneous pocket according to the surgical procedure followed to create the pocket where the device will be housed.

To position of the Port-a-Cath in the model, the patients CT-scan post implantation was used. Two reference bones and the device were segmented and imported in the FE model to be used as reference to correctly position the device in the model of the torso (see Figure 5). A rectangular window was created in the skin to simulate the cut performed in the skin during the surgical procedure to introduce the device. In addition, the mesh was refined in this region in both, the skin and the underlying muscle to accurately describe the interaction of the device with the surrounding soft tissue.

Figure 5. Final human torso model.

To simulate the impact of ball, a CAD model of a soccer ball was created and imported into ANSA and meshed with 5mm triangular shell elements. The material properties of all materials that make up the torso and the ball model were defined as shown in Table 1 [9] [10] [11] [12] .

Part	Young's modulus E [MPa]	Poisson's ratio ν	Mass density ρ [g/ mm³]	Material	Section
Bone	13000	0.3	0.002	RIGID	SOLID
Costal Cartilage	24.5	0.3	0.0015	ELASTIC	SOLID
Muscle	1	0.3	0.0011	ELASTIC	SOLID
Skin	2	0.5	0.001	ELASTIC	SHELL
Port-a-cath	30000	0.4	0.001	RIGID	SOLID
Ball	48	0.49	0.00116	ELASTIC	SHELL

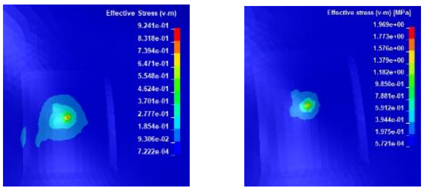
Table 1. Material properties of the different elements of the torso and the ball.

The simulation was performed in two steps. The first step simulated the implantation of the device in the torso, and the second step simulated the impact of a soccer ball with the torso at the point coincident with the location of the Port-a-Cath. To simulate the Port-a-Cath implantation the skin pocket was first raised with a small pressure and then released to let it enter in contact with the device. The simulation defined skin-device and skin-muscle contacts with a soft constraint penalty formulation. To simulate the impact with the ball, the soccer ball was accelerated for 1 sec until reaching a constant velocity of 10 m/s corresponding to a shot of a 10-year-old boy [7]. A pressure-cavity model was used to inflate the ball at a pressure of 0.9 bar, following the work of Prince et al. [13]. In addition, the impact of the ball with a torso without a Port-a-Cath implanted was also performed. Finally, the impact of the ball against the torso with the implanted device in presence of an individual protection device positioned in correspondence with the port-a-cath was also performed. The protective device consisted of a rectangular patch made of polyurethane foam 2.5 mm thick and equal in size to the subcutaneous pocket. The polyurethane foam was simulated as a linear elastic material with a young modulus of 2 GPa and a Poisson's ratio of 0.49 [14].

Mass damping was used to stabilize the dynamic simulations, with different damping values assigned to muscle tissue and skin depending on velocity and shooting angle considered (α=8 ms^{-1} for the muscle and α=5 ms^{-1} for the skin for standard cases, whereas α=10 ms^{-1} for the muscle and α=30 ms^{-1} for the skin were used for critical scenarios). A mesh sensitivity analysis was performed by varying the mesh size around the Port-a-Cath since it is the most stressed region during the implantation and loading phases. The mesh sizes considered for the sensitivity analysis were: 1 mm, 1.2 mm, 1.4 mm, and 1.6 mm for the skin and 1 mm, 1.2 mm, and 1.5 mm for the muscle. The average Von Mises stress value reached in the area of interest for each case, and the percentage difference in the results obtained with different mesh sizes, were assessed: the mesh is considered acceptable if the deviation in the results obtained with different meshes is less than 5%. The best mesh size in terms of quality-computational cost ratio will be chosen. All simulations were performed with the finite element software LsDyna (Ansys, Canonsburg, PA, USA).

4. Results and Discussion

The findings show that the implantation of the Port-a-Cath induces stress in the skin of the order of 0.9 MPa in the device's region, due to the adaptation process of the skin to accommodate the presence of the device. In this regard, as expected the maximum stress in the skin corresponds to the region of maximum protrusion of the device (see Figure 6a). When the ball impacts the torso, since the Port-a-Cath can move inside the pocket, the stress distribution in the skin changes slightly as seen in Figure 6b.



(a) (b)

Figure 6. Stress distribution in the skin around the Port-a-Cath: a) after the implantation of the device, b) after the impact of the ball with the torso.

The previous observation results are clear when looking at the displacement field of the Port-a-Cath before and after the impact of the ball. Figure 7 shows a sequence of the displacement field of the Port-a-Cath before, during, and after the impact of the ball. The results show that the device moves about 0.5 mm from its implanted position after the impact. This displacement may explain the alterations in the stress field observed in Figure 6.

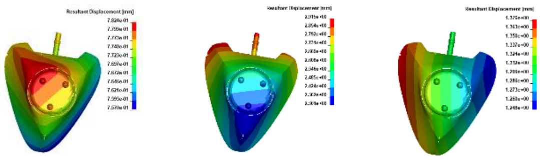


Figure 7. Port-a-cath result displacement contour map right before the ball impact (left), in the instant of the ball impact (in the middle), in the instant right after the ball impact (right).

As expected, as the velocity of the impacting ball increases, the maximum Von Mises stresses in the skin near the location of the Port-a-Cath increases too. When the impact velocity increases from 10 m/s to 20 m/s, the maximum average Von Mises stress in the skin around the Port-a-Cath during the impact increases from 0.779 MPa to 0.944 (see Figure 8). However, these values are found to be below the skin's ultimate stress of 15 MPa [10].

Figure 8. Von Mises contour map for skin tissue in the ball-torso contact instant for a shooting velocity of 10 m/s (left) and 20 m/s (right).

A similar evaluation was conducted for the muscle. The results showed that the exterior muscular surface doesn't appear to be affected by the soccer ball impact. However, the muscle's inner surface, corresponding to the subcutaneous pocket, results to be severely strained, with respect to the rest conditions, in particular at the interface between the Port-a-Cath and the muscle, near the sharp edges of the device.

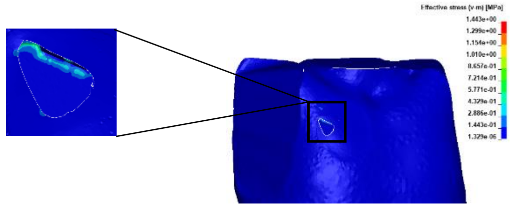


Figure 9. Von Mises contour map for muscle tissue in the ball-torso contact instant for a shooting velocity of 10 m/s, with a detail of the same map for the internal surface of the port-a-cath pocket.

In fact, the maximum value of the average Von Mises stress in the muscle portion in contact with the device, reaches a value of 0.493 MPa during the ball impact, and in some regions, the registering values are three times this one (1.4 MPa). Considering that the ultimate stress of the muscle ranges between 0.3-0.5 MPa [11], this may suggest that a potential injury of the muscle may occur because of the impact. Also, for the muscle, as the shooting velocity increases, the maximum Von Mises stresses in the muscle portion in contact with the device, increases too.

The stress on the bone tissue during the impact has been also analyzed. The results indicate that the impact of the ball is quite localized, being evident mainly at the level of the second and third rib. Since both, the port-a-cath and the bone, are very rigid parts, higher stresses will be generated in the bone than those recorded in other tissues. However, this stress (maximum value of the order of 7 MPa) results to be much smaller than the ultimate stress of bone tissue (around 124 MPa [9]). So, the bone does not suffer damage due to the ball impact.

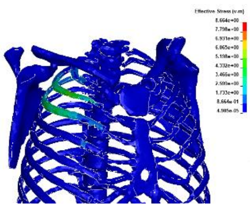


Figure 11. Von Mises contour map for the ribcage in the ball-torso contact instant for a shooting velocity of 20 m/s.

To evaluate if a different impact could result in more harm to the patient, two cases considering the impact velocity, 16 m/s, but different impact angles were simulated: i) frontal impact, ii) oblique impact at 45 degrees. In the oblique impact the Port-a-Cath moves more with respect to the frontal impact, and the stresses generated in the tissues result also higher.

Results of the simulation with patients without Port-a-Cath report maximum stresses in the muscle about half of those developed in the presence of the device. In addition, the energy of the impact results more uniformly distributed in the muscle as evidence by the smoother evolution of the Von Misses stress during the impact in the same region where the Port-a-Cath is located (see blue line in Figure 12). Further, the muscle fully returns to its original configuration after the impact, consistent with a purely elastic response.

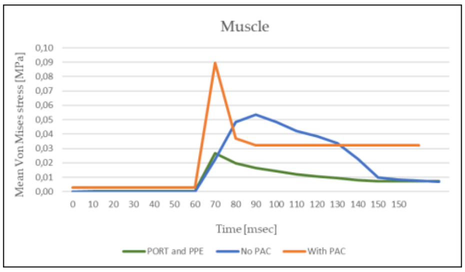


Figure 12. Mean Von Mises stress in the function of time for the muscle where the port-a-cath is located, in a patient with PAC, without the PAC implanted, and a patient with PAC and PPE.

Results from Figure 12 corroborate that is the accommodation of the Port-a-Cath after the impact of the ball that causes the alteration in the stress field distribution around the muscle pocket.

It results evident from the findings that the presence of the Port-a-Cath, and in particular its displacement, could cause a local injury in the muscle, and eventually in the skin due to the impact of an object close to the area where the device has been implanted. With the intention of reducing the probability of injury, the effect of a personal protective equipment (PPE) positioned in contact with the skin outside of the torso, at the location of the Port-a-Cath, was simulated. Results from the simulation of an impact with the ball at 10 m/s indicate that the presence of the PPE is able to reduce the maximum displacement of the Port-a-Cath inside the pocket by a factor of 7 during the impact (see Figure 13), and, more importantly, the maximum Von Mises stress in the muscle portion in contact with the device is reduced by a factor of 5, to levels even lower than those achieved in the absence of the device (see Figure 12). Hence, the protective patch can absorb the impact energy preventing the stress transfer to the underlying tissues and minimizing the port-a-cath displacement.

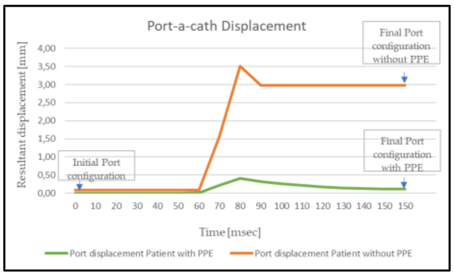


Figure 13. Resultant displacement in the function of time for the whole port-a-cath in the case of a patient with port-a-cath and a patient with port-a-cath wearing a protective patch.

Also, the skin surrounding the device appears to be much less stressed by the ball impact, and no stresses are generated in the muscular wall in contact with the device since it barely moves. In this way, with the use of a protective patch, the mean Von Mises value reached in the interior portion of the muscular cavity at the instant of the ball impact is equal to 0.073 MPa, which is out of the muscle UTS range reported in the literature [11]. So, the use of PPE can significantly reduce, or prevent, the damage suffered by muscle tissue in patients with Port-a-Cath in a general unfortunate event of everyday life.

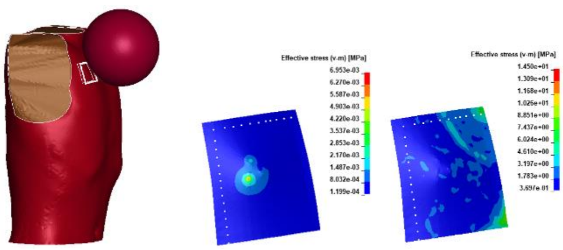


Figure 14. Human torso model with protective patch (left), highlighted with a white rectangle. Von Mises stress contour map for the protective patch worn by the patient with the port-a-cath, at the ball-torso contact instant (in the middle) and in instant right after the ball impact (right), for a shooting velocity of 10 m/s.

5. Conclusion and Future Perspectives

This study aims to evaluate the safety of port-a-cath implantation during traumatic events in daily life using a patient-specific human torso computational model. Results indicate that in the case of a soccer ball impact with a velocity of 10 m/s, the maximum stress in the skin and bone are both below the limit of causing tissue damage. However, high stresses are generated in the muscle, at the areas in close contact with the device, where the maximum stress generated during the ball impact may result higher than the ultimate stress of muscle tissue, implying possible muscle injuries. However, our results indicate that, the use of a personal protective equipment, for example, a polyurethane foam patch, may effectively reduce the stresses in the tissue during a ball's impact, and also reduce the displacement of the device after the impact. These results can be extended to other situations of everyday life that may be unknowingly risky for the patient with the port-a-cath. However, further investigation is needed to assess the severity of tissue injury in critical scenarios, such as soccer ball impacts with higher velocities. Since, higher damping factors must be set for skin and muscle to stabilize the simulation, underestimating the results by more than 20%, a strategy must be devised to perform a finite element study without increasing damping factors to obtain reliable results also for critical scenarios.

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