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Original Research Article

The role of additive manufacturing in the development of a biofidelic instrumented human head surrogate for impact tests

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Abstract: The prevention of damage resulting from head injuries is a topic of great interest for the scientific community, due to the social consequences arising from the high mortality and disability rates associated with these events. In particular, research focuses on the study of the biomechanical pathways that lead to the development of the various types of brain injury that occur as a result of impacts. In this context, instrumented devices capable of acquiring data during the collision, such as the skull and brain kinematic physical quantities and the stress development inside the brain tissue, will prove to be very helpful; these data can subsequently be analysed and used for numerical simulations with techniques such as finite element analysis. On this subject, the use of advanced technologies for the production of the components of a physical headform, including also a biofidelic skull and a brain simulant, can play an outstanding role, allowing the creation of replicas of the human head characterised by a high level of biofidelity. This feature will be very important for the development of protective devices, such as helmets. The present work describes the development of a physical head prototype, highlighting the importance of the choice of materials and identifying the aspects where the use of advanced additive manufacturing technologies may be expected to provide an effective contribution. Experimental activities on an Instrumented Human Head Surrogate (IHHS) implemented at the University of Padova confirmed the importance of this subject, giving interesting suggestions for future developments. The porous structure of the trabecular bone could be reproduced using additive manufacturing technologies and the brain simulant biofidelity could be improved by means of new materials like gelatines and new elements simulating bridging veins.

I. Introduction

Traumatic brain injuries (TBIs) represent a major cause of death and disability in the world, therefore testing protective gear results to be important to decrease the risk of damages to the brain caused by sudden trauma [1]. The strong need to examine the biomechanical response of brain tissue related to traumatic events was the basis for the development of some human head replicas with a brain simulant [2, 3]. This was required to overcome the lack of biofidelity of standard rigid headforms, like the head of Hybrid III 50th Percentile Anthropomorphic Test Device (ATD) or EN960, used to simulate impacts in the standards for helmets effectiveness testing. In fact, these devices don't include a brain surrogate, so they are generally designed for the analysis of the kinematic of the head as a whole. In this perspective, projects involving the Department of Industrial Engineering of Padua University led to the development of some biofidelic instrumented human head surrogates equipped with a brain simulant. The construction technique of the parts of the head models, including the additive manufacturing, plays an important role in achieving the required bio-fidelity. This results to be particularly challenging when working with materials, such as silicone rubbers, which are required to reproduce the most peculiar properties of biological tissue.

I.I. Standard rigid headforms

Two examples of ATDs are the Hybrid III 50th Percentile and the THOR (Test device for Human Occupant Restraint), shown in Fig. 1. These devices were developed by Humanetics along with the National Highway Traffic Safety Administration (NHTSA) and the biomechanics committees of the Society of Automotive Engineers (SAE). These dummies are generally used in automotive to assess the severity of injuries resulting from a road accident

[4]. However, accurate testing on specific body parts like the head require specific instruments for analysing the effects of localized impacts on the head, while the general-purpose instrumented dummies are generally designed for analysis on the body as a whole, as mentioned before.

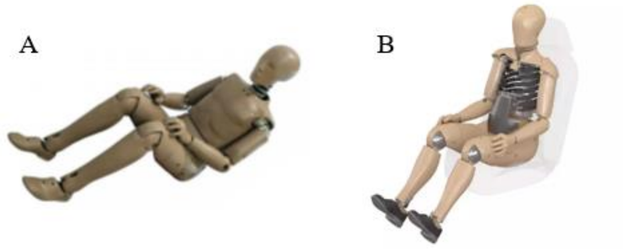


Figure 1: (A) Hybrid III 50th Percentile and (B) THOR ATDs.

For example, the head of Hybrid III 50th Percentile (Fig. 2 A) is a hollow aluminium body wrapped with a silicone rubber layer to mimic the external soft tissue, without any simulant for the brain. Instruments located in the head of dummies like Hybrid III or THOR are typically triaxial accelerometers and gyros at the head centre of mass [4]. However, the data collected are focused on the kinematics of the head, not considering the brain. Another example of rigid headform is the EN960 (Fig. 2 B), which consists of a hollow aluminium or magnesium skull, with an accelerometer at the centre of mass. Nevertheless, standard rigid headforms are constructed based on a possible correlation between the only global head acceleration history and the risk of bearing a certain level of injury. Since multiple mechanisms may lead to the generation of the tissue damage, and they aren't mutually exclusive, a larger set of biofidelic features is needed to find the more representative biomechanical pathways [2]. For example, NOCSAE (Fig. 2 C) is a more biofidelic headform which consists of a nylon skull covered with a urethane layer simulating the external soft tissue along with a gelatine mass representing the brain; it is instrumented with triaxial accelerometers at the centre of mass.

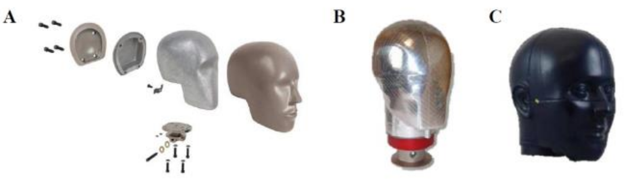


Figure 2: (A) Head of Hybrid III ATD, (B) EN960 headform, and (C) NOCSAE headform.

The project carried out at Padova University aims to improve the biofidelity of human head surrogates, thus proposing an instrumented human head replica equipped with a brain simulant incorporating multiaxial stress sensors.

I.II. The project: previous prototype

The experimental activity carried out is part of a long-term project, also in collaboration with Mid Sweden University, aiming to design and build a biofidelic Instrumented Human Head Surrogate (IHHS), equipped with different types of sensors (accelerometers, gyroscopes and pressure sensors) for the acquisition of data obtained from impact tests. The development of the project lead to build five instrumented prototypes (IHHS 1.0, 2.0, 3.0, 4.0, and 5.0) with progressive improving level of biofidelity. In particular, the IHHS 4.0 (version prior to the current one), which is the result of adjustments made to the first three versions to improve both biofidelity and the geometry of the various components, is described below.

The IHHS 4.0 included a silicone rubber brain surrogate, which was wrapped by a polyester layer to simulate the arachnoid trabeculae. Distilled water was included to simulate the damping effect of the cerebrospinal fluid. The skull was 3D printed in polyamide PA12 and it was enclosed by a silicone rubber skin surrogate. Fig. 3 shows the components of the replica and Table 1 summarizes the aforementioned simulant materials chosen to mimic skin, skull, cerebrospinal fluid, arachnoid trabeculae, and brain.

Figure 3: Skin, top skull, arachnoid trabeculae, bottom skull, jaw, and brain surrogates of the fourth version of Instrumented Human Head Surrogate (IHHS 4.0) developed by the DII (Dipartimento di Ingegneria Industriale) Department of the University of Padua.

Table 1: Materials used for the components of the fourth UNIPD Instrumented Human Head Surrogate (IHHS 4.0).

Component	**Material**
Skin	PlatSil Gel-10 1A:1B
Skull	Polyamide PA12
Cerebrospinal fluid	Distilled water
Arachnoid trabeculae	6 mm thick nonwoven polyester
Brain	PlatSil Gel-OO 1A:1B:1D

This prototype was equipped with a triaxial accelerometer in the front of the skull surrogate and 4 pressure sensors inside both halves of the skull. A MAPS (Multi-Axial Stress Sensor) [5], provided with a triad of orthogonal pressure sensors p1, p2, p3 plus three auxiliary pressure sensors p4, p5, p6 at their bisectors, was fitted to detect stresses inside the brain simulant, along with 2 triaxial accelerometers and 1 triaxial gyroscope.

The achievement of an adequate biofidelity is the main difficulty to deal with in the implementation of this type of surrogates. In fact, the human head is composed of complex anatomical structures, which exhibit peculiar mechanical and physical properties. For example, the brain tissue is characterized both by time-independent hyperelasticity and time-dependent viscoelasticity. Thus, to characterize the hyperelastic mechanical behaviour of the brain simulant materials in use in the replicas, quasi-static tensile, compressive and shear tests are needed, along with tensile, compressive and shear Dynamic Mechanical Analysis (DMA) to evaluate their viscoelastic response. The aim of these experimental tests is to identify the brain simulant material that exhibits the most similar response compared to the findings in literature on human or swine brain tissue. Furthermore, the peculiar sandwich structure of the skull tissue, which provides resistance but also lightness, is difficult to simulate. Thus, quasi-static mechanical tests are needed to evaluate the resistance and the flexibility of the materials chosen to mimic the bone in the replicas. The mechanical characterization will also allow to identify the constitutive parameters which define the behaviour of the material itself, to be used in a Finite Element Analysis (FEA) software for the implementation of the numerical model of the whole prototype.

II. Material and methods

The current version of Instrumented Human Head Surrogate (IHHS 5.0), shown in Fig. 4, was realized to provide some refinements to the previous replica.

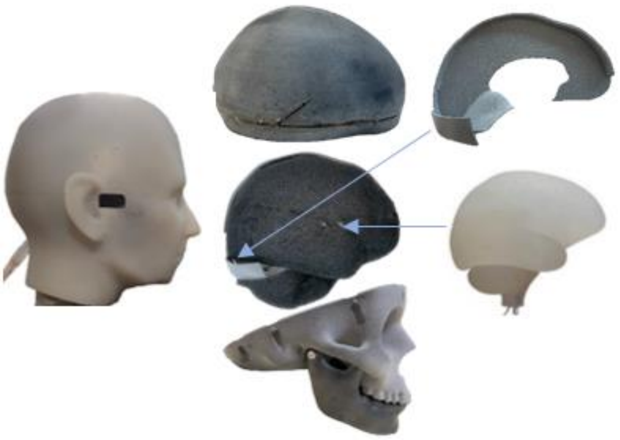


Figure 4: Skin, top skull, arachnoid trabeculae, falx-tentorium, bottom skull, jaw, and brain surrogates of the current version of Instrumented Human Head Surrogate (IHHS 5.0) developed by the DII Department of the University of Padua.

The aim was to improve the force transmission and the assembly. In particular, the coupling of top and bottom skull was improved by a triangular indentation. Furthermore, by adding ten metric screws M3 along with brass inserts it was possible to achieve a solid and removable closure of the skull. Simulant materials for skin, skull, cerebrospinal fluid, and brain are unchanged with respect to IHHS 4.0. Unlike the previous version, the arachnoid trabeculae are here made of open-cell polymer foam with 30 PPI (pores per inch), to simulate the cushioning effect of the trabeculae in the subarachnoid space (SAS) while subjected to compressive loading. Additionally, the current replica is equipped with 3D printed falx cerebri and tentorium cerebelli simulants, which are made of thermoplastic polyurethane (TPU, Shore 95A). Table 2 summarizes the materials used for the prototype. A DTS 6DX PRO-A triaxial accelerometer with a dynamic range of ±500 g and a gyrometer with ±8000 °/s (dps) were located under the mouth floor of the skull surrogate. Furthermore, unlike the previous prototype, 12 piezoresistive pressure sensors (MS5407, 700 kPa) were all installed on the internal skull upper half. A MAPS (700 kPa), a triaxial accelerometer (ADXL 377, 200 g), and a triaxial gyrometer (LPR+LPY, 2000 dps) were all sited in brain center of mass.

Table 2: Materials used for the components of the last UNIPD Instrumented Human Head Surrogate (IHHS 5.0).

Component	Material
Skin	PlatSil Gel-10 1A:1B
Skull	Polyamide PA12
Cerebrospinal fluid	Distilled water
Arachnoid trabeculae	Open cell polymeric foam with 30 pores per inch (PPI)
Falx-tentorium	Thermoplastic polyurethane (TPU), shore 95A
Brain	PlatSil Gel-OO 1A:1B:1D

Regarding the manufacturing technique, in all the IHHS versions the skin and brain simulants were obtained by casting, while their moulds and the skull surrogate were manufactured by additive manufacturing (Fused Deposition Modeling (FDM) and Selective Laser Sintering (SLS) technologies).

The skull surrogate .stl file was downloaded from Thingiverse.com website, and it was realized by means of MRI scans available from Anatomography website [6]. The original triangulated surface had flaws, along with partially detached, floating, or overlapping mesh elements, as shown in Fig. 5. Therefore, it needed to be accurately treated in order to obtain the solid model to be 3D printed. For this purpose, Meshmixer by Autodesk® software was used for surface optimization and repair steps. In detail, it was needed to close holes and repair defects by:

- 3D surfaces free-form sculpting (*Sculpt*).
- Mesh selection and smoothing tools (*Select → Deform → Smooth*).
- Boolean operations (*Analysis*).

- Auto-repair tool (*Analysis → Inspector*).
- Thickness analysis (*Analysis → Thickness*).

To summarize, the main objectives of these operations were the attachment of each floating part to the main body, the closure of the holes, apart from the foramen magnum, the flattening of the bottom part to prepare a good surface for head-neck connection, and the achievement of a symmetrical component.

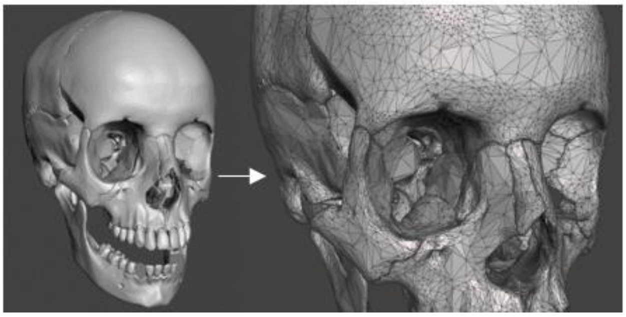


Figure 5: The original .stl file of human skull from Thingiverse.com and detail of the mesh defects.

Each one of the aforementioned operations needed to be executed maintaining the anatomical details (especially in brain housing) [7]. In particular, the average thickness stated in literature for both cortical and diploë bone is about 5.5 mm. Since the chosen material for the IHHS 1.0 (ABSplus-P430 styrene thermoplastic) is between 40% and 290% lighter than the skull, it was decided to thicken the skull by 165%, to obtain at least a thickness of 9 mm. This choice also granted to get a higher skull surrogate resistance. However, this original skull was slightly smaller with respect to the average male subject one. To overcome this, the whole model was scaled to reach the head length (horizontal distance from the glabella to the back of the head) of 200 mm, which was the average from literature anthropometric surveys [8, 9, 10]. The resulting IHHS 1.0 whole skull after these operations is shown in Fig. 6. Starting from the .stl file of the whole skull, top skull, bottom skull, and jaw models were then obtained to be 3D printed with Fused Deposition Modeling (FDM) technology, using the uPrint SE Plus model 3D printer, manufactured by Stratasys. In detail, top and bottom skull surrogates were assembled with a sawtooth suture [11].

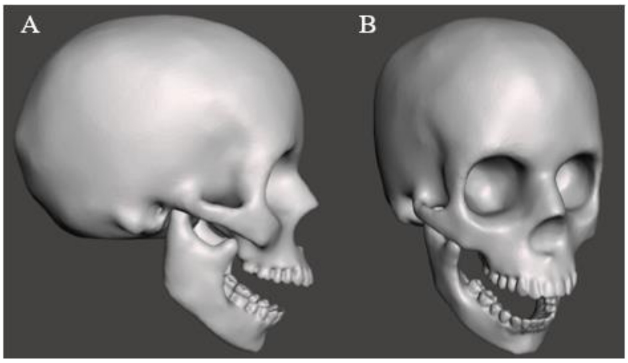


Figure 6: Resulting whole skull simulant of the first Instrumented Human Head Surrogate (IHHS 1.0). (A) Side view and (B) isometric view.

Nevertheless, the final circumference of the IHHS 1.0, including the skin simulant, is of 64 cm, which is too high to allow the appropriate wearing of an average helmet (Size M, 58cm of circumference). For the IHHS 2.0, the first adjustment was to use Meshmixer software to rescale the 3D model of the components (*Edit → Transform*), achieving a 10% smaller skull. Moreover, there was an enhancement in the connection between top and bottom skull surrogates. This was required because the sawtooth suture didn't guarantee the proper sealing. Furthermore, the improved connection geometry, shown in Fig. 7, was easier to assemble. The surrogates were then 3D printed in Polyamide PA2200 with Selective Laser Sintering (SLS) technology, using the FORMIGA P110 (EOS, Krailling, Germany) machine. The choice of the material and the printing technology allowed to avoid a possible leakage of the silicone oil simulating cerebrospinal fluid, which occurred instead in the first prototype. This latter was replaced with distilled water in the following versions, to avoid brain swelling due to oil absorption.

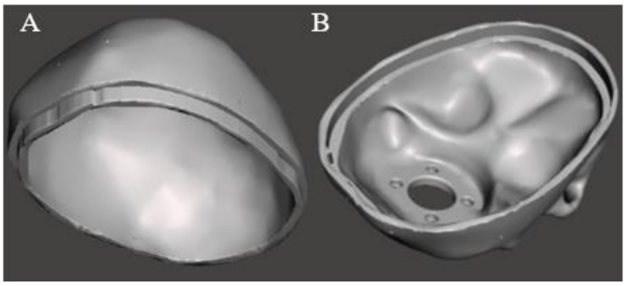


Figure 7: Top-bottom skull connection geometry of the second Instrumented Human Head Surrogate (IHHS 2.0). (A) Top and (B) bottom skull .stl files.

An o'ring was then interposed at the top-bottom skull coupling in the IHHS 3.0 and IHHS 4.0, as shown in Fig. 8 A, to ensure a waterproof sealing. Moreover, polyamide PA12 is slightly permeable to water, so a layer of Plasti Film was applied inside the skull surrogate. To guarantee both a resistant and removable sealing, three 1 mm thick rectangular shaped aluminum plates have been created and fixed with 4 screws. The jaw was connected to the skull with two M4 holes and relative inserts, and the joint was reproduced using two rubber bands. Fig. 8 B shows the final assembly of the skull surrogate components, which were 3D printed using SLS technology to obtain a surface finish without porosity. Finally, the distilled water was inserted from below, with the prototype placed upside down (Fig. 8 C), to remove the air in the volume.

The coupling of top and bottom skull in the current replica (IHHS 5.0) was improved by a triangular indentation, as shown in Fig. 9 A. Moreover, a solid and removable closure was allowed by adding ten M3 metric screws and brass inserts, as shown in Fig. 9 B. To realize the final .stl file for top skull, bottom skull, and jaw to adjust the mesh, MeshLab by ISTI-CNR software was required for cleaning and optimization operations using the following *Filters*:

- *Cleaning and Repairing* to remove duplicate faces and vertices, to repair non-manifold edges, and to select self-intersecting faces.
- *Remeshing, Simplification, and Reconstruction* to reduce the number of mesh elements and regularize the size of the elements composing the triangulated surface.

Figure 8: Third and fourth versions of the Instrumented Human Head Surrogate (IHHS 3.0 and IHHS 4.0) skull. (A) O'ring placement in skull surrogate, (B) final assembly of the skull surrogate components, and (C) distilled water insertion in the prototype.

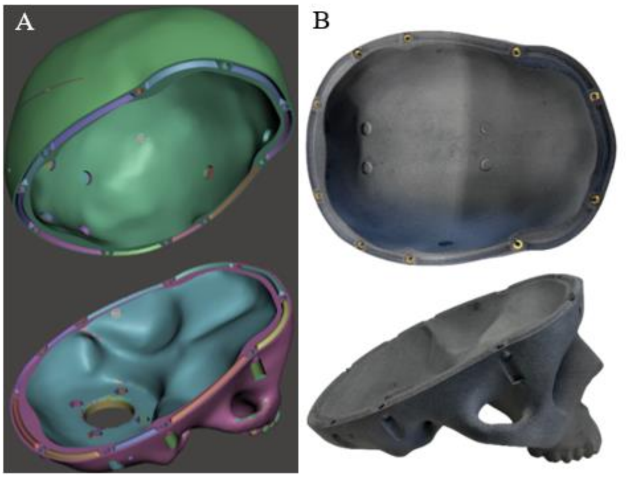


Figure 9: Skull surrogate modeling for the current Instrumented Human Head Surrogate (IHHS 5.0). (A) Triangular indentation as coupling among top and bottom skull and (B) 3D printed skull with holes for the screws and brass inserts.

The final .stl files (Fig. 10) were then 3D printed using SLS technology.

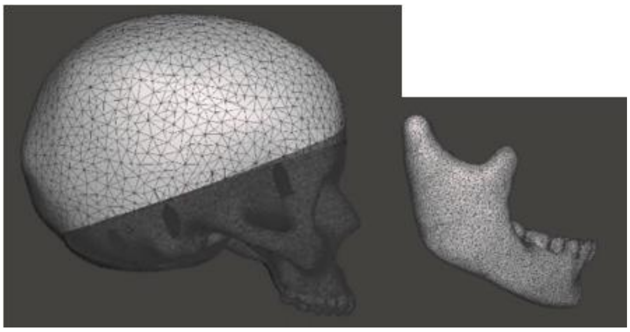


Figure 10: The skull geometry after surface optimization, cleaning and repair steps: top skull, bottom skull, and jaw .stl files.

As for the skull, the brain surrogate .stl file was created from MRI scan image taken by Thingiverse.com website. In this case, raw DICOM files were needed to perform the segmentation and to obtain the original brain model for the first prototype, as shown in Fig. 11 A and B. The mesh defects were removed using Meshmixer software, thanks to the same tools mentioned before for the skull geometry. The aim was to recover the separation between the hemispheres and the cerebellum and between the hemispheres themselves, to ensure the brain symmetry, and to thicken the brain stem (thus allowing the cables from the accelerometers to pass). The sulci were not represented to allow the demoulding phase to be easier and more robust. Moreover, since the subject of the brain and skull MRI were not the same, it was required to fit the brain shape to the skull [7]. Considering just 0.5 mm thickness for the dura mater [12] and 3 mm thickness for the arachnoid trabeculae [13], it was assessed a total gap of 3.5 mm. For safety, Meshmixer *Analysis* → *Clearance* tool was used to verify the presence of at least a 5 mm thick interspace between the inner surface of the skull and the outer surface of the brain. Fig. 11 C and D show the final .stl brain file.

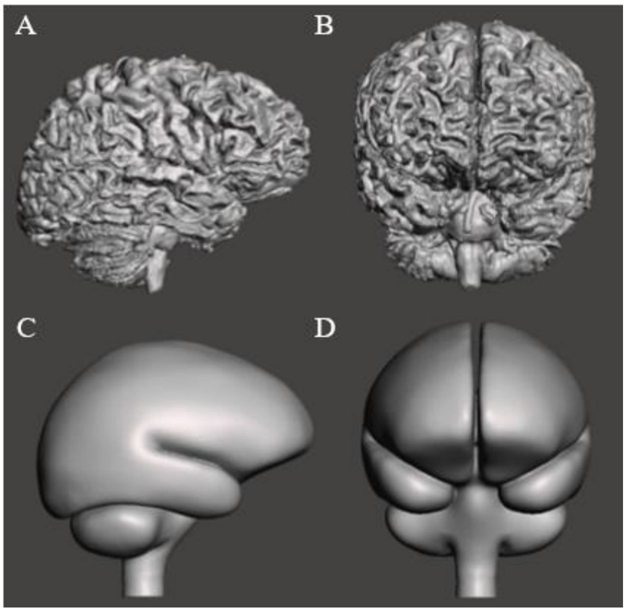


Figure 11: The first Instrumented Human Head Surrogate (IHHS 1.0) brain simulant model. (A) Side view, original file, (B) frontal view, original file, (C) side view, final geometry, and (D) frontal view, final geometry.

As described for the skull surrogate, the brain .stl file was scaled by 10% to fit the helmet. The final .stl file, shown in Fig. 12, was needed to realize the moulds to be 3D printed and then used to cast the silicone rubber in the IHHS 2.0, 3.0, 4.0, and 5.0. The material used for the moulds is ABS plus-P430 for IHHS 1.0 and 2.0, while polyamide PA12 was chosen for the following prototypes (IHHS 3.0, 4.0, and 5.0). The ABS plus-P430 moulds were 3D printed with FDM technology (uPrint SE Plus machine), while SLS technology was used to print the moulds in PA12.

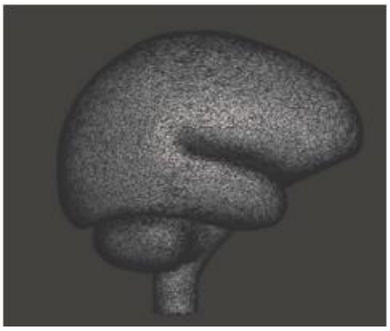


Figure 12: Final .stl file of the brain after 10% scaling.

In detail, seven moulds were designed using Meshmixer software. The brain was casted in three steps layer by layer [7, 11], from the brain top to the bottom, in order to prevent the creation of bubbles and to allow the placement of the sensors in the correct position within the uncured rubber simulating the brain. An orthogonal grid of channels was designed for all the three levels of molding (lower layer, middle layer, and upper layer casting), with the aim to guide the positioning of the sensors. These grooves were needed to house thin wires to be pulled, thus indicating the planar coordinates of the sensors at that specific molding level. Fig. 13 shows the .stl files of the moulds used for the brain molding process, along with the 3D printed moulds upside-down, as they were used for brain casting from the bottom to the top layer.

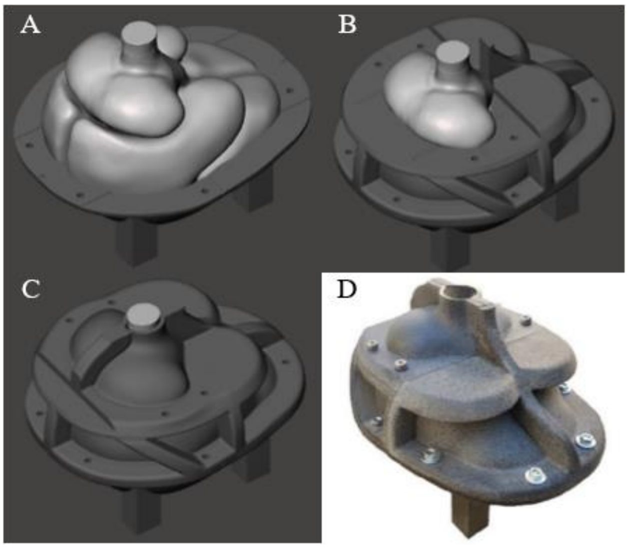


Figure 13: Brain moulds. (A) First and lower layer, (B) second and middle layer, (C) third and upper layer, and (D) 3D printed PA12 moulds for IHHS 3.0, 4.0, and 5.0.

The skin moulds were 3D printed with ABS plus-P430 for IHHS 1.0 and 2.0 (uPrint SE Plus machine, FDM technology) and Nylon PA12 for IHHS 3.0, 4.0, and 5.0 (SLS technology), once scaled to obtain the fitting around the skull. The skin moulds were designed in Meshmixer to cast the skin in several steps thus avoiding bubbles creation. In detail, the assembly was composed of 2 female moulds, representing the frontal and rear parts of the human face, and 1 male mould reproducing the skull geometry. Once the moulds were assembled, as shown in Fig. 14, the resulting gap between male and female moulds was to be filled with the silicone rubber simulating the skin.

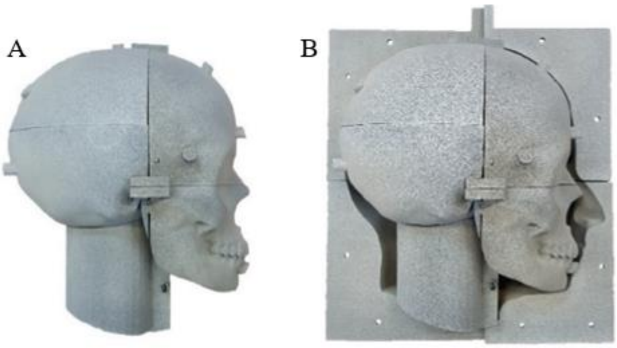


Figure 14: PA12 3D printed skin moulds. A) Male part and B) male and female left side moulds once assembled, with the gap to be filled with silicone rubber simulating skin.

The solid model representing the gap between the brain and the skull, anatomically occupied by both cerebrospinal fluid and meninges, was obtained using Autodesk's Fusion 360 software via Boolean operations (*SOLID → MODIFY → Combine*). Fig. 15 shows the resulting model of the gap, denoted as full meninges model hereafter. This model was the basis for the design of falx and tentorium models.

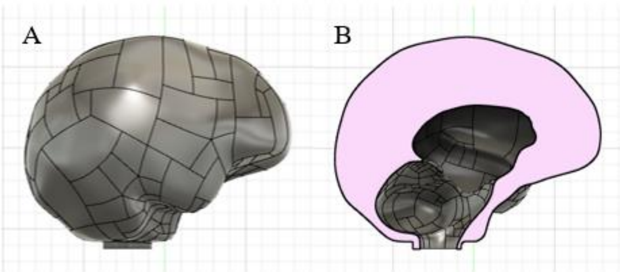


Figure 15: Building of the solid model of the gap between brain and skull. (A) Cerebrospinal fluid - meninges model and (B) section of the cerebrospinal fluid - meninges model.

The solid model of the falx was built in Fusion 360 thanks to Boolean operations (*SOLID → MODIFY → Combine*). In particular, the falx cerebri shape (Fig. 16 A) was achieved intersecting the full meninges model with a 1 mm thick parallelepiped. Then, to ensure an appropriate gluing of the physical falx to the inner surface of the skull, it was designed a 20 mm width band of about 1 mm thickness (Fig. 16 B) to be combined with the falx shaped model. In detail, this band was built thanks to Boolean operations (*SOLID → MODIFY → Combine*) and it was limited (*SOLID → MODIFY → Split Body*) to restrict the gluing zone to the top skull inner surface only. The final band was then unified with the falx shaped model to obtain the final falx model (Fig. 16 C).

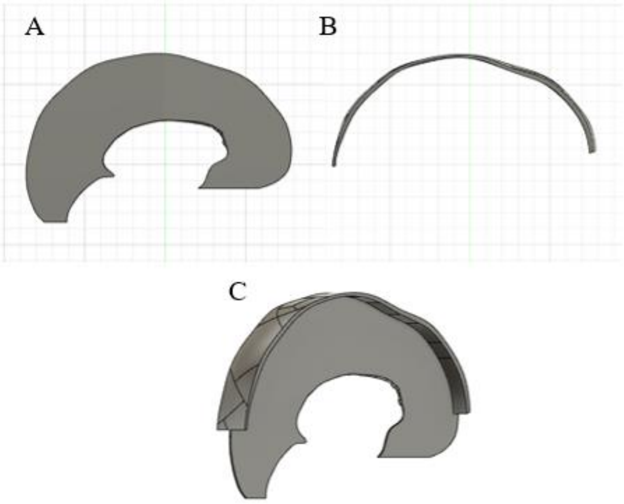


Figure 16: Construction of the falx solid model. (A) Falx shaped model, (B) 1 mm thick connection band to ensure the gluing of the falx to the inner surface of the top skull only, and (C) final solid model of the falx with the connection band.

The tentorium solid model was designed using the Loft tool (*SURFACE* → *CREATE* → *Loft*) in Fusion 360. This tool was required to sketch both right and left loft surfaces inside the volume enclosed by the occipital lobes of the cerebrum and the cerebellum. The obtained surfaces were then symmetrically thickened to get 1 mm thick solid models of the right and left parts of the tentorium (right model shown in Fig. 17 A). As for the falx, a 1 mm thick band was designed along the rear profile of both right and left models to allow the gluing to the skull surrogate (right band shown in Fig. 17 B). The two bands were unified with the tentorium models obtained before to get the final right and left tentorium solid models (right tentorium model shown in Fig. 17 C).

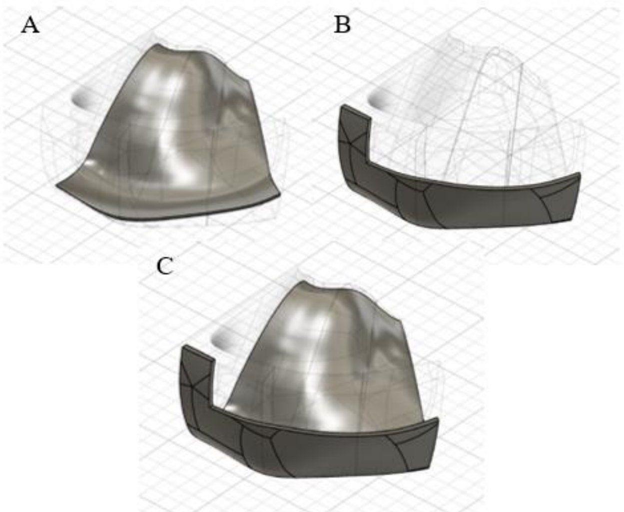


Figure 17: Construction of the right tentorium solid model. (A) Right tentorium loft surface after symmetrical thickening, (B) 1 mm thick right band, and (C) final right tentorium solid model.

Finally, falx, right tentorium and left tentorium solid models, shown in Fig. 18, were exported as .stl files to be 3D printed with Multi Jet Fusion (MJF) technology. The material chosen was thermoplastic polyurethane (TPU), shore 95A. Fig. 19 shows the 3D printed physical surrogates after their assembling.

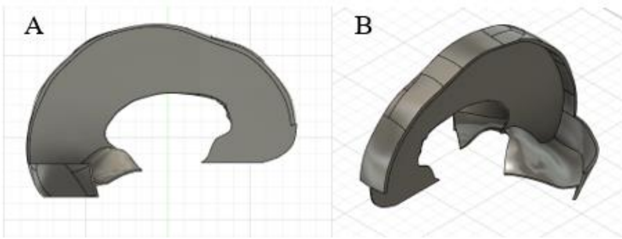


Figure 18: Views of the assembly of final falx, left and right tentorium solid models. (A) Lateral view and (B) isometric view.

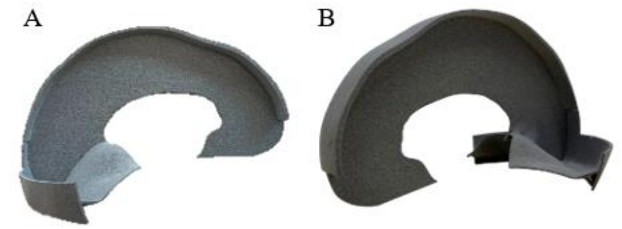
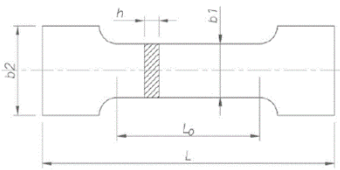


Figure 19: Final 3D printed falx, left and right tentorium models. (A) Lateral view and (C) isometric view.

The materials proposed to simulate the skin, the skull, the arachnoid trabeculae, and the brain were characterized by means of mechanical tests to establish their mechanical response and to compare their behaviour with literature data. Testing methods are extensively described in the Supplementary Material of Petrone et al. [11].

Regarding the skull simulant, six PA12 dog-bone specimens were subjected to uniaxial tensile tests following the standard BS EN ISO 527-1: 1996. The dimensions of the specimens are shown in Fig. 20. MiniBionix II machine was used to perform the trials, with the aim to assess the stiffness in the elastic range and the yield strength of the material proposed. MTS 634.12F-24 Axial Contact Extensometer was used to measure the axial strain.



Overall length	L = 82 mm
Gauge length	L_0 = 40 mm
Thickness	h = 4 mm
Narrow portion width	b_1 = 15 mm
Overall width	b_2 = 25 mm

Figure 20: Dog-bone specimens dimensions according to BS EN ISO 527-1: 1996.

The achievement of the bio-fidelity of the skull simulant material was then assessed by evaluating the stiffness of the PA12 in the elastic range.

The silicone rubber used in the current prototype as brain simulant, together with three other potential similar materials, was tested under DMA and quasi-static tensile and compressive tests:

- PlatSil Gel-OO 1A:1B:1D silicone rubber, used in IHHS 5.0.

- PlatSil Gel-25 1A:1B:2D silicone rubber.
- Dowsil^{TM} EE-3200, a two-component polydimethylsiloxane.
- Humimic Medical Gelatin #5, a 100% synthetic gelatine used to simulate blood clots and brain tissues.

Thus, four 50x50x30 mm specimens were prepared and tested using the MiniBionix II machine, and their viscoelastic response was evaluated by assessing the storage and loss moduli and the phase angle during shear DMA.

In order to evaluate the risk of TBIs with helmet protection, 750 mm height drop tests were conducted on a 45° inclined anvil to assess the BrIC (Brain Injury Criterion) with the Hybrid III head and the IHHS 5.0. Moreover, it was studied the influence of MIPS® (Multi-Directional Impact Protection System). This device consists of a low-friction layer, placed inside the helmet, which reduces the rotational force transmitted from the helmet to the head in multidirectional impacts. The following equation was used to assess the BrIC:

$$BrIC = \sqrt{\left(\frac{\omega_x}{\omega_{xC}}\right)^2 + \left(\frac{\omega_y}{\omega_{yC}}\right)^2 + \left(\frac{\omega_z}{\omega_{zC}}\right)^2}. \qquad (1)$$

In detail, this criterion is based on head maximum angular velocities about x, y, and z axes (ω_x, ω_y, and ω_z) and on the critical values ω_{xC}, ω_{yC}, and ω_{zC}, corresponding to 66,25 rad·s^{-1}, 56,45 rad·s^{-1}, and 42,87 rad·s^{-1} respectively.

III. Results and discussion

Time, displacement and force data from Mini Bionix II were processed using MATLAB R2022b software to remove noise.

The resulting engineering stress-strain curves for each one of the six PA12 specimens are shown in Fig. 21 (Specimen 01 to 06).

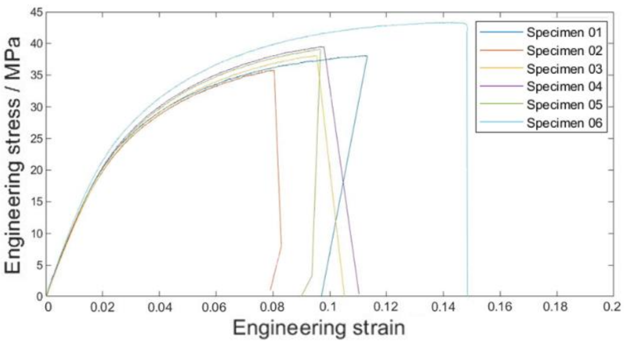


Figure 21: Engineering stress-strain curves from quasi-static uniaxial tensile tests on six PA12 dog-bone specimens.

As it can be observed, the mean Young's modulus, resulting from the average slope of the six curves in the elastic range, was found to be 1127,07 MPa. The average yield strength, defined as the stress corresponding to the strain value at which the material begins to undergo plastic deformation, was about 20 MPa. The Young's modulus was then compared to data available from literature on human skull compact bone and diploë [14]. In detail, the Young's modulus of the compact bone is between 5465 MPa [15] and 15000 MPa [16, 17], while for the diploë the value is in between 1000 MPa [17] and 8000 MPa [18]. These wide ranges are due to aspects like the subject morphological characteristics (sex, age, etc.) and conservation (fresh or frozen), the type of mechanical tests (tension-compression, torsion, bending), the strain rate, and the geometry of the samples [19]. However, even if the average Young's modulus of the PA12 results to be in the interval admitted for the spongy cancellous bone, it is about 5 times lower with respect to the inferior limit of the range which is stated for the compact bone. Therefore, the proposed material does not fulfil the stiffness requirements that are typical of the skull compact bone and thickness compensation was then justified.

On the other hand, the PA12 density (900-950 kg/m^3) is lower with respect to the average compact (2202 kg/m^3) and cancellous (1502 kg/m^3) bone ones [19]. This aspect was mitigated by increasing the skull model thickness in Meshmixer software, as previously stated.

As mentioned before, the bone tissue is difficult to mimic due to its sandwich structure, which ensures its resistance, rigidity, and lightness. In detail, the two skull layers of compact tissue are responsible for the mechanical resistance and the rigidity of the skull. Conversely, the layer of cancellous bone (diploë), which is made of trabeculae which are oriented as needed to bear loads, allows the tissue to be light. Polymers, like PA12, generally represent the best compromise to simulate human bones, but it's difficult to accomplish the desired biofidelity of the tissue. In fact, these materials only allow to reproduce a one-layer skull surrogate, which doesn't provide the adequate rigidity, resistance and lightness of the sandwich structure. Moreover, as evinced by the mechanical characterization, polyamide PA12 is not suitable to mimic the skull bone. This motivates the interest in finding a material capable of reproducing the sandwich structure and thus also guaranteeing the bone typical mechanical properties. In fact, replicating the peculiar structure of the cranial bones with the trabecular bone of the intermediate layer, in addition to making the impact behaviour of the structure more realistic, would also contribute to a better fidelity in the transmission of the impact energy to the brain tissue simulant. Therefore, headforms structured in this way would likely provide more reliable results in laboratory tests, which would be helpful for the development of protective devices. In order to improve this aspect, the use of the latest and most advanced additive manufacturing technologies seem promising, as they make it possible to replicate even complex structures such as trabecular bone, also using innovative materials designed for research applications and pre-clinical training (e.g. BoneMatrix™ by Stratasys).

In order to compare the viscoelastic response of the brain simulants tested with literature data on the human brain, the results of the shear DMA were evaluated. Fallenstein et al. performed DMA imposing a sinusoidal 7%-24% shear strain with a cycle frequency of 9-10 Hz [20]. Thus, the average shear storage modulus obtained in the 10%-20% strain range for the samples tested by DMA at 7 Hz cycle frequency (the most similar to 9-10 Hz among the ones adopted [11]) was compared with literature results (Fig. 22). As evinced, PlatSil Gel-25 1A:1B:2D average shear storage modulus is about half the value of the current simulant material, suggesting that it could be a better choice for a future prototype. Nevertheless, its average storage modulus results to be still too high (about 14 times) with respect to literature and it is very sticky and therefore difficult to handle. Dowsil average shear modulus is very similar compared to PlatSil Gel-25 1A:1B:2D one (-5,2% percentage difference), thus being about 13 times higher than human brain one. The material that shows the most promising viscoelastic response is Humimic Medical Gelatin #5, whose average storage modulus is less than 3 times that of the human brain, but further testing is needed because of issues related to the gluing method to the aluminium plates. Furthermore, gelatine is difficult to handle and it's prone to cut.

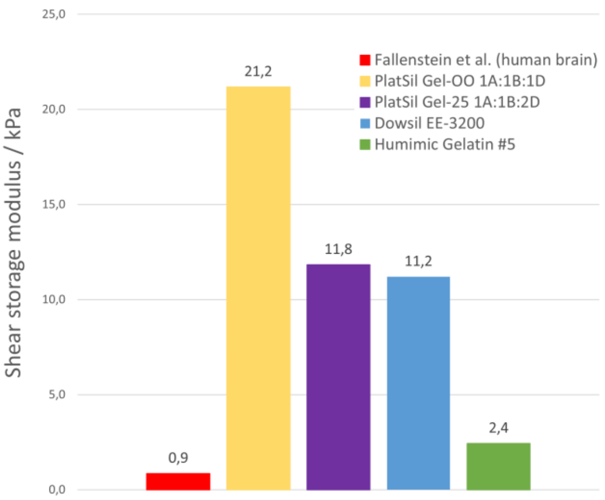


Figure 22: Average storage modulus for each material tested under 7 Hz shear DMA (10%-20% strain range) compared to literature data from Fallenstein et al. (7%-24% strain range).

In conclusion, the current brain simulant storage modulus is about 24 times higher than the one stated in literature for human brain tissue. However, Fallenstein et al. testing was performed in 1969, so further investigations and checks are needed. On the other hand, gelatine was found to be the most promising in terms of viscoelastic behaviour, but handling problems and issues related to the embedding of sensors inside the surrogate need to be considered. In fact, Humimic Medical Gelatin must be melted by heating it up to 125°C and then poured into the moulds, making sensor placement problematic. Indeed, if the casting were done in two steps to allow the sensors to be housed after the first of the two layers of gelatine has cooled, it would then not be possible to join the two halves of the surrogate. The availability of a material with the same properties as gelatine, but 3D printable, could hopefully solve the problem.

For what concerns the full-scale test with or without MIPS® device in the helmet, the Brain Rotational Injury Criterion resulting from the drop tests on the Hybrid III dummy head compared to IHHS 5.0 with and without MIPS® are reported in Fig. 23.

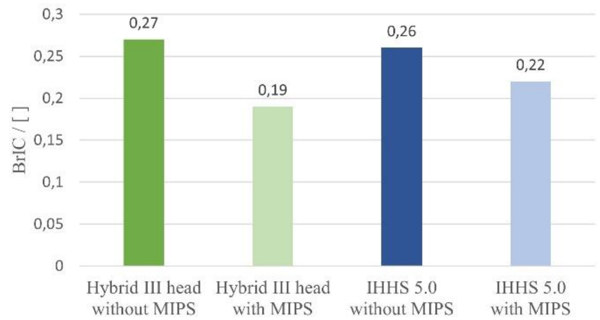


Figure 23: BrIC assessment for Hybrid III head and IHHS 5.0 resulting from drop tests wearing the helmet with and without MIPS®.

Considering the drop tests using the same headform with and without the MIPS®, a reduction of the BrIC value with the MIPS® can be observed, confirming a certain degree of effectiveness of the protection system. In detail, a reduction of 29,6% for Hybrid III head and of 15,4% for IHHS 5.0 can be observed. This means that the protection effectiveness evaluated with the IHHS 5.0, including a biofidelic brain simulant, is almost half the effectiveness evaluated with the rigid hollow skull surrogate. The different values obtained with/without MIPS® suggest that the use of a biofidelic headform can influence the evaluation of the effectiveness of the device, as the presence of the brain surrogate and its relative motion with respect to the skull can have a delay effect on the skull motion peaks. This justifies the research towards an increased biofidelity of the material used to surrogate the brain tissue in order to lead to a more accurate reproduction of injuries mechanisms.

IV. Conclusions

This project, involving both the University of Padova and the Mid Sweden University, aimed to develop biofidelic Instrumented Human Head Surrogates (IHHS), equipped with a brain simulant, to acquire data from impact tests. The purpose was to improve the biofidelity of the materials, the design of the components, and the sensors equipment of each replica with respect to the previous one. The results of drop tests performed on a 45° inclined anvil, using both Hybrid III head and the IHHS 5.0, confirmed the significance of biofidelity in the assessment of brain injury.

Considering the last surrogate (IHHS 5.0), skin, skull, cerebrospinal fluid, and brain simulant materials were unchanged with respect to the previous prototype. Arachnoid trabeculae were simulated by an open-cell polymer foam to mimic their cushioning effect under compressive loading. Moreover, the open-cell design allowed a proper flow of the cerebrospinal fluid simulant. The inclusion of the falx and tentorium surrogates, which were designed and 3D printed in TPU by MJF technology, enriched the biofidelity of the replica by partially limiting the extent of brain damage resulting from shaking trauma. In terms of geometry, the coupling of top and bottom skull was enhanced by a triangular indentation, along with the addition of metric screws and brass inserts to allow a solid and removable closure. The skull surrogate sensors equipment was adjusted to make it easier the wires route, thus placing all the piezoresistive pressure sensors on the upper half (top skull) internal surface.

One of the improvable aspects in the surrogate design is the biofidelity of the skull simulant material, which is difficult to accomplish with the normally employed polymers. In fact, polyamide PA12 was found to be not suitable to fulfil the stiffness requirements of the skull bone sandwich structure. The use of additive manufacturing technologies could be auspicious to reproduce the complex cancellous bone. The trabecular arrangement among two compact layers would allow to obtain the required sandwich layout. A possibility could imply the use of innovative materials designed for research applications and pre-clinical training.

A further improvement could come from the application of innovative materials and techniques to construct soft tissue surrogates, such as the brain one. In this area, the field of 3D printing of materials such as gelatine, agarose, phytagel, hyaluronic, and PVA hydrogels is considered worthy of further research.

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Author's statement
The authors state no conflict of interest. Informed consent has been obtained from all individuals included in this study.

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