ARL-TR-9270 ● AUG 2021

Development of a Biofidelic Surrogate Scalp Using an Additive Manufactured Mold

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)* August 2021	**2. REPORT TYPE** Technical Report	**3. DATES COVERED (From - To)** September 2019–December 2020

4. TITLE AND SUBTITLE
Development of a Biofidelic Surrogate Scalp Using an Additive Manufactured Mold

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Ryan Neice, John Brown, Joshua Taggart-Scarff, and Thomas Plaisted

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
DEVCOM Army Research Laboratory
ATTN: FCDD-RLW-MA
Aberdeen Proving Ground, MD 21005

8. PERFORMING ORGANIZATION REPORT NUMBER
ARL-TR-9270

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release: distribution unlimited.

13. SUPPLEMENTARY NOTES
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14. ABSTRACT

Biofidelic surrogate materials that mimic the mechanical response of the human skull and scalp serve as convenient and repeatable alternatives to using postmortem human tissue in survivability assessments of head protection equipment. Recent work at the US Army Combat Capabilities Development Command Army Research Laboratory has led to the development of a biofidelic surrogate of the human skull. This report outlines the development and validation of a compatible human scalp surrogate. Using the geometry from the surrogate skull, an additively manufactured mold was created, allowing for the injection of a scalp surrogate material. The scalp material was selected for its demonstrated correlation to the tensile response of human skin. Scalp surrogates were checked for dimensional consistency and through-thickness hardness (durometer) across the surface and compared to similar measures in human scalps from the literature.

15. SUBJECT TERMS
human scalp, tissue surrogate, additive manufacturing, behind helmet blunt trauma, head form

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			Thomas Plaisted
Unclassified	Unclassified	Unclassified	UU	18	**19b. TELEPHONE NUMBER (Include area code)** (410) 306-4960

Standard Form 298 (Rev. 8/98)
Prescribed by ANSI Std. Z39.18

Contents

List of Figures

List of Tables

1. Introduction

Biomechanical experiments are best performed on representative human test subjects to ensure a biofidelic response. In scenarios where there is a high likelihood of injury to a human test subject, biofidelic surrogates must be used to accurately represent the motion and response of the human body. These surrogates range from complex mechanical devices to tissue harvested from human cadavers. This technical report details the fabrication of a tissue surrogate of the human scalp for performing impact experiments to evaluate head protection equipment.

The intention of this scalp surrogate was to provide an outer covering for the US Army Combat Capabilities Development Command Army Research Laboratory (ARL) Skull Surrogate. The skull surrogate was developed to mimic the flexure and fracture of the human skull in blunt impact and ballistic loading events.[1–4] One application of the skull surrogate is in the assessment of behind-helmet blunt trauma (BHBT), where deflection of the helmet shell due to ballistic impact may cause traumatic loading to the skull and brain, despite stopping the penetration of the threat. Prior biomechanical experimentation to understand these high-energy events have used postmortem human subject (PMHS) heads to examine injury patterns and thresholds.[5–7] While achieving a high level of biofidelity, ballistic testing with PMHS tissue requires stringent protocols to safely handle and store biohazardous material. Moreover, the tissue may have a large range of variability in mechanical response depending upon the age and health of the donor and the tissue preservation techniques. Alternatively BHBT testing has been performed with anthropomorphic test devices (ATDs), including metal head forms filled with malleable clay, to achieve a rapid and repeatable test methodology at the expense of biofidelity.[8] Indentation of the clay provides a measure of dynamic helmet shell deformation, which is then related to a probability of skull fracture. The ARL Skull Surrogate offers a compromise between the high biofidelity of PMHS testing and the convenient and repeatable format of clay head form testing.

The role of the human scalp in attenuating energy from impact events and the incidence of skull fracture is unclear. Generally the scalp is loaded in compression over a localized region between the helmet shell/liner and skull in these events. Its inherent elasticity likely filters out the higher frequencies of the impulse and may attenuate the peak forces by extending the impact duration. The resistance of the skin to indentation provides a first-order approximation of its mechanical response in this type of loading. In elastomers and other polymers the resistance to indentation, or hardness, is defined by its durometer reading. In this report we describe the selection of an elastomer to mimic the scalp and compare its durometer readings to measurements of the human scalp. Likewise we seek to create a surrogate with a cross-sectional thickness that is in line with that of the human scalp. We detail the creation of a mold to make surrogate scalps with the targeted thickness and contours to mate with the outer surface of the ARL Skull Surrogate.

2. Scalp Surrogate Material Selection

Historically, the mechanical response of human skin has been researched for a variety of applications including cosmetics product development, clinical practices, and biomechanical evaluations. The commonly used Hybrid III crash test dummy utilizes a vinyl surrogate skin, which plays an important role in the biomechanical response of the test dummy.[9] Characterizing the mechanical response of human skin is difficult due to a range of different variables owing to its collagen fiber orientation, mechanical and physical loading history, loading rate, anatomical location, age dependency, and hydration dependency.[10] Selection of a material to serve as a surrogate skin is highly dependent on its intended use.

Chanda examined the suitability of various combinations of two types of a two-component elastomer as a surrogate for human skin.[11] These combinations consist of a very soft two-part elastomer with a Shore hardness of 00-10 (Ecoflex Part A and B) and a stiffer two-part elastomer with a Shore hardness of 30A (Moldstar A and B). Twenty-three different combinations of these elastomers were used to fabricate surrogate human skin coupons. The tensile response of these formulations was compared to human skin tensile test data from Ní Annaidh et al., which characterized various coupons of human skin from the back region at different orientations.[12] The selected formulation was chosen to fall between the upper and lower bounds of the human tissue response (Fig. 1), corresponding to "Type 23" as described in Chanda.[11] The ratio of the four-part elastomer chosen per 100-g batch was as follows: 4-g EcoflexPart A, 4-g Ecoflex Part B, 46-g Moldstar Part A, and 46-g Moldstar Part B. The Moldstar Part B gives the skin cap mixture a distinctive blue color.

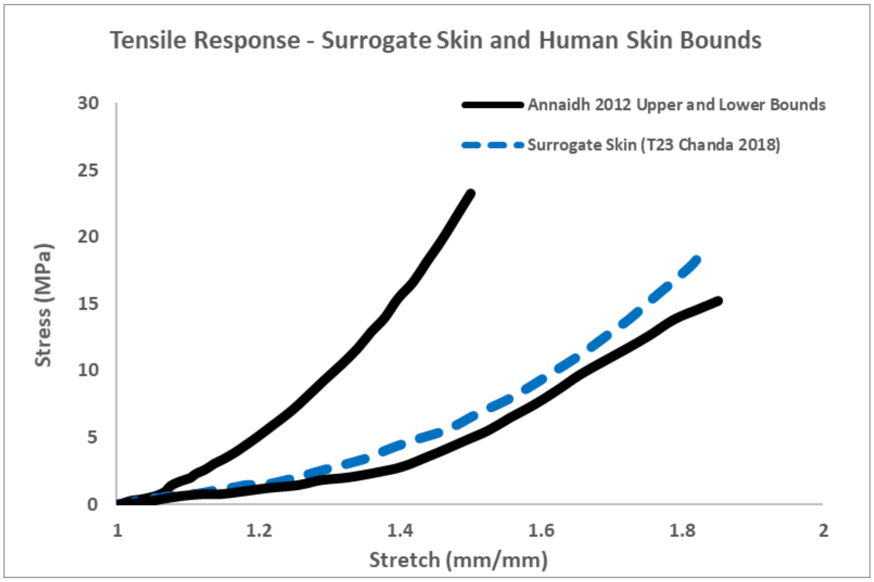

Fig. 1. Tensile response of surrogate skin formulation T23 from Chanda.[11] Solid lines represent the upper and lower bounds of tensile response of human skin measured in Ní Annaidh et al.[12]

3. Mold Design

The geometry of the ARL Skull Surrogate is based upon a computed tomography scan of a male between the age of 20 and 25. As such it contains biofidelic features and contours throughout its volume (Fig. 2). The computer-aided design (CAD) geometry files of the skull serve as the basis for creating the mold for the surrogate skin.

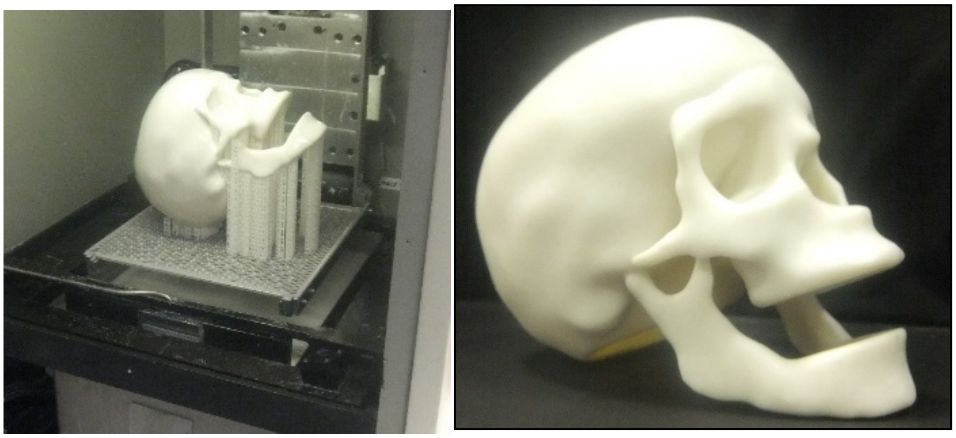

Fig. 2 Additive manufacturing (left) of the ARL Skull Surrogate (right)

The CAD was first segmented in the transverse plane at a location just above the brow ridge to retain only the skull cap region. The superior surface of the skull cap, which interfaces directly with the scalp, provided the geometry and contour of one surface of the mold. The other surface was created by using the *Offset Surface* feature in Solidworks 2019 to achieve the desired thickness of the scalp surrogate. That thickness was set to 3 mm in close agreement to that of the average scalp thickness of the male population.[13,14] Combining these two surfaces created the positive volume of the scalp surrogate. A separate part was created within the CAD design to represent the mold. The positive volume representing the scalp was then removed from the interior of the mold part to leave a cavity where the scalp surrogate material would fill. The mold cavity was then sectioned into male and female halves to enable extraction of the scalp and reuse of the mold. Keyed features were placed at two opposing ends around the perimeter of the mold to enable precise fitting of the top and bottom halves. A fill port consisting of a conical hole was created on the surface of the top mold. Finally, a series of vent holes placed approximately every 10 mm around the perimeter enabled entrapped air to escape as the mold was filled from the bottom to top. The two mold halves and salient features are illustrated in Fig. 3.

The surrogate scalp mold was produced in two pieces using a 3DSystems Projet 6000 stereolithographic printer. Epoxy acrylate polymer Accura Clearview was chosen for its strength, modulus, dimensional tolerance, and transparency, allowing visual examination that the cavity was completely filled with the molding material. Each half of the mold was post-cured in a 3DSystems ultraviolet chamber for 30 min.

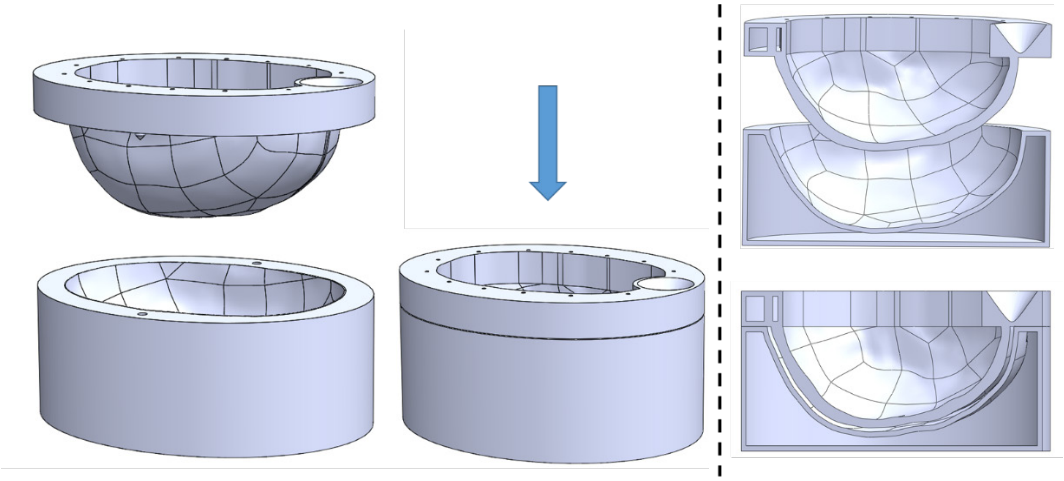

Fig. 3 (Left) Isometric view of opened and closed mold CAD. (Right) Sectioned view of mold CAD; visible is the 3-mm thickness mold cavity.

4. Procedure for Surrogate Scalp Production

To prepare the scalp cap mold, the inner surfaces were coated with a mold release (CRC General Purpose Boron Nitride Mold Release) to aid in release of the cured material from the mold surface once cured. The elastomer formulation detailed in Section 3 was mixed for 4 min in a clear container using a stirring rod and then examined to confirm the blue and clear liquids were mixed homogenously. The material was degassed in a vacuum chamber over four vacuum/purge cycles to extract air bubbles from the mixture. The material in the container was closely monitored in the first vacuum cycle to prevent possible overflow of the container. A reservoir of 100 mL of material was poured in the bottom cavity of the scalp mold. Next, the top of the mold was placed tightly against the bottom cavity, allowing the material to begin to take the shape of the scalp cap. Additional material was injected by syringe into the mold to fill the remaining space until it escaped out of the vent holes (Fig. 4). A 4-kg mass was placed on the top of the mold surface to ensure the two halves were fully mated and remained so during the cure process. The material and mold were left untouched for at least 12 h to cure at ambient temperature.

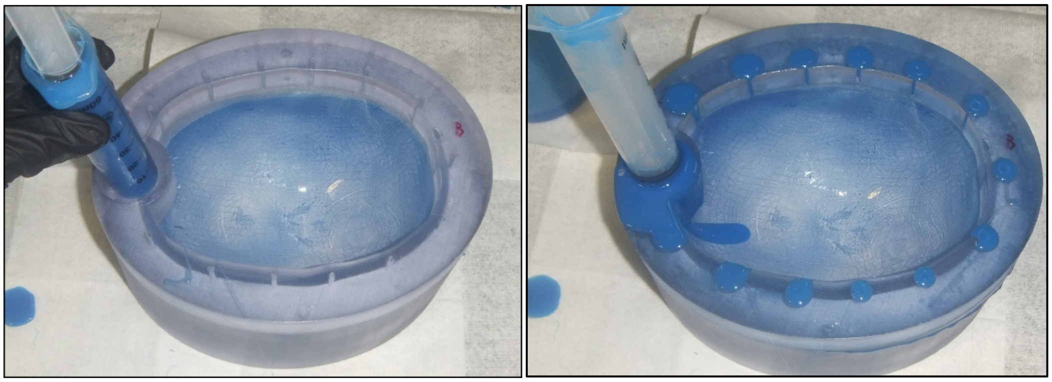

Fig. 4 Injection of the "Type 23" elastomer formulation (left). The mold was injected until the vent holes produced overflow material (right).

The mold was separated with the use of thin spatulas to drive apart the mating surfaces of the two halves of the mold. The use of mold release helped reduce the amount of effort needed for this process. Residual cured elastomer material was carefully cleaned from the mold cavity and mating surfaces after demolding in preparation for subsequent pours.

5. Analysis of Results

The mass and regional thickness of five demolded scalp caps were compared to verify consistency in the molding procedure. Thickness measurements were taken at locations corresponding to approximately 25 mm above the front, left, right, and back side of the inferior bottom surface of each scalp cap. The standard deviation of thickness measurements of the five surrogate scalps was 0.1 mm at each regional location and the standard deviation of the scalp mass was 0.2 g. The results of this consistency check given in Table 1 underscore the repeatable nature of the surrogate scalp manufacturing process.

Table 1 Scalp surrogate mass and dimensional measurements over five moldings

Measurement	Location	Scalp 1	Scalp 2	Scalp 3	Scalp 4	Scalp 5	Average	S.D.
Surrogate Scalp Thickness (mm)	Front	3.1	3.1	3.2	3.2	3.2	3.2	0.1
	Left Side	2.8	2.7	2.8	2.6	2.8	2.7	0.1
	Right Side	2.9	2.7	2.7	2.8	2.6	2.7	0.1
	Back	3.1	3.1	3.1	3.1	3.3	3.1	0.1
Surrogate Scalp Mass (g)	-	146.5	146.1	145.9	146.3	146.1	146.2	0.2

Resistance to indentation is considered an important material property for the application of these surrogate scalps in BHBT testing. Pittar et al. measured the hardness of the human scalp with a Shore A-type durometer on 30 human volunteers.[15] The study population consisted of five males and five females in three different age groups: 18–30, 31–40, and 41–50. The hardness was measured at nine locations on the scalps of each volunteer. The mean Shore-A durometer measurement calculated from the sample population was 20.6, with a range from 18.0 to 28.0. For comparison, the surrogate scalp was attached to ARL Skull Surrogate head form (Fig. 5) and durometer measurements of the scalp surrogate were recorded in similar locations using a PTC Classic Style Durometer (model PTC306L). The mean Shore-A durometer measurement for the surrogate scalps was 26.4, with a range from 23.0 to 30.0. The regional durometer measurements in the surrogate scalp tended to be slightly higher (average 5.5 points on the Shore A scale) than those detailed in Pittar et al.[15] while having a comparable min-max range.

Fig. 5 Top, front, and isometric views of the skull cap placed on a surrogate skull

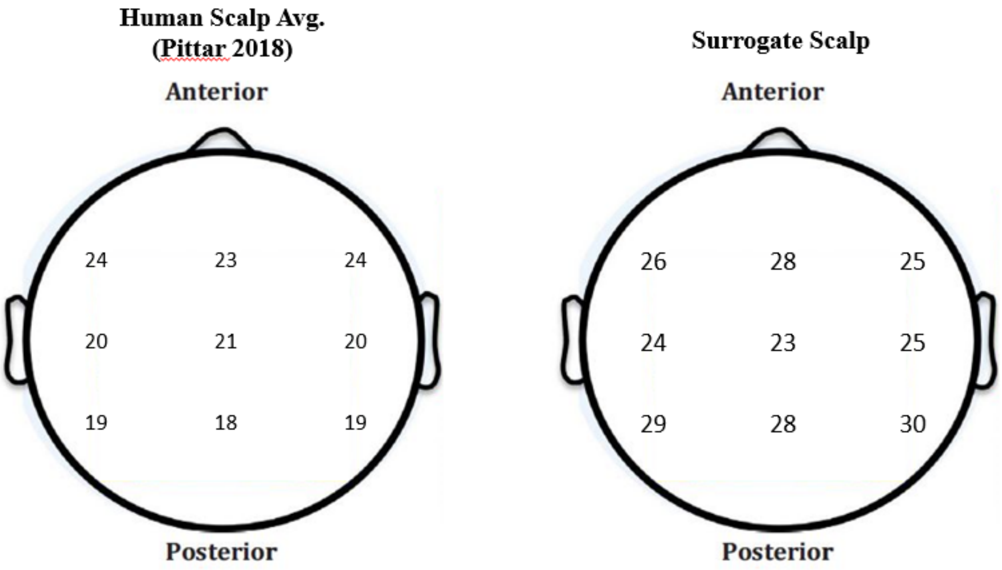

Fig. 6 Shore-A durometer measurements from human volunteers (left), compared to the surrogate scalp (right)[15]

The authors acknowledge that durometer measurements are typically obtained on specimen with thicknesses of at least 6.0 mm to achieve the greatest accuracy, per ASTM D 531-00.[16] As such, the values reported here may not reflect the true Shore-A durometer values of the elastomer if measured on a thicker sample. Nonetheless this condition applied to both the human and surrogate measurements, wherein a thin compliant material (human or surrogate scalp) was backed by a rigid substrate (human or surrogate skull), enabling relative comparison between both data sets.

6. Conclusion

There are inherent strengths and weaknesses of using ATDs versus PMHSs in biomechanical experimentation. Human tissue surrogates serve as an intermediary between the two in that they offer biofidelity that can approach that of PMHSs while retaining the ease of use, repeatability, and availability of ATDs.

Using the geometry from a prior developed surrogate skull head form, a mold capable of producing a human scalp cap geometry was designed and fabricated via additive manufacturing. A consistent 3-mm thickness was targeted for the surrogate scalps in agreement with anatomical measurements of the human scalp in the literature. Based on prior studies in the literature geared toward development of surrogate skin materials, an elastomer formulation was selected that demonstrated quasi-static tensile properties comparable to that of PMHS skin. The elastomer was cured within the mold to produce scalp surrogates with relatively uniform thickness and repeatability between specimens. The Shore-A durometer of the scalp surrogate was compared to experimental measurements of the human scalp. The overall average Shore-A durometer of the surrogate versus the human data was 26.4 versus 20.6, considered well within acceptable range for the intended blunt impact testing applications.

Future application of the scalp surrogate will include BHBT testing under representative ballistic conditions as well as impact at lower speeds as used when evaluating Army combat helmets for blunt impact protection of the head.[17] Further development may seek to integrate additional functionality such as contact indication and sensing via mechanophore chemistry.[18]

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List of Symbols, Abbreviations, and Acronyms

ARL	Army Research Laboratory
ATD	anthropomorphic test device
BHBT	behind-helmet blunt trauma
CAD	computer-aided design
DEVCOM	US Army Combat Capabilities Development Command
PMHS	postmortem human subject

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