# Customized Manufacture of Protective Headgear for Primary Prevention of Fall Related Traumatic Brain Injuries

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### ABSTRACT

This paper summarizes efforts to develop a primary prevention intervention to reduce traumatic brain injury (TBI) for older adults and for persons prone to falls based upon a patented highly efficient dilatant/honevcomb impact resistant material system. The protective headgear is designed for aesthetic appeal and comfort by using advanced materials and customized manufacturing techniques. Currently two major issues to commercialization related to manufacturing are being resolved; the need for custom fit for efficacy and comfort, and the need to automate the manufacturing process of this individualized product. Proper fit enhances the functionality and eliminates the need for stigmatizing straps that are typically used for retention in other helmet protection products. Customized design will lead to a value added product that enhances function and compliance.

*Keywords*: Impact protection, fall injury mitigation, headgear

#### **1 INTRODUCTION**

According to the U.S. Center for Disease Control (CDC) in a 2006 study published in the Journal of the American Geriatrics Society, more than one third of adults 65 and older fall each year in the United States, with falls being the most common cause of traumatic brain injury (TBI) (Thompson, 2006). In 2010, 2.3 million nonfatal fall injuries among older adults were treated in emergency departments and more than 662,000 of these patients were hospitalized (Faul, 2010). In that same year, the direct medical costs of falls, adjusted for inflation, was \$30.0 billion. Every year, between 700,000 and 1.0 million patients suffer a fall during their hospital stay (Agency for Healthcare Research and Quality), and the average increase in hospital operational costs due to these fall injuries exceeds \$13,000 and patient lengths of hospital stay (LOS) increases by an average of 6.27 days. With the average charges for a TBI hospitalization at about \$17,500, which may not be reimbursed if Medicare deems the fall-related injury as a preventable event; results in an estimated cost of more than \$1 billion in direct hospital expenses.

With falls being the most common cause of TBI and more than one third of adults 65 and older falling each year, it is imperative action be taken. Since 2008, patient falls with injury have been listed by Centers for Medicare & Medicaid Services (CMS) as non-reimbursable HAC's (hospital acquired conditions) and in 2014 hospitals with high rates of HAC's will receive a 1% cut in Medicare reimbursement. Beyond the immediate costs of treating these injuries, long-term societal costs are high as well. There is a fourfold increased risk of significant cognitive decline from head injuries in adults over age 70 years, and 60% of adults over age 85 will require long-term care and/or home health services following an admission for a TBI. Furthermore, the challenge of fall prevention is increasing as the older population increases - 22% of hospital patients are now 74 years and older (CDC) meaning that every state, especially those with high elderly populations (Maine, Pennsylvania, Florida, Arizona) will need to seek TBI risk abatement solutions.

Non-stigmatizing protective headgear is a viable method to mitigate head injury for persons at risk for falls. To that end, a protective system for reducing head injury due to falls needs to be designed with specific criteria in mind including appearance, injury protection level, thickness, stiffness, weight and cost among others. Use of higher impact energy levels in the design typically requires the resistive system to become thicker and or stiffer. Systems that become too thick or stiff can be objectionable to the user due to comfort and aesthetic reasons. Unattractive fall protection helmets often are stigmatizing, contributing to poor adherence even if prescribed by a medical doctor for a patient at risk for falls. Therefore use of an advanced material system that results in thinner more aesthetic designs and a comfortable product could provide the only primary prevention approach for older adults.

Alba-Technic LLC is an early stage company with a proprietary technology being specifically applied to the development and production of customizable, comfortable, and fashionable headwear called SMARTY® to reduce the risks and costs associated with TBI in the elderly. SMARTY® qualifies for reimbursement under existing CMS and commercial payer coverage, coding and payment

policies related to protective headwear. related to protective headwear.

## **2** TECHNICAL DEVELOPMENT

Alba-Technic, LLC and the University of Maine are collaborating to develop an automated small batch manufacturing system that streamlines both the customization and manufacture of the product while ensuring a functional and desirable design. The design and manufacturing efforts have been supported by a National Institutes of Health/National Institute on Aging SBIR Phase I/II award, the Maine Technology Institute (MTI) and currently by a National Science Foundation (NSF) STTR Phase I award under the small batch manufacturing program and the Maine Technology Institute (MTI). SMARTY® is currently the subject of a manufacturing research and development effort that has several technical objectives including: 1) Optimize and validate the functional performance of the headgear; 2) Develop an automatic system to quantify parameters required for custom fit of the protective headgear; and 3) Design and develop the manufacturing system to automate the small batch production process. The custom fit system uses 3-D image capture techniques to assess the shape of a customer's head. This shape information is then sent to a design/selection algorithm. Advanced manufacturing techniques are being developed to create a contoured impact resistant structure for the headgear. The shape of the internal impact resisting system is designed for fit, aesthetic appeal, function and comfort and then covered with a fabric material that can be selected by the end user.

Alba-Technic's SMARTY, shown in Figure 1, offers a headgear option for older adults that is designed to be integrated into fashionable headwear, while providing protection against head injury. The fact that this technology is lightweight and can be incorporated into caps, scarves, hats, etc. is important, given that commercially available products are bulky and draw attention in an undesireable manner. Additionally, focus groups of experts in healthcare of older adults and end-users expressed that the technology would only be worn if it looked like typical headwear.

In a recent social marketing and consumer preference trial conducted by UCLA in a Southern California senior community [3], the prototype SMARTY product demonstrated a significant increase in acceptance as measured by a pre-post attitudes questionnaire based on the theory of planned behavior. The social marketing approach provided information on the extent of the public health issue, the risk of TBI and information about the advanced materials and the biomechanical impact testing of the SMARTY®, via a flyer, a 3-minute video, and a 3-page article. The Factor Analysis of the the validated attitudes questionnaire identified that three factors covered the majority of the variation in the attitudes data; appearance/self-consciousness, please others/usefulness and value. Focus groups were conducted following the consumer preferences trial and feedback included the need for space for eyeglasses around the ears (minimum redesign) and in some limited cases a relatively "poor" fit. For some people the headwear was too big and others it was too small and concerns were expressed over headaches or fears that the headgear would fall off.



Figure 1: Alba-Technic Prototype Headgear.

### 2.1 Custom Fit System

Research on a custom fit manufacturing process was embarked upon to address the concerns. Figure 2 provides a schematic view of the proposed process. The analysis of the geometric information from the head measurement system is used to develop a method for exporting the optimized key manufacturing parameters to an automation controller. The current molding technique has been proven to result in a reliable product but the fit would be improved by producing automated parts contoured to the head while keeping the product affordable. To that end, we are developing an automation system based upon the proven molding process and embed the potential for expansion into 3-D printing of required tooling into the automation controller architecture. In this manner, the customization process will be versatile and can plug-into either manufacturing method, or any other viable technique that emerges. The focus is on developing a highly functional product with a custom fit using the most cost effective manufacturing methods available.

## **3 PRODUCT ASSESSMENT**

A verifiable test protocol for assessing the performance of the headgear is of utmost importance especially in the absence of standards for such type of impact resisting headgear. Development of these testing methods is based upon data collected on fall impact using a combination of anthropomorphic test dummy (ATD) testing, numerical analysis, cadaver testing and on a limited basis human testing. Based upon this data a repeatable test methodology was developed using the American Society of Testing Materials (ASTM) standard for impact testing of helmets in combination with an apparatus modified with an ATD head and neck assembly. The purpose of this impact testing is to characterize the injury mitigation capability of the initial prototypes and to develop a baseline for assessment of future design.



Figure 2: Schematic of the Customization Process

### 3.1 Performance Test Apparatus

A test apparatus was fabricated for the purpose of assessing fall protective headgear [4]. The apparatus is based upon a Hybrid-III head/neck assembly provided by Humanetics<sup>TM</sup> of Plymouth, MI. The drop mechanism consists of a twin wire fall system equipped with a drop arm that includes a 50th percentile male Hybrid-III head/neck assembly. The twin wire drop tower, shown in Figure 3, was designed and constructed at the University of Maine and has a 6 m maximum drop height. It was originally built for an ASTM F1446 type test but has been retrofit with the current head/neck apparatus.

Components of both linear and angular accelerations were measured and the maximum linear acceleration. maximum angular acceleration and the head injury criteris  $(HIC_{15})$  values are reported. The relative performance of the protective headgear compared to the unprotected case is also quantified. Head injury measures summarized for an unprotected drop include maximum linear and angular acceleration, HIC<sub>15</sub>, rotational injury criteria (RIC), and power rotational head injury criteria (PRHIC). The drop test apparatus results in a repeatable test method that has potential to be used in studies of headgear designed to reduce head impact injury. Tests were done in frontal, rear and side impact orientations. A series of tests were performed at various impact energy levels to quantify the performance of the device over a range of impact energy. A minimum of 3 complete trials sets was performed at each energy level.

#### **3.2 Baseline Performace**

The baseline for performance is developed using a cast honeycomb [5] and dilatant material. The baseline Alba-Technic headgear impact resistant material is designated as EV02<sup>TM</sup>. This design consists of a Shore 55A durometer honeycomb in the front and Shore 40A durometer honeycomb in the rear. The honeycomb was subsequently covered with a single layer of dilatant material (Design-A) and a double layer of dilatant material in the rear (Design-B). The total thickness of material is approximately 10 mm for Design-A and 14 mm in the rear for Design-B. This selection was based upon one of the primary objectives to construct a design with good impact resistance and can be made into an aesthetic device.



Figure 3: Performance Testing.

The peak translational acceleration for Design-A and Design-B were significantly lower than the unprotected case in frontal, rear and side drops with p<0.0001. Figure 4 shows the results specifically for the rear impact case where Design-B has more protection capability. Similarly, HIC reduced significantly (p<0.002) in both designs in comparison with the unprotected drops for all cases as shown in Figure 5. Reduction in peak translational acceleration directly correlates to intracranial pressure which is known as one of the principle mechanism of head injury. A parallel reduction in HIC was expected because HIC represents the rate of change of kinetic energy as the head protection gear dissipates energy.

A total of two hundred and seventy drops with the same head protection wear were performed and resulting impacts were analyzed in this study. Little to no damage was observed to the material system due to the highly elastic characteristic of the urethane material used. This is highly desirable in design of protective headgear.

The maximum translational acceleration recorded for any of the trials in the rear impact case was 474 g at an impact velocity of 3.54 m/s, which corresponds to 52.9 J impact energy. For the rear impact, Design-B with the double thickness of dilatant material showed a 73% reduction while the thinner Design-A showed 54% reduction, which was a significant difference (p<0.003). This demonstrates the influence of incorporating thicker layers of the impact resisting materials.





Figure 4: Peak Acceleration for a Rear Impact.

Figure 5: HIC for a Rear Impact.

## 4 COMMERCIALIZATION STATUS

The research and development on the technology project has been a success and the SMARTY is nearly ready to be sold into the market once the manufacturing issues related to small batch manufacturing is complete. The company has received a \$15,000 Business Accelerator Grant from the MTI for business development activities related to the NSF Phase I. The funding is being used in part to hire an industrial designer to ensure the fabric covering the impact resistant system has the desired properties for moisture wicking, air flow, and maintenance. The funding is also being used to support NSF Phase II efforts. Alba-Technic is in discussions with a large risk management groupwho has expressed an interest in our product. We are also seeking commercialization partners who would guide and expedite our entry into the following target markets: aging in place (wellness market), assisted living facilities, nursing homes and hospitals. This device will be registered with the FDA as a Class I Medical Device and CMS should reimburse providers under existing codes. We are in the processing of preparing a \$750,000 Phase II proposal to the NSF. If awarded the Phase II, we are anticipating limited prototype sales in year 2 to the target markets.

Future funding sources include finding the commercialization partner(s) to provide match for the NSF Phase IIB program. In addition, MTI offers a \$50,000 MTI Business Accelerator Grant, Development Loan opportunities and an Equity Capitalization Fund which we will actively pursue.

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