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Custom-Made Helmet Fabrication for Occupational Therapists Treating Patients with Traumatic Brain Injury

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Custom-Made Helmet Fabrication for Occupational Therapists Treating Patients with Traumatic Brain Injury

by

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This Scholarly Project Paper, submitted by Megan Schill and Michael Shae in partial fulfillment of the requirement for the Degree of Master’s of Occupational Therapy from the University of North Dakota, has been read by the Faculty Advisor under whom the work has been done and is hereby approved.

Faculty Advisor

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Date
PERMISSION

Custom-made Helmet Fabrication Specifications for Occupational Therapists Treating Patients with Traumatic Brain Injury

Department  Occupational Therapy
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Abstract

Soldiers within the Veteran’s Administration who have sustained a traumatic brain injury (TBI) were the focus of this project. Reports showed a growing number of soldiers have returned from Iraq with head injuries, including cranial and brain defects (Defense and Veterans Brain Injury Center, 2007). Symptoms individuals with TBI commonly exhibit include dizziness, balance problems, sleep problems, excessive fatigue, headaches, and difficulties with cognitive processes. Other symptoms associated with a TBI are blurred vision, ringing in the ears, and bad tastes in the mouth (National Institute of Neurological Disorders and Stroke, 2007). The purpose of this project was to develop a cranial helmet that would be custom-fit to the individual who has sustained a TBI to protect his or her cranium during the healing process to prevent a secondary TBI or additional complications.

A literature review was conducted using PubMed, CINAHL, and electronic organizational resources to identify existing occupational therapy resources pertaining to the fabrication process of custom-made helmets. Information was also obtained from textbooks, seminars, and library searches. Limited resources existed for the use of custom-made helmets in the area of adult TBI. Instead, we used research literature regarding the fabrication of helmets for children with cranial defects to guide the development of our project.

The helmet was designed incorporating the client’s values and interests. A mold of the individuals head was created with plaster around which we formed materials in
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subsequent steps. The helmet was comprised of insulated foam used for protection and comfort. Thermoplastic splinting material was then formed on top of the foam to create the shell of the helmet. The helmet had four quadrants for air circulation to allow cool air along the head. A chin strap was added to support the helmet in place. An accompanying manual was also designed to guide the fabrication of the helmet.

For the purpose of the scholarly project, time and financial aspects, this fabricated prototype is the first step in the development of the helmet. The final product will need extensive testing from competent engineers to ensure the safety of the clients using the helmet.
Chapter I: Introduction

In 2007, the Centers for Disease Control declared traumatic brain injury (TBI) as a major cause of death and injury in the United States, resulting in approximately 1.1 million emergency room visits and 50,000 deaths annually (Center for Disease Control, 2007). A report by the Defense and Veterans Brain Injury Center (Defense and Veterans Brain Injury Center, 2007) indicated veterans returning to the United States are being diagnosed with head injuries at an alarming rate. Iraqi insurgents have chosen improvised explosive devices as their weapons of choice which have directly influenced the number of individuals returning from the war with head and brain injuries. These explosives are resulting in a number of soldiers returning with internal and external head injuries.

Internal head injuries occur when the forces resulting from an explosion or possible vehicle accidents cause damages to the brain. Often in these accidents, there are direct and indirect injuries to the brain. Direct injuries occur when the brain and inner surface of cranium collide. Indirect brain injuries occur when the brain bounces off the initial cranial impact and collide with the cranium on the opposite side. These collisions can result in a variety of symptoms including; dizziness, balance problems, sleep problems, excessive fatigue, headaches, and difficulties with cognitive processes. Other symptoms associated with a TBI are blurred vision, ringing in the ears, and bad tastes in the mouth (National Institute of Neurologic Disorders and Stroke, 2007). Further symptoms may arise due to an uncontrollable increase in intracranial pressure (ICP).
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Increases in ICP result from an imbalance between arterial flow into the cranium versus venous flow out of the cranium. An increase in pressure may cause damages to brain tissues surrounding the ventricular spaces of the brain. Control of intracranial pressure is essential to avoid further damages. Medications and external ventricular drains work for most situations, but occasionally decompressive craniectomy procedures must be performed. This procedure consists of removing portions of the patient’s cranium to relieve the pressure and prevent further damages, but leaves the patient vulnerable to secondary injury if a fall should occur. (Ladanyi & Elliot, 2008)

External head injuries vary from small cracks of the cranium to entire sections of the cranium being destroyed by explosive devices. The variability of these injuries can seriously complicate the medical treatment provided. The severity of medical needs may lead to multiple reconstructive surgeries and a prolonged recovery processes.

Whether the injuries are internal or external, it is often essential for the patient to enter therapy while still in a vulnerable state due to missing or healing cranial sections. Currently the Veteran’s Administration (VA) hospitals commonly use helmets ordered from a catalog. Our project is a custom-made helmet for individuals returning from the war with cranial injuries who require the safety and security of a comfortable helmet to wear while awaiting the completion of the cranial reconstructive process. These helmets would be fabricated on-site for the individual patient. Occupational therapists will use low temperature thermoplastics to form a helmet designed for the variations of the patient’s injuries and personality characteristic of the individual who will wear the helmet.
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The helmet design was based on concepts presented in the Model of Human Occupation theory. The key concept of the model is client-centered therapy. The helmet design will allow occupational therapists to individualize each helmet for optimal fit and comfort, along with consideration of the patient’s values, interests and needs (Kielhofner, 2004). Further key concepts follow the Rehabilitative Frame of Reference. This helmet will be designed to allow the wearer to participate in therapy sessions safely. Its design will not directly influence an increase in performance (Blesedell Crepeau, Cohn, & Boyt Schell, 2003).

The following chapters include more details of current literature regarding key concepts of the helmet design, steps used to develop the helmet idea, and a supplemental handout to accompany the actual prototype developed while completing this project.
Chapter II: Review of Literature

A Population in Need

According to the Centers for Disease Control (CDC, 2007), traumatic brain injury (TBI) is a major cause of death and injury in the United States and results in approximately 1.1 million emergency room visits and 50,000 deaths annually. Falls are the major cause of TBIs while motor vehicle accidents are responsible for the most hospitalizations due to TBI. Gromley (2008) reported that physicians diagnose 300,000 people with TBIs each year due to youth sports; a number that did not include the estimated 20% to 40% of individuals who elected not to seek medical attention. The initial focus for this product was soldiers within the Veteran’s Administration who have sustained a TBI. Reports indicate an alarming number of soldiers returning from Iraq with head injuries, including cranial and brain defects (DVBIC, 2007).

According to the National Institute of Neurological Disorders and Stroke (NINDS, 2007), a traumatic brain injury (TBI) is damage to the brain caused by sudden trauma and can be classified as mild, moderate, and severe. This sudden trauma is usually caused by an individual striking his or her head against an object or when an object suddenly impacts the individual. Symptoms that individuals with TBI commonly exhibit include dizziness, balance problems, sleep problems, excessive fatigue, headaches, and difficulties with cognitive processes. Other symptoms associated with a TBI are blurred vision, ringing in the ears, and bad tastes in the mouth. While the aforementioned
symptoms result from the direct damage to the brain, other issues related to subsequent edema are of equal cause for concern. (NINDS, 2007)

Secondary problems may result due to a rise of intracranial pressure (ICP) causing more damage to brain tissues. ICP is normally maintained by the body at 0 – 10 mmHg by balancing the input of cerebral spinal fluid and blood flow (Ladanyi & Elliot, 2008). Approximately 30% of individuals with a brain injury progress through two phases of change regarding ICP. The first phase, the hypoprofusion phase, transpires within the first 72 hours post injury. A main characteristic of this phase includes a drop in cerebral blood flow resulting in a decreased ICP. Treatment goals during this phase include re-establishment of blood flow to prevent further brain damage due to oxygen deprivation.

Phase two, the hyperanemic phase, consists of an increase of cerebral blood flow and last up to ten days post injury. Nursing staff must monitor the patient closely as increased blood flow along with cerebral swelling due to injury may raise ICP to the extent damage to tissue occurs. If pressure increases significantly and cannot be controlled by medication and/or positioning, an external ventricular drain may be inserted or for more severe cases a decompressive craniectomy procedure may be necessary to reduce pressure. (Ladanyi & Elliot, 2008)

A craniectomy is commonly performed to relieve ICP. A craniectomy is the surgical removal of a section of the skull, frontal, temporal, parietal, or a small portion of the occipital bone to relieve the pressure so the brain can swell in the absence of restrictions, thereby reducing the likelihood that further damage to the brain will occur (Ziai et al., 2003). In a study by Aarabi et al. (2006), depressive craniectomy was found to lower ICP by significant levels in 85% of the cases. Compared to a control group, the
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craniectomy group presented with a greater return to function. Following the craniectomy, the patients with TBI’s may still be awaiting cranioplasty surgery while engaging in rehabilitation treatments including cognitive restructuring, active movement retraining, and activities of daily living restructuring.

Cranioplasty consists of surgical intervention to repair or replace the damaged cranium. According to Redford and Pulhorn (2007), cranioplasty has been practiced as far back as the Incas and Neolithic Celts when gold, silver and animal bones were used to replace damaged cranial bone structure. Current surgeons prefer to reattach the damaged bone flap (Redford & Pulhorn, 2007). For some individuals, the injury may be too extensive so the surgeon must use alternative methods such as using bone from other areas of the body or metal/synthetic prosthetics made for the individual patient (Redford & Pulhorn, 2007).

The recent war in Iraq has increased more attention to individuals with TBI and their needs. Nineteen and a half percent of all soldiers returning from the war have experienced a TBI due to an event or multiple events involving improvised explosive devices (IEDs) (Tanielian, Jaycox, & Invisible Wounds Study Team, 2008). As in the general public, falls and automobile accidents are two major causes of TBI among military personnel, while bullets, fragments, and blasts constitute a large percentage of other causes (DVBIC, 2007). Blasts, in particular, are a major cause of TBIs while soldiers are in theater (DVBIC, 2007). The prevalence has been significant enough that House Veteran’s Affairs Committee Chairman, Steve Buyer, representative of Indiana, has created and promoted legislation to encourage research and development of new and standardized combat helmets to reduce the number of soldiers with TBI diagnoses.
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returning from the war front (Spotswood, 2004). Stateside, the Veterans Affairs Department (VA) has provided support for individuals with TBI in four newly developed polytrauma rehabilitation centers (2004). The military’s planning for TBI rehabilitation follows the mission statement provided by the Home of Defense and Veterans Head Injury Program (DVHIP), “the mission of the Defense and Veterans Brain Injury Center is to serve active duty military, their dependents and veterans with traumatic brain injury (TBI) through ensuring state-of-the-art medical care, innovative clinical research initiatives and educational programs” (DVBIC, ¶ 1, 2007). The DVBIC has also published systematic treatment guidelines for use by U.S. military personnel, their dependents and veterans with TBIs to improve the care of individuals returning from the war with mild TBI. The goal of this guide is to improve the individual’s medical and functional outcomes through quick and accurate assessment and reduction of secondary effects.

Two major concerns during rehabilitation of individuals with TBI diagnoses are patient safety and avoiding secondary TBIs that are possible due to balance and dizziness issues that occur from initial injury (DVBIC, 2007). Hospital staff reported safety belts and helmets are required at any time the patient is mobile. Helmets used currently by the Veteran’s Administration Hospitals are mass-produced and ordered from a catalog. Presently, the helmet is available in three colors and seven sizes from the manufacturer (Southwest Medical Online, 2008, ¶ 1-4). Health care professionals customize the helmet by adding foam to the lining of the helmet. The modification process is often completed by the therapist sending the helmet outside the facility to a manufacturing company. This
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process is problematic, as the patient must then function without a helmet until the company returns the finished product.

Addressing the Need

Our intention and the purpose of this scholarly project was to develop a customized helmet that can be fabricated on-site by an occupational therapist. Rice Berg (2008) highlighted a nine-step process to developing medical rehabilitation equipment in the initial development phase: (1) product development, (2) interaction between members of the design team to identify deficits in existing products, (3) establishment of the design objectives, (4) task/function analysis, (5) development of performance criteria, (6) measurement selection, (7) walk through/training, (8) assessment, and (9) product. For the purpose of this scholarly project, we concerned ourselves with primarily steps one thru three while recognizing that these steps may be revisited during later development steps. Further, should development of this product ensue, we recognize additional phases of product development and clinical trials would be needed to ensure a patient safety factors associated with orthotic use.

Development of medical rehabilitation equipment requires first identifying the need for the product. This requires the characteristics of the intended user be examined carefully as should the background of those who are qualified to design the equipment. (Rice Berg, 2008)

Occupational therapists are well suited to complete helmet fabrication for persons with TBIs due to their knowledge and skills related about the use of splinting materials, anatomy, and biomechanics. Many occupational therapists, particularly those practicing in outpatient and hand therapy settings, use low-temperature splinting materials on a
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daily basis. Splint fabrication in the aforementioned settings occurs for the purpose of improving the functional capacities of their patients. Occupational therapists are also knowledgeable about the precautions inherent to the use of these splinting materials. Further, occupational therapists possess a strong knowledge and understanding about evaluating clients and structuring interventions (including customization of orthotics) that are client-centered and meet the client’s needs and abilities. We were not able to locate any published literature on fabricating protective helmets for this client population. There is, however, published literature about populations other than adults that support the engagement of occupational therapists in helmet fabrication.

Custom helmets have been fabricated on-site for children to help manage craniosynostosis. The custom-made helmets have been found to be a successful component in cranial orthotic molding therapy in children when supplementing surgical treatments. (Barone, 2007; Jimenez et al., 2002). These helmets are formed to assist in shaping the child’s head by applying pressure to the appropriate areas of the cranium to control the resulting shape. This process of fabricating customized helmets on-site is the closest example found in literature to the product described in section four. It is, however, much more intensive helmet than the requirements of our population.

Occupational therapy developed from ideas presented to the medical community by a group of physicians, nurses, architects, and craftsmen (Kielhofner, 2004). The founding group proposed methods of treating individuals with disabilities by following the principles of moral treatment. One major premise of moral treatment was improved health could be accomplished through involvement in daily activity (Kielhofner, 2004). In 1922, one of the founding members of Occupational Therapy, Adolf Meyer, offered
the following quote, "our conception of man is that of an organism that maintains and balances itself in the world of reality and actuality by being in active life and active use" (Kielhofner, 2004, p. 32). The profession of occupational therapy grew around these ideals of helping people using occupation. Occupation has been defined as "a collection of activities that people use to fill their time and give life meaning, is organized around roles or in terms of activities of daily living, work and productive activities, or pleasure, for survival, for necessity, and for their personal meaning" (Hinojosa & Kramer, 1997, p. 5). Simply stated, occupation is any activity that holds meaning and purpose for an individual (Hinojosa & Kramer, 1997).

During the 20th century, there was a movement in the medical field towards a scientific approach to treatments called reductionism. (Kielhofner, 2004). Occupational therapists shifted their focus from a holistic perspective to one concerned primarily with biomechanical and physiological properties, medications, and psychotherapy. The primary assumption was that therapy could extinguish negative symptoms of a disease by addressing the defective system. This focus included consideration for the anatomical structures and the systems they form. This idealism was based on similar concepts used by other medical professionals. In the past four decades, many occupational therapists have promoted that the profession to return to the more holistic approaches of its inception (Kielhofner, 2004).

Contemporary occupational therapy has combined the earlier thoughts and ideals of moral treatment with the later knowledge gained through the period of reductionism to build a holistic approach to practice. This approach has been referred to as the systems theory. A primary assumption of this theory includes, that humans are comprised of
multiple systems that work independently and with each other to make up the human body (Kielhofner, 2004). Disruptions in a single system will often affect others; a proposition which promotes the provision of holistic treatment. Occupational therapists use the assumption of the systems theory to transform occupation into the primary medium used during therapy. The profession has once again recognized the natural need for individuals to be occupied in meaningful activity for healthy recovery (Kielhofner, 2004). The knowledge of anatomy, physiology, neurology, psychosocial factors and multiple theoretical concepts lends to occupational therapist competence in several areas of rehabilitation.

Occupational therapists are well suited for the design, fabrication, and application of the proposed helmet, which falls under article one section 1.04C in the Model Occupational Therapy Practice Act (2007): “interventions and procedures to promote or enhance safety and performance in activities of daily living, instrumental activities of daily living, education, work, play, leisure, and social participation”. 1.04C subsection nine further addressed the scope of practice: “assessment, design, fabrication, application, fitting, and training in assistive technology, adaptive devices, and orthotic devices, and training in the use of prosthetic devices” (Model Occupational Therapy Practice Act, 2007, p. 4). According to Blesedell, Cohn & Boyt (2003) the process of design, fabrication, and application of splints are expected duties of occupational therapists in many settings. Low temperature thermoplastics are often used by occupational therapists for upper extremity splinting; therefore, occupational therapists have a familiarity with this product that will be beneficial during the fabrication of the helmet. The familiarity with the use of splinting materials combined with the occupational therapists’
understanding of the clients’ needs and abilities make occupational therapist a logical and appropriate choice for the creation and provision of individualized helmet orthotics.

How Will This Product Help?

Client safety is the primary concern during the development of this product. Identified factors affecting patient safety include parameters of cranial defect, client factors, material characteristics, and fabrication process (Dynamed, 2008; Krach, 2008).

To ensure the client’s safety, the therapist must be cautious of the medical consequences that often accompany the occurrence of a traumatic brain injury. Common symptoms of a TBI include: heterotopic ossification, central autonomic dysfunction, post-traumatic epilepsy, and multiple cognitive difficulties (Krach, 2008). Heterotopic ossification is an ossification within muscle or fatty tissues following a trauma to the site (Dynamed, 2008). The therapy for this diagnosis consists of range of motion exercise for joints in the involved area to avoid contractures and limited range of motion, medications to decrease pain and ossification, and surgery to remove masses once created (Dynamed, 2008; Krach, 2008). Occupational therapists may be involved in this rehabilitation as they work with the clients to maintain the individual’s range of motion and function. It is imperative that precautions, such as helmet use, be addressed during intervention activities due to the vulnerable state of the client who may have multiple symptoms.

Dysfunctions within the autonomic systems affect the patient’s ability to regulate heat, heart rate and gastro-intestinal functions. The patient may have difficulty maintaining a sufficient posture to ensure safety; therefore, precautions should be taken to eliminate falls, when possible; but falls are often unavoidable and thus, protection is
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needed. It is imperative that therapists remain aware of their patients’ precautions and are vigilant in addressing those precautions. (Krach, 2008)

Posttraumatic epilepsy results in seizures and is more common in adults than children (Krach, 2008). The diagnosis of posttraumatic epilepsy constitutes a need of extreme caution during therapy sessions as patient may injure himself or herself during an unexpected fall or if he or she fall or experiences trauma due to head contact with surrounding objects. In a study conducted by Deekollu, Besag and, & Aylett (2005), participants attending a special epilepsy center were provided helmets if they had previously had facial or head injuries due to seizures. Protective measures, seizure frequency, types of injuries, circumstances, and outcomes were measured. These researchers found scalp and facial bruises were the most common seizure-related injuries with medical attention needed. Ice hockey, hard foam, and leather helmets were used in this study but altering the equipment was needed by the supplier or the occupational therapist to assure a quality fit, comfort, and protection (Deekollu, Besag & Aylett, 2005). Providing patients with safety is the most important aspect when fitting an individual with a helmet. Individuals experiencing a TBI remain in a vulnerable state while healing from the event and, therefore, many do not have the natural protection inherent in other individuals, such as an intact cranium. The use of helmets, among other precautions, is essential to the safety of these clients.

Most individuals with a TBI will have a resulting cognitive deficit. Difficulties with memory, sequencing, attention, organization, communication, motor control, balance, and abstract thinking are common in both mild and severe traumatic brain injuries (Gormley, 2008). The type and extent of deficit depends on the area of the brain
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affected. Veterans with TBIs may exhibit an array of cranial defects. De Kruijk, Twijnstra and Leffers (2001) reported that within the first month of sustaining a TBI, cortical lesions were apparent and predominately localized in the frontal lobes in study participants. The temporal lobes are responsible for learning and memory within the brain (Bear, Connors & Paradiso, 2001). A TBI that affects the temporal lobes could potentially have an effect on the extent to which the user understands helmet donning and doffing the helmet, the orthotic schedule, and the overall protective purpose of the helmet. Authors of recent literature described the memory functions of the parietal lobe (Olson & Berryhill, 2009). If the parietal lobe is damaged, long-term memory and working-memory will be affected. These deficits may present the client and the therapists with difficulty during the fabrication process. The occipital lobe is responsible for visual processing (Serendip, 2008). Injury to the occipital lobe may result in loss of vision and use of the helmet could prevent a second TBI from occurring.

The variations of function in the lobes of the brain will guide the design process. The process will have to be such that the helmet is supported by existing healthy tissue and avoid pressure on areas that are soft or damaged. The helmet will be fabricated so it is supported by the cranium above the ears and eyebrows for the majority of patients. For some patients with damages in this area of support, adaptations to the fabrication process will need to be made to incorporate other areas of support. This helmet will be contra-indicated for patients without the supporting structure. There currently is no literature published in this area to assist in the development of the process.

Therapists must remain aware that these deficits may lead to secondary injuries due to lapses in sufficient decision-making, attention, balance, and/or motor control
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issues, while engaging these individuals in the therapy needed to address those specific symptoms. (Gormley, 2008)

Individuals with TBIs may be present with many functional challenges. It is essential therapists remain aware of the multiple difficulties that a client may encounter with the TBI diagnosis and be concerned primarily with client safety before other rehabilitation related interventions. The use of safety procedures and devices, such as protective helmets, are critical to ensuring the safety of the individuals. To maximize safety, it is important the client be committed to wearing the protective orthotic. Clearly, the client’s desire to wear the helmet or at least the “tolerance” of the orthotic is paramount to adherence to safety precautions (including wearing a helmet). The focus of this project is to devise a helmet and fabrication process to address the patient’s client factors to increase the likelihood the client will approve of the helmet and choose to wear it independently.

Client factors play a significant role when designing any orthotic including the fabrication of a protective helmet. McKee and Rivard (2004) studied whether client input prior to fabrication of an orthotic produced a better outcome than no input. The authors reported by addressing clients’ likes, dislikes, and lifestyle, the therapists were able to fabricate an orthotic that the client was happier with and, subsequently, used with greater frequency and with proper application. The success of the any orthotic is dependent on proper application. Many factors should be considered and include: client’s preference for color, wearability/comfort, client occupations, and environment. Color choices may allow for individuality as clients can choose from up to twelve different colors in the Aquaplast thermoplastics from Sammons Preston Medical Supply. Additional orthotic
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materials are available through a variety of other manufacturers. A thorough investigation of the client’s occupational profile and discussions with treating medical/health care personnel should be conducted to gain information about the client’s occupational preferences, environment, values, needs and safety concerns (Occupational Practice Framework, 2008).

*How Will the Product be Made?*

The information on orthotic materials for this project was obtained exclusively from the Sammons Preston Hand Rehabilitation 2008 Catalog. There are many resources and vendors from which an occupational therapist may obtain materials (which may be needed depending on the results of extensive testing of the helmets use) but for the scope of this project we chose to use the materials from a single provider.

A number of factors, including safety, comfort, cosmetics, ease of use, drapability and availability influenced the choice of materials used for this project. Low temperature thermoplastics are used in many Occupational Therapy Departments and can be purchased through catalogs or online from manufactures websites. The ease of use of these thermoplastics comes from the ability to make it pliable with low heat, yet it is firm at room temperatures. Other benefits of these thermoplastics include the variety of colors, thickness to provide support and perforations to allow for maximum air flow (Patterson Medical, 2008). However, questions persist regarding the characteristics of the thermoplastic for this application. A search of literature describing a universal grading system for the properties and integrity of the material resulted on the procurement of one article. Shimeld, Campbell, & Ernest (1982) identified the need for standardization of qualities concerning low temperature thermoplastics. Due to the lack of current
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regulatory guidelines, extensive testing will need to be completed prior to use of this product to establish proper usage guidelines and ensure safety of the client considering the information is from an old study.

The shell of the helmet will be formed out of Aquaplast splinting material. Aquaplast is a low temperature thermoplastic which becomes workable after a one-minute bath in 160 to 170 degree water (Patterson Medical, 2008). The material becomes translucent when ready to use and allows the therapist four to six minutes of working time to mold it into the desired shape. Once cooled to room temperature Aquaplast has excellent rigidity giving it the theoretical ability to disperse impact forces should the user fall or bump head into another object. The extent of this ability will be determined through extensive testing. Other key components of this material are its resistance to fingerprints, resistance to stress fatigue, thirteen color choices, three perforation choices, and it is latex-free (Patterson Medical, 2008). The variety of colors and resistance to fingerprints will allow the therapist to make a helmet that is cosmetically pleasing to the user. The perforations in the material will allow for airflow to the head making the helmet more comfortable on warmer days while retaining structural integrity. (Patterson Medical, 2008) The lining of the helmet will be made up of two separate foam components to provide comfort breathability and support.

To maximize client safety, it is necessary to note, once again, these materials are chosen based on the literate within the catalog and thorough testing will need to be completed to determine optimal materials to use and safest combination of materials when considering the safety of the user. Current literature fails to discuss standardized characteristics of splinting materials; therefore, the materials were chosen based on
Clinical reasoning and the assumption that extensive testing will be completed to ensure user safety prior to implementing helmet for use with clients.

_A Product Based on Theory_

Theory guides both the development and organization of articulated knowledge for education and practice of the Occupational Therapy profession (Henderson, 1988, p.1). Two theories, the Model of Human Occupation (MOHO) and the Rehabilitation Frame of Reference were used as a guide to the design and fabrication of the helmets for this project.

The Model of Human Occupation Theory was first introduced in the 1980s and was based around three key concepts: volition, habituation, and performance capacity (Blesedell, Cohn & Boyt, 2003). Environmental factors play a role in this theory by addressing a person’s values, interests, personal causation, roles, habits, and performance capacities (Kielhofner, 2004).

Volition is the key component addressed by this project (Kielhofner, 2004). Volition refers to a person’s motivation, values, thoughts and ideas of self-worth, and desires to find life enjoyable and satisfying (Blesedell, Cohn & Boyt, 2003). The primary goal of this project was to fabricate a helmet for an individual with a focus on his or her interests and needs. We anticipate the helmet will fit better than the production line versions thereby increasing client comfort. The client will have the opportunity to choose from a variety of colors allowing some individual expression. Through these variations, the client’s values and desire for enjoyable and satisfying life are addressed. The client’s feelings of self-worth are supported through the interaction with the therapist and the client’s being able to have some input in the design of the helmet. Habituation is the
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human characteristic to develop common tasks into behavioral patterns such as habits and roles (Blesedell, Cohn & Boyt, 2003). Habituation will be addressed by occupational therapists to develop a wearing pattern for the helmet that will ultimately become a habit and routine for the user.

Performance capacity of the individual is dependent on the location and severity of the injury. Performance capacity refers to the person’s functional ability to do what he/she wants or desires to (Blesedell, Cohn & Boyt, 2003).

The goal of this helmet is to allow the user to engage in rehabilitation occupation as soon as possible to increase positive results within the realm of performance capacity. We were able to observe programs, in which individuals were engaged in activities to promote performance capacity while wearing production line helmets to maintain safety.

The concept of this helmet is based on providing the user with a safe, comfortable helmet incorporating input from the user on cosmetic variations to increase the user’s satisfaction. Ivins et al. (2007) found soldiers are more likely to wear a helmet more frequently that is comfortable, lightweight, fits appropriately, and sustains maintainability. Since engagement in therapeutic activities is dependent on the user wearing a helmet, greater user compliance will allow more opportunity for increased performance capacity.

The use of the helmet will follow the Rehabilitative Frame of Reference. This frame of reference focuses on the maximizing the client’s functional performance using assistive technology, compensatory methods, and modifications to the environment. It is an assumption of this frame of reference that the client’s impairment has stabilized and may not improve through therapeutic activities. Clients must use other methods to
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achieve desired tasks due to decreased functional capacity (Blesedell Crepeau, Cohn, Boyt Schell, 2003). Internal cranial pressure produced following a TBI is commonly treated by removing a portion of the cranium. Some personnel have had portions of the cranium removed due to cranial damage sustained in the same accident producing the TBI. These particular injuries must be treated through surgery, as they will not respond to therapeutic interventions. While individuals recover from surgery their vulnerability to secondary injury warrants the use an adaptive device such as this helmet to ensure safety. By using this helmet, users will be able to engage in therapeutic activities addressing other symptoms such as cognitive deficiencies, which are associated with TBI (Blesedell Crepeau, Cohn, & Boyt Schell, 2003).

Although current literature can provide plenty of information to be used during the design and fabrication process for a custom-made protective helmet for patients with brain and cranial injuries, no literature detailing the current use of such a helmet in health care was found. Chapter III will present the fabrication of the prototype customized helmet; a process developed from the application and integration of aforementioned literature.
Chapter III: Methods

The concept for the product described in Chapter IV arose during a clinical school assignment. While in the clinical setting, the question was raised whether customized helmets fabricated on-site would meet current needs within the healthcare system. We conducted a literature review to identify resources and to address the aforementioned question. Our findings resulted in further questions regarding current helmet use, the target population, guidelines to helmet use within specific healthcare settings, and the fabrication process.

The literature reviewed was composed of articles obtained using the Pub Med and CINAHL search engines on the University of North Dakota School of Medicine and Health Sciences website along with other web-based search engines. Information was also obtained from textbooks and seminars. The initial focus of the literature review was to identify current trends for helmet use in the medical community. Our experiences in the clinical practice settings included observations of the application of two helmet options but no literature was found to support the use of either. We located a number of literary sources concerning the use of customized helmets for children with cranial defects. These helmets were fabricated on-site and used to assist in the reshaping of the cranium (Jimenez & Barone, 2007, and Jimenez et al, 2002) While these helmets support the feasibility of fabricating customized helmets on-site, the process used was more intensive than required by this product and the population to be served due to the actual reformation of bone tissue caused by the helmets.
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Next, we focused on the topic of individuals with traumatic brain injuries. We sought to identify a potential need this population may have for this product. The authors of the literature we located outlined the client factors affected when a person sustains a traumatic brain injury, the more common methods of injury, and prescribed treatment methods in which a client may be engaged while using this product. The information we obtained was used to establish a need and guide the development of the product.

It is necessary that medical supervising bodies develop guidelines dictating the use of assistive technology within their facility. It is important that this product conform to those guidelines before being implemented in that facility. It was important to review these guidelines for the Veteran’s Administration as that is our current target market. Although current literature does outline specific criteria that needs to be followed in the use of cranial shaping helmets such as the ones introduced in the previous paragraph, it does not indicate specific guidelines for protective helmets such as our project is developing. The literature review regarding the needs of the target population culminated in the development of a helmet fabrication process. Our intention is that eventually helmets could be designed on-site for clients with traumatic brain injuries.

After the need for a helmet for persons with traumatic brain injuries was established, an additional literature review was conducted to gain an understanding of the multiple properties of materials to be used during the fabrication process. Although these materials will need to be tested thoroughly prior to implementation of the helmet, the literature allowed us to make an educated decision about which materials to incorporate in the prototype. It was also necessary to establish the competency of occupational
therapists to design, fabricate, and implement the device in a manner that is safe and beneficial to the patient.

Following the literature review, an outline was formulated to establish a guide for creation of the product and supporting literature. This outline provided direction and ensured the necessary developmental steps were conducted.

Actual product development started with a miniature prototype which was created using scraps of splinting material. The miniature helmet was formed by creating a cranial ring with two crossing supports over what would be the crown of the head. The cranial ring was then folded over the ends of the supports to secure them in place. It was believed at the time, that this process would be done on the actual patient. Later discussion would lead to attempts to make a mold of the patient’s head and create a helmet using the mold as a guide.

Multiple trials were completed using foam to create a casting of a simulated patient’s head. Bricks of floral foam were trialed first. The bricks were used to line a plastic crate that would be placed over the individual’s head. Different patterns of brick placement were used, but all were unsuccessful. Our hope was to use foam that would compress under light pressure leaving a negative mold of the patient’s head. We anticipated that plaster would then be poured into this mold to create a casting to be used during helmet fabrication. All the foam products used were too dense and required excessive force to achieve the necessary results. We chose to pursue another option.

Casting material was found to be a viable alternative and was easy to work with along with providing the results needed to create the mold desired. The material consisted of a roll of gauze material inundated with plaster that could be dipped in water and
formed over an object. For the purpose of this product, the person simulating the patient wore a swim cap and petroleum jelly was applied to prevent adhesion of the mold to the head. The strips were then cut from the roll and applied to the person’s head. A ring around the cranium, just above the eyebrows and ears was formed first, followed by coverage of all areas above that ring. All areas were covered in a minimum of three layers while the cranial ring was comprised of five layers. The mold was allowed twenty minutes to dry on the person’s head before removing and placing in the microwave on high for six minutes to completely cure the plaster. The test sample was allowed to harden overnight before it was sprayed with cooking spray. Plaster of Paris was then poured into this mold. This was also allowed to cure overnight before the casting was removed from the mold resulting in a plaster replica of the individual’s head. We used this replica to form the helmet.

The thermoplastics used to form the helmet were donated by a representative from the Sammons Preston Patterson Medical Supply Company. The foam used to line the helmet was obtained locally. Fabrication of the first helmet consisted of taping foam strips on the casting in strategic areas and forming the thermoplastic material over the foam and casting. A cranial ring was formed first, followed by the longitudinal cranial brace then angular braces. The ends of the longitudinal and angular braces were secured to the cranial ring. A second layer of thermoplastic was then placed over the first cranial ring further securing the bracing and reinforcing the original ring. All the edges of the materials were rubbed smooth to prevent sharp edges and to ensure sufficient contact with other layers.
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The final process of helmet fabrication consisted of application of a chinstrap. For this prototype, a button chinstrap set-up borrowed from hockey helmets was utilized. It was comprised of two button screws and backs secured through holes drilled through the thermoplastic cranial ring. A 1-inch wide strap with two buckles attached was snapped onto the buttons to secure the helmet on the patient.

Several concerns arose during the development of this product. The chief concern was the feasibility of this idea for a scholarly project. The final product will need extensive testing by competent engineers to ensure the safety of the clients using the helmet. This is currently beyond the scope of the student’s resources, particularly time and financial aspects. These concerns were discussed with University of North Dakota Occupational Therapy Department staff who indicated that step one, fabrication of a prototype, would be sufficient as a scholarly project. Further pursuit of this product will need to be continued post graduation or by other researchers or professionals.

Two prototype helmets were developed, but unfortunately, they cannot be included in this documentation. Chapter IV consists of a supplemental packet that provides information about the prototype helmets. This supplemental packet would be used during seminars and educational sessions to educate interested individuals of the details regarding the design and fabrication of the custom-made helmet.
Chapter IV: Product

Cranial Protection Prototype 1

The Cranial Protection Prototype 1 (CPP 1) was developed to address a need in the current medical field. During clinical experience assignments the developers observed patients with traumatic brain injuries (TBIs) and secondary cranial injuries. Three hundred thousand incidents of TBIs are diagnosed by medical professionals each year and it is estimated that another 20% - 40% go unreported (Gormley, 2008). The recent war in Iraq has contributed to a shift of attention to individuals with TBI and their needs. A report by the Defense and Veterans Brain Injury Center (2007) indicated that soldiers were returning from Iraq with brain and cranial injuries at an alarming rate. Nineteen and a half percent of all soldiers returning from the war have experienced a TBI due to an event or multiple events involving improvised explosive devices (IEDs) (Tanielian, Jaycox, & Invisible Wounds Study Team, 2008). These individuals arrive at one of the five regional polytrauma centers with injuries ranging from minor to extensive. It is essential these individuals wear helmets for safety reasons to prevent further injury to their already fragile cranium. Four of the six individuals observed wearing helmets were seen adjusting their helmets multiple times within a 30-minute therapy session. Our experience when discussing with center staff and patients during clinical rotations led us to believe clients would benefit from better fitting and more aesthetically pleasing protective headgear. The question was raised, “how to create a better helmet for these individuals?”
An initial literature study was completed to determine whether there currently was a better helmet to be used or a method of fabricating one. No literature was found indicating current procedures for fabricating protective helmets at a medical facility.

A secondary literature search was completed focusing on related procedures currently being used in practice that would lend ideas to assist in the design and fabrication of protective helmets at the same medical facility in which the patient is staying. Areas of focus included the target population, helmet fabrication for children with craniosynostosis, occupational therapy theory, and splinting materials and procedures.

The primary target population for this product was the soldiers returning from Iraq with brain and cranial injuries. These individuals present with a variety of difficulties due to the multitude of injuries they may be experiencing. In most cases, the primary TBI diagnosis is accompanied by physical injuries also caused by the mode of injury. Common practice is to begin therapy, such as cognitive restructuring, retraining of daily activities, and physical rehab, between cranial surgeries. A common concern following a TBI is the possibility of intercranial pressure that may occur due to the injury. A craniectomy may be necessary to relieve high pressures that cannot be regulated through medications. This procedure increases the time required for the cranium to heal fully. The individual must therefore wear a protective helmet while participating in any activities until the healing occurs.

Individuals within the general public with cranial injuries are a secondary population that may use this device. We determined, during development, this device could be beneficial for any individual who is diagnosed with a brain and cranial injury, regardless if they are affiliated with the Veterans Administration.

Orthotists currently fabricate custom molding helmets for children diagnosed with craniosynostosis. The custom-made molding helmets are used in conjunction with surgical intervention to reshape the child’s head by maintaining pressure in specific areas during healing (Jimenez, 2002). Due to the reshaping nature of the molding helmet, it is beyond the scope of our population. Our population needs a helmet for protection with minimal pressure on the cranial surfaces.
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Occupational therapists are a logical choice of professionals for the implementation of this device. The fabrication of this device falls within section 1.04c of the Model of Occupational Therapy Practice Act (American Occupational Therapy Association, 2007). The extensive knowledge they possess in human anatomy, physiology, neurology, and kinesiology partnered with the holistic approach of their profession gives them the theoretical background needed. The experience occupational therapists have regarding splinting materials and procedures are essential for the fabrication of a high quality device.

An occupational therapy model was used to guide the development of this product. The Model of Human Occupation highlights principles of patient values, interests, motivation and abilities. The concept of this helmet is to provide a device that the patient feels is comfortable, looks good, and considers individual values and interests. As a result of the therapist addressing these areas in the fabrication of the helmet, we anticipate the patient will be more motivated to wear the helmet. Consistency of helmet use will eventually become habit. We also used the Rehabilitative Frame of Reference to define the purpose of this product. This device will be used to allow the patient the opportunity to participate in personal and therapy based activities. The helmet, itself, is not designed to improve health, but to protect the patient while participating in occupations to promote health improvements. (Kielhofner, 2004)

The splinting materials themselves where chosen by color, ability to drape, temperature needed to form, resistance to stretch and thickness (Sammons Preston, 2008).

The CPP1:
The CPP1 was fabricated in a two step process. Step One involved the production of a cast of the individual’s head. Step Two consisted of fabricating the final product over the casting.

Materials needed:
- Swim cap
- Petroleum jelly
- 1 package of casting material
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- 1-5 lb. pail of plaster
- ½ foot of ventilated foam
- 1 sheet of splinting material (choice of color by individual)
- Scissors
- Towel
- Piece of drywall sanding material
- Small plastic bowl of water
- Large plastic bowl
- Utility knife
- Large splinting tub

Step One: Production of the Cast:

1. The patient was sitting and informed of the procedures to follow.
2. An apron or towel was draped over the patient’s shoulders to protect his/her clothing.
3. A swim cap was placed over the patient’s hair and petroleum jelly applied in a light layer to any area the casting material may touch. The petroleum jelly allows for non-adherence of the casting material when attempting to remove the casting from the swim cap after drying.
4. A plaster based casting material was cut into strips of six to twelve inches in length and each was dipped in water and placed on the swim cap in multiple layers to ensure adequate coverage of the cranium. The patient should be warned that this process will have a cooling affect when done.
   a. It is recommended that an initial ring around the cranium be done first.
   b. Strips may then be applied to the initial ring to ensure full coverage.
   c. A final cranial ring should be done to finish off the strips and provide added strength to the initial ring.
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5. The casting material was then allowed to dry for 15 minutes before removing (Fig. 2). The swim cap was also removed.
   a. *PRECAUTION* It is recommended the casting material be allowed to sit only until the minimal time stated in the instructions, for example, if the instructions state 15 to 20 minutes, remove at 15 minutes. The material may be difficult to remove if allowed to harden too long.

6. The casting material was placed in the microwave as per package instructions.

7. Once the casting material was hardened as per instructions (Fig. 3), Plaster of Paris was mixed and poured into the new mold (Fig. 4). This was allowed to harden for at least 24 hours or as per the package instructions.

8. A longitudinal line was cut the length of the casting material in center of the top allowing removal of the new cast.

9. Sanding of the new cast with high grit drywall sanding pads was necessary to remove wrinkles created by the swim cap.

Step Two: Fabricating the final product:

1. The foam to be used as the liner of the helmet was cut into three inch strips.

2. The circumference of the cast was measured along the bottom and a strip cut to fit. This strip was in a similar location as the cranial ring was during casting. The ends can be taped together using duct tape (Fig. 5).

3. A longitudinal strip was measured and placed from front to back over the cranium.

4. Shorter strips were attached just above the ears, between the cranial ring and the longitudinal piece (Fig. 6).
a. The foam pieces all had slight pressure on the cast and were secured to each other with duct tape.

b. The fabricator test fit the device at this point to ensure a snug fit without too much pressure (Fig. 7).

5. The splinting material was then applied.
   a. The splinting material needs to be measured and cut to the appropriate length. Length will vary from helmet to helmet depending upon the shape and size of the patient’s head.
   b. A preparation chemical was applied to any splinting materials that came in contact with another section of splinting material to ensure adhesion of the two pieces. This chemical increases the chance of adhesion by removing the thin outer surface of the thermoplastic. Fingernail polish may be a low-cost alternative to more specific chemicals sold in catalogues.
   c. Splinting material was heated in a tub of hot water.
   d. *CAUTION* Caution must be taken around hot water and splinting materials to avoid burns.

6. Splinting material was cut into eight 3x18 inch strips.

7. Two strips were used to make the initial cranial ring with $1\frac{1}{2}$ inch overlaps.
   a. The cranial ring has two $1\frac{1}{2}$ inch overlaps that were placed to the one and seven o’clock positions if the cranial ring were a clock face.
   b. Example, for a cranial ring measurement of 30 inches, two pieces of $16\frac{1}{2}$ inches are cut and formed together with two $1\frac{1}{2}$ inch seams, resulting in a ring of 30 inches.

8. The crossing arch from ear to ear was then measured, cut to the appropriate length, heated and placed.
   a. Piece was measured to ensure it overlaps the cranial ring for $2 - 2\frac{1}{2}$ inches for adherence.

9. The longitudinal strip was now placed over the initial cranial ring and crossing arch.
   a. Piece was measured to ensure it overlaps the cranial ring for $2 - 2\frac{1}{2}$ inches for adherence.
b. Chemicals were applied to the top of the crossing piece and the bottom of the longitudinal piece to ensure adhesion where they cross.

10. An outer cranial ring was formed to add rigidity to the cranial ring and hold the longitudinal and crossing strips in place.
   a. Chemicals were applied to the inside of this ring to ensure adhesion to the initial cranial ring and strips.
   b. 1 ½ inch overlaps were placed at the four and ten o’clock positions.

11. A heat gun was used to smooth rough edges.
   a. **CAUTION** must be taken as heat should not be applied to foam as risk of fire may occur.

12. A chinstrap was fabricated from a snapping buckle on one inch wide webbed straps riveted to the shell of the helmet. This too could be color coordinated with the shell to match the user’s interests.

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**PRECAUTIONS:**

1. Casting materials may shrink as they dry causing difficulties when removing from patient’s head. The material should only be left on the patient’s head for the minimal drying time indicated on the product package.

2. Heat gun can carefully be used to smooth any rough edges left on splinting materials.

3. Splinting materials must be handled carefully to avoid stretching and material sticking to itself prior to proper application.
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CAUTIONS:

1. Care must be taken when working around hot water and splinting materials to avoid burns.
2. Care must be taken when using heat gun around foam liner to avoid fires.
3. Chin strap must be attached for helmet to work as designed
4. *** This is a prototype and extensive testing must be completed to ensure its safety prior to use with patients.***

Recommendations:

1. Testing must be done to ensure product safety and quality. Actual materials used may be determined in part by the completed testing.
2. A dual foam liner should be used to increase safety while reducing weight. The inner surface of the helmet shell will be lined with 1/8 inch closed-cell foam padding. This padding provides some cushioning while also resists bottoming out, keeping the users head from impacting with the helmet shell. This product may also be purchased in 1/2 inch thicknesses if so deemed necessary during testing. The innermost layer of padding will consist of softer open-celled foam to provide comfort during everyday use and increased shock absorption should an impact occur. Open-celled foam is available in thicknesses ranging from 1/4 to 1 inch thick.
3. The cranial rings were made from two pieces of thermoplastic due to the constraints of the material acquired. Longer thermoplastic pieces will allow the cranial rings to be fabricated from a single piece resulting in a lighter product and improved aesthetics.
4. Three-inch wide strips of foam and thermoplastic were used in the fabrication of this prototype. Thinner strips may be used in future models if testing indicates them to be safe, reducing weight and cost due to less materials being used.
References


Chapter V: Summary

The war in Iraq has influenced the lives of those living in the United States. The medical field is no different with increasing numbers of individuals returning home with brain and cranial injuries. This project has designed a prototype helmet that will be further developed for use with these soldiers within the VA system.

The process developed to fabricate the helmet will determine ultimately the success and feasibility of the helmet’s use. Testing and trials will be completed to determine necessary precautions and guidelines needed for successful fabrication of the unit. These guidelines and precautions must then be presented formally to individuals within the respective facilities to ensure safe reliable construction of the helmets. We anticipate knowledge distribution will be accomplished through lecture sessions and hands-on lab sessions. Hands-on application tests will follow to ensure individuals are competent in the fabrication process prior to client application occurs. Occupational therapists will be the primary audience for this training due to their experience with the use of low temperature thermoplastics, their knowledge of the anatomy of the area, and their holistic approach to client care.

The helmet design is based on concepts from two occupational therapy theories to provide protection, comfort and personal satisfaction to the user. By following the concepts presented by these theories we can assume that by addressing the values, desires, interests, and environment while fabricating the patient’s helmet he/she will have
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increased motivation and satisfaction regarding the use of the helmet. Higher compliance with helmet use can lead to lower secondary injury occurrences.

The focus of this project was to initiate the development of a helmet that can be used for individuals having a cranial and/or brain injury while engaging in early rehabilitation activities. A prototype was design using a preliminary fabrication process. Testing of materials and fabrication processes is necessary to ensure the safety of the patients who will use the helmet. Further development is needed to produce an educational curriculum to qualify occupational therapist in the fabrication process.
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