Development of Ankle Foot Orthoses (AFO) to enhance walking and balance on Foot Drop Patients in India by Additive Manufacturing

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1 INTRODUCTION

The proportion of foot drop patient’s people is rising in India and now represents .2 billion people—10% of the global population, which leads to increasingly demand for orthotic device. However, moulds for orthoses manufacturing through traditionally manual technique are often dedicated, and this causes problems such as long lead time, lack of flexibility, low-efficiency and material waste, further leading to serious financial burns and environmental pollution as well. In this paper, an innovative method is proposed to replace traditionally process to additive manufacturing at low cost for the fabrication of orthoses.

An Ankle Foot Orthosis (AFO) is an orthopedic device that can be prescribed to support the ankle during walking. In general, an orthosis is defined as “an externally applied device used to modify the structural or functional characteristics of the neuro-muscular system”. An AFO is an orthosis that is specifically designed to modify the functioning of the ankle and/or the foot. AFOs are produced in various forms, composed of different materials, and prescribed with a wide variety of aims.

Cerebrovascular accident (stroke) is one of the main causes of disability and mortality in the developed world. Stroke victims experience a number of neurological deficits and disabilities, such as hemiparesis, communication disorder, cognitive impairment and visual-spatial perception disorder. Foot drop (sometimes called drop foot) can affect either one (unilateral) or both (bilateral) feet. Patients with foot drop are not able to raise the front of their foot because of weakness or paralysis of the muscles involved in lifting the foot. When walking, their toes scuff along the ground and they may raise their thigh to lift their foot higher than usual to avoid the scuffing. This results in a form of gait abnormality, called “steppage gait,” which is associated with the loss of dorsiflexion.

The first AFOs were made from a combination of leather and steel, but nowadays most AFOs are made from thermoplastics, such as polypropylene. It has recently become possible to construct AFOs out of carbon composites. The construction of a custom-made AFO starts by molding a plaster cast of the lower leg, which is subsequently covered with flexible sheets of polypropylene or layers of carbon fibers. This cover is then hardened chemically, or by cooling in ambient air, after which it is extracted from the plaster cast and finalized by the orthotist. In this process of finalization, the orthotist decides which parts of the AFO need to be trimmed off, referred to as the trimline. The leaf spring AFO is a brace that is made from an impression, or mold of a patient’s leg and foot. Leaf spring AFOs positions patient’s foot in dorsiflexion during swing phase of gait, although being designed to be semi-flexible during stance phase to allow for normal tibial progression. The aim of the present study was to conduct a systematic review of the literature to determine the manufacturing techniques and design procedure of an AFO of foot drop patients. This paper is organized as follows: - Section 2 is Literature review with subtitle as in Design, Manufacturing Techniques & Clinical Trials of AFO’s.

1.1 LITRATRURE REVIEW

For the development of a systematic review, searches were performed for randomized controlled clinical trials that analyzed the effect of an AFO on stroke/Drop foot patients. Studies involving a combination of AFO use and co-intervention were avoided. We searched for studies involving three-dimensional movement analysis of gait parameters as well as measures of manufacturing techniques.

The papers identified were evaluated based on the following inclusion criteria first design for foot drop/stroke patients and second manufacturing techniques of ankle foot orthoses and third in clinical trial population using AFO’s.
1.1.1 Ankle Foot Orthoses Design

Ranky et al (2009) have reported developments in non-invasive three-dimensional scanning that have made it possible to acquire digital models of freeform surfaces typical of the human body. Combined with rapid prototyping (RP) techniques, these technologies have the potential to transform personal medical devices by streamlining fabrication and providing a quantitative means to monitor patient physiology. The medical orthotics field contains opportunities for streamlining and improving the process for fitting a patient-specific ankle-foot orthoses (AFO). A novel process architecture was developed to utilize 3D photogrammetric scanning as the patient specific form data input, and selective laser sintering (SLS) as the patient-specific RP form output ideally suited for medical orthoses where form fit and comfort are paramount. Two examples have been presented of medical mechatronic devices for assisting patients with quantifiable evidence-based rehabilitation. Current rapid prototyping (RP) technology allows for single step manufacturing of complex objects with embedded electronics and is currently being implemented in all major fields of medicine. When combined with non-invasive 3D scanning techniques it allows clinical assessment and treatment in a telemedicine context regardless of geographical borders.

Talaty et al (2010) have reported a molded ankle foot orthosis (MAFO’s) an essential tool to assist walking function and thus independence to a large number of people with widely varying pathologies. The number of MAFO options and the process, by which they are administered, however, contribute a great amount of variability to the final outcome. One piece of this variability stems from inadequate description of the material properties of MAFO’s and how those mechanical properties contribute to the function of the brace. Ongoing research in our lab seeks to address these two issues by characterizing material properties and estimating the contribution of the brace to walking function. In general, the loading encompassed a brace deflection of approximately 30 degree where as the unloading returned only 5-7 degree. This response is likely also dependent on the settings of both anterior and posterior channels. In the present test conditions, the brace was ‘locked’ so that both channels were set to the same position. In this way, there was no free range of motion during which both elastomers were uncompressed. In the current testing paradigm, one channel was always compressed, and the other was at the threshold when the brace was unloaded. This represents a somewhat extreme case for how the brace may be used. How this hysteresis response changes when there is a free range present in the brace will also be assessed and reported.

Cappa et al (2011) have reported Biomechanics, the scientific domain which deals with the study of biological systems, such as the human body, using physical concepts and mechanical engineering methodologies. It allows the development of new medical devices and provides a quantitative analysis of the subject being studied. In the present work, the effect of an ankle foot orthosis was studied on a healthy male subject. For this purpose, a biomechanical multi-body 2D-model was developed in code MOBILE. The model was made of 9 rigid bodies connected by 9 frictionless hinged joints. Three additional degrees-of- freedom (DoF’s) were added so the model can move freely in the plane. Kinematic data acquired in a gait lab were used as time functions to drive the joints and a foot model were designed based on three Hunt-Crossley’s spheres-plane contact model. In the present work, a biomechanical model 2D-model was developed in MOBILE. The model was created in the sagittal plane and is made by 9 rigid bodies constrained by 9 frictionless revolute joints and has 3 additional dofs added at the hip. A simple contact model was developed in the foot-floor interface with three sphere-plane contacts. The model is prepared to solve forward dynamics problems and the ankle kinematics obtained in the gait lab was positively reproduced, with and without orthosis. Thus, the model was validated and proved to be appropriate for this study, since it is efficient and simple to define.

Assawapalangchai et al (2012) have reported the effects of flexible anterior ankle-foot orthosis on gait patterns of stroke patients. The flexible anterior ankle-foot orthosis were custom-made from 3M™ Scotchcast softcast tape. The subjects were assigned to walk with a flexible anterior ankle foot orthosis on the paper walkway. All gait parameters including velocity, base of support, cadence, Step length and gait symmetry were immediately evaluated and compared with and without applying the afo’s. The sequences of testing were randomly assigned and concluded that applying the flexible anterior ankle-foot orthosis provided
no immediate effect on gait parameters of the stroke patients walking with foot drop. Walking ability may be potentially improved with this design in some cases.

Brackx et al (2012) have reported current commercially available prosthetic feet that have succeeded in decreasing the metabolic cost and increasing the speed of walking compared to walking with conventional, mostly solid prosthetic feet. However, there is still a large discrepancy when compared with a non disabled gait, and the walking pattern remains strongly disturbed. During the stance phase of the leg, these prostheses store and return energy using a spring element. This spring returns to its neutral position, which generates a push off, but the foot extends much less than with a non disabled gait. The walking pattern may improve with a more extended push off. A new passive prosthesis was designed and tested. Unlike other advanced passive foot prostheses, such as the CESR foot by Collins et al., this foot regenerates Energy during the dorsiflexion phase and releases its energy over the entire push off phase. The device incorporates a planetary gearing and pawl ratchets to change the equilibrium position of a spring. The spring as an energy storing element together with the gear switching generates an extended push off to about 20°, while ESR feet only return to 0°. The prototype was tested with a transfemoral amputee and the results confirm the theoretical principle. The torque and angle data were measured on the device and the resulting torque angle characteristics are close to the theoretical curve. The prototype has shown itself to be reliable for prolonged tests, which need to be performed with multiple individuals to study the clinical effects of the extended push off characteristics.

Telfer et al (2012) have reported the design of foot and ankle orthoses currently limited by the methods used to fabricate the devices, particularly in terms of geometric freedom and potential to include innovative new features. Additive Manufacturing technologies, where objects are constructed via a series of sub-millimetre layers of a substrate material, may present the opportunity to overcome these limitations and allow novel devices to be produced that are highly personalised for the individual, both in terms of fit and functionality. The adjustable, pressure relieving foot orthosis was found to be able to significantly reduce pressure under the targeted metatarsals heads. The ankle-foot orthosis was shown to have distinct effects on ankle kinematics which could be varied by adjusting the stiffness level of the device. Further research is however required to confirm that these changes translate into clinically relevant outcomes. Full integration with computer aided design and analysis software such as finite Element or musculoskeletal modelling software may be used.

1.1.2 Ankle Foot Orthoses Manufacturing Techniques

Woodburn et al (2013) have improved the fit tolerance of personalized ankle and foot orthoses by 20%. This was achieved by evaluating and selecting a 3D scanning technique to provide digital models of surface anatomy and moving all orthotic designs from plaster casts, templates and blueprints to digital design solutions and also integrating co-created digital design, personalized design optimization and digital manufacturing to provide complete geometrical design freedom. This will be delivered as a co-created, industry platform ready, computer-aided design software system and prototype orthotic devices. A 20% reported increase in fit, comfort and aesthetic ratings for prototype orthotic devices in comparison with industry standards among consumers during pilot factory evaluation and field testing is reported.

Connolly et al (2013) have improved by 15% the functionality of personalized ankle and foot orthoses. This will be achieved by developing personalized anatomical and functional models of the ankle/foot region in 15 healthy adults and 10 patients with common disabling conditions, utilizing 3D medical scanning (magnetic resonance imaging and computed tomography) and gait analysis techniques. Optimization routines in biomechanical modeling platforms (anybody and MADYMO) are developed and exploiting new capabilities in digital design and rapid manufacturing and embedded sensors to develop radically new and novel orthotic devices. This will be delivered as personalized digital data sets, software optimization routines for integration in the CAD/CAM software platform and prototype devices incorporating variations for joints, hinges, and variable stiffness and sensing for physical activity and pressure monitoring. The objective will be verified by a 15% improvement in function, defined as motion control, pressure relief, and muscle activity and clinical outcome (pain, mobility and health related quality of life) for prototype orthotic devices in comparison with industry standard among targeted consumers during pilot factory evaluation and field testing.

Shamaei et al (2014) have been reported in this paper, we present the mechanical design, control algorithm, and functional evaluation of a quasi-passive compliant stance control knee-ankle-foot orthosis.
The orthosis implements a spring in parallel with the knee joint during the stance phase of the gait and allows free rotation during the swing phase. The design is inspired by the moment-angle analysis of the knee joint revealing that the knee function approximates that of a linear torsional spring in the stance phase of the gait. Our orthosis aims to restore the natural function of a knee that is impaired by injury, stroke, post-polio, multiple sclerosis, spinal cord injury, patellofemoral pain syndrome, osteoarthritis, and others. Compared with state-of-the-art stance control orthoses, which rigidly lock the knee during the stance phase, the described orthosis intends to provide the natural shock absorption function of the knee in order to reduce compensatory movements both in the affected and unaffected limbs. Preliminary testing on three unimpaired subjects showed that compliant support of the knee provided by the orthosis explained here results in higher gait speed as well as more natural kinematic profiles for the lower extremities when compared with rigid support of the knee provided by an advanced commercial stance control orthoses.

The latest literature indicates that the assumption of using different methods for manufacturing orthotic devices is feasible. Some studies tried to show how the shape of the orthotic devices can be altered to save weight, improve functional properties, be more suitable and patient customized. Orthoses can be highly customized, through the incorporation of gait and surface pressure measurement analysis into the design process. However, this is not done in current clinical practice. This is mostly because of time, cost and manufacturing constraints since the orthotic and prosthetic industry does not have a tradition of engineering and expert design.

1.1.3 Clinical Trials of Ankle Foot Orthoses

Milusheva et al (2005) have reported ankle-foot orthoses used mainly in case of disability of Neurological origin (cerebral palsy, stroke, spinal cord injury) or musculoskeletal origin (trauma, ageing). The study is oriented to develop new orthoses to assist the very frequently observed gait abnormalities relating the human ankle-foot complex using CAD modeling. Computer modeling is a perspective method for optimal design of prosthesis and orthoses. Using CAD geometry different tests could be made without loosing of material and essential design variables could be modified. An appropriate ankle-foot design is achieved and manufactured using rapid prototyping technology. The difference with the Traditional approaches is that the proposed ankle-foot othoses is made using optimal orthoses design on the base of laser scanning by manipulating Cad/Cam methods. The designed ankle-foot othoses is under FEA tests for breaking resistant by frequency and temperature loads.

Mavroidis et al (2005) have reported prefabricated orthotic devices currently designed to fit a range of patients and therefore they do not provide individualized comfort and function. Custom-fit orthoses are superior to prefabricated orthotic devices from both of the above-mentioned standpoints. However, creating a custom-fit orthosis is a laborious and time intensive manual process performed by skilled orthotists. Besides, adjustments made to both prefabricated and custom-fit orthoses are carried out in a qualitative manner. So both comfort and function can potentially suffer considerably. A computerized technique for fabricating patient-specific orthotic devices has the potential to provide excellent comfort and allow for changes in the standard design to meet the specific needs of each patient. The rapidly prototyped orthoses fabricated in this study provided good fit of the subject’s anatomy compared to a prefabricated ankle-foot othoses while delivering comparable function (i.e. Mechanical effect on the biomechanics of gait). The rapid fabrication capability is of interest because it has potential for decreasing fabrication time and cost especially when a replacement of the orthosis is required.

2 Discussion

All studies comparing drop foot patients wearing an ankle-foot othoses with healthy individuals found no statistically significant differences between the groups in spatiotemporal gait variables, kinetics or kinematics. Dropped foot is described clinically as poor ankle dorsiflexion during the swing phase along with a forefoot or flat-foot initial contact in stance. Stroke related impairments causing dropped foot include weakness of the ankle dorsiflexor muscles and increased spasticity of the ankle plantar flexor muscles. The challenges with understanding how dropped foot impairs gait function are two-fold; 1) there is no standardized method to assess dropped foot, and 2) different underlying impairments may result in various joint kinematic deviations and EMG profiles. This makes it difficult for clinicians to develop targeted and effective intervention
strategies. Stroke survivors with dropped foot may be prescribed an ankle-foot orthotic and functional electrical stimulation (FES) device to improve gait kinematics in the swing phase. However, divergent results were reported for cadence with and without the use of an ankle-foot othoses, as some studies report an improvement in this variable and others report no significant improvement. Since cadence is the number of steps take in a certain time, these patients showed significant improvements in gait speed without changing the number of steps per minute. Computer assisted design (CAD) systems have also been used to assist in creating the positive improving consistency and repeatability of this process, but the process remains slow and complex and it requires considerable input from experienced craftsmen. Furthermore, in these traditional processes the possibilities for innovation or product development are limited. With CAD systems it has been observed that othoses rejection ratio has been reduced combined with time reduction up to 50% and cost saving up to 25% to 50%. The biomechanical effect of the ankle-foot othoses will depend on properties of the design, such as articulation type, force system, stiffness and range of motion permitted. Technology of ankle-foot othoses designs are continually evolving to address current issues with the goal of improving ankle kinematic and kinetic profiles towards ‘normal’. While the majority of studies demonstrated improved ankle dorsiflexion during the swing phase with ankle-foot othoses application, other biomechanical outcomes that varied across studies may be explained by differences among stroke participants and ankle-foot othoses design. Therefore, specific investigation is required to determine clinical characteristics of stroke survivors who would benefit from each type of ankle-foot othoses device.

3 Future Direction

Ankle-foot othoses are that encompass the ankle joint and the whole or part of the foot. Ankle foot orthoses can be designed through reverse engineering and fabrication by rapid prototyping. An othoses is defined by the international standards organization as an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system. Ankle-foot othoses are intended to control motion, correct deformity and/or compensate for weakness of the leg. With our current technology, we can speed up the manufacturing process by using reverse engineering to collect 3D CAD data on the patient’s foot. The process of designing orthoses using reverse engineering software would permit changes in the standard design to meet the exact needs of each patient.

Figure 1: Flow chart of ankle-foot othoses prototype development.
Additionally, the use of 3D scanner and computerized software in fabricating patient-specific orthotic devices has the potential to deliver outstanding comfort due to the accurate data provided through 3D scanning. Figure 1 shows a proposed AFO fabrication plan. The process that is required to create a form fitting orthotic device. After the initial scan of the body part is taken using the 3D software, the CAD model of the orthotic is created. Once the model is complete, the data is then transferred to a compatible file and sent to the AM machine. The orthotic will be manufactured in sections if the design is outside the usable range of the AM machine. Once completed, the orthotic will be tested on the patient to make sure that a proper design and fit have been achieved.

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This research explores the possibilities of using current technology in bringing the manufacturing process of AFO much faster and reliable. By using 3D scanner to obtain the geometric data of the foot, the process of fabricating patient-specific orthotic devices has the potential to deliver outstanding comfort due to the accurate polygon data. The process of designing orthoses using reverse engineering software would permit changes in the standard design to meet the exact needs of each patient. In order to test the effectiveness of the AFO made using the new modern method, gait analysis was conducted and comparison was made.

References

Graber, G. 2003, Efficient and Reliable Multibody Simulation of Regularized Impacts between Elementary Contact Pairs. Ph.D., Technische Universitaet Graz, Austria.


Slavyana Milusheva, Dimitar Tochev, Liliya Stefanova, Yuli Toshev, 2005, Virtual Models And Prototype Of Individual Ankle Foot Orthosis Iss Xxth Congress - Asb 29th Annual Meeting July 31 - August 5, Cleveland, Ohio.


