AC 2007-482: SENIOR DESIGN PROJECT IN BIOMEDICAL ENGINEERING EDUCATION

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Senior Design Project in Biomedical Engineering Education

Abstract

The Senior Design Project for the 2005-2006 academic year's biomedical engineering students was a capstone experience, in which students participated in a real-world engineering project in consultation with their advisor. The topic of the project was "A Positive Reinforcement System for Children with Hemiplegic Cerebral Palsy". The main goal of this project was to develop an auditory and visual therapy device for infants and children with hemiplegic cerebral palsy (CP) through a non-invasive approach with the incorporation of positive reinforcement. The proposed device incorporates proximity sensors and auditory/visual aids to encourage children between the ages of seven months and three years to perform therapeutic movements of the affected arm. Two modifications of the proposed device were developed and tested in the laboratory by the two groups of students. The first modification was designed to train an infant or toddler to open his or her fist without the need for casting the unaffected arm. The second modification (described in this work) encourages the child to raise the affected arm. Multiple criteria and testing parameters have been created in order to ensure the safety, effectiveness, functionality, and accuracy of the device. Three 11-week terms were devoted to the research, development, and testing of this device, which required precise planning of each milestone. Funding for this project was the responsibility of the group; however, numerous corporations were contacted for contributions.

Introduction

At Drexel University, the Senior Design Project is a three-term, nine-credit course that engineering and engineering technology students take during their senior year. The senior design project is a capstone experience, in which students select a topic in consultation with their advisor according to a department's guideline and design and develop the working prototype. The following topic, among others, was introduced to the biomedical engineering students at the School of Biomedical Engineering, Science, and Health Systems: "A Positive Reinforcement System for Hemiplegic Cerebral Palsy Children". Three groups of students chose this topic for their Senior Design Project. Two groups were finally selected based on their experience in hardware and software development. The experience of one of the groups (Steven Calhoun, Sarah Myers, Laura Suhadolnik, and Nitu Thakore) is presented in this work. Dr. Chong-Tae Kim of the Children's Hospital of Philadelphia was invited by the students to Drexel University to discuss the medical concept of the project and the design criteria that would satisfy the FDA and hospital's requirements for medical investigation of the device. Within the frame of the proposed project, only laboratory testing of the device was the students' responsibility.

The main objective of this project was to develop a device that would provide auditory and visual feedback to the affected arm of a hemiplegic infant or toddler when the child uses that arm to engage in a given activity. Cerebral palsy (CP), defined broadly as "a

non-progressive motor impairment syndrome caused by a problem in the developing brain", affects at least 2 in 1000 children in the United States and more than one million children in the industrialized world[1]. Cerebral palsy was initially framed to describe the disorder in infants characterized by "spastic rigidity of limbs"[2]**.** Having undergone many transformations in the defined scope of such a condition, it is now commonly used to "name a group of conditions characterized by motor dysfunction due to non-progressive brain damage early in life"[3]. CP is widely classified on the basis of topography and types, such as Tetraplegia (asymmetrical limbs and arms), Diplegia (affected limb and arms), and Hemiplegia (one side of limbs is affected). Affected children widely lack postural stability in head, shoulder griddle balance, eye co-ordination, and arm co-ordination. Behaviorally, children who were diagnosed with mild cerebral palsy (hemiplegia affecting one side), hold their affected arms flexed at the elbow, and tend to clench the fist. Such children can be helped using what is called "constraint-induced movement therapy", where the unaffected arm is put in a cast and the child is intensively encouraged to use the "bad" arm using a variety of reinforcement techniques. Our goal was to develop a device for treating children with hemiplegia where they have a non-coordinated arm movement; either the left or the right extremity is diseased[4,5].

The following procedural steps were undertaken by the students during the described Senior Design Project:

1. Formation of the team
2. Project and advisor selection
3. Literature survey
4. Creation and presentation of the design proposal
5. Cost and budget analysis
6. Design and development of the device
7. Laboratory testing of the developed device (corrections if necessary)
8. Final presentation

Rationale of the project.

Constraint-induced movement therapy (CIMT) has been found as a promising treatment for substantially increasing the use of extremities affected by neurological injuries. The elements of CIMT are: 1) constraint of the unaffected arm to encourage the use of the affected hand, 2) massed practice of the affected arm, and 3) use of intensive techniques to train the affected arm[5]. Earlier successful results of the use of CIMT on children have proved that there is an improvement in the usage of the diseased extremity up to 52.1%, compared to a mere 2.1% in general physical therapies[6]. As an integral part of CI therapy, the normal arm extremity would be restricted in movements by using a convenient day or night fiberglass splint. This will greatly encourage the use of the diseased arm extremity[4,5]. Problems with CIMT exist, however. First, it is expensive because of the required amount of professional expertise and investment in training. Second, it is limited to older children who have already learned to use their unaffected extremity to manipulate objects. Third, it is, at present, limited to control of the arms and neglects the legs. Fourth, during the casting session, some children became upset, particularly when

the cast saw was used to bivalve the just-applied cast into two parts. Also, during the weekly removal of the cast, children have some skin redness, rash, or pinching. Finally, there has been concern expressed that casting the less-affected arm for three weeks results in short-term or long-term loss of function in that extremity[1].

The treatment of children with CP is, theoretically, much more effective at early stages of development as certain motor dysfunctions resulting from cerebral palsy occur at the later stages[7,9]. There exists a considerable body of research demonstrating that infants can learn to modify the environment through operant conditioning techniques[4,8]. It is likely that effective interventions given at earlier ages may be even more beneficial due to CNS plasticity effects. Specifically, the development of a device for infants and young children from 7 months to 3 years of age that would help to emphasize self-generated voluntary actions in a variety of settings was proposed. Moreover, the combination of auditory and visual feedback would create a will of its own in the child's mind to work with both arms[4]. The goal of this project was to develop a device, which would allow the child to receive feedback (auditory and visual) when the child lifts an affected arm with a glove containing a proximity or pressure sensor. When the child lifts the arm and touches the board installed on a certain level in the front of a child, the audio/video module will be activated. The level of the board will be changed from time to time as the child progresses in this training.

Costs

CIMT is a costly intervention. A major concern in the practitioner community is that there are strong pressures to recommend only the amount of rehabilitation therapy for which health care payers are currently willing to reimburse. Usually, each child is assigned one or two trained interventions for 60 hours, and they are supervised by a trained therapist[4]. The intervention requires suitable space and activities appropriate for the child's age. Substantial time is also involved in training and supervising interventionists. The use of the proposed device will not only increase effectiveness of treatment for infants and young children but also will significantly reduce health-care costs for both parents and the third-party payers. After a short training period, the need for physical or occupational therapist could be eliminated and the training procedure conducted by the parents can be continued as long as necessary to achieve desired results.

Design Criteria

The block diagram of the proposed device is presented in Fig. 1. The use of the proximity sensors for reliable activation of audio/video module was chosen to eliminate the transmission of the acoustical signal and satisfy safety requirements. The proposed device was composed of inductance proximity sensors, a metallic object (to activate sensor), and numerous visual/auditory aides. The first sensor was placed on an elastic band located around the child's chest so that it was positioned directly beneath the palm of the child's affected arm. Four other sensors were placed on the soft board that the child would be reaching towards.

Fig. 1. The use of the proximity sensor.

The soft board was a 14" by 14" framework with hard back and soft front panel. The soft board was cushioned with no rigid edges that could be hazardous to the child. Finally, a small metallic object was embedded into the cotton mitten that would be worn by the child on the affected arm. The proximity sensors were able to detect the metallic object due to a change in inductance (Fig. 2).

Fig. 2. The proximity sensor.

This change in inductance would trigger the sensor's output signal and consequently activate the visual/auditory device. The associated electronics consisted of an LC (inductance-capacitance) oscillating circuit, a signal evaluator, and a switching amplifier. The visual/auditory aides could be active for a certain period of time before stopping. To reactivate the device, the child would be encouraged to reach the board again for the positive feedback (Fig. 3).

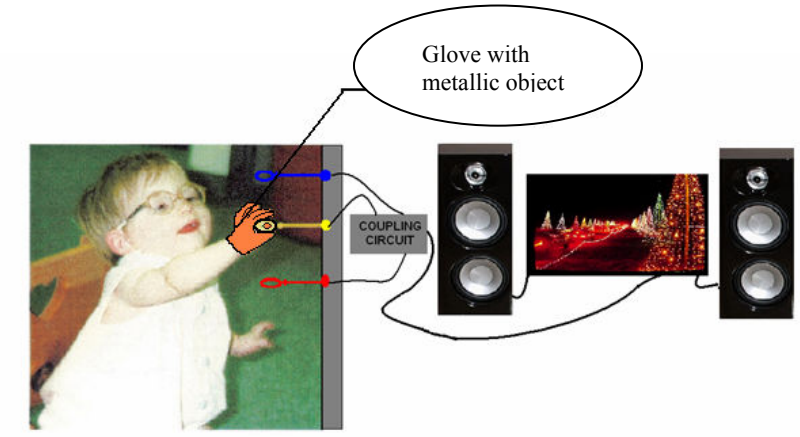

Fig. 3. Training the child to raise the affected arm.

The operation of the device is illustrated in Fig. 4.

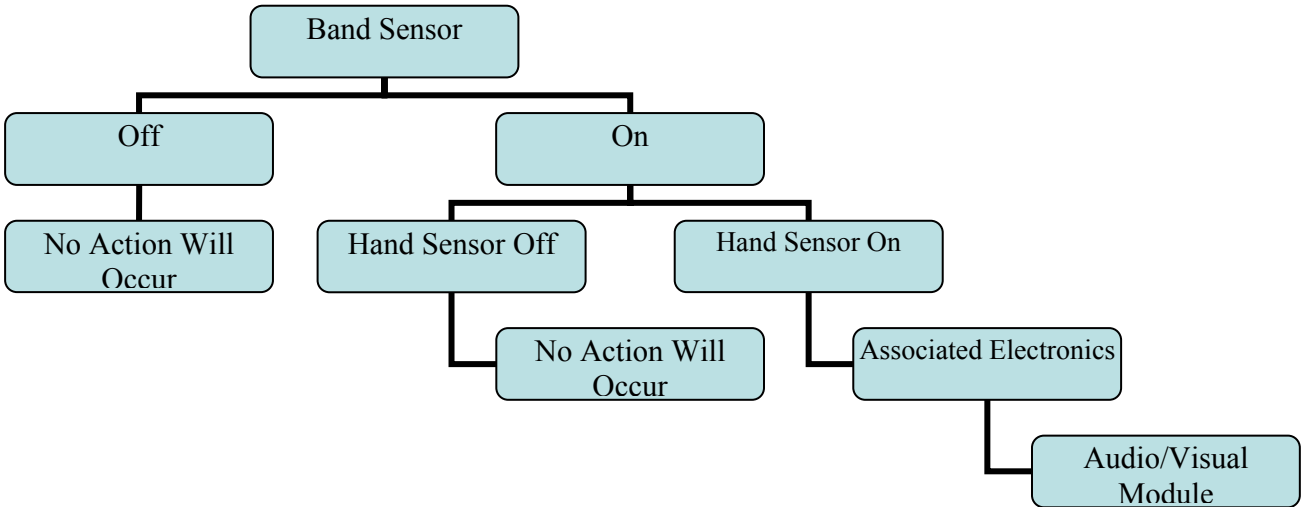

Fig. 4. Interaction of Auditory/Visual Module with an "if, then" sensor.

The operation of the device relies on the activation of the band sensor. The child must first trigger the sensor on the band by reaching his or her affected arm a set distance away from the chest before the sensor placed on the soft board would activate the feedback. This feature ensures that the child would be unable to activate the sensor by simply walking or leaning towards it. Once the "if, then" sensor on the band is activated, the child can continue to reach towards the soft board, which requires further arm extension, and activate the feedback module. The soft board can be at different distances away from the child. The board can also be mounted on a movable rack that would allow for height changes when the child is able to sit on his or her own. This progression is essential because it allows the device to be used over a larger age group (7 months to 3 years) and allows for advancement of therapy (Fig. 5).

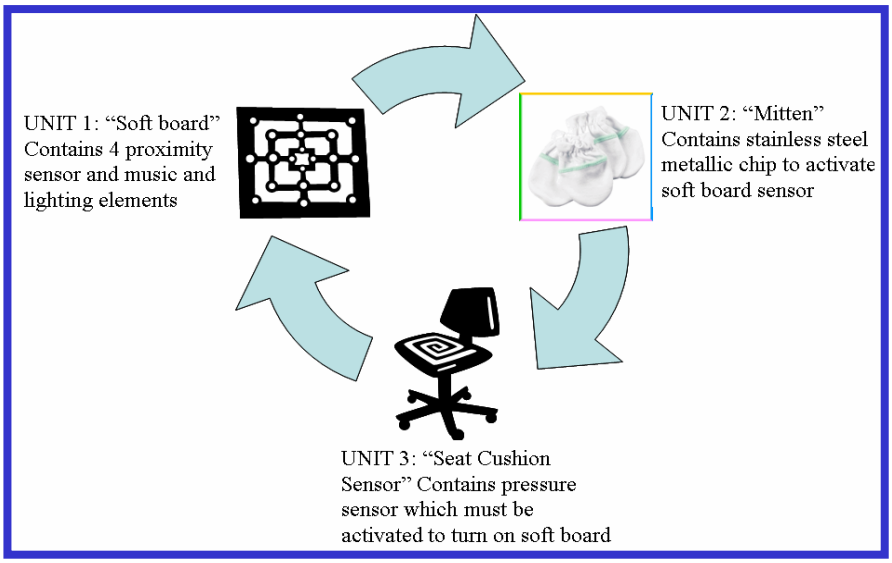

Fig. 5. Schematic diagram of the device activation

Device Testing

Numerous criteria have been developed to help ensure proper use of the device. The first requirement serves to help ensure that the device does not produce false positives and false negatives ninety percent of the time. A false positive is defined as the generation of feedback without the performance of the specified motion. For the device, this correlates to the soft board sensor being activated without the child extending his or her affected arm away from their chest. If feedback is not triggered 90% of the time, then the device is proven to not produce a false positive. A false negative was defined when the feedback was not activated even though proper use and desired arm motion were performed. This criterion was investigated by extending an artificial hand away from the band sensor, mocking an arm extension away from the body, and recording if the visual/auditory aides have been activated. Testing for this parameter includes triggering both sensors, first the band sensor, and then the soft board sensor. If feedback is generated 90 out of 100 times, then the device will be considered operational. This test also investigates the functionality of the sensors' ability to activate the visual/auditory aides.

The next criterion for the design of this device is focused on accuracy of range. The range for this device must be easily adjustable for the length and growth of the child's arm. The sensor field's activation must be accurate within one inch of the soft board. One inch accuracy ensures success of the system and would aide in the elimination of false positives/negatives. The test designed for this requirement involves placing the soft board ten inches away from the mitten, which contains the metallic piece. The soft board must be capable of being triggered at nine inches 90 out of 100 times.

Another criterion for the auditory and visual aides is based on longevity. This criterion requires the auditory and visual aides to turn on at least 1,000 times before a replacement of the feedback component. Assessment of this standard was determined by activating both sensors 1,000 times. If the components last 1,000 times without fail, then the device would be considered operational.

To monitor the progression of the child's arm extension, a counter was included. This counter allows parents and physical therapists to gauge the child's performance. This device must be accurate within ninety percent of the actual evaluated performance. To test for this accuracy, the soft board sensor was properly activated 100 times and compared with the counter's reading.

The final criterion to be evaluated was the proper activation of the "if, then" logic of the sensors. According to this criterion, the soft board sensor would be activated only after the activation of the band at least 90% of the time. This criterion will ensure the child extends his or her arm away from the body as opposed to any other way of activating the feedback. Without the "if, then" logic and the belt sensor, the child would be able to activate the sensor without arm extension. The belt sensor and "if, then" logic eliminate this possibility. Testing of the "if, then" sensor would compose of initially breaking the "if, then" logic and continuing to trigger the soft board sensor one hundred times. Once

the efficiency, functionality, and accuracy of the tests are optimal, the device will be considered to be refined and ready for use.

Project Schedule

The following schedule was developed to identify major topics, milestones, and deliverables.

FALL TERM

During the fall term, students spent time primarily on the research of hemiplegia and its current treatments. This information has fueled the project. Also, students established the contact with a physical therapist who worked with hemiplegic children. It has been determined that beginning of a treatment for hemiplegia prior to 3 years of age would greatly increase the patient's use of their affected arm. Research has also been conducted on the types of safe sensors that would activate the feedback elements, audio/visual aides, and fabrics for the glove and the soft board. Students came up with the conceptual design and block diagrams for the prototype that was built during the winter term. Important milestones in the fall included defining the problem and the need for the said device along with identifying the criteria for a successful device and the constraints on the solution. The schedule was provided to the advising faculty.

WINTER TERM

Design and development of the prototype was the major component of the project. Also, numerous institutions were contacted for information on the treatment of the children with hemiplegic cerebral palsy and safe sensors. Most of the time has been allotted for design, construction, and testing the prototype. The major milestone in the winter term was to have a working prototype that has been tested successfully for functionality by the week six of the term. The goal was to have the final prototype ready for the final presentation in the spring. Necessary documents and test data were generated. Students revised the design report according to their advisor's and reviewers' comments.

SPRING TERM

Although the group planned to have the final prototype completed by the end of the winter term, time has been allotted for final adjustments and testing of the prototype during the spring term. This term was devoted to the final report on the prototype's functionality as well as the preparation of the oral presentation and showcasing of the device. The final presentation took place during the fourth week of May 2006.

Specific tasks of the project management are presented in Table 1.

		Start Date	End Date
Fall			
Hemiplegic CP Research			
	Article Review	09/26/05	12/08/05
	Interview Physical Therapist	09/30/05	12/08/05
	Contact with Institutions	09/30/05	12/08/05
Device Research			
	Sensors	09/26/05	12/08/05
	Counter	10/03/05	12/08/05
	LED Lights	09/26/05	12/08/05
	Musical Elements	09/26/05	12/08/05
	Fabric	09/26/05	12/08/05
Design			
	Conceptual Design	10/10/05	12/08/05
	Block Diagrams	10/31/05	12/08/05
Documents			
	Project ID Draft	09/26/05	10/03/05
	Project ID Final	10/03/05	10/10/05
	Project Outline Draft	10/10/05	10/17/05
	Project Outline Final	10/17/05	10/31/05
	Project Proposal Draft	10/31/05	11/07/05
	Project Proposal Final	11/07/05	11/28/05
	Oral Presentations	11/28/05	12/09/05
Winter			
Research			
	Article Review	01/09/06	03/17/06
	Interview Physical Therapist	01/09/06	03/17/06
	Contact with Institutions	01/09/06	03/17/06
Design			
	Prototype Design	01/09/06	01/23/06
	Prototype Testing	01/23/06	02/06/06
	Prototype Redesign	02/06/06	02/20/06
	Prototype Retest	02/20/06	03/06/06
	Prototype Redesign 2	03/06/06	03/13/06
	Prototype Retest 2	03/13/06	03/20/06
Documentation			
	Project Proposal Draft	01/0906	01/16/06
	Project Proposal Final	01/16/06	01/30/06
	Progress Report Draft	01/30/06	02/13/06
	Progress Report Final	02/13/06	02/27/06
	Oral Presentations	02/27/06	03/17/06
Spring			
Design			
	Final Adjustments	04/03/06	04/17/06
	Final Testing	04/17/06	05/01/06
Documentation			
	Final Report Draft	03/03/06	03/10/06
	Final Report	03/10/06	05/15/06
	Practice Oral	05/15/06	05/19/06
	Oral Presentation	05/22/06	05/26/06

Table 1. Project Schedule.

Budget

Funding for this project was the responsibility of the group; however, numerous corporations were contacted for contributions. The final budget for the project indicating all purchased and donated components is presented in Table 2.

BUDGET			
Item	**Purchase Date**	**Cost**	**Supplier**
Mittens	1/30/2006	$9.30	www.Babyant.com
Counter	donated	$0.00	J.E. Quinones & Associates, Incorporated
Seat Cushion Sensor	4/4/2006	$62.86	AliMed Supply
Inductance Proximity Sensors	2/3/2006	$197.16	Newark InOne Outlet
LED Lights	donated	$0.00	J.E. Quinones & Associates, Incorporated
Musical Elements	2/7/2006	$10.11	Planet Teddy
Buzzer	4/25/2006	$5.00	RadioShack
PLC	donated	$0.00	J.E. Quinones & Associates, Incorporated
RSLogix Software	donated	$0.00	J.E. Quinones & Associates, Incorporated
Plywood	2/13/2006	$4.67	Home Depot
Hardboard	2/13/2006	$1.37	Home Depot
Screws	2/13/2006	$3.57	Home Depot
Sandpaper	2/13/2006	$2.17	Home Depot
Side panels	3/7/2006	$10.70	Home Depot
Stainless Steel Washers	3/7/2006	$1.05	Home Depot
Electrical Tape	3/7/2006	$0.74	Home Depot
Brackets	3/7/2006	$3.62	Home Depot
Blocks	3/7/2006	$3.75	Home Depot
Tacking Nails	3/14/2006	$3.22	Home Depot
Mounting Brackets	4/25/2006	$6.78	Home Depot
Batting	2/13/2006	$17.11	A.C. Moore
Fabric	4/25/2006	$7.29	Walmart
Meeting Costs	3/9/2006	$35.00	Papa Johns
Visual Light Aides	4/25/2006	$45.31	Electronics123
Visual Light Aides	5/2/2006	$20.00	RadioShack
NYP = not yet purchased	**Total Cost:**	**$450.77**	

Table 2. The final budget.

Evaluation of safety and effectiveness

After completion of the prototype, the developed device was tested in the laboratory to evaluate its safety for children. No direct contact to the child's skin by any sensors, electronic components, or wires was permitted. All parts and components used in the project satisfied the standards for medical applications. Electrical isolation of the gloves with the built-in metallic object was tested for both dry and wet gloves. All necessary wires and cables were fixed reliably to the sleeves to prevent any possibility of misuse or

suffocation. Inability to reach the batteries or any other parts or components that could be swallowed by the child was tested, and all possible percussions were implemented. The material of the boards, gloves, and other parts touching the child's skin was chosen to prevent electrostatic discharge, skin irritation, redness, or any other undesirable side effects. Installation of the boards and audio/video equipment was reliably tested to make sure that any child's efforts to overturn, remove, or drop them will not be possible. All necessary changes and improvements were performed according to the advisor's and reviewers' recommendations.

Conclusion

The Senior Design Sequence is a capstone experience, which provides students the opportunity to apply their knowledge and skills gained in the previous years of coursework. It is the most important challenge of the senior year. This three-term sequence stimulates students' interest in engineering and engineering technology. Also, it demonstrates students' technical competence and ability to work in teams and communicate orally and in writing on the progress and results of the project. During the fall term, students formed a team, selected project and advisor, and submitted the pre-proposal, which was approved by the team's advisor and the School's Senior Design Committee. Emphasis was placed on the problem and its solution, not on the technologies that were used by the team. During the winter term, students revised design report and began implementation of the project. By the end of this term, students demonstrated the functionality of the prototype and made necessary modifications according to their advisor's recommendations. At the end of the term, the team made a15-minute presentation on their progress to the advisor and Senior Design Committee representatives. In the spring term, the team completed the project, conducted the final tests of the functionality and safety of the developed prototype, and prepared the final report and presentation. During the fourth week of May, the project was presented to the School's Committee. The successful completion of this open-ended project motivated other students to continue research related to the treatment of children with cerebral palsy.

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