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Development of a Convergence Product Design Process for a Wearable Orthotic Device to Prevent Hip Dislocation in a Pediatric Patient with Cerebral Palsy

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Abstract

Background/Objectives: The purpose of this study is to propose a convergence product design process of a wearable orthotic device that will aid pediatric patients' normal development, with the goal of preventing hip dislocation in patients with severe cerebral palsy.

Methods/Statistical analysis: The subject of the study was a five-year-old male pediatric patient with cerebral palsy, presumably classified as GMFCS level IV. Taping was performed using medical bandages on a 3D-printed model of the patient made with his actual measurements. Based on the X-ray images, six designs (drafts) were produced as the prototypes, and the colors were unified as black to limit the variables. The evaluation of the orthotic device was conducted through a discussion with a panel of five persons, consisting of a few experts and of the guardian of the patient.

Findings: The following findings on the convergence product design process of a wearable orthotic device for the prevention of hip dislocation in a pediatric patient with cerebral palsy were obtained from the result of this study. The experts and the guardian evaluated that the function of assisting the femoral head of the hip joint to be positioned in the acetabular was outstanding in Designs D and E, and the abduction of the femur was outstanding in Design F. Many openings in Designs B and C were removed and modified to relieve the patient's discomfort when wearing them. The rigid tri-glide buckles in Designs A and F were removed, and the length of the overlapping part of the band in Design E was modified to minimize the factors that could restrict any movement.

After a thorough discussion, Design D, which presents a good closing position around the waist and the abdomen, and Design E, which presents a stable hip joint position were converged into the applicable hip joint position; and Design F, which presents an excellent closing method around the thighs was converged into the femoral region, respectively. As a result, the final orthotic product design of the prototypes A1 and B1 was presented with minimized compression in the abdomen to facilitate smooth digestion and enhancement in the overall fittings.

Improvements/Applications: The final orthotic product design proposals of the prototypes A1 and B1 will proceed with further improved follow-up research by conducting advanced pattern designing work in order to enable mass production in the coming years.

***Keywords*:** convergence product design, design process, cerebral palsy, prototypes, hip dislocation, acetabular

1. Introduction

There have been prior studies[1-10] on children with severe cerebral palsy, but research on wearable devices that can prevent hip dislocation is as yet insufficient [11-13]. Therefore, in this study, we plan to prevent hip dislocation in patients with severe cerebral palsy by designing a device that can be worn on a daily basis before the initiation of hip subluxation, and is intended to reduce pain and physical deformations to assist in the individual's normal development. Also, we plan to propose a product design process that will prevent dislocation by analyzing the materials of each design and observing their differences.

2. Materials and Methods

2.1. Subjects

The subject of this study is a five-year-old (51M) male pediatric patient diagnosed with cerebral palsy (CP) presumably classified as GMFCS (Gross Motor Function Classification System) level IV with some dislocation in progress, but with no surgical operation performed. This subject was selected based on his ability to stand in an upright posture and the capability of communication at some level. This study was conducted after obtaining prior approval from the Chungbuk National University Industry Academic Cooperation Foundation (IRB. No. CBNU-202004-SBETC-0063).

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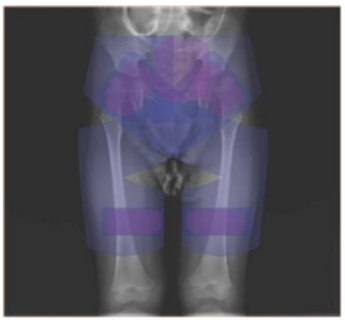
.*2.2. Design Settings*

Using medical bandages (7 cm), pressurized taping was performed on the 3D-printed (SBbot 200, 2018) model of the CP patient, made with his actual measurements, which allowed for upward and downward compression centered at the key point of this design, the greater trochanter, and the femoral rotation [Table 1]. Based on the result of this taping, the position of the patient's hip joint was confirmed through radiography, and the pressurizing point of dislocation and the position of the genitalia (the non-pressurizing region) were also identified. Based on the X-ray images, several designs of an orthotic device were mapped out, and six designs (drafts) with minimum compression in the genitalia and the abdomen were deducted.

Table 1. Design Process

Real Body	Actual Model	Virtual X-ray Images of the Fitting
		

2.3. Design

In order to prevent hip dislocation, it is necessary to display the function of assisting the femoral head of the hip joint to be positioned in the acetabular. For this purpose, a compression design was laid out from the perspectives of garment construction specialists in order to fix the femoral head in place around the greater trochanter. A total of six designs were produced as prototypes, and the colors were unified as black to limit the variables and reduce errors during the evaluation.

2.4. Analysis

The evaluation of the orthotic devices was conducted by a total of five individuals consisting of a medical specialist, a researcher (physical therapy major), two garment construction specialists, and the guardian of the patient through the discussion of design selection and revisions.

3. Results and Discussion

3.1. Main Contents of Design Advancements

Since the femoral head of the hip joint should be assisted to be positioned in the acetabular to prevent hip dislocation, compression to fix the femoral head in place around the greater trochanter is required. In order to rotate the hip externally and assist in maintaining the flexed position, upward and downward compression is needed to spread out both thighs at 45° angles for such abductions. As a daily wearable device, wearing the device should be easy, and the compression in the abdomen should not be distracting to the patient. Additionally, for a male pediatric patient, it is necessary to verify any possible compression in the genitalia and identify the level of comfort when lying down or sitting up[Figure 1]. Major design elements are as follows.

Component 1. upward and downward compression centered around the greater trochanter of the femur at about 45°
Component 2. Reduction of compression in the genitalia
Component 3. Abduction of the femur
Component 4. Convenience in Dressing and Undressing

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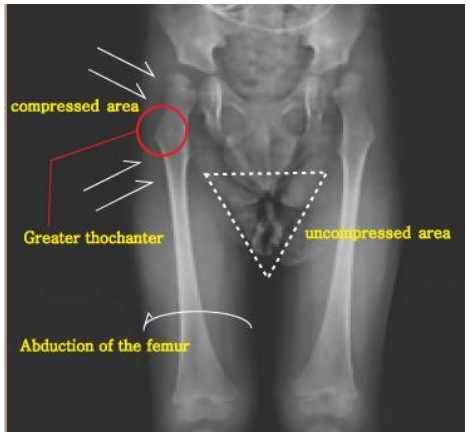
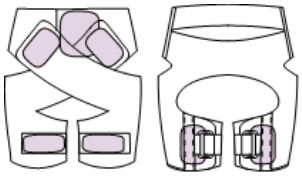
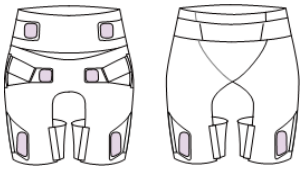
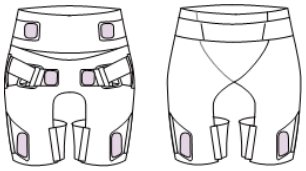
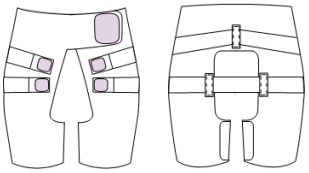
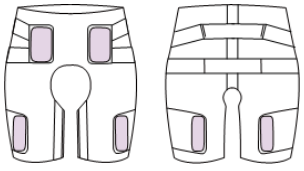
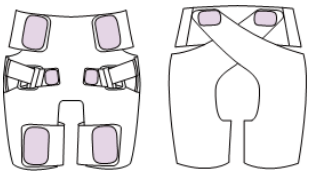


Figure 1. X-ray Image

3.2. Design Draft

Differences in each design are as follows [Table 2]. In Design A, the product is designed to allow two processes of upward and downward compression by using the Velcro to fix the waist and the hip joint once horizontally, and again around the greater trochanter in an X-shape. Also, the product is designed to allow compression in the thighs through double fixation using the Velcro and the belt. Design B allows for an adjustable closing in the waist, and it is designed to effectively compress the curved surfaces through the extensive addition of fabric on the hip. Different from Design B, Design C is devised to attach a fixed strap to a closing near the great trochanteric of the femur. Design D lacks side seam lines, and it is designed to maximize the strength of a hip joint position by fixing the back as the shape of an 11 and then closing it at the front. This design allows the guardian to dress up the young patient easily. Design E can be worn like a tight brief because it lacks side seam lines. Also, the Y-shaped band presses on the hip joint, and the Velcro compresses the front and back of the femoral region. Similar to Design E, Design F does not have side seam lines, and it is designed to adjust the compression area accordingly by fixing the waist of the front panel and crossing it from the back to hold them in place.

Table 2. Design

A	B	C
		
D	**E**	**F**
		

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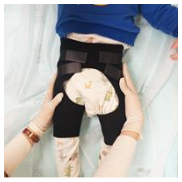
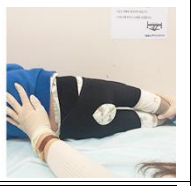
3.3. Fitting Evaluation

Table 3. Fitting Evaluation

	Front	Side	Back		Front	Side	Back
A				B			
C				D			
E				F			

	Advantages	Disadvantages	Suggestions for Revision
A	• Excellent fit for left and right hip joints • Comfortable in sitting positions due to a back opening	• Pressing on the thin band of the femoral region and the tri-glide buckles	• **Removal of the tri-glide buckles** • Minimization of the attachments
B	• Stably spreads the leg at a 45° angle • Adjustable compression in the abdomen	• The patient feels uncomfortable during the fitting due to the multiple openings overall	• Excessive openings were omitted • Direction of compression in the femur revised (Internal→External)
C	• Adjustable according to the patient's body size • Adjustable compression in the abdomen	• Low compression • Sitting position caused discomfort in the back	• Revised to display a single band • Minimization of the back band and the attachments • Direction of compression in the femur revised (Internal→External)
D	• Convenience in dressing and undressing of the product • Excellent closing position for the waist and the abdomen	• The band split into two causes discomfort • Sitting position caused discomfort in the back	• Revised to display a single band • Minimization of the back band and the attachments
E	• Outstanding fit for the hip joint and the greater trochanter position • Excellent compression in the hip joint	• Direction of compression in the band of the femoral region needs revision • Waist in the back short in length • Excessive overlaps in the waist	• Direction of compression (Internal→External) • Revision of the crotch length • Direction of compression in the femur revised (Internal→External)
F	• Excellent abduction of the femur	• Lying on the side caused discomfort • Insufficient hip joint compression	• Replace the rigid tri-glide buckles • Compression from the hip to the hip joint

Six products were devised based on the designs of the waist and the femoral region, using the actual 3D-printed model. Each device was evaluated by the patient through his actual fittings [Table 3]. The experts and the guardian evaluated that the function of assisting the femoral head of the hip joint to be positioned in the acetabular was outstanding in Designs D and E, and the abduction of the femur was outstanding in Design F. Many openings in Designs B and C caused discomfort in the patient when wearing them, so the removal and modifications of such openings were necessary. In general, since the rigid tri-glide buckles in Designs A and F and the overlapping part of the band in Design E could cause some restrictive movements from being pressed down on and feeling discomfort, the evaluation suggested modifications for an alternative design that omits the tri-glide buckles

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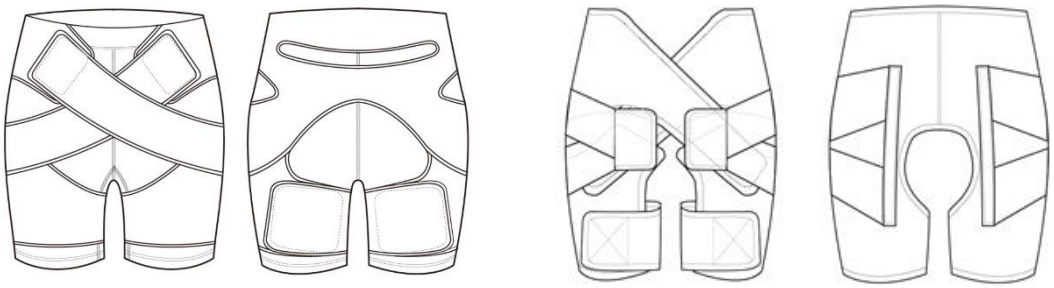
and allows for a closing. In addition, in order to effectively position the greater trochanter within the femoral head of the hip joint, the hip joint regions of Designs D and E and the thigh region of Design F were converged after a thorough discussion. Based on the previously illustrated designs, 1. Enhanced fit by minimizing compression in the abdomen to facilitate smooth digestion. 2. A total of two final prototypes, A1 and B1, were proposed in which the design elements of the double compression of the hip joint around the greater trochanter were added [Figure 2].



A1 B1

Figure 2. Final Prototype

4. Conclusion

The following findings on the convergence product design process of a wearable orthotic device for the prevention of hip dislocation in a pediatric patient with cerebral palsy were obtained from the result of this study. Based on the actual fittings of each of the six designs, the experts and the guardian evaluated that the function of assisting the femoral head of the hip joint to be positioned in the acetabular was outstanding in Designs D and E, and the abduction of the femur was outstanding in Design F. Therefore, Design D, which had a good closing position on the waist and abdominal regions, and Design E, which had a stable hip joint region, were converged into the hip joint region, and Design F, which had an excellent closing method around the thighs was converged into the femoral region, respectively. As a result, final designs of the prototypes A1 and B1 were proposed. There are plans to have the final design of this study undergo further developments, and to conduct a follow-up study in pattern designing work in the near future.

5. Acknowledgment

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