DESIGN AND MANUFACTURE OF A TIBIA AND KNEE PROTECTOR FOR EHLERS DANLOS PATIENT

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ABSTRACT:
The design of prosthetics and orthotics products has gone from being a slow and laborious process to taking on a new dimension thanks to 3D printing. The use of new digital technologies allows the creation of sanitary material, orthoses and prostheses quickly and economically, as well as being personalized to each patient.
There are mainly 2 technologies involved on this process: the first is scanning process that allows to digitalise any part of the body of the patient. This will allow to work with specific software in order to design this final product, adapted to the anatomy of the patient. The second technology is 3D printing: this technology will make production cheaper, avoiding intermediate devices like moulds, to produce the tailored final part.
This article presents an example of these technologies applied to a real case.
A 6-year-old patient with vascular type Ehlers Danlos disease, unique in the Basque Country (Spain), needs a custom-made protector for the tibia and knee to protect herself from possible scratches, impacts or falls that cause open wounds that need stitches.
For this aim, digital measurements of the lower limbs are taken with the 3D scanner Sense from 3D Systems. Using Autodesk's Meshmixer software, a 4mm-thick lattice-type breathable and lightweight protector is designed. Manufacturing is done using 3D printing technology on HP Multi Jet Fusion 4200 on PA12. Subsequently, it is lined with 5mm Multiform to cushion and obtain a soft contact surface. Currently, the portfolio of services of the Basque health system does not cover this type of protectors and the costs are paid by the patient.

Keywords: protector; lattice; Ehlers Danlos

1. INTRODUCTION

A 6-year-old patient with Ehlers Danlos vascular type came in search of orthotics technical help. A clinical examination and evaluation of the lower limb is carried out where it is observed (Image 1.0 and 1.1):

- Flat foot valgus
- Beginning of claw toes
- Abnormal growth of the first metatarsal head
- It does not make an impulse with the forefoot in the take-off phase when walking
- Low muscle tone of the vertebral column (spine) and the extremities
- Skin that is stretched, bruised, and easily damaged
- Poor wound healing

She currently wears a CASCADE DAFO CRICKET (DAFO Fast Fit). It is used for patients who exhibit moderate pronation with a fully correctable foot position, where medial arch is reduced but visible and there is moderate heel eversion and forefoot abduction. The CASCADE DAFO CRICKET (DAFO Fast Fit) offers sensory feedback by wrapping the foot inside the shoe.

She mentions frequent blows, rubbing and involuntary falls due to lack of impulse and rigidity of the metatarsal joints. She has suffered 40 falls in 4 months, all of them with open wounds that have required stitches. She refers to the last fall from a recent open wound with 20 stitches at the level of the left tibia.

Her case is unique in the Basque Country (Spain).

Due to this situation that seems to be getting worse, the family looks for a knee and tibia protector to minimize or prevent these injuries. Currently, orthopedics in Spain does not consider customized protectors in its coverage of health system services.

1.1 Ehlers Danlos syndrome

Ehlers-Danlos syndrome (EDS) is a group of inherited disorders characterized by extremely loose or lax joints, highly elastic (hyper elastic) skin that bruises easily, and easily damaged blood vessels.

There are six major types and at least five minor types of EDS.

A variety of genetic changes (mutations) cause problems with collagen. That is the material that provides structure and strength to:

- Skin
- Bones
- Blood vessels
- Internal organs

Abnormal collagen leads to symptoms associated with Ehlers-Danlos syndrome. In some forms of the syndrome, rupture of internal organs or abnormal heart valves may occur.
Family history/background is a risk factor in some cases.

Symptoms of Ehlers-Danlos syndrome include:

- Back pain
- Ligament hyperlaxity
- Skin that is stretched, bruised, and easily damaged
- Poor wound healing and abnormal scarring
- Flat feet
- Increased joint mobility, creaking in the joints, early arthritis
- Joint dislocation
- Joint pain
- Premature rupture of membranes during childbirth
- Very soft and velvety skin
- Vision problems

There is no specific cure for EDS, so individual problems and symptoms must be appropriately evaluated and addressed. Physical therapy or evaluation by a physician specializing in rehabilitation medicine is often needed.

People with EDS generally have a normal lifespan. Their intelligence level is also normal.

People with the rare vascular type of EDS are at increased risk of organ or major blood vessel rupture. These people are at high risk of sudden death.

Possible complications of EDS include:

- Chronic joint pain
- Early-onset arthritis
- Difficulty in closing surgical wounds or in removing stitches
- Premature rupture of membranes during pregnancy
- Rupture of large blood vessels, including rupture of an aortic aneurysm (vascular EDS only)
- Rupture of a hollow organ such as the uterus or intestine (vascular EDS only)
- Rupture of the eyeball

2. METHODOLOGY

The objective of this work is to find a solution to protect the tibia and knee from possible falls, blows or friction that cause an open wound. For this reason, it is desired to design and manufacture a custom-made protector using 3d technology.

2.1 Taking measurements

To obtain the patient's geometry, a conventional negative mould cannot be taken with plaster bandages, because the pressure exerted in taking the mould can cause bruising. For this reason, a scan of the lower limb is performed with the low-cost 3D Sense 3D scanner from 3D Systems with a precision of 0.9mm (Image 2.1.1).

2.2 Cleaning the scan

Cleanup of the scanned mesh is performed in Autodesk's free Meshmixer software. Possible noises from the scan are eliminated, as well as any geometry that would not be necessary for the production of the protector (Image 2.2.1).

2.3 Custom protector design

Subsequently, using the Canfit (Vorum) orthopedic software, the bone areas of the tibia and knee are regrowth. In this way, if there is an impact on the prominent areas, they would be protected since the protector would not collide with the bone during the impact. The areas contiguous to the region performed are smoothed (Image 2.3.1).

In addition, the patient presents a reducible genu recurvatum or hyperextension of the knee that is corrected by bending to achieve a neutral and functional anatomical position.

With the cut line, the protection area of the tibia and knee is limited to design the protector (Image 2.3.2). Finally, on both sides, 2 hook systems are designed to be able to place riveted Velcro straps to attach to the leg (Image 2.3.3).

In the final design of the protector, it is intended to generate an interior area with lattice-type reticulated structures to lighten weight and improve skin breathability. For this, the free mesh software MeshMixer is used. The protector and the four fastening systems are imported separately in the same file, where the exact alignment and a Boolean union between them are performed.

To obtain a rigid protector in the corners while ensuring breathability in the middle, the mesh is separated into two different meshes (Image 2.3.4). The outer mesh is given an offset that allows the corners of the protector to be solidified to a thickness of 2mm (Image 2.3.5).

The inner mesh has a reticulated and light design. For this, it is necessary to reduce to the maximum (maintaining the necessary definition of the file) size of the triangles of the scan, since the greater the mesh, the greater the size of the reticle/lightened weight (Image 2.3.6). Make

Pattern (generation of the reticles/lattice) is made to obtain a mesh of 4mm thickness (Image 2.3.7).

Subsequently, a boolean union is made between the outer and inner mesh to be able to combine both in a single file again (Image 2.3.8).

Finally, the leg and the protector symmetry are made to obtain the complete pair (Image 2.3.9).

2.4 Manufacture of custom-made protector/orthosis

Additive Manufacturing is the fabrication of three-dimensional objects using computer-aided design (CAD) data, typically through a layer-by-layer deposition process.

There are several techniques or processes available for obtaining parts. According to the ASTM organization and its F42 standard, there are 7 different categories or processes by which parts can be obtained by additive manufacturing:

1. Powder bed fusion
2. Binder injection
3. Extrusion
4. Material injection
5. Directed energy deposition
6. Lamination by layers
7. Photopolymerization in tank

In this work, powder bed fusion technology has been used with HP Multi Jet Fusion 4200 technology in the thermoplastic material PA12 (lighter polyamide with infinite mechanical, chemical and electrical properties) (Image 2.4.1).

To finish completely cleaning the protector, sandblasting is performed (Image 2.4.2).

Extrusion technology (FDM) is used, Ultimaker 2+ Extended machine, to manufacture the positive cast of the patient's legs. The material used is a PLA (polylactic acid).

Subsequently, the protector is padded with 5mm Multiform (Ortoiberica) in blue colour.

To make the padding, the plate previously cut to the dimensions of the knee and calf is introduced in the oven between 110-130º. When it is soft, it is vacuum thermoformed on the mould printed in PLA, previously covered with cotton tubular (Image 2.4.3 and 2.4.4). The excess is cut to a size slightly larger than that of the protector to avoid friction or discomfort.

The male and female Velcro are riveted to fasten the protector to the knee and calf (Image 2.4.5). The padding and the protector are glued with a special glue for orthopedic use, Ortec (Image 2.4.6).

3. RESULTS

The result is a protector that protects the tibia and knee from scratches, impacts or falls, with highly resistant padding against pressure. The structure of the protector is breathable and light.

The materials used have been PA12 2mm for the rigid central part and a 5mm Multiform for padding. Along with rivet and Velcro accessories to adjust it to size.

If any of the Velcro straps rub, the patient could add a cotton tubular or sock prior to placing the protector on.

The final protector is shown below (Image 3.1).

4. DISCUSSION

Any personalized protector improves the quality of life of the patient.

Future lines of research derived from the work carried out are exposed:

- Design and manufacture an articulated protector at the level of the centre of the knee.
- Analyse the durability of the design/material against different impacts or falls throughout its life cycle.
- Analyse different padding materials such as plastazote foam, air foam and different thicknesses throughout the protector to achieve greater or less rigidity/flexibility and adapt to her needs.

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