Self-adjusting orthoses design

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Abstract: This paper proposes an approach to the development of a customized 3D printed multi-material cervical orthosis that combines new production techniques with smart materials and biomimetic structures. It suggests a lightweight, waterproof, ventilated, hygienic and comfortable orthoses designed specifically for each patient in collaboration with doctors, additive manufacturing specialists and designers. The combination of innovative production techniques with smart materials can generate an enhanced product, whose added value can be perceived by differentiated attributes and applications.

Keywords: Human factor in design, Customized and personalized product development, Smart product engineering.

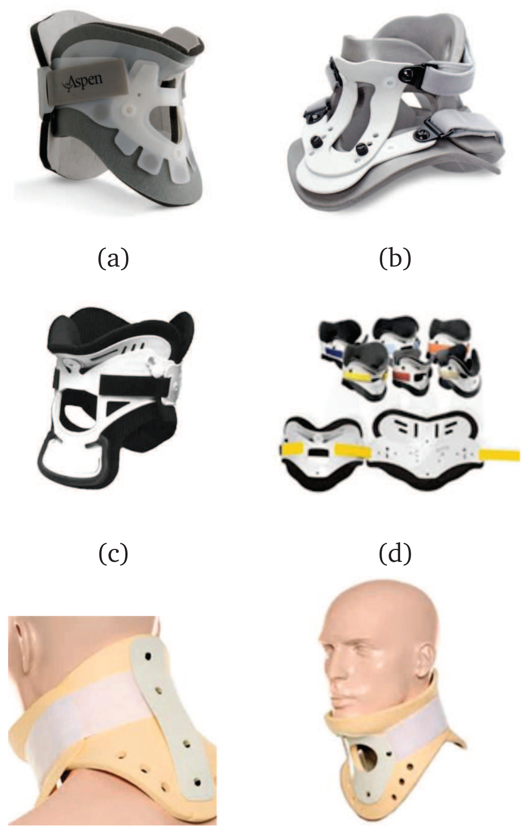
1 Introduction

Through many years orthoses had no apparent innovation. The traditional manual methods for creating customized orthoses have many drawbacks including the intensive work, time-consuming and imprecise process which may affect the comfort of orthoses and limit treatment quality. Today designers are taking orthoses to another level with the use of forward thinking methods, integrating both innovative technologies and new materials, contributing to a more accurate treatment. There is a large variety of cervical collar orthoses with different characteristics for different clinical indications, of various materials, prefabricated in different sizes. Focusing on the most commonly used cervical collar orthoses and their characteristics and purpose we will explore a new solution of orthosis trough the introduction of novel product development techniques meeting the user's morphology instead of purely adjusting a standard solution.

The integrated methodology approach of medical image processing and reverse engineering can be applied to construct 3D printed models with biomimetic structures and smart printed material/shape memory material which are programmed to respond as desired. In the following sections, these topics are described in detail, referring to the corresponding stage of the development. In general, the result is a 3D printable material that when in contact to the user's body temperature, changes itself into an ergonomic shape. The organic structure is developed based in strategies of growth of the coral reefs.

2 Cervical Collar Orthosis

An Orthosis is an external medical device designed to stabilize, immobilize, prevent deformity, protect against injury, or assist with the function of a body part. The purpose of cervical collar is to alleviate instability of a compromised cervical spine, while being patient-friendly, lightweight and economic. The most commonly used semi rigid cervical collars are the Aspen, Malibu, Miami Jackson, Nec Loc and Philadelphia collars, as pictured in Figure 1.



(a) (b) (c) (d) (e) (f)

Figure 1 - (a) Aspen; (b) Malibu; (c) Miami Jackson; (d) Nec Loc; (e) and (f) Philadelphia.

There are some known problems usually associated with its use:

- Muscle atrophy
- Heavy
- Odor
- Skin rash or breakdown
- Psychological dependence
- Soft tissue contracture
- Pain
- Lack of hygiene
- Discomfort

The pressure applied in soft tissues and poor circulation is a high risk for developing ischemic wounds and cause of discomfort and pain. The psychological dependence and the sensation of movement or strain of the neck especially in cases when the collar is worn over a longer period of time as well as muscle atrophy, skin friction and facial hair growth in men, should also be considered.

Combinations of rigid and flexible materials in collar types of cervical orthoses are usually the choice to prevent pain. Comfort is also an issue and for that reason cervical motion restriction efficacy is often sacrificed. The more effective ones are frequently more uncomfortable. In general, the cervical orthoses are more effective in restricting the flexion and extension than restricting lateral bending and axial rotation.

The adequacy of the orthosis must be followed whether its purpose is to support, prevent, immobilize or correct the spine. For this matter we will focus only on the first two alternatives. It is also essential to determine the degree of freedom and in which motion of the spine would be controlled, flexion, extension, lateral bending or axial rotation. The rigidity of the components at the chin and the occiput along with the increase of the vertical length, are the main elements in restricting motion.

3 Design Methodologies

When we talk about methodology, we refer to the process that is used to reach a solution. Centered on the virtual model of the patient body and with specific medical data, the main object is to develop a cervical collar with high level of customization in order to satisfy functional requirements and an adequate immobilization or support with maximum comfort and with specific motion control.

Starting from the customer/patient needs and the disadvantages/cons of traditional orthoses and the desirable features for developing a novel orthosis based on medical data, reverse engineering, 3D printing and smart materials, some solutions are explored in order to create a functional, more accurate and comfortable model.

Desirable features:

- Prevent muscle atrophy
- Ventilated
- Lightweight
- Customized
- Waterproof
- Recyclable
- Localized intervention
- Hygienic
- Comfortable

The design intent is building a lightweight, washable, most accurate and ventilated orthosis designed especially for each patient that is both comfortable and functional with particular goals:

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- to innovate and optimize the product (materials selection, manufacturing, use, end of life)
- to improve custom-fit product process
- to increase the sensation of comfort
- to reduce costs (efficient use of materials)
- to reduce manufacturing times

4 Biomimetic

The combination of 3D technologies and new design inspired in algorithms that mimic patterns and processes in nature, give us new ways of thinking about form, material behavior, structure performance, etc. The main thrust of biomimetics is also to transfer functions, mechanisms and principles from one field to another. Inspired by the algorithmic structures of coral reefs and the systematic exploration of how pattern and form emerge in nature and its strategies of growth, we're interested in using these same rules of growth for design, instead of merely mimicking nature.

A smart material with streching memory effect that when in contact to the user's body temperature, changes itself into an ergonomic shape. Surfaces of multilevel branching fibers with specialized tips that helps reduce the risk of shear and control friction, suggesting a "body's natural (biological) cover". Reduction of the adhesion, using a material inspired in nano filaments of lotus flower with hydrophobic characteristics that allows skin to breath and perspire without getting wet; promotes a more comfortable orthosis.

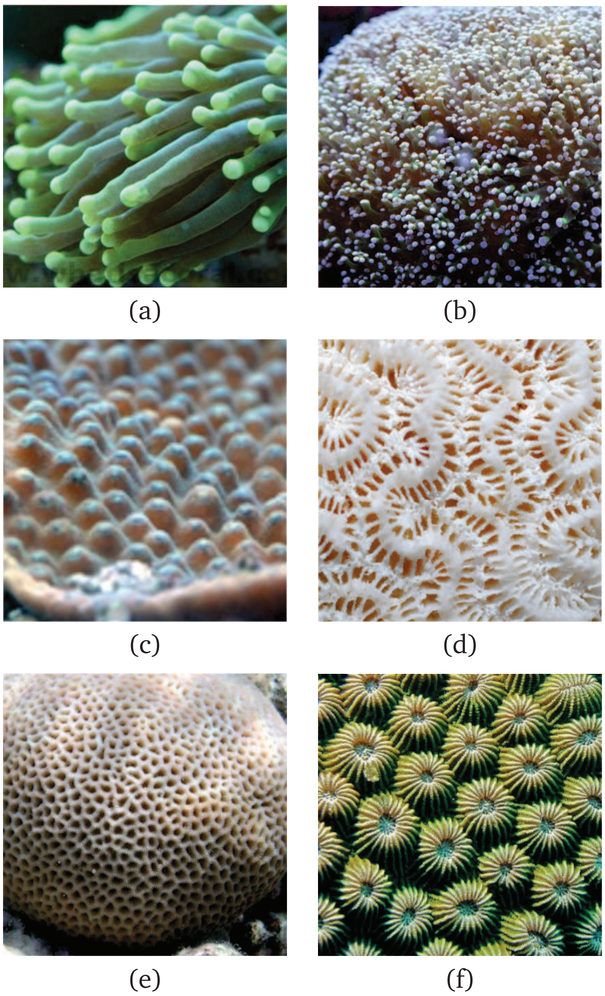


Figure 2 - (a) Euphyllia glabrescens; (b) Euphyllia paradivisa; (c) Turbinaria sp; (d) Faviidae;(e) Gardineroseris; (f) Diploastrea heliopora.

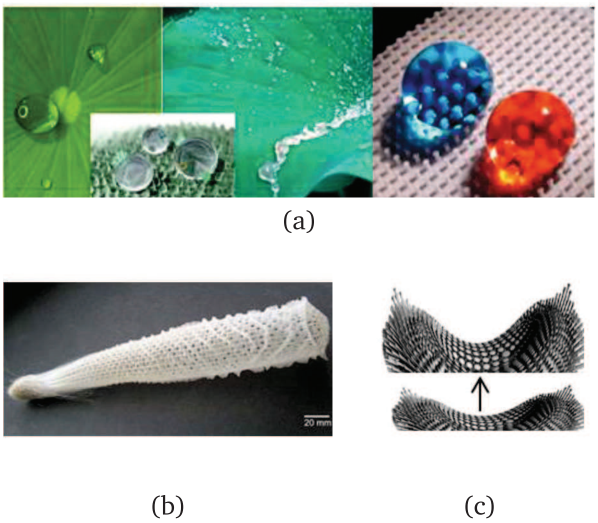


Figure 3 - (a) Hidrophobic lotus leaf effect; (b) Skeleton of Euplectella sp, showing the lattice-like skeleton of fused siliceous spicules; (c) Stretching memory effect.

The skeletal structure of the glass sponge Euplectella aspergillum displays a remarkable multi-level hierarchical design that gives it superior structural properties. Also in nature we find fractal honeycomb structures which are responsible for excellent stiffness, various patterns and forms with an economic design.

Analyzing this pre-optimized structures from nature and their functional properties we can get to a hyper-structural carcass and a super hydrophobic surface with shape memory material organic behaviour and with material being efficiently applied, only where it is necessary.

5 Customization

Customization of orthoses design can also bridge the gap between personal and technological fields assuming an extension of the user style and personality. Used temporarily or for long periods of time, these medical devices reveal also a social burden of a negative impact.

The negative impact may be reduced when the identity of the user and their lifestyle is reflected, uniting the technological and social aspects. The cervical collar is custom-fit with the ability to adequate the users personality in the design stage. In this phase the user can introduce some personal details in order to change the way he will perceive and relate to the final product without interfering with the functional characteristic of the model.

With the customization of this medical device, we can enhance the therapeutic treatment, having the ability to look at a patient on an individual basis allowing a more accurate diagnosis and specific treatment plan. In this model, the structure will be reinforced in the injury located area and restrain motion where is necessary with higher accuracy, tailored to each individual patient. It is through the diagnostic that is selected the appropriate and optimal treatment based on the context of each patient.

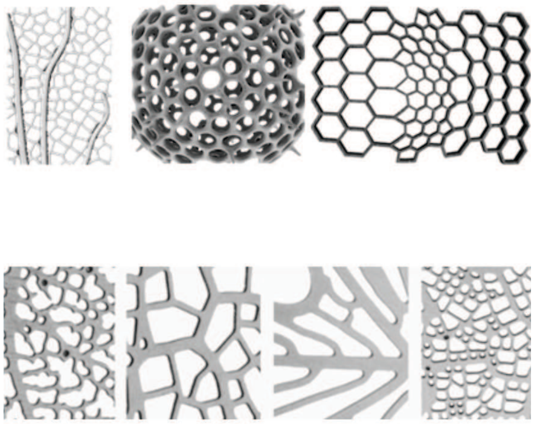


Figure 4 - bioinspired patterns.

6 The development of a new design framework

As indicated, the development of the cervical collar is supported in the patient's treatment plan and the type of lesion to be intervened. This will start at first in the hospital and will end in a custom application orthosis manufactured by 3D printing.

The inner surface of the structure with streching memory effect and hydrophobic characteristic, adapts to the patients neck making it more comfortable, allowing free skin perspiration, as well as the daily hygiene, without requiring removal. The rigid outer structure fulfills its immobilizing function.

The necessary elements for the development of the orthoses can be provided through medical imaging and patient's data identified by the doctor. This can be also complemented through 3D scanning tools.

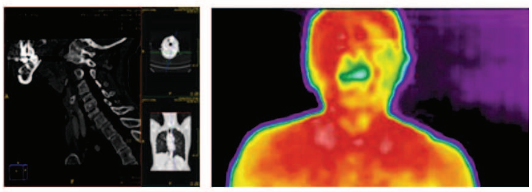
The CAD / CAM (Computer Aided Design / Computer Aided Manufacture) for orthopedics are a very promising technology. The RX is still the most frequently used exam in cervical trauma. However, the use of CT scan allows rapid acquisition of images in axial and sagittal and coronal reconstructions, although the risks linked with high levels of radiation, that the patients are subjected to.

These are the main steps of the development procedure that can be followed after an injury occurs:

First diagnose in the hospital Identification of the exact injury location by an orthopedist with medical imaging (Figure 5). A computed tomography (CT) scan is an imaging method that uses x-rays to create pictures of cross-sections of the body, typically called slices. Three-dimensional models of the body area can be created by stacking the slices together.

CT scan is saved as a 3D medical data model of affected soft and/or hard tissues.

(a)



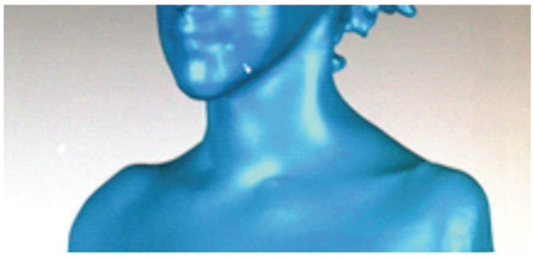
(b)

Figure 5 - Diagnosis.

Digital 3D model Together with medical data, we can reproduce a structure related to the area to be intervened. Through a 3D scanning equipment, it is possible in a few minutes to acquire the patient 3D surface coordinates generating a three-dimensional geometry data. This two approaches can be complementary (Figure 6).

(a)

(b)



(c)

Figure 6 - 3D model.

Development of a pattern structure Directly related to the injury location, following biomimetic principles along with full evaluation by an Orthopedics Doctor, the Additive Manufacturing Technician generates a structure based on medical data and planning, through 3D scanning and 3D modeling tools (Figure 7).

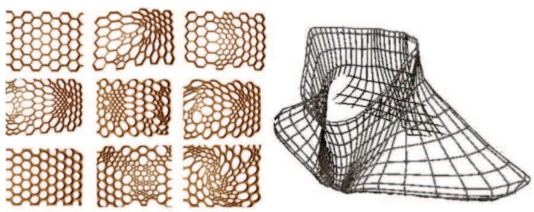
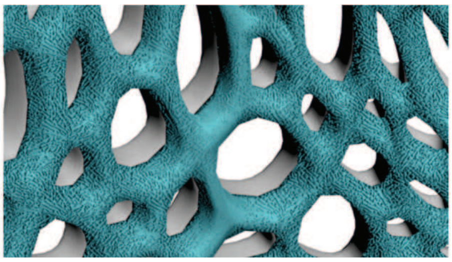


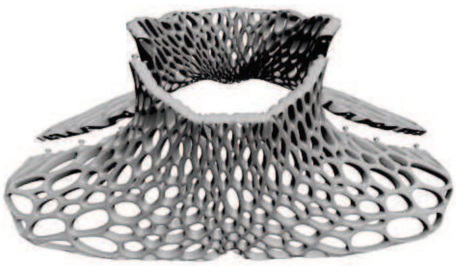
Figure 7 - Bio inspired structure with medical evaluation

Model is sent to multimaterial 3D printer The cervical orthoses will be 3D printed with multi-material. In the inner surface a shape memory and flexible material would continuously optimize its shape in response to the user's body temperature. The outer structure would keep its rigid status so the immobilization occurs making it both effective and comfortable (Figure 8).

(a)



(b)



(c)

Figure 8 - AM printing

Application to the patient This custom-made orthoses may be immediately applied to the patient after 3D printed, providing a more accurate and comfortable treatment. The patient will be able to use it throughout personal hygiene routine and won't be concerned with the odor addressed to perspiration being lightweight through every day usage (Figure 9).

(a)

(b)

Figure 9 - Application of final orthosis to the patient

7 Future Work

Nowadays we're living in a manufacturing revolution that promises to change the way we make things. After 3D Printing becoming increasingly accessible and optimized, 4D printing will unquestionably make the difference expanding the boundaries of "making".

The 4D printing concept was initially proposed by Massachusetts Institute of Technology faculty member Skylar Tibbits earlier this year. The 4D printing concept proposed, allows materials to "self-assemble" into 3D structures. The few existing studies are now being developed. These recent studies represent strong advances in additive manufacturing with programmed shaped memory polymer composites using glass fibers.

Last October 2013, researchers at the University of Colorado Boulder have demonstrated the importance of fibers location and orientation within the composite material, in order to determine the degree of shape memory effects like folding, curling, stretching or twisting and the ability to control those effects by heating or cooling the composite material. For future work we intend to integrate into the product development of the cervical orthoses this novel approach and innovative concept.

8 Conclusion

The collaboration and inputs brought into design development starting from medical ground to designers, engineers, manufacturing specialists and the product user itself, can generate an enhanced product. Also the combination of innovative production techniques with smart materials, whose added value can be perceived by differentiated attributes and applications.

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