ANALYSIS OF A NOVEL HEAD SUPPORT FOR PEOPLE WITH HYPERMOBILE-TYPE EHLERS-DANLOS SYNDROME

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1. Objective

The objective of this project is to design a head support for people with Ehlers-Danlos Syndrome (EDS). EDS is a hereditary connective tissue disorder. It is caused by genetic changes that affect the connective tissue that stabilize and support the joints and organs throughout the body. There are many different types of EDS, the most common one is the hypermobile type (hEDS). The hEDS characterized by connective tissue laxity resulting in excessive joint mobility due to weak and less elastic ligaments and tendons.

A particularly common symptom amongst people with hEDS is pain and instability in the neck. Due to the hypermobility of the joints, the cervical ligaments cannot provide a normal support in the neck and endpoints for range of motion, this involves fatigue in the muscles and pain.

The prototype of the head support consists of a polystyrene frame mounted to shoulder supports that are custom-molded to fit the user. The head support contacts the user's head at the occipital bone and on the bottom side of the mandible. The contact surfaces are covered with memory foam to provide cushioning and to allow the contact surfaces to mold to the user. A desirable design characteristic is the ability for the head support to flex in a controlled manner as the head is rotated. The support should allow a limited head rotation while also preventing excessive rotation which can lead to injury.

Therefore, in order to carry out this project, it is necessary to carry out a series of studies that are defined below.

The first one will consist of a study of the basic concepts of anatomy and physiology. This is intended to achieve a knowledge of the subject at the undergraduate level. In order to understand the functioning of the human body to be able to apply it into the project.

The second one consists of investigate EDS disease (Ehlers-Danlos Syndrome). It is important to know all the characteristics of it in order to design the support correctly. With this I will study the general characteristics of it and analyze what are the main difficulties that people with this disease find in order to help them as much as possible with the support of the head.

The last one consists of finding the parameters to design the head support. These parameters will be the range of angles of movement of the head that a person with EDS can perform and compare it with the ranges of movement of a person without any disease. Subsequently define the range of motion for the "Activities of daily living". Also, in this section the forces exerted by the head on the support will be defined.

2. Anatomy and Physiology

In order to understand the needs of people with EDS syndrome and its characteristics, it is necessary to know the basic concepts of anatomy and physiology.

The term anatomy refers to the study of the structure of an organism and physiology is the study of function.

2.1. Levels of organization

The human body is organized into structural and functional levels of increasing complexity. Each higher level incorporates the structures and functions of the previous level. The different levels are listed below:

- CHEMICALS

Recall that the body is a container of chemicals. The chemicals that make up the body may be divided into two major categories: inorganic and organic.

- CELLS

The smallest independently functioning unit of a living organism are cells, and the human body consists of more than 200 different types of cells.

- TISSUE

Tissue is a group of cells with similar structure and function, these cells work together to perform a specific function.

- ORGANS

An organ is a structure of the body composed of two or more tissue types precisely arranged to accomplish specific functions. Examples of organs are the kidneys, individual bones, the liver, the lungs, and the stomach.

- ORGAN SYSTEMS

An organ system is a group of organs that all contribute to perform major function. Examples are the urinary system, the digestive system, and the respiratory system.

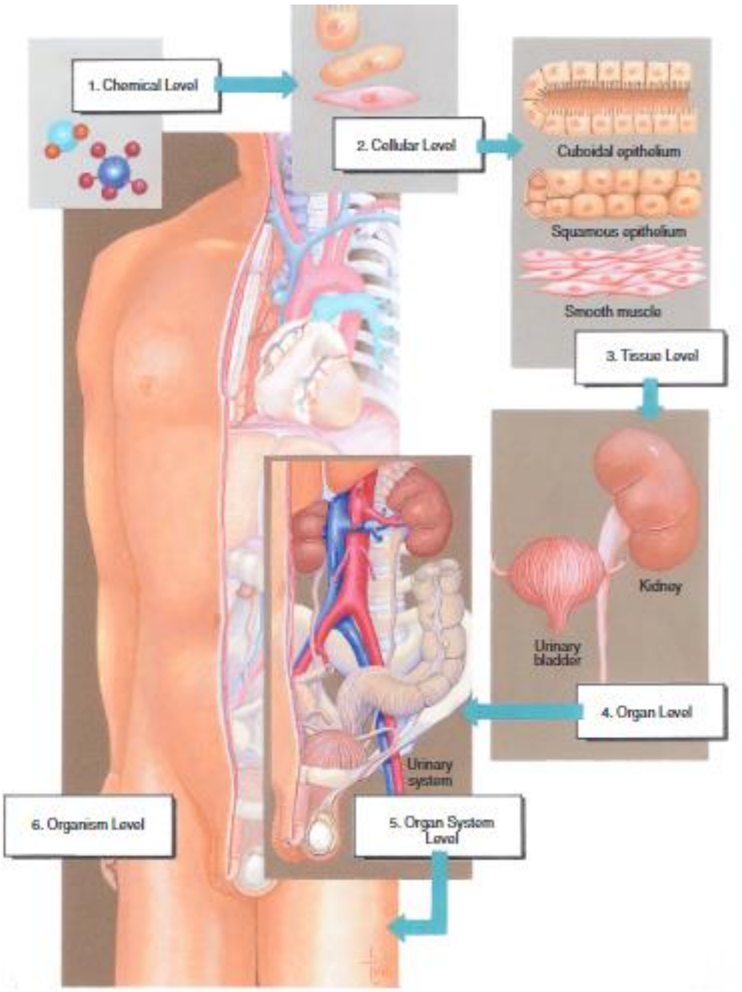


Figure 1: Levels of structural organization of the human body [1]

2.2. The muscle system

The definition of muscle is as follows: Organ composed mainly of contractile fibers.

2.2.1. Muscle structure

Muscle tissue is made of thousands of contractile cells called myocytes or muscle fibers. When these cells contract, they shorten and pull a bone to produce movement. They represent the active part of the locomotor system. That is, they are the ones that allow the skeleton to move and, at the same time, maintain its stability both in motion and at rest.

Muscles are anchored firmly to bones by tendons. Most tendons are rope like, but some are flat; a flat tendon is called an aponeurosis.

“**Tendons** are made of fibrous connective tissue, which, is very strong and merges with the fascia that covers the muscle and with the periosteum, the fibrous connective tissue membrane that covers bones. A muscle usually has at least two tendons, each attached to a different bone. The more immobile or stationary attachment of the muscle is its origin; the more movable attachment is called the insertion. The muscle itself crosses the joint of the two bones to which itis attached, and when the muscle contracts it pulls on its insertion to move the bone in a specific direction.” [1]

2.2.2. Muscle arrangements

The movements are due to the coordinated action of various muscles, some contract while others relax. The two general types of arrangements are the opposing antagonists and the cooperative synergists.

- Antagonists muscles

Antagonists are opponents, so we use the term antagonistic to describe a set of muscles that act in opposition to the force and movement that another muscle generates. Example: biceps triceps.

- Synergistic muscles

Synergistic muscles are those that produce movement through joint and coordinated contraction.

2.2.3. Types of muscle tissue

There are three types of muscle tissue:

- Skeletal, which has a structure large cylindrical cells with striations and multinucleated. This type of tissue is attached to bones or the skin and is in charge of moving the skeleton and produces heat. It is essential to cause voluntary contraction.

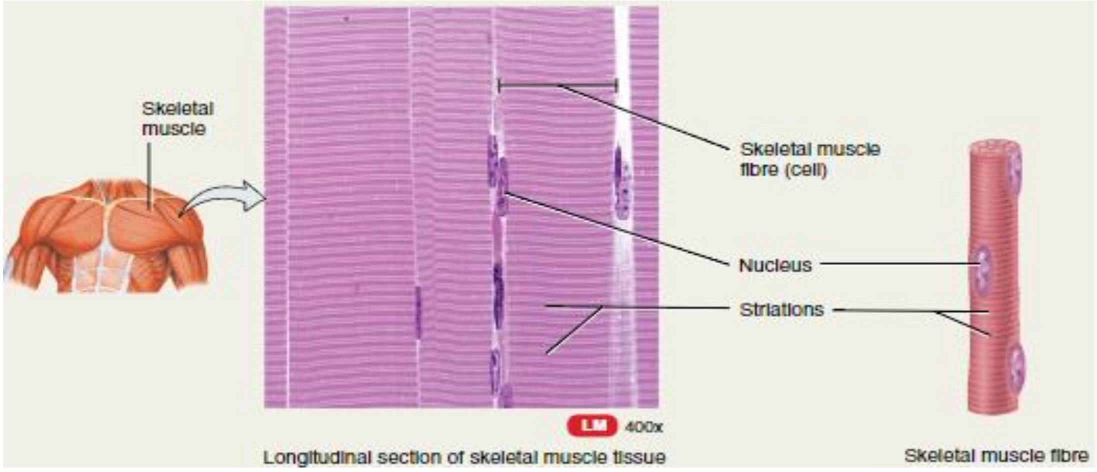


Figure 2: Skeletal tissue [2]

- Smooth, this type of tissue has small tapered cells with no striations and one nucleus each. It is located within walls of hollow internal organs, and blood vessels of the body. Its function is maintaining blood pressure, peristalsis and regulate the size of the pupil.

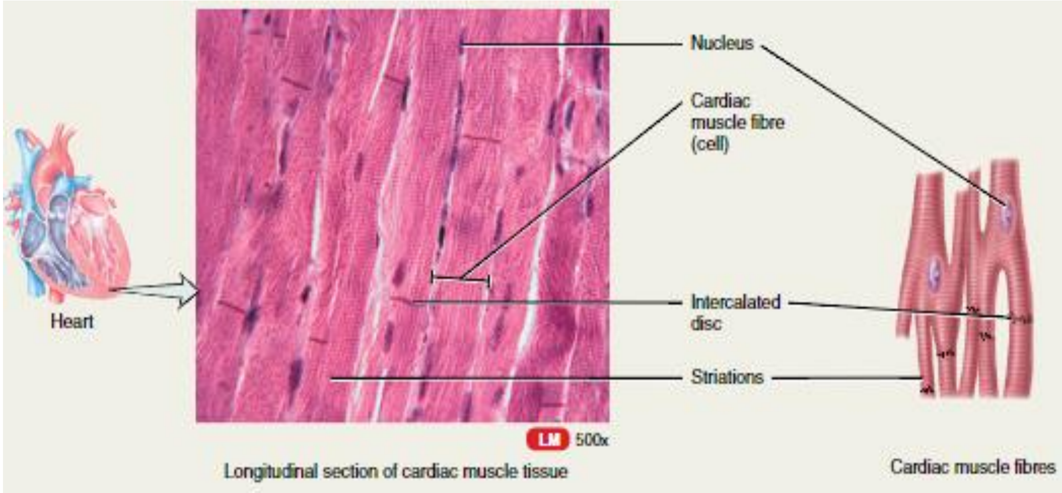


Figure 3: Smooth tissue [2]

- Cardiac, it is composed of branched cells, non-striated and one nucleus each. Form the walls of the chambers of the heart and are in charge of pumping blood.

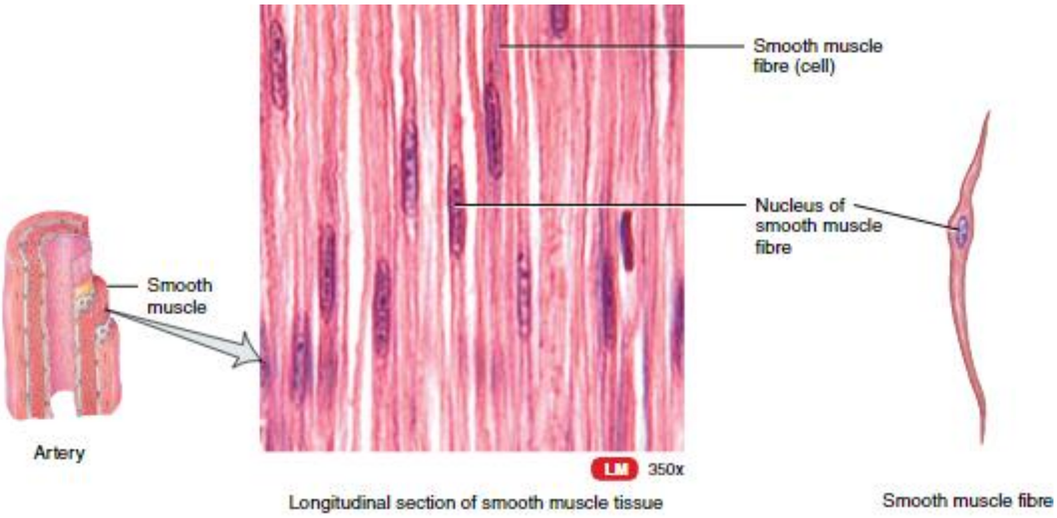


Figure 4: Cardiac tissue [2]

2.3. Bones

2.3.1. Definition

A bone is each of the hard pieces that make up the skeleton of vertebrates, yellowish white; It is formed by organic substance and mineral salts and wrapped by a fibrous membrane.

The skeletal system consists of bones and other structures that make up the joints of the skeleton. The types of tissue present are bone tissue, cartilage, and the fibrous connective tissue that forms the ligaments to connect bone to bone.

2.3.2. Functions of the skeleton

- **Support**: The skeleton functions as a rigid structure, which shapes the body; the muscles that are attached to bones move the skeleton.
- **Protection**: Protects some internal organs from mechanical injury. For example: the ribs protect the lungs and heart, the skull protects the brain.
- **Blood cell production**: Inside some large bones is the red bone marrow, which is responsible for producing blood cells such as leukocytes and erythrocytes.
- **Metabolic storage:** Bones store calcium and phosphate salts and regulate their distribution. Calcium maybe removed from bone to maintain a normal blood calcium level, which is essential for blood clotting and proper functioning of muscles and nerves.

2.3.3. Classification of the bones

- **Long bones**: Length predominates over its other dimensions. For example, the bones of the arms, legs, hands and feet.
- **Short bones**: The dimensions are more or less equivalent, its shape being approximately cubic. For example, the bines of the wrists and ankles.
- **Flat bones**: They are thin bones, like the ribs, shoulder blades, hipbones and cranial bones.
- **Irregular bones**: They are irregularly shaped bones. For example, the vertebrae and facial bones.

2.3.4. Bone Tissues

Bones are composed of different types of tissue, which include compact bone, spongy bone, bone marrow and periosteum.

- **The compact bone** can be located in the outer layer of the bones. Its functional unit is osteons. The compact bone is very hard and strong.
- **The spongy bone** is inside the bones, the lamellae are arranged in trabeculae, which follow different directions of space, in a framework with holes, similar to a sponge. It is lighter and less dense than the compact bone. This is because the spongy bone is porous.
- **The bone marrow** is the spongy center inside the bones where blood cells are made.

- **The periosteum** is a hard and fibrous membrane that covers and protects the external surfaces of the bone.

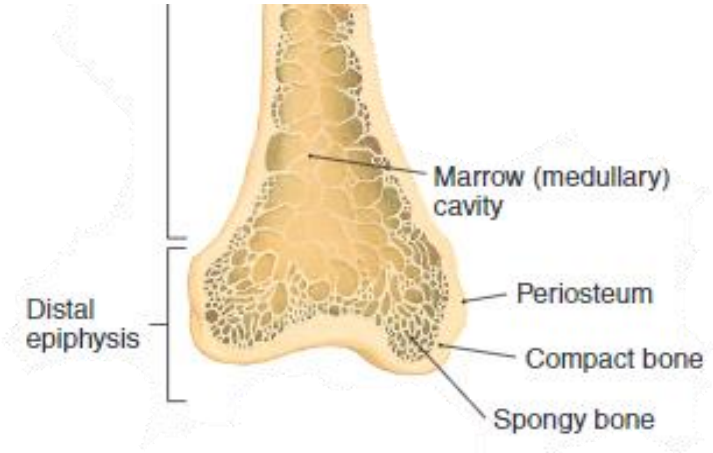


Figure 5: Bone structure [1[

2.3.5. Joints-Articulation

A join is where two bones meet or articulate. What they do is allow a movement to be created between the bones. In this way we can move freely and constantly with our body.

The classification of joints is base on the amount of movement possible. They are classified according to their mobility in:

- Diarthrosis (very movable).
- Amphiarthrosis (semi-mobile).
- Synarthrosis (immobile).

The Figure 6 shows the different types of joints.

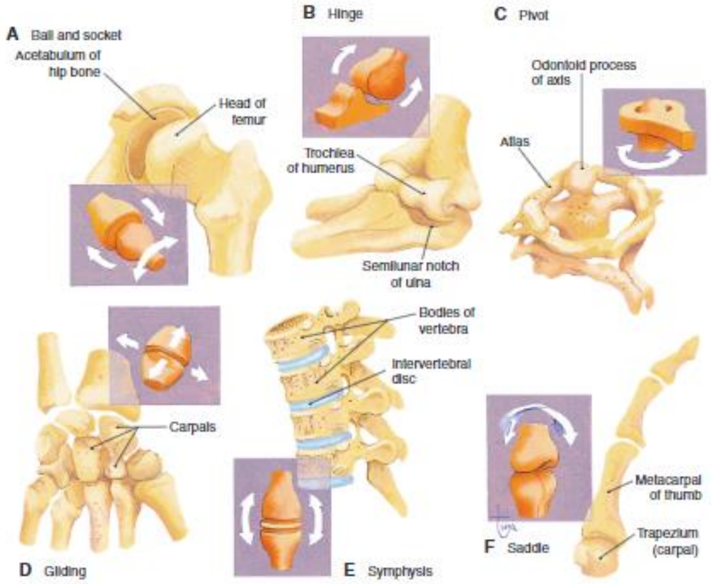


Figure 6: Types of joints [1]

2.4. Ligaments

The ligaments are bundles of connective tissue that connect a bone with another adjacent bone. The basic element of the ligaments is collagen fibers. These fibers are very strong, flexible and resistant to damage caused by tensile or compression stresses. Collagen fibers are generally arranged in parallel beams, which help multiply the resistance of individual fibers. The collagen bundles are attached to the outer lining that surrounds all bones, the periosteum.

Therefore, the ligaments are connective tissue structures that join the joints allowing their physiological movements and limiting abnormal or damaging movements.

2.4.1. Collagen

Collagen is a protein molecule or protein that forms fibers, collagen fibers. They are secreted by connective tissue cells such as fibroblasts, as well as other cell types. It is the most abundant component of the skin and bones, covering 25% of the total protein mass in mammals.

Collagen fibers are flexible but offer great tensile strength. The breaking point of the collagen fibers of human tendons is reached with a force of several hundred kilograms per square centimeter. At this stress only a small percentage of its original length has been lengthened.

2.4.2. Composition

The ligaments consist mainly of type 1 collagen (70%) [3] and there is a large amount of elastin fibers, and some fibroblast type cells (elongated and fusiform cells that are arranged along the longitudinal axis of the ligament).

Most ligaments are extra articular. These ligaments maintain continuity with other tissues that are close to them, sometimes they intermingle with the joint capsule, with the synovial tissue, with the connective tissue, adipose tissue ... all the structures that are around the joint.

2.4.3. Function

The function of the ligaments is the union and stabilization of anatomical structures, being common to find between the bones and cartilage of the organism, especially in those in which they form joints. Unlike tendons, which connect muscles with bone, the ligaments interconnect adjacent bones with each other, having a very significant role in the skeletal muscle system. In a joint, the ligaments allow and facilitate movement within natural anatomical directions, while restricting those movements that are anatomically abnormal, preventing injuries or protrusions that could arise from this type of movement.

They facilitate proprioceptive information by sending information, through nerve endings to the central nervous system.

2.4.4. Biomechanical properties of the ligaments

The ligaments have no elastic behavior, except one: the yellow ligament that is located in the spine.

The ligaments are easily elongated, but as traction increases, the ligament becomes increasingly stiff. This is produced by the arrangement of the collagen fibers.

The deformity in the ligaments depends not only on the magnitude of the force that deforms them, but also on the time of application of that force.

2.5. Tendon

Tendons are very resistant bands of connective tissue that are located at each end of the muscle and attach it to the bone. Its main function is to transmit the force generated by the muscle to the bone.

2.5.1. Structure

Tendons are continued with muscle fibers. Unlike these, they are made up of connective tissue, it is a type of tissue formed by collagen fibers arranged in parallel and firmly joined together. This composition allows it to have resistance, but it does not allow it to have the ability to contract.

2.5.2. Factors that influence the biomechanical properties

- With age the tendons become stiffer.
- Exercise speed: Stiffness depends on the speed of movement, the faster it becomes the stiffer.
- Prolonged immobilization due to synovial adhesions will decrease the elasticity of the ligaments due to proliferation of fibro-fatty tissue and will increase joint stiffness. This stiffness can be recovered with a lot of exercise and for quite prolonged periods of time. Performing physical exercise on a scheduled basis will improve the resistance to breakage.

3. Ehlers-Danlos syndrome

The Ehlers-Danlos Syndrome is a group of heritable connective tissue disorders, mainly characterized by a variable degree of generalized joint hypermobility, skin hyperextensibility, easy bruising and skin fragility.

3.1. Classification

There are many types of Ehlers-Danlos syndrome, but the most common is the hypermobile (hEDS).

The hypermobile EDS is dominated by generalized joint hypermobility and its possible sequelae, in particular chronic pain, which can be severe and invalidating, and possibly early osteoarthritis. In order to determine the degree of joint hypermobility, the Beighton Score Criteria is used.

The clinical diagnosis of hypermobile EDS needs the simultaneous presence of 3 criteria:

- Criterion 1 = generalized joint hypermobility.
- Criterion 2 = 2 or more of the features a, b and c (a = systemic manifestations of a more generalized connective tissue disorder; b = positive family history; c = musculoskeletal complications).
- Criterion 3 = absence of unusual skin fragility and exclusion of alternative diagnosis.

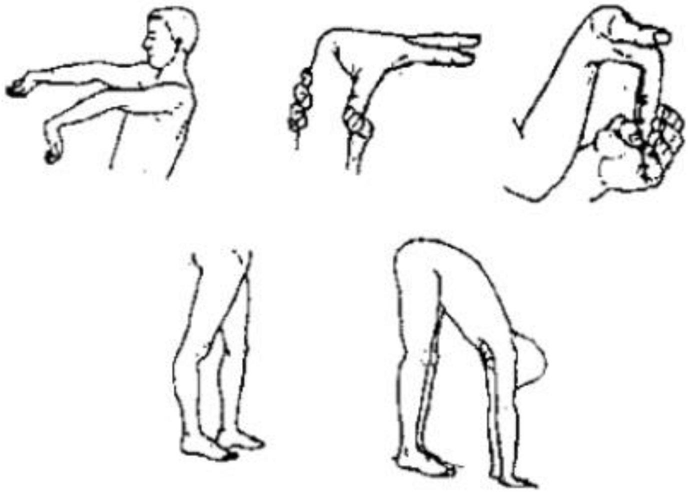


Figure 7: Examples of joint hypermobility [4]

3.2. Hypermobility

A hypermobile joint is characterized by having a greater than normal range of motion. When an individual has multiple hypermobile joints, we speak of generalized joint hypermobility.

3.2.1. Symptoms

The main symptoms of patients with hypermobile joints are pain and fatigue, although they typically suffer from signs of autonomic dysfunction, functional gastro-intestinal manifestations and joint (sub)luxation, musculoskeletal pain. [5]

- Pain

For patients with generalized joint hypermobility, arthralgia (joint pain), chronic generalized myalgia and fibromyalgia (chronic generalized pain in muscles and joints) predominate.

Although the relationship between joint hypermobility and pain is not established, the most agreed theory is that pain is due to repetitive stress, strain, and microtrauma of muscles and ligaments due to the range of abnormal movement allowed by hypermobile joints.

This chronic pain is also related to depressive feelings and anxiety, which has an amplifying effect on pain and fatigue. This leads the patient to enter a vicious circle.

Lastly, the symptoms of depression and anxiety can produce a reduction in the physical activity of the patient and, failing that, a physical deconditioning, thus increasing the propensity for injury, chronic pain and fatigue and initiating a negative downward spiral.

- Insufficient effect of local analgesics

Patients with hypermobile EDS, have reported that the effect produced by local pain relievers is insufficient.

- Fatigue

EDS hypermobility syndrome is associated with increased fatigue. There are several hypotheses to explain the cause of it. One hypothesis is that fatigue is a symptom of autonomic dysfunction or dysautonomia. Others suggest that due to ligamentous laxity, increased vigilance, muscle tension, and coordination are required to maintain desired joint position and body balance, so this excess effort leads to fatigue. Furthermore, these patients often show muscle weakness, reduced exercise tolerance, physical deconditioning, and lung muscle weakness. Finally, generalized joint hypermobility can also cause depression and other associated psychological problems that may also be associated with fatigue.

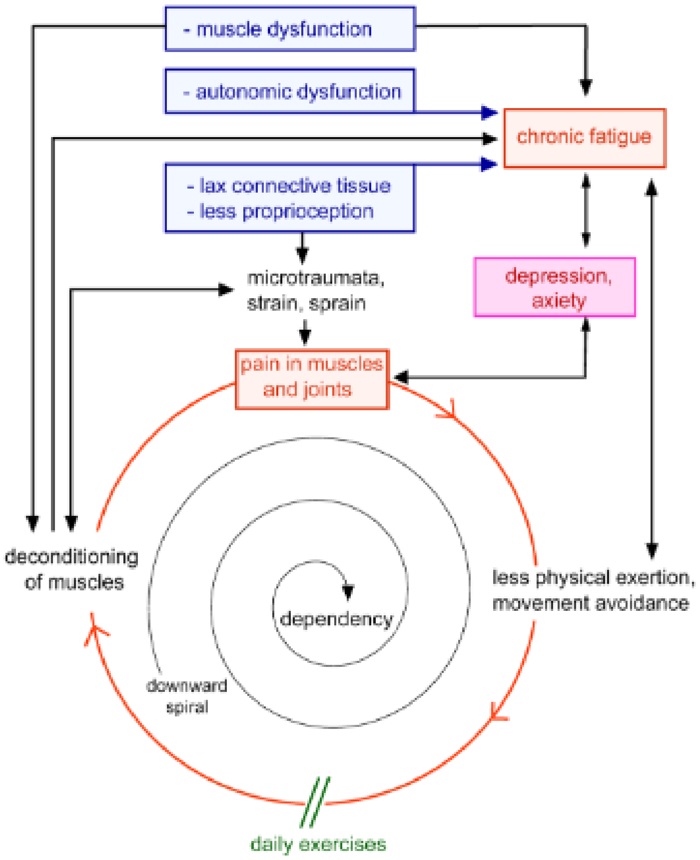


Figure 8: Vicious circle in generalized hypermobility of chronic pain and fatigue [5]

- Joint subluxation

Although joint dislocation and subluxation are not specific features of joint hypermobility, they can occur due to joint laxity, decreased local muscle strength, and coordination. If subluxation occurs frequently in a specific joint, a decrease in pain may occur, and sometimes the patient may demonstrate subluxation on demand.

- Decreased bone mass and increased risk of fractures

"In EDS and Marfan syndrome, a higher prevalence of low bone mineral density, osteopenia or osteoporosis are reported in most studies, but not all. In a study with 23 patients with hypermobile EDS and 23 matched controls, EDS subjects had a significantly lower bone mineral density at the femoral neck, but this difference disappeared after adjustment for body height, weight and physical activity levels. Thus, reduced exercise or immobility induced by generalized joint hypermobility may be important in determining osteopenia, probably in association with the inherited structural deficit. Furthermore, an increased incidence of falls (and thus increased risk of fractures) has been reported in hypermobile EDS, due to impaired balance and muscle weakness. This might be at least partially preventable by appropriate exercise programs. Earlyonset osteoporosis and increased risk of fractures are features of rare EDS types with marked bone involvement, such as the EDS/osteogenesis imperfecta overlap.”[5]

- Osteoarthritis

It would be expected that there is a relationship between joint hypermobility syndromes and osteoarthritis, especially in patients with frequent subluxations. However, it is not known with certainty if this relationship exists since while some articles describe a relationship between the two, others also indicate an inverse relationship.

4. Mechanical characteristics of biological tissues

These biological tissues are viscoelastic. The viscoelasticity is: “The property of a substance of exhibiting both elastic and viscous behavior, the application of stress causing temporary deformation if the stress is quickly removed but permanent deformation if it is maintained.” [6]

Structurally, both tendons and ligaments are organic materials composed of corrugated collagen fibers that become longitudinal when a small tension is applied on them, equivalent to deformations of 4% of the initial length of the tendon. When these solicitations subside, the tendon or ligament returns to its conventional morphology.[7]

4.1. Mechanical behavior of a ligament

“Mechanical properties characterize the behavior of the ligament substance and are represented by a stress-strain curve. These properties depend on the collagen composition, fiber orientation, and the interaction between collagen and the ground substance.

Determination of Strain. Strain (e) is defined as the deformation per unit length of a ligament and can be found by placing markers on the soft tissue in the region to be studied (such as midsubstance). Strain is calculated by the formula $\varepsilon=(l-l_o)/l_o$; where l_o represents the initial distance between the markers and l is the length after a load is applied. Strain has no units but is usually expressed as a percent.

Determination of Stress. Stress (measured in newtons per square millimeter) is defined as the load per unit cross-sectional area of a ligament. It can be calculated by the formula: $\sigma = F / A$ where σ is stress, F is the externally applied load, and A is the cross-sectional area of the ligament. Because stress is defined as the tensile load per cross-sectional area, an accurate measure of cross-sectional area is necessary. The earliest biomechanical studies used gravimetric methods in which the volume of water displaced by a specimen could be related to cross-sectional area by assuming a simple cross-sectional shape. Mechanical devices like calipers have also been used to measure the width and thickness of a specimen, with the cross-sectional area obtained by assuming a rectangular or elliptical shape. These methods are adequate for simple geometric structures but may introduce large errors for ligaments that have more complex geometries.

Noncontact methods have been developed that have the advantages of avoiding tissue deformation and providing more accurate cross-sectional area measurements for more complex geometries. These methods involve an optical system (either visible or laser light) for measurement, or an image-reconstruction technique to determine the cross-sectional area or shape, or both.

Stress-Strain Curve. During a uniaxial tensile test, the mid-substance strain is measured while simultaneous load-elongation behavior is recorded. Using the load data, along with the cross-sectional area measurement of the ligament, stress can be calculated. The stress-strain curve for a ligament is nonlinear and can be divided into several regions. The first region is the nonlinear toe region. The second region is linear; the stress is linearly proportional to the strain and the slope of this region is called the Young's (or tangent) modulus (E, measured in megapascals).

Strain in ligaments has been measured by a wide variety of devices including liquid mercury strain gauges. Hall-effect strain transducers (Micro strain, Inc., Burlington, Vermont), and the differential-variable-reluctance-transducer (Micro strain). These devices are attached to the tendon or ligament along the direction of the soft tissue. Noncontact methods have also been developed to measure strains." [8]

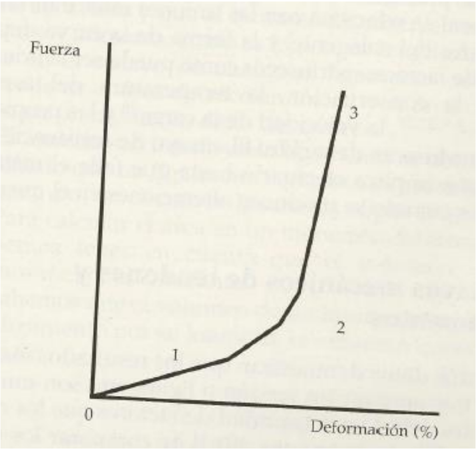


Figure 9. Stress / strain curve characteristic of collagen fibers [7]

When a longitudinal force is applied to a ligament, it shows a non-linear response with a characteristic strain curve. Initially, a small load produces a very large deformation that keeps a linear relationship. When the applied load increases, the ligament resists until it loses the linear relationship. This behavior continues until breakage. The non-linear behavior is related to the inter and intramolecular junctions of the collagen and the shape of the curve will depend on extrinsic factors such as orientation, conservation, temperature, loading speed and intrinsic tissue properties.

A “relaxed” cartilage has disorganized collagen fibers, as the fibers are stretched, they align and increasingly oppose the effort, so it costs more effort to perform the same deformation.

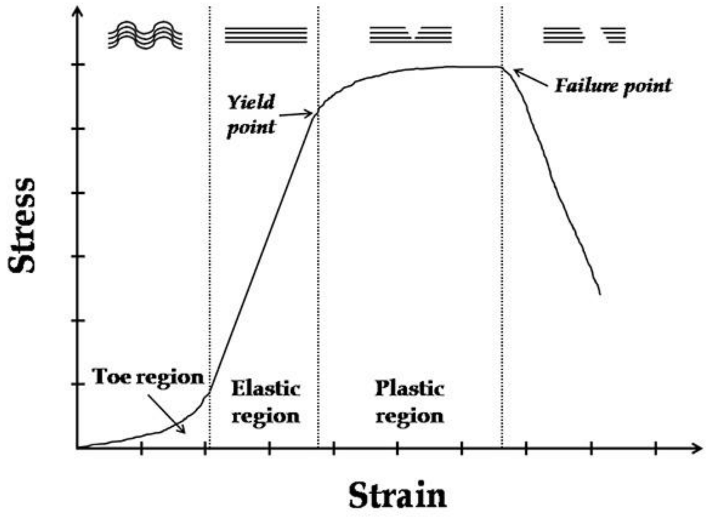


Figure 10:Force-deformation curve [9]

Four areas are appreciated. Part 1 of the graph is where the fibers are not fully extended. Part 2. is the elastic deformation zone, the fibers extend until they reach their total elongation and from there the stress begins to increase proportionally to the deformation. Part 3. plastic area, there is already a rupture of the fibers until the complete rupture is reached, which would be part 4.

Elastic hysteresis

The elastic material recovers its shape instantly when stress is stopped, it can be said that it goes back along the same line in the stress-strain graph. However, viscoelastic materials return with a temporary delay and a path to the right of the graph.

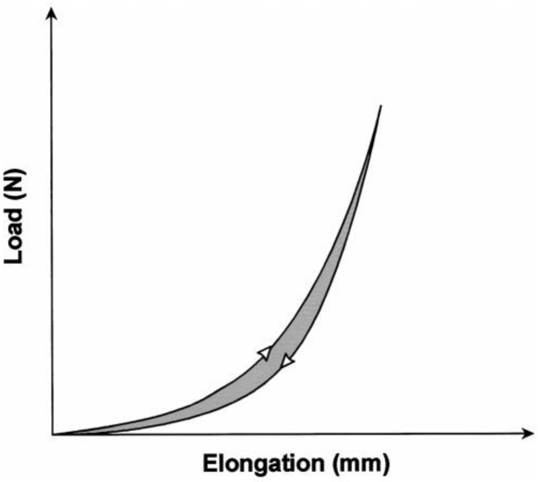


Figure 11: Elastic hysteresis [10]

The lack of coincidence of the increment and decrease stress curves is called elastic hysteresis and is represented by the area formed by the deformation and return paths.

The greater the elastic hysteresis, the less elastic the material will be. The speed of recovery depends on how long the viscoelastic material has been stretching.

When a viscoelastic material is stretched, the resistance to deformation exerted by the tissue depends on the speed at which it is stretched.

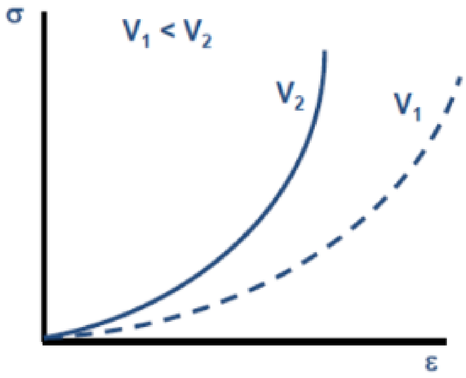


Figure 12: Graph of deformation resistance as a function of stretching speed [11]

4.2. Biologic Factors

"The biomechanical properties of ligaments and tendons depend on several biologic factors.

- Effects of Maturation and Age. Skeletal maturation has significant effects on the biomechanical properties of ligaments and tendons. In general, these properties seem to improve once skeletal maturity is reached. Several studies performed on the rat tail tendon have shown an increase in collagen fibril size, ultimate load, and ultimate tensile strength as the animal ages from puberty to adulthood with no further changes observed until senescence. Similarly, rapid increases in the cross-sectional area, stiffness, and ultimate load of the rabbit medial collateral ligament were found with maturation.

- Effect of Exercise. Recent research has suggested that an increase in physical activity could improve the biomechanical properties of the medial collateral ligament.
- Effect of Immobilization/Remobilization. After musculoskeletal injuries, immobilization is often used to protect damaged tissue from further harm during the early stages of healing. However, the effect of joint immobilization can have profound, adverse effects on the joint. Joint stiffness as a result of synovial adhesions and proliferation of fibrofatty connective tissue has been observed both clinically and experimentally after immobilization.” [10]

4.3. Mathematical models of the biologic structures

As previously explained, biological tissues have a non-linear behavior characterized by an exponential toe region, described with $\sigma = A(e^{B\varepsilon}-1)$ followed by a linear elastic region. To analyze this data several methods can be used such as the continuous method or the piecewise method.

“Piecewise Method - The Piecewise Method employs a linear curve fit to the high-strain end of the stress-strain data. Data points are included in the linear region until the R^2 of the fitted line dips below an a priori determined threshold value. The remaining lower strain points are fit to an exponential curve as described above.

Continuous Method - A mathematical model was developed that contains an exponential region and a linear region of the stress-strain curve. To maintain a continuous elastic modulus E, the slope of the linear portion was defined as the slope of the stress-stain curve at the transition point (p, q) between the exponential and linear regions. The stress-strain function is thus defined by,

$$\sigma = \begin{cases} \mathrm{A}\left(\mathrm{e}^{\mathrm{B}\varepsilon} - 1\right) & \forall \varepsilon \leq \mathrm{p} \\ E_{(p,q)}(\varepsilon - \mathrm{p}) + \mathrm{q} & \forall \varepsilon > \mathrm{p} \end{cases}$$

where E(p, q) is the elastic modulus at point (p, q).”[8]

5. Neck movement range for daily activities

The neck can perform many movements, because it is formed by a multitude of rigid overlapping pieces joined by elastic elements, which allow them to move in any of the three axes and planes of movement.

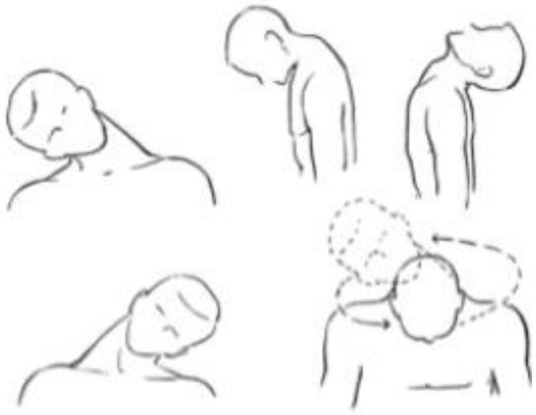


Figure 13: Neck movements [12]

The cervical vertebrae correspond to the neck area and are seven. They are the least thick of the entire column and the ones with the greatest mobility.

They are called with the letter capital C followed by the corresponding number from one to seven. They are in the neck area and form the so-called cervical spine.

Its function is basically to provide mobility to the neck and head.

5.1. Types of neck movement

The ranges and angles of movement that the neck has are the following:

- **Flexion**: Flexion is the motion that allows you to bend your head toward your chest. In normal flexion, you can touch your chin to your chest. Beginning in a neutral position, an acceptable range of motion for flexion is 40 to 60 degrees [13]. Flexion is caused by a sliding of the superior vertebra over the inferior, due to the thickness of the intervertebral disc. The nucleus pulposus slides back. It is performed by: the anterior rectus of the head, lateral rectus of the head, rectus longus of the head, and the anterior rectus of the neck. Both flexion and extension is verified by the cited muscles, when they contract on both sides.

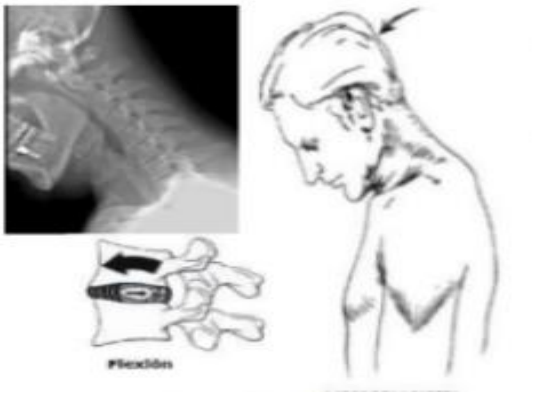


Figure 15: Flexion of the neck [12]

- **Extension**: In the same way the movement will change almost 90 degrees but in this it will be back in normality. This movement will allow us to see the surface immediately above us. The extension is produced by sliding the upper vertebra over the lower one. The nucleus pulposus slides forward. The limitation is caused by the collision of the spinous processes of the cervical vertebrae. It is performed by: the trapezius (the upper limb belt being fixed), the upper fascicles of the deep muscles of the back that are inserted into the skull (splenic, long dorsal, semi-spiny, the posterior rectus, major and minor, of the head , the upper oblique of the head. The extension of the head is carried out by both sternocleidomastoids; however, they flex the cervical part of the spine.

Figure 14: Extension of the neck [12]

- **Rotation**: Movement given by the articulation of C1 and C2, in normal state the arc of movement will allow us to turn the head 90 degrees to the left and right side, giving a total of 180 degrees of total mobility, clinically we will see the chin align with the shoulder. The Inclination - Rotation. It occurs, due to the existence of wedge-shaped joints, which provide an oblique support of one vertebra over another, which means that when tilting, one vertebra slides on the other. It is performed by the following muscles: external and internal oblique of the head, the upper oblique fascicle of the length of the neck, splenic and sternocleidomastoid. The rotation is verified by the unilateral contraction of the cited muscles.

Figure 16: Rotation of the neck [12]

- **Lateral flexion**: approximates the auricular pavilion to the shoulder, under normal conditions this movement reaches about 45 degrees on both sides which gives a total angle of 90 degrees of total lateral mobility. Lateral flexion: it is carried out by the same muscles that perform extension and flexion, when contracted unilaterally, and also by the lateral rectus muscles of the head and long dorsal.

Figure 17: Lateral flexion of the neck [12]

6. Range of motion for the daily living

To achieve a correct and functional design of the head support it is necessary to know the range of movement that it must have. For this, various studies are analyzed to obtain the range of motion (ROM) for activities of daily living (ADL).

6.1. Article number 1

In this first article ten healthy young adults were fitted with a portable motion measurement device that recorded movement about each primary axis. Participants were instructed to wear the unit continuously over a 5-day period and record their daily activities with corresponding times. After the collection period, subjects' activity logs were analyzed and data were partitioned into five categories which provided the most primary representation of ADLs: athletics, work, travel, sleep, and miscellaneous.

The mean range of motion interval (degrees) between all subjects for primary and secondary activities is shown in the Table 1.

Table 1: Median range of motion interval (degrees) among all subjects for primary and secondary activities. [14]

	FLEXION / EXTENSION	LATERAL BENDING	AXIAL ROTATION
ATHLETICS	**18**	**12**	**16**
Running	27	13	19
Lifting Weights	15	10	15
Light Intensity	14	11	13
TRAVEL	**12**	**10**	**12**
Biking	13	12	15
Driving	9	8	10
Walking	19	9	12
WORK	**13**	**10**	**14**
MISCELLANEOUS	**13**	**10**	**13**
High	14	10	13
Shopping/Errands	13	9	14
Getting Dressed/Ready	14	10	14
Out With Friends	16	10	12
Medium	13	10	13
Cooking/Eating	14	11	14
Undefined	13	10	12
Multi-Categorical	13	10	13
Low	10	10	11
Reading/Studying	10	9	10
TV/Movie/Relaxing	12	10	12
SLEEPING	**9**	**10**	**8**

“Most movements required less than 25° of motion, while a small percentage of movements (< 6%) were greater than 50°. The median range of motion interval was also higher for greater intensity activities and lower for less intense activities.” [14]

6.2. Article number 2

“In this article a noninvasive electro goniometer and torsiometer were used to measure the ROM of the cervical spine. The accuracy and reliability of the devices were confirmed by comparing the ROM values acquired from dynamic flexion/extension and lateral bending radiographs to those provided by the device, which was activated while the radiographs were obtained. Intraobserver reliability was established by calculating the intraclass correlation coefficient for repeated measurements on the same subjects by 1 investigator on consecutive days. These tools were employed in a clinical laboratory setting to evaluate the full active ROM of the cervical spines (i.e., flexion/extension, lateral bending, and axial rotation) of 60 asymptomatic subjects (30 females and 30 males; age, 20 to 75 y) as well as to assess the functional ROM required to complete 15 simulated ADLs.”[15]

The results were the following:

“The absolute ROM of full active cervical spinal ROM used during the 15 ADLs was 13 to 32 degrees for flexion/extension, 9 to 21 degrees for lateral bending, and 13 to 57 degrees for rotation. By quantifying the amounts of cervical motion required to execute a series of simulated ADLs, this study indicates that most individuals use a relatively small percentage of their full active ROM when performing such activities.” [15]

6.3. Article number 3

“This was a descriptive study to examine active range of motion required in the cervical spine during functional tasks of daily living. The objective of this study was to determine the mean active range of motion of the cervical spine required to perform 13 daily functional tasks. Previous research has examined the absolute ranges of cervical motion for women and men 20-60 years of age; however, no previous study has determined the amount and type of motion that is required for routine activities of daily living. Twenty-eight college-aged students (n = 28) served as healthy subjects and performed three trials of 13 daily tasks of functional activity. The subject's starting position and end range of motion for flexion-extension, rotation, and side bending of each task were observed and recorded using the cervical range of motion device. The three trials were averaged, and ranges of motion across the 28 subjects were reported. Of the 13 daily functional tasks performed, tying shoes (flexion-extension 66.7 degrees), backing up a car (rotation 67.6 degrees), washing hair in the shower (flexion-extension 42.9 degrees), and crossing the street (rotation head left 31.7 degrees and rotation head right 54.3 degrees) required the greatest full active range of motion of the cervical spine. Flexion-extension and rotation of the cervical spine are important to enable functional activity. Four of the 13 daily tasks performed required 30-50% of active range of motion. Side bending was seen to be coupled with rotation in completion of tasks. This article provides a baseline of normal motion of the neck required for activities of daily living and can be used in the assessment of disease states and disability.” [16]

6.4. Summary

Considering the data provided in the previous articles, a table is made showing the degree of involuntary and voluntary movement for the different types of neck movement.

The data of the first article is taken as a reference to create the involuntary range of motion. For this, the highest value of each subject of daily activities is taken as a criterion. For all types of neck movements, the highest range of motion corresponds to the subject of athletics.

For the voluntary movement part, the maximum movement data of article number two are taken since the objective is to achieve the maximum possible mobility in the support so that the people who use it can carry out most of the daily activities.

Table 2: Maximum voluntary and involuntary movement

	Maximum incidental motion (Degree)	Maximum intentional motion (Degree)
Flexion / Extension	18	32
Lateral Bending	12	21
Rotation	16	57

7. Background of the first design

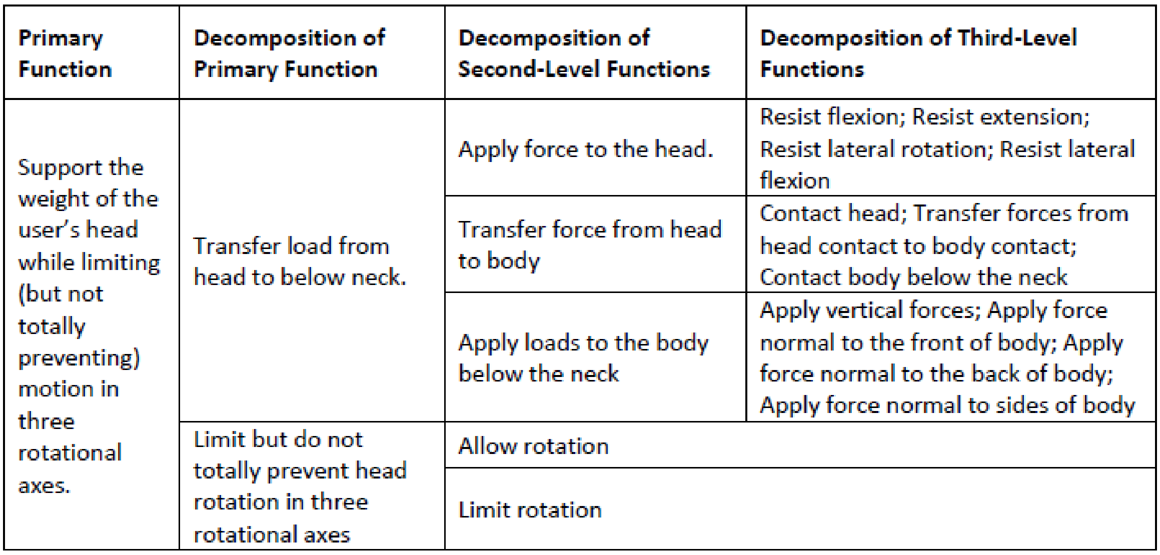
For the development of this project, the following studies cited in the bibliography are taken as a basis [17,18]. These studies confirm the absence of adequate collars or supports for the cervical spine for patients with hEDS, failing that, they should use cervical collars that are not suitable for them due to their stiffness and their design focused on head immobilization.” Furthermore, by completely immobilizing the head, the post-surgical type of collars may contribute to atrophy, weakening the muscles in the neck that are needed to support the head.

An alternative to post-surgical collars is the soft collar, usually made from foam wrapped in a cloth cover. These collars allow some movement of the head, however they are bulky, do not dissipate heat, provide minimal support, and completely enclose the neck. This makes them very uncomfortable for many hEDS patients who are intolerant of pressure on their neck."[19]

Thus, the human-centered design (HCD) method is used whose objective is to make the systems usable and useful, by focusing on users, their needs and requirements, while applying ergonomics techniques and usability knowledge.

After carrying out the study, it was concluded what are the main functions that the support must fulfill, as shown in the Table 3.

Table 3: Decomposition of functions [19]



Primary Function	**Decomposition of Primary Function**	**Decomposition of Second-Level Functions**	**Decomposition of Third-Level Functions**
Support the weight of the user's head while limiting (but not totally preventing) motion in three rotational axes.	Transfer load from head to below neck.	Apply force to the head.	Resist flexion; Resist extension; Resist lateral rotation; Resist lateral flexion
		Transfer force from head to body	Contact head; Transfer forces from head contact to body contact; Contact body below the neck
		Apply loads to the body below the neck	Apply vertical forces; Apply force normal to the front of body; Apply force normal to the back of body; Apply force normal to sides of body
	Limit but do not totally prevent head rotation in three rotational axes	Allow rotation	
		Limit rotation	

Taking into account the previous study, the following design shown in Figure 18.

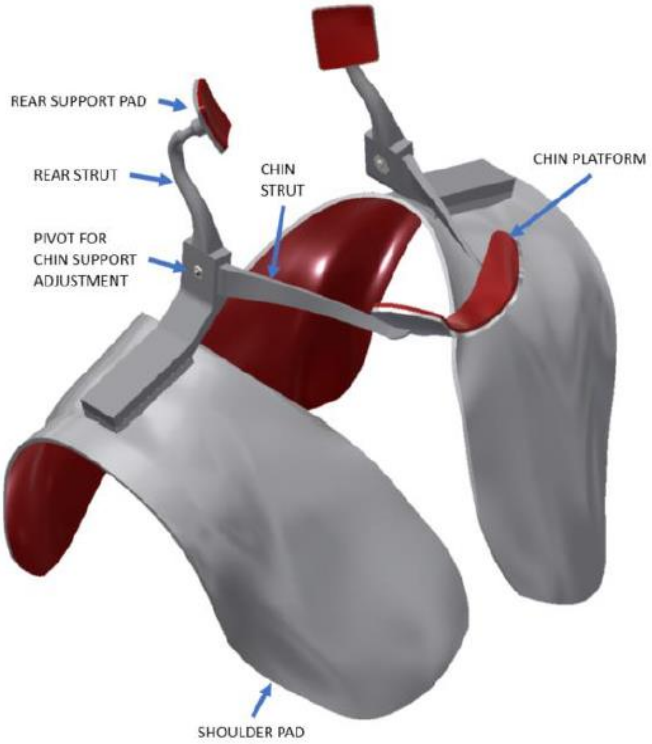


Figure 18: Components of the improved head support design [17]

8. Additive Manufacturing

The different types of additive manufacturing to manufacture the support are studied. Additive manufacturing is beneficial when there is a need for unique parts, tailored to each patient's circumstances. These pieces also have complex geometries, more difficult to manufacture with other types of processes. Furthermore, this technology is cheaper when the number of units of a piece that we want to produce is low. It is ideal for rapid prototyping, where we want to make only one or a few units of a piece to check for possible failures.

- Material extrusion

“Material extrusion is an AM process in which material is selectively dispensed through a nozzle or orifice. Material extrusion machines force semi-liquid material through a nozzle as the extrusion head or the build platform moves in the x-y plane. After a layer is completed, the build platform moves down, or the extrusion head moves up, and the next layer is extruded and adhered to the previous layer. The raw material is typically a filament of thermoplastic coiled onto a spool that is melted as it is extruded. Support structures are required for bottom surfaces and overhanging features. These structures are removed, often manually, after the parts are completely built and removed from the build platform.

Compared to other AM processes, material extrusion systems are often a less expensive alternative and relatively easy to operate. Most systems are equipped with a single extrusion head, but machines with two or three extruders are also available.

- Material jetting

The material jetting process uses inkjet printing heads to deposit droplets of build material. The droplets are dispensed selectively as one or more print heads move across the build area. Substances used in material jetting are typically photopolymers or wax-like materials that can be used as investment-casting patterns.

- Binder jetting

Binder jetting is a process by which a liquid bonding agent is selectively deposited through inkjet print head nozzles to join powder materials in a powder bed. Binder jetting is similar to material jetting in its use of inkjet printing to dispense material. The difference is that with binder jetting, the dispensed material is not build material, but rather a liquid that is deposited onto a powder bed to hold layers of powder in the desired shape.

- Sheet lamination

Sheet lamination is defined as a process in which sheets of material are bonded to form an object. Sheet materials can be adhesive-coated papers that form a plywood-like solid when laminated into a 3D object or metal tapes and foils that form metal parts.

- Vat photopolymerization

Vat photopolymerization is a process by which liquid photopolymer in a vat is selectively cured by photopolymerization. Stereolithography (SL), the first patented and commercialized AM process, uses an ultraviolet laser and x-y scanning mirrors on computer controlled galvanometers to scan and present UV light to the top surface of liquid photopolymer in a vat.

- Powder bed fusion

Powder bed fusion is a process by which thermal energy fuses selective regions of a powder bed. The thermal energy melts the powder material, which changes to a solid phase as it cools. Terms that are also used in the AM industry for polymer-based powder bed fusion processes and systems include laser sintering and selective laser sintering. For metal-based systems, terms include selective laser melting, direct metal laser sintering, and electron beam melting.

- Directed energy deposition

In the directed energy deposition process, focused thermal energy melts and fuses material as it is being deposited. In most cases, a laser is the source of the energy, and the material is a metal powder. This process is sometimes referred to as blown powder AM and laser cladding." [18]

The method of material extrusion, 3D printing, is chosen, mainly due to several factors, the enormous variety of materials that can be used, as well as at a reduced price, ease of use and accessibility to them.

8.1. Materials for 3D printing

The materials that can be used for 3D printing of the pieces are studied. Choosing the right material is essential to obtain the correct properties.

The three most common types of filaments are:

- **Polylactic Acid Filament (PLA)**. It is biodegradable because it is made of materials like cornstarch. The tensile strength and modulus of elasticity of PLA is also comparable to that of polyethylene. However, it is more hydrophilic than polyethylene, since it has a lower density.
  PLA is more difficult to handle due to its high cooling and hardening speed. It can also be damaged and drip on contact with water. This generally translucent material is used by most 3D FDM printers and comes in a wide variety of colors. Its main drawbacks are that it does not withstand too much heat, since the standard PLA softens around 50 ° C.
- **Acrylonitrile butadiene styrene (ABS) filament**. It is used today in a wide variety of industry applications. It is generally very durable and strong, slightly flexible and quite resistant to heat. ABS also has a few drawbacks, it is a non-biodegradable, petroleum-based plastic that can, however, be recycled.
- **Ethylene polyterephthalate (PETG) filament.** It is the most widely used plastic in the world. It is also widely used in thermoforming processes and can be combined with fiberglass to create resins that are used in the engineering world. It is the ideal filament for parts intended for food contact, it is semi-rigid and with good resistance.

Special filament types:

- **Thermoplastic polyurethane (TPU) filament**. These filaments are basically printable rubber, allowing you to create complex elastic designs that would otherwise be impossible.
  In general, most rubbers are thermoset, they heat up, they are shaped, they are allowed to cool, and that shape is final. This is not useful when your 3D printer needs to change the filament shape of a cylinder to your model. The opposite of thermosets is thermoplastic, you can melt and reshape your material almost indefinitely.
- **Nylon filament.** It is quite flexible. Compared to PLA, which is much stiffer, the impression is that nylon is already cast. Its color is usually a deep white and is quite difficult to make transparent.
- **High Impact Polystyrene (HIPS) filament.** It has excellent impact resistance and machinability. It is an easily moldable material with excellent dimensional stability and is easy to paint and paste. In the field of 3D printing, HIPS is probably the best-known support material.
- **Polycarbonate (PC).** Less used than the aforementioned types of plastic, polycarbonate only works on nozzle-design 3D printers that operate at high temperatures. It is a high strength material designed for engineering applications. This material is capable of withstanding high temperatures and can be kept without deformations up to 150ºC.

After studying the different materials that can be used in a 3D printer, taking into account their mechanical properties, it is concluded that the most suitable material to print the parts of the head support is the high impact polystyrene.

9. First analysis of the head support

This section studies whether the design shown in the previous section fulfills the design functions. For this, the ranges of movement described in section 6.4 are taken as an objective.

To analyze this, a finite element analysis (FEA) is carried out. This analysis is a tool that uses the finite element method (FEM) to solve problems. The fundamental equation of the FEA is:

$$[F] = [K] \cdot [d]$$

Where,

[F] is the known vector of nodal loads

[K] is the known stiffness matrix

[d] is the unknown vector of nodal displacements

The finite element method is a general numerical method for approximation of solutions to very complex partial differential equations used in various engineering and physical problems. In this case we use Inventor's Nastran program to run it.

A first linear analysis of the complete model is performed. Inventor's Nastran program is used to run it, is the finite element calculation software integrated in the CAD system.

To carry out the analysis the following configurations are made:

- Specify the support material, which will be high impact polystyrene for the head support and Aluminum 6061 to simulate the skull.
- Rigid type connectors are created to simulate the movement of the head and connect with the surrogate pieces that rest on the support.
- Constrains are established:
  - Fixed constraint for the bottom surface of the base, because this is connected to the shoulder pads, so it shouldn't move.
  - Rotation constrain about the z axis in the center connection point.
- Connections between the parts:
  - Separation type connection is used between the head pad and the surrogate skull, a static coefficient of friction of 0.9 is used. This coefficient is high since it reflects the friction between the head and memory foam. A separation type allows sliding and opening between the entities at the contact location
  - Bonded type connections are used in the rest of the contacts, the pair cannot separate, nor can the items move relative to one another.
- The mesh is created using parabolic, solid, tetrahedral elements. A mesh control is created for the elements where a higher tension is seen to be produced in order to obtain better results from the analysis.
- Rotation is applied to the center point of the rigid connectors.

All settings are shown on the Figure 19.

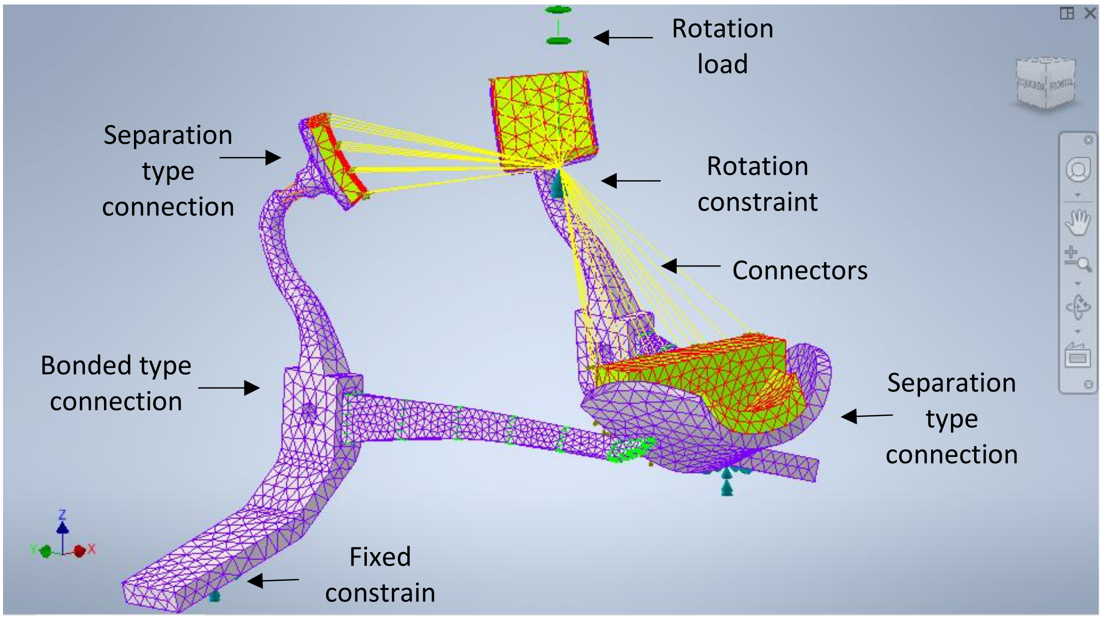


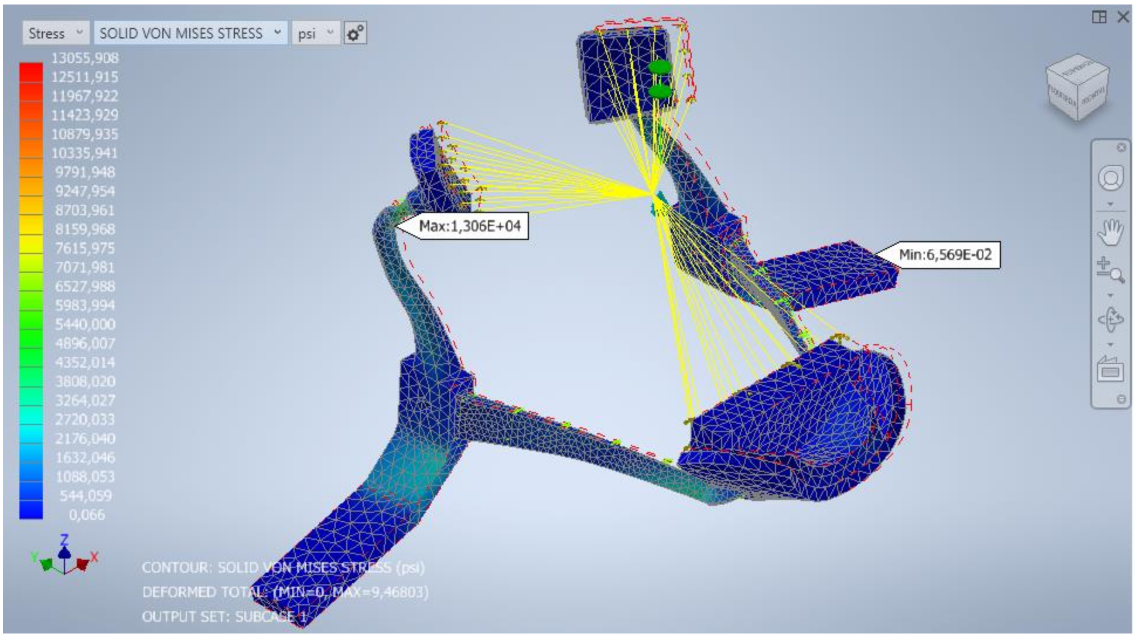
Figure 19: Settings for the lineal analysis

Initially, it is intended to observe how the designed support responds to small efforts. Therefore, a forced rotation of 3 degrees on each axis is established in each analysis. These three rotations simulate the flexion, rotation and lateral flexion movements of the head.

9.1. Z Axis

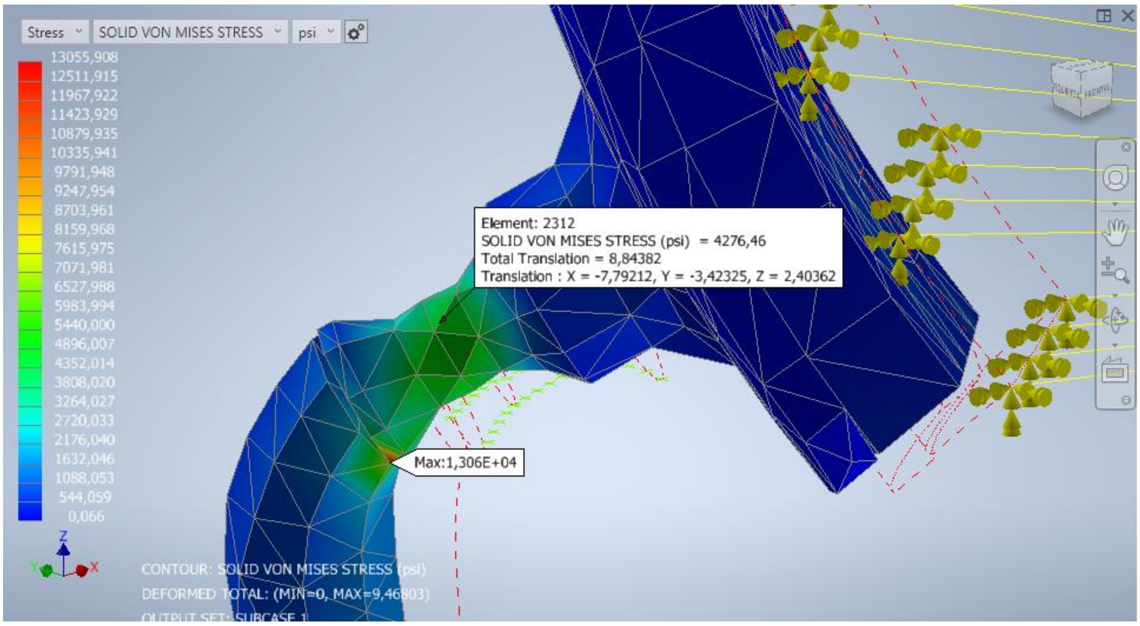
After having applied a rotation in the central point of the connectors along the z axis, the results shown in the following figures 20 and 21 are obtained. This is intended to simulate a rotational movement of the head.

As expected, due to the effort they bear and their section, the maximum stresses are found in the rear strut support bar, there is a peak of $1.01 \cdot 10^3$ psi. It is important to note that this peak is located in the connection between the two pieces as shown in the figure. So it can be seen that although there is a restriction between them, they move between them so this peak can be caused due to the way they are designed. In the upper part you can see how due to the lower section of the piece a large tension of also appears.



CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=9,46803)
OUTPUT SET: SUBCASE 1

Figure 20: Von mises stress when applying a rotation about the Z axis of 3 degrees.

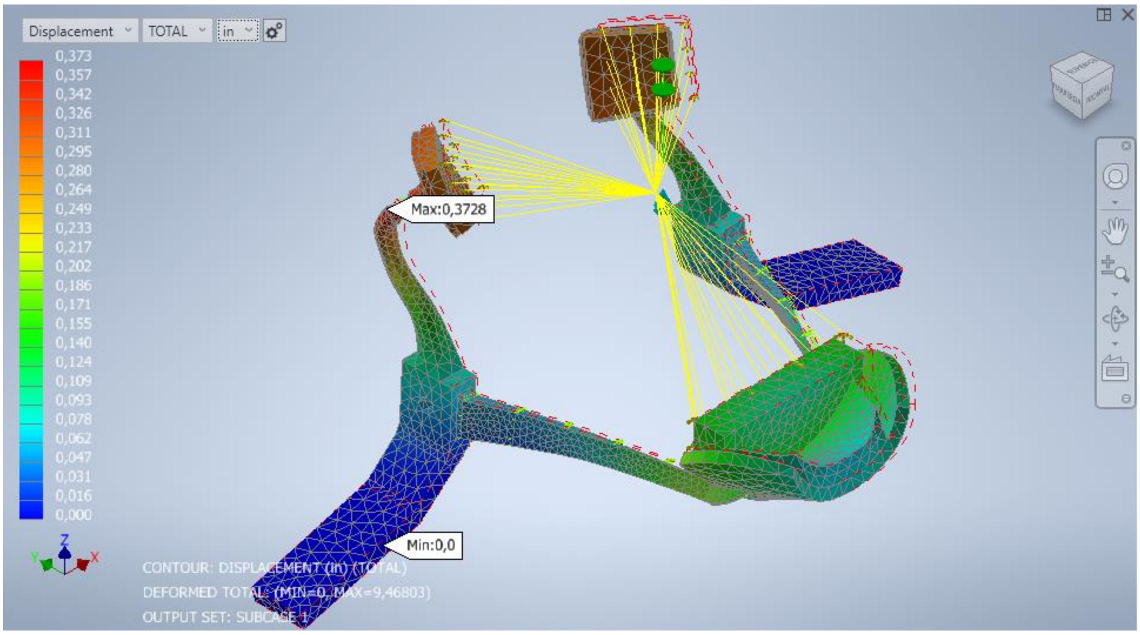


Element: 2312
SOLID VON MISES STRESS (psi) = 4276,46
Total Translation = 8,84382
Translation : X = -7,79212, Y = -3,42325, Z = 2,40362

CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=9,46803)
OUTPUT SET: SUBCASE 1

Figure 21: Zoom where the maximum peak of tension around the Z axis is

The maximum displacement of the support is at the same point where the maximum tension is. This is also due to what was previously explained. Although in this case the difference between this displacement and the rear support pad, is very small.

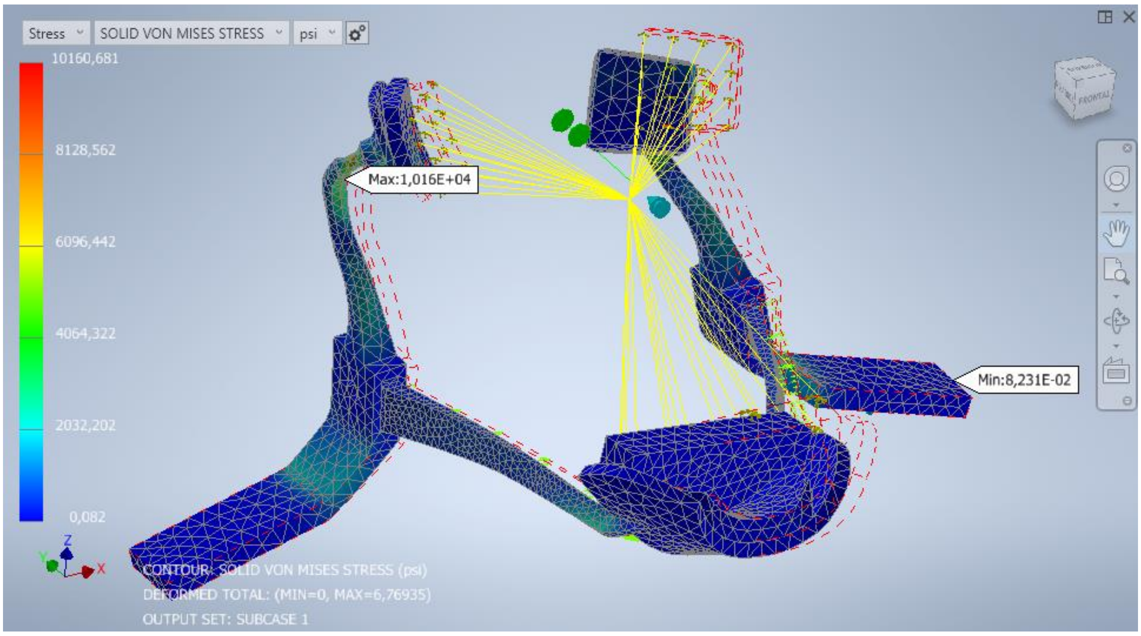


CONTOUR: DISPLACEMENT (in) (TOTAL)
DEFORMED TOTAL: (MIN=0, MAX=9,46803)
OUTPUT SET: SUBCASE 1

Figure 22: Displacement when applying a rotation about the Z axis of 3 degrees.

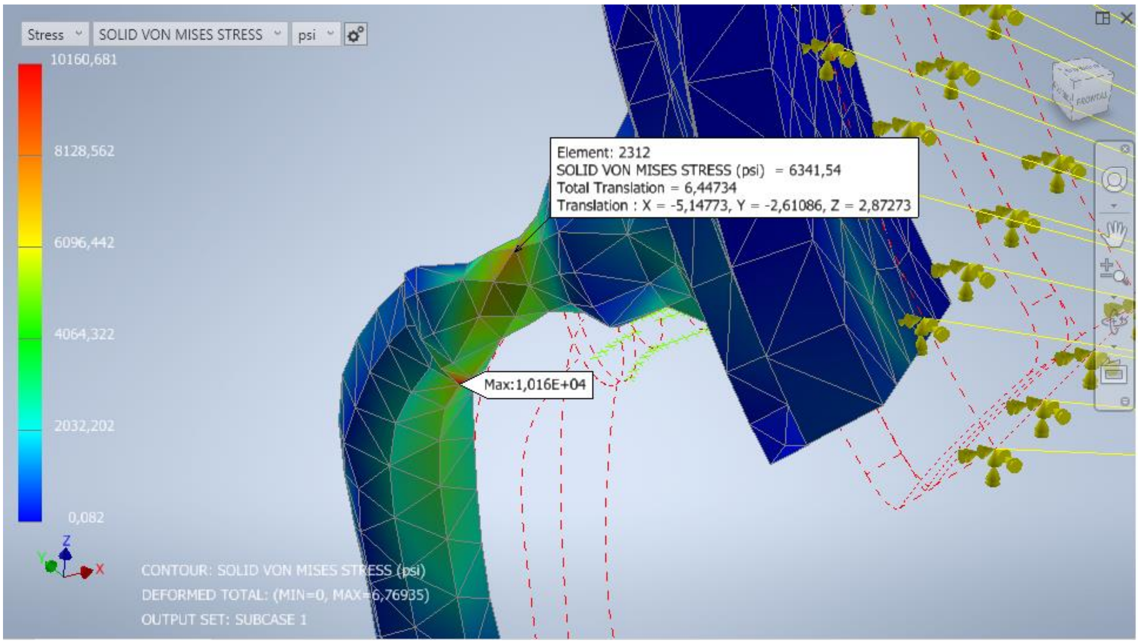
9.2. Y axis

The same procedure is now performed for the y axis. Very similar results are observed. The maximum tension occurs again at the same point as for the z axis, due to the causes explained above. Although in this case, the tension produced in the rear support pad is greater, as shown in the Figure 24 .



CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=6,76935)
OUTPUT SET: SUBCASE 1

Figure 23: Von mises stress when applying a rotation about the Y axis of 3 degrees

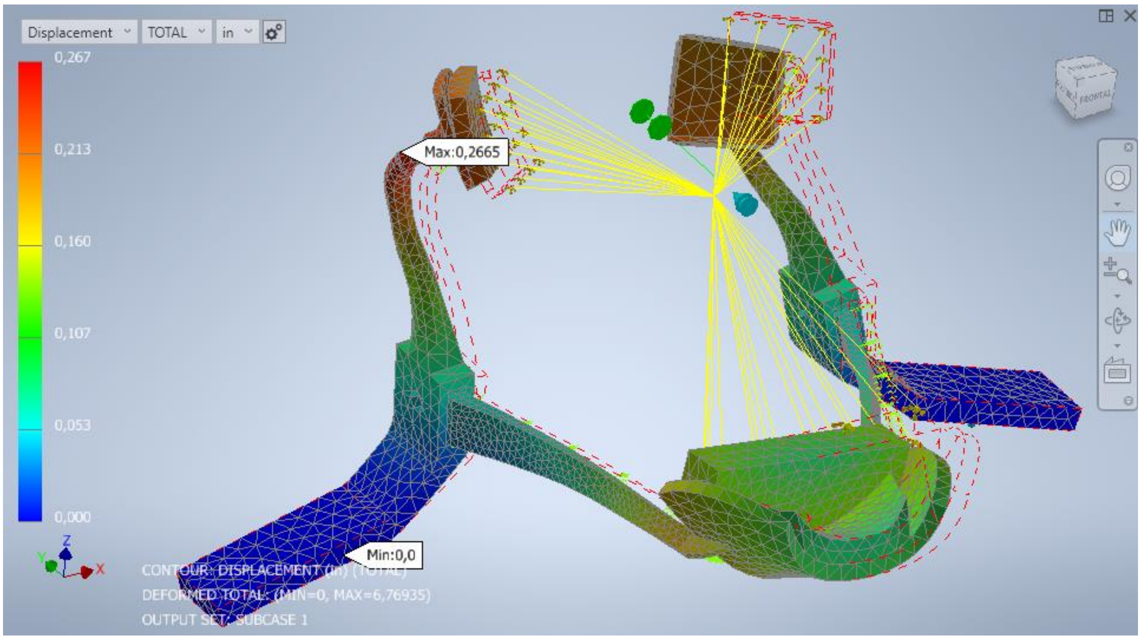


```
Element: 2312
SOLID VON MISES STRESS (psi) = 6341,54
Total Translation = 6,44734
Translation : X = -5,14773, Y = -2,61086, Z = 2,87273
```

```
CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=6,76935)
OUTPUT SET: SUBCASE 1
```

Figure 24: Zoom where the maximum peak of tension around the Y axis is

The maximum displacement in this case is 0.267 in, also occurring in the upper part of the head support that includes the rear support pad and the top of the rear strut.

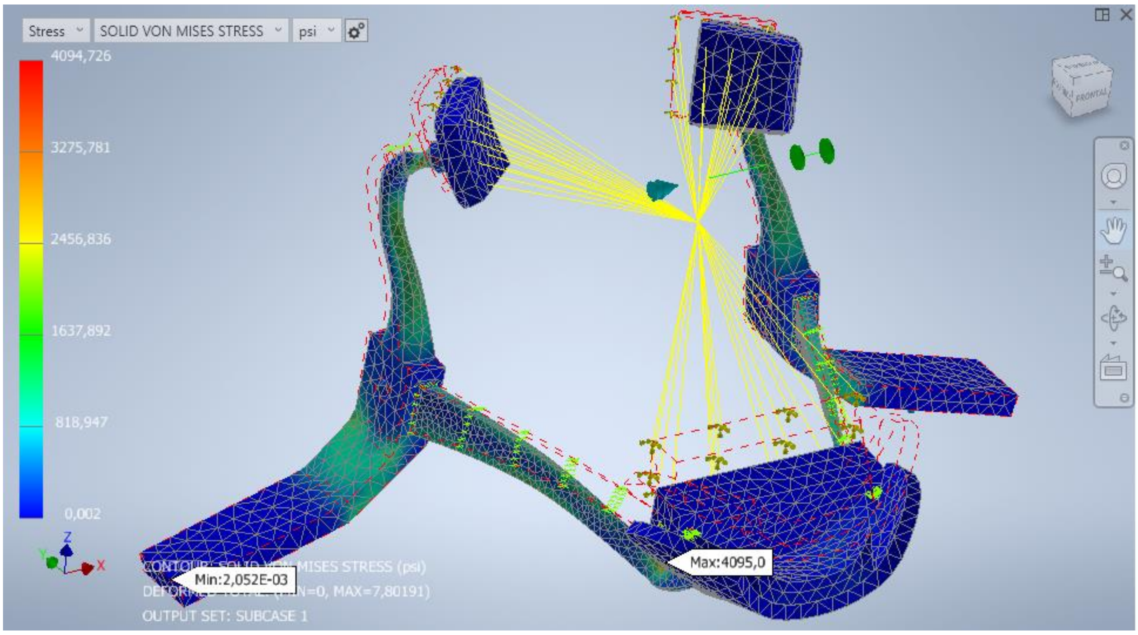


```
CONTOUR: DISPLACEMENT (in) (TOTAL)
DEFORMED TOTAL: (MIN=0, MAX=6,76935)
OUTPUT SET: SUBCASE 1
```

Figure 25: Displacement when applying a rotation about the Y axis of 3 degrees

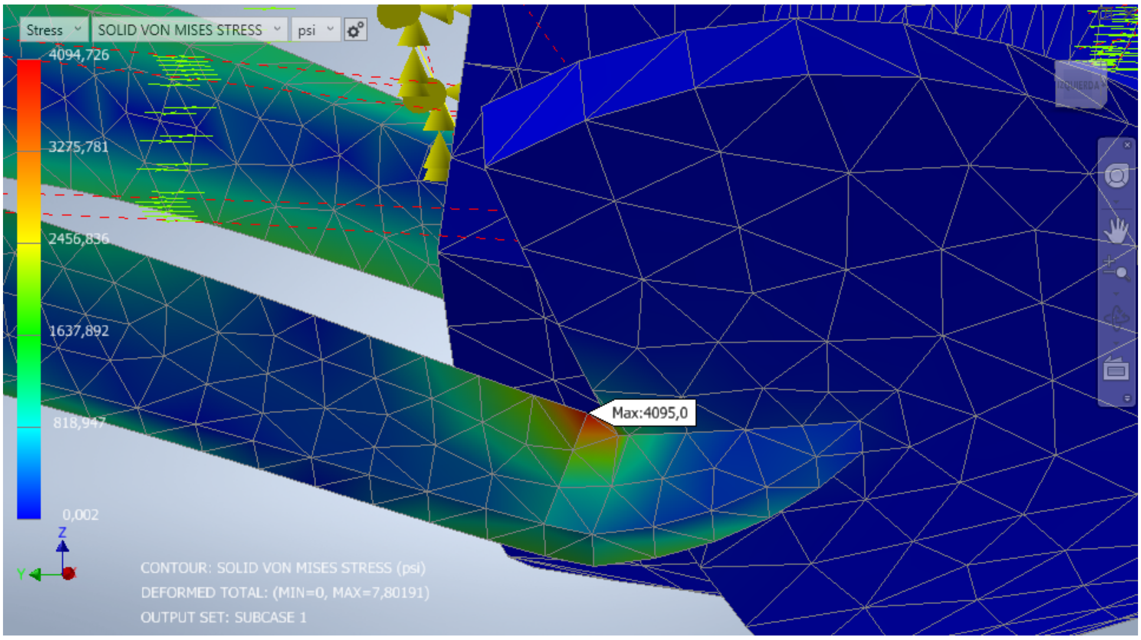
9.3. X axis

Finally, the analysis of the rotation around the x axis is performed, which would simulate the flexion movement of the head. In this case the maximum voltage is in the connection zone of the chin strut with the chin platform, of 4094 psi.



CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=7,80191)
OUTPUT SET: SUBCASE 1

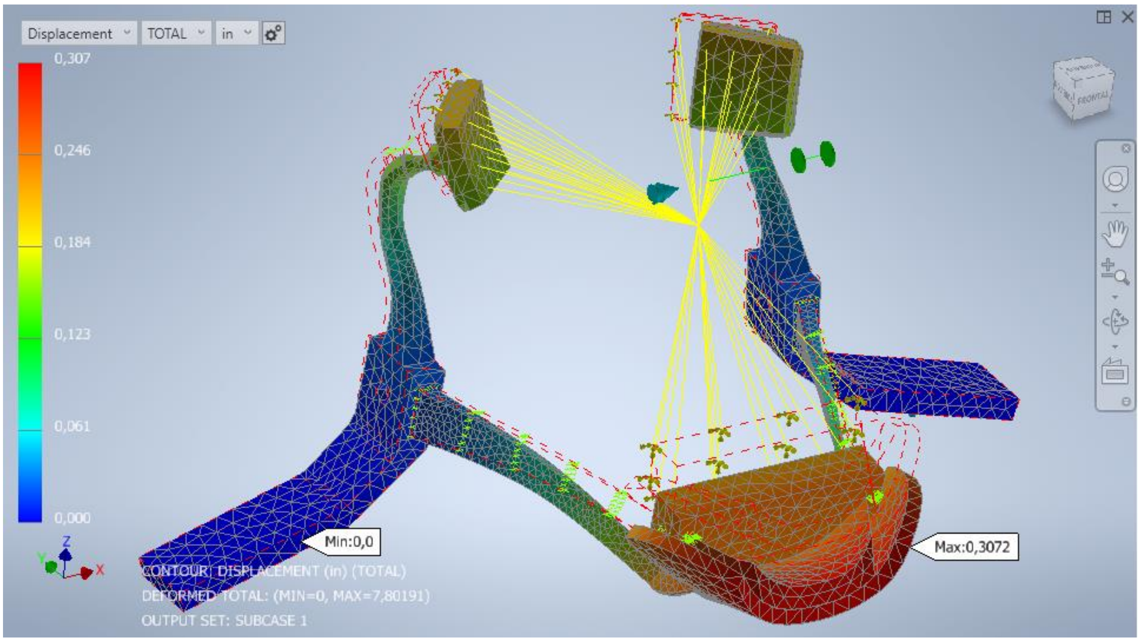
Figure 27: Von mises stress when applying a rotation about the X axis of 3 degrees



CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=7,80191)
OUTPUT SET: SUBCASE 1

Figure 26: Zoom where the maximum peak of tension around the X axis is

Maximum displacement occurs in the area of the chin platform, of 0.307 in, as shown in Figure 28.



CONTOUR: DISPLACEMENT (in) (TOTAL)
DEFORMED TOTAL: (MIN=0, MAX=7,80191)
OUTPUT SET: SUBCASE 1

Figure 28: Displacement when applying a rotation about the X axis of 3 degrees

9.4. Conclusions

As can be seen in the results obtained, the areas of maximum tension correspond to the areas of union between the pieces, either between the rear support pad and the rear strut, or between chin platform and chin strut.

If we do not take into account the first connection since it should be fixed. The maximum stress corresponds to that present in the rear support part due to the rotation in the Y axis, of 6341 psi. This turn would correspond to a lateral flexion movement of the head. This tension is at a point of less section with respect to the rest of the piece.

In two of the three cases of movements the support would break for this degree of movement.

The displacements produced in the support are very small, in the order of hundredths.

10. Cantilever beam

To corroborate that the same result is obtained by hand as with the Inventor Nastran program, an analysis of a cantilever beam is subjected to a specific force at its end. The force necessary to create an angle of 3 degrees at its end is calculated.

In order to try to simulate the support of the head support chin, a rectangular section of 0.15 in by 0.4 in is chosen and with a length of 4.5 in.

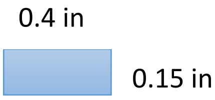


Figure 29:Rectangular section measurements

10.1. Theoretical analysis

The first step is to calculate the moment of inertia (I_x) of the beam:

$$I_x = \frac{b \cdot h^3}{12}$$

Where,

- b is the base of the rectangle
- h is the height of the rectangle

$$I_x = \frac{b \cdot h^3}{12} \qquad \rightarrow \qquad I_x = \frac{0.4in \cdot (0.15in)^3}{12} = 1.125 \cdot 10^{-4} in^4$$

For an angle of 3 degrees, we get the following force to apply:

$$\theta = \frac{FL^2}{2EI_x}$$

Where,

- F is the force
- E is the modulus of elasticity, in this case we are using high impact polypropylene so it is equal to $2.7557 \cdot 10^5$ psi
- I_x is the moment of inertia
- L is the length of the beam

Substituting in the equation:

$$\theta = \frac{FL^2}{2EI_x} \qquad \rightarrow \qquad F = \frac{\theta 2EI_x}{L^2}$$

$$F = \frac{2 \cdot 2.7557 \cdot 10^5 psi \cdot 1.125 \cdot 10^{-4} in^4 \cdot 0.0523\, rad}{(4.5\ in)^2} = 0.16\ lbf$$

So the force to apply on the beam is 0.16 lbf to obtain an angle of 3 degrees.

Figure 30: Cantilever beam subjected to a punctual effort of 0.16 lbf

The maximum tension occurs in the left part of the beam and corresponds to:

$$\sigma_{max} = \frac{M_{max} \cdot \frac{h}{2}}{I_x}$$

Where M$_{max}$ it is the maximum moment that occurs in the beam, which corresponds to the product of the force applied in the beam by the distance,

$$\sigma_{max} = \frac{M_{max} \cdot \frac{h}{2}}{I_x} \qquad \rightarrow \qquad \sigma_{max} = \frac{(0.16\ lbf \cdot 4.5\ in) \cdot \frac{0.15\ in}{2}}{1.125 \cdot 10^{-4} in^4} = 480\ psi$$

The maximum deformation on the y axis is as follows,

$$y_{max} = -\frac{FL^3}{3EI_x}$$

Substituting in the equation,

$$y_{max} = -\frac{0.16\ lbf\ (4.5\ in)^3}{3\ 2.7557 \cdot 10^5 psi \cdot 1.125 \cdot 10^{-4} in^4} = -0.1567\ in$$

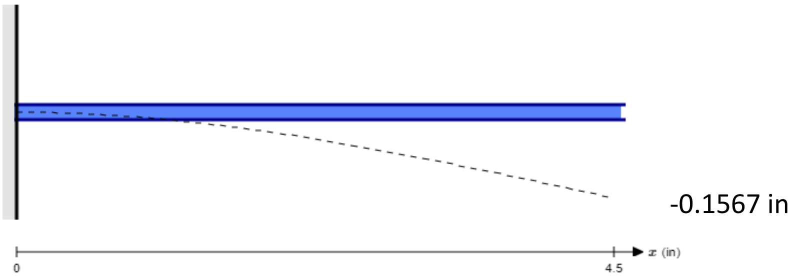


Figure 31: Deformation of the beam subjected to a force of 0.16 lbf

10.2. Analysis in Inventor Nastran

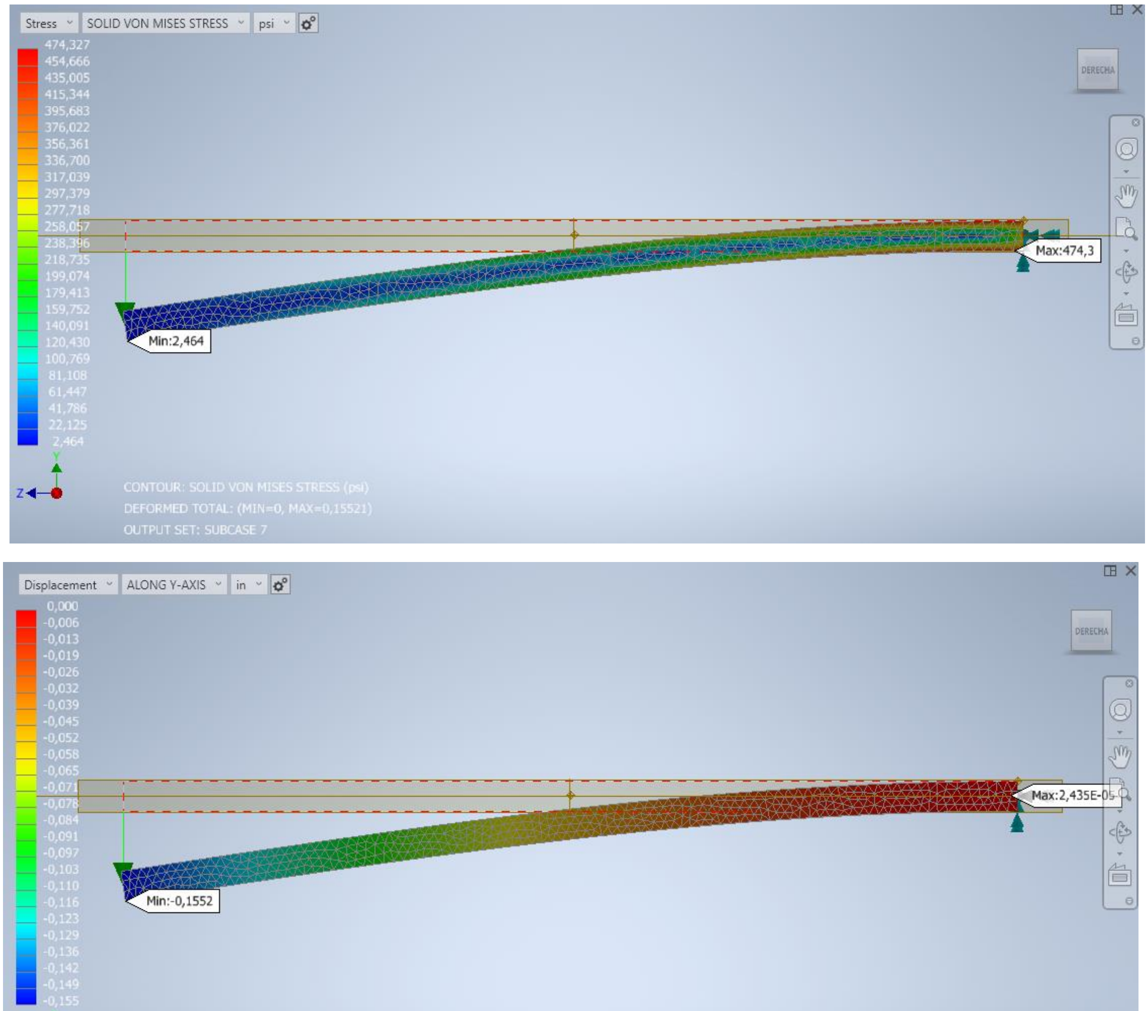
Once the calculations have been done by hand, I use the Inventor Nastran program to perform the finite element analysis.

10.2.1. Linear analysis

Linear static is one of the most common types of analysis. Determines the force, stress, and strain resulting from applying static loads and constraints.

- The deformation is directly related to the applied stress.
- Absence of movements.
- Linear materials.

Once the linear analysis has been performed, the results shown in the Figure 33 and Figure 32.


Stress | SOLID VON MISES STRESS | psi

CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=0,15521)
OUTPUT SET: SUBCASE 7

Displacement | ALONG Y-AXIS | in

CONTOUR: DISPLACEMENT (in) (TY)
DEFORMED TOTAL: (MIN=0, MAX=0,15521)
OUTPUT SET: SUBCASE 7

Figure 32: Displacement on the cantilever beam with the linear analysis

Obtaining a maximum tension of 474.327 psi and a maximum displacement of -0.15521 in.

10.2.2. Non-linear analysis

A nonlinear analysis is one that considers the tensile-deformational behavior of materials and geometric nonlinearity, directly ruling out the superposition principle. The term "stiffness" defines the fundamental difference between linear and non-linear analysis. Stiffness is a property of a part or assembly that characterizes the response to the applied load. A number of factors affect stiffness:

- Form
- Material
- Workpiece support

When a structure is deformed under a load, its stiffness changes, due to one or more of the factors mentioned above, so it is recommended to perform non-linear analysis.

Another important factor to keep in mind is that in the case of large deformations, the load direction can change as the model is deformed. This load direction is shown in Figure 34 the figure on the left corresponds to a tracking load due to a large deformation, this load is kept in a plane normal to the deformed beam, while the figure on the right is corresponds to a non-tracking charge, which maintains its initial direction.

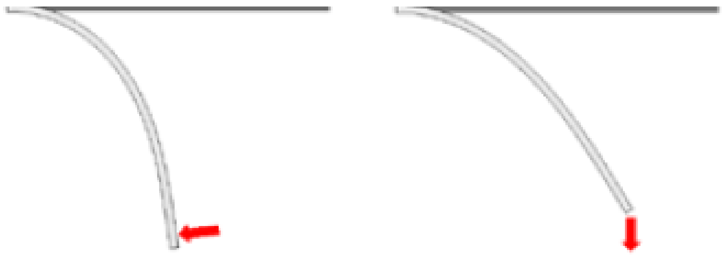
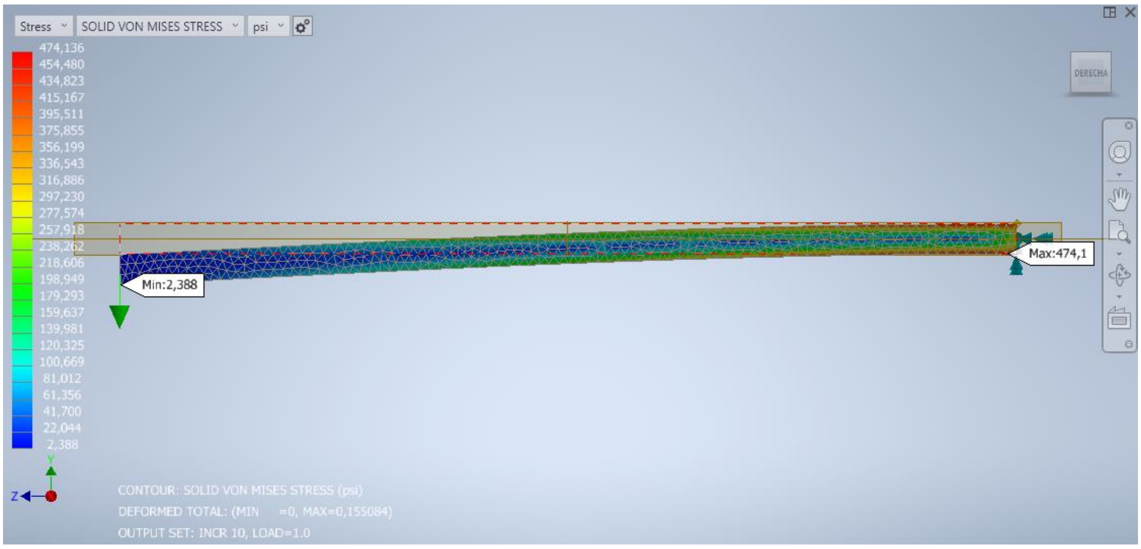


Figure 34: Following and non-following load [20]

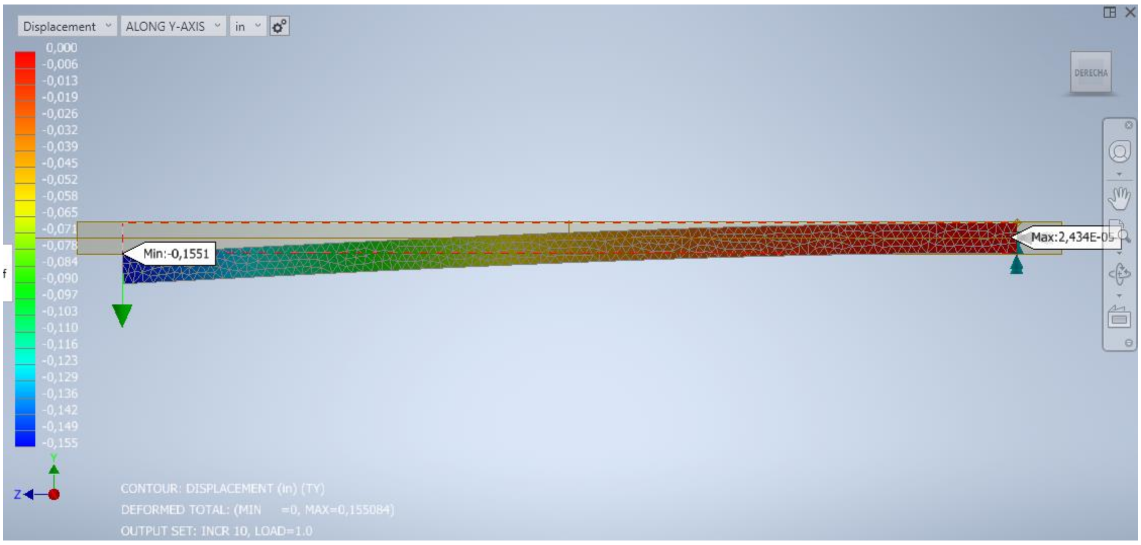
For this analysis, a number of increments of 10. The solver of Nastran must break up the total load into this number of increments. This should not be confused with an iteration. The nonlinear solution algorithm may take many iterations to solve an increment. The results obtained are shown in the Figure 35 and Figure 36.



```
CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN     =0, MAX=0,155084)
OUTPUT SET: INCR 10, LOAD=1.0
```

Figure 35: Stresses on the cantilever beam with the non-linear analysis

Obtaining a maximum tension of 474.136 psi and a maximum displacement of -0.15508 in.



```
CONTOUR: DISPLACEMENT (in) (TY)
DEFORMED TOTAL: (MIN     =0, MAX=0,155084)
OUTPUT SET: INCR 10, LOAD=1.0
```

Figure 36: Displacement on the cantilever beam with the non-linear analysis

10.3. Conclusions

As can be seen in the tables, both for the stress analysis and for the displacement we obtain a smaller error if we perform a linear analysis instead of a non-linear one, although the error in both cases is very small. The reason why the linear analysis is more accurate may be because the angle we are calculating is very small.

Table 4: Results of the stress calculation in the beam

Stress					
Force (lbf)	Theorical (psi)	Linear analysis (psi)	Error (%)	Non-linear (psi)	Error (%)
0.16	480	474.327	1.182	474.136	1.222

Table 5: Results of the displacement calculation in the beam

Displacement					
Force (lbf)	Theorical (in)	Linear analysis (in)	Error (%)	Non-linear (in)	Error (%)
0.16	-0.157	-0.155	0.951	-0.15508	1.034

10.4. Analysis for a greater range of motion

After having performed the linear and nonlinear analysis for a small rotation, we study how the support responds for a greater range of rotation. For this, a force is applied to the end of the beam from 0.2 lbf to 30 lbf.

The results obtained are shown in Table 6 and Table 7.

Table 6: Stresses obtained by performing a linear and non-linear analysis on a beam with a force range of 0.2lbf to 30 lbf

Stress					
Force (lbf)	Theorical (psi)	Linear analysis (psi)	error	Non-linear (psi)	error
0,2	600	592,918	1,180%	592,486	1,252%
1	3000	2964,243	1,192%	2892,613	3,580%
5	15000	14825,357	1,164%	10817,962	27,880%
10	30000	29642,428	1,192%	16274,134	45,753%
15	45000	44469,137	1,180%	20157,217	55,206%
30	90000	88945,695	1,171%	28588,66	68,235%

Table 7: Deformations obtained by performing a linear and non-linear analysis on a beam with a force range of 0.2lbf to 30 lbf

Displacement					
Force (lbf)	Theorical (in)	Linear analysis (in)	error	Non-linear (in)	error
0,2	-0,195	-0,194	0,513%	-0,194	0,513%
1	-0,980	-0,970	1,020%	-0,931	5,000%
5	-4,848	-4,850	-0,041%	-2,823	41,770%
10	-9,790	-9,697	0,950%	-3,976	59,387%
15	-14,690	-14,547	0,973%	-3,696	74,840%
30	-29,390	-29,096	1,000%	-3,975	86,475%

As can be seen from the tables, in all cases small errors are obtained in the linear analysis for both stress and deformation, but as the load increases, the error obtained in the linear analysis also increases. This is because there comes a point where the material reaches its elastic limit so when applying that force, the element should break. Therefore, the results obtained from that moment are not valid.

With this we can conclude that a linear analysis of the head support for small loads is enough to see the response of the same, not being necessary to perform a non-linear analysis.

11. New design

11.1. New proposed designs

In order to improve both the aesthetic and physical aspects of the design, three new designs are proposed. The new designs are following the previous model with two supports for the head and one for the chin.

Finally, taking into account the stated objectives, the number one design is chosen. This design is aesthetically discreet, it is intended to be resistant as well as flexible in order to allow some head movement. It is also designed so that later both mobility and assembly mechanisms can be added easily.

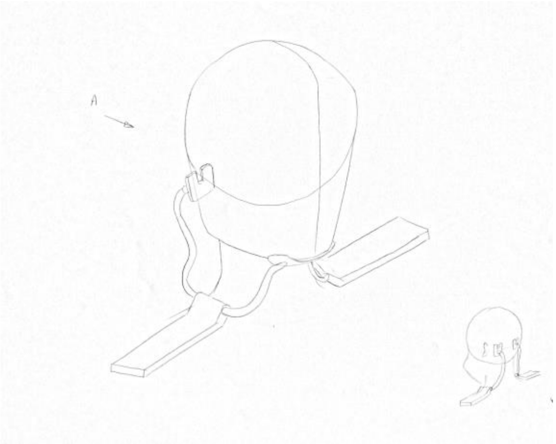


Figure 37: Design number 1

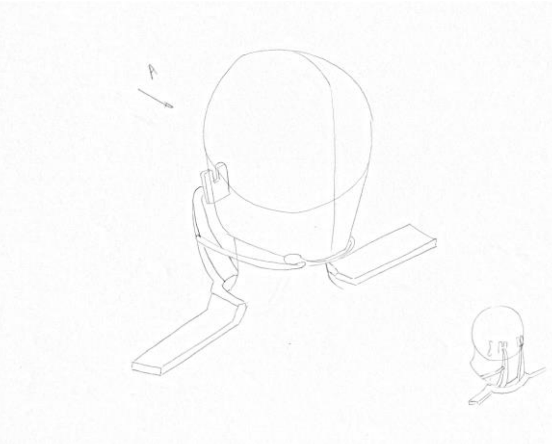


Figure 38: Design number 2

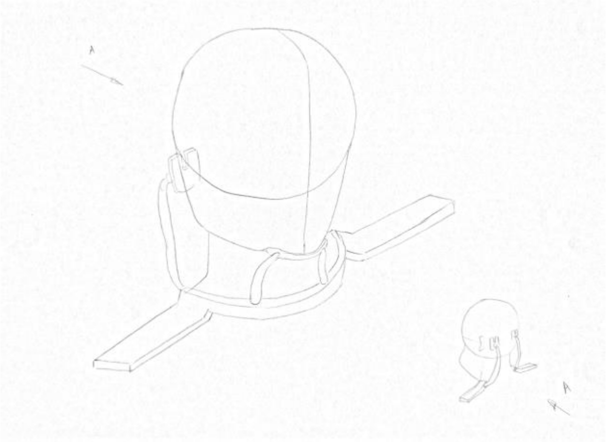


Figure 39: Design number 3

11.2. New design in Inventor

The inventor support model is designed to fit the user's model. Trying to adjust it as much as possible to the draft made by hand, the design shown in the figure is obtained.

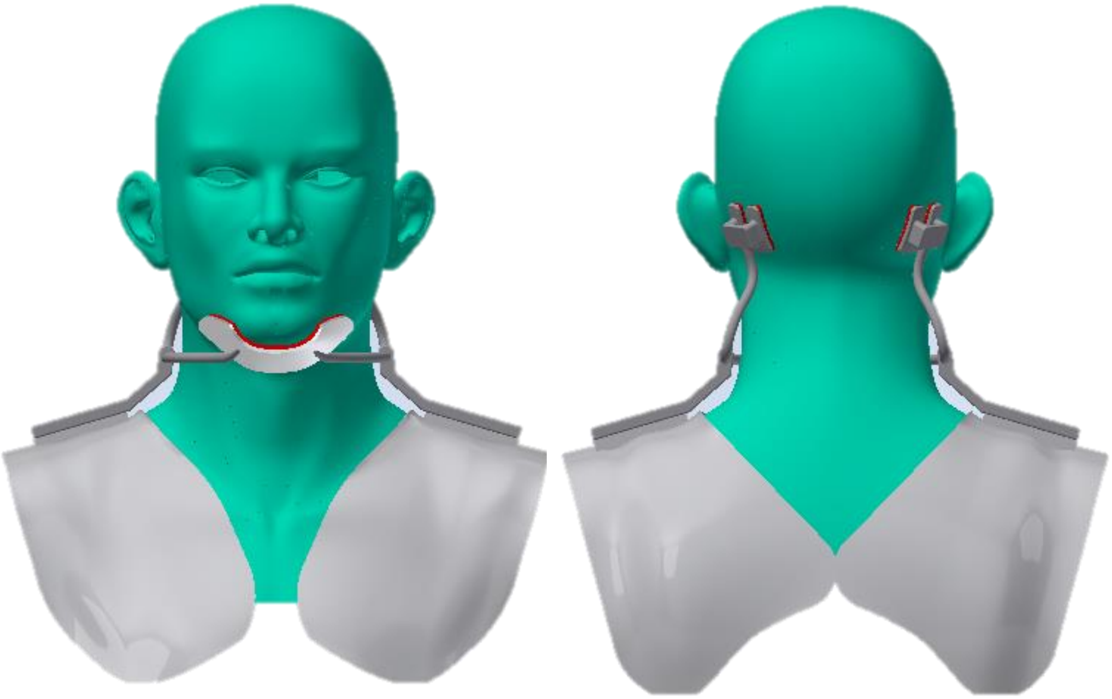


Figure 40: Front and back view of the new model in the user

11.2.1. Model parts

The head support consists of five pieces. All parts are intended to be manufactured using a 3D printer except shoulder pads.

- **Shoulder pad**. This part was not modified from the previous model, as it correctly satisfied the functionality for which it was designed. 3mm thick thermoplastic (LTTP) sheets is used. “This material has a softening temperature of 70-75°C and becomes soft and pliable when heated to this temperature range. In this state, the sheet can be draped over the user’s shoulder and molded to the desired shape. When worn, this close fit locks the shoulder pad to the person’s chest, shoulders, and upper back. The contours of the shoulder pad surrounding the user’s clavicle in front and scapula in back serve to anchor the shoulder pad and minimize slipping.” [17]

Figure 41: Shoulder pads

- **Base.** It is attached to the shoulder pad, supports the rear strut and the chin platform. Both the shoulder pads and the base are designed so that they can be worn discreetly under clothing.

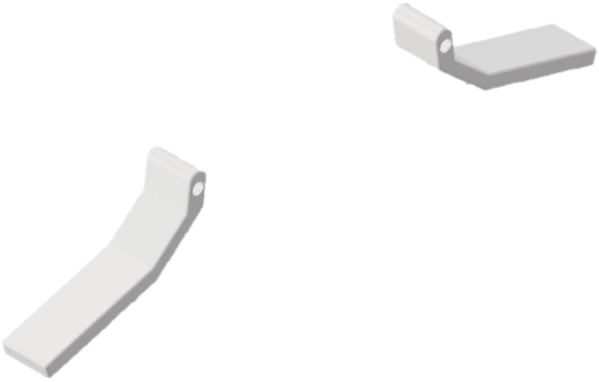


Figure 42: Base

- **Rear support pad.** These are placed over the occipital bones at the bottom of the skull. A slot is added so that when placed on the head, it can be more hidden by placing the hair on top. The location of (rear strut) is modified, passing it from the back to the bottom. Above them is placed a memory foam to cushion the contact point.

Figure 43: Rear support pad

- **Rear strut.** They are the supports of rear support pad, which connect from the bottom of it to the base, it is a circular bar of 0.25 in diameter.

Figure 44: Rear strut

- **Chin support.** The oval support where the chin rests directly. This is specifically designed to match each user's chin. This support is lined with memory foam to make contact more comfortable. This support is attached to a strut on each side which in turn are connected to the base of the support. These struts are 0.25 in diameter.

Figure 45: Chin support

The assembled full head support is shown in the Figure 46.

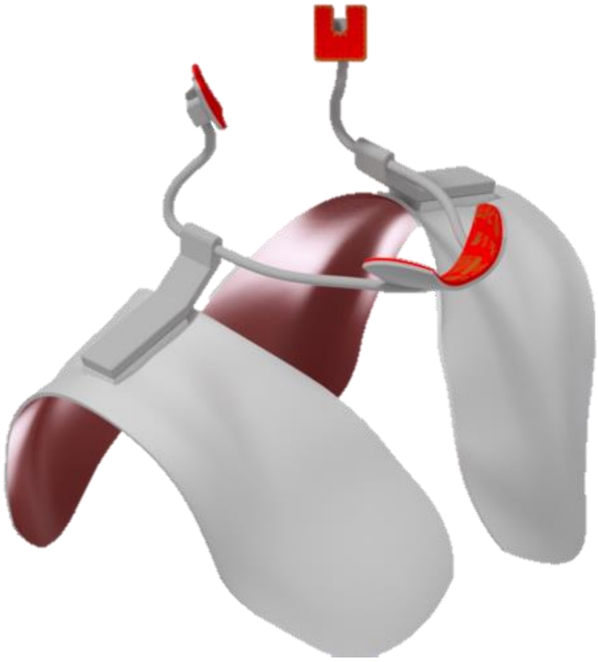


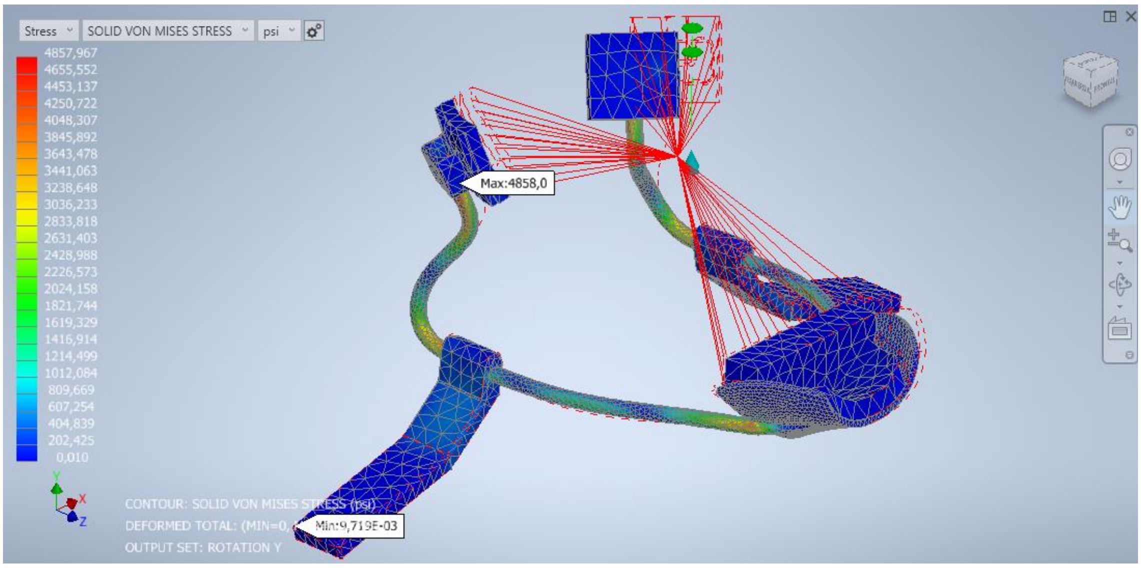
Figure 46: Full assembled head support

11.3. Finite element analysis of the model

In the same way as for the previous model, an analysis of finite elements is carried out for the new design in the Nastran program. The same adjustments are made as for the previous model.

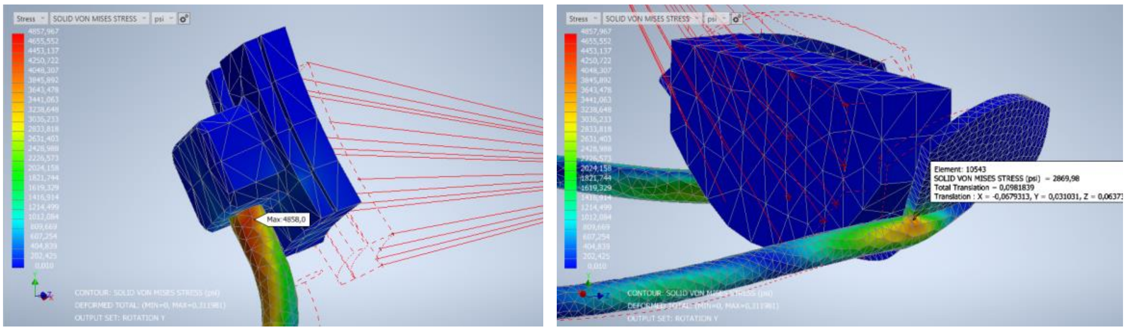
11.3.1. Y axis

A rotation of 3 degrees around the Y axis is applied, simulating the rotation movement of the head. The greatest stresses occur in the struts, the peak is 4858 psi at the top of rear strut. The value of the stress at the connection point between the piece that holds the chin and the struts is the 2870 psi.



CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0,
OUTPUT SET: ROTATION Y

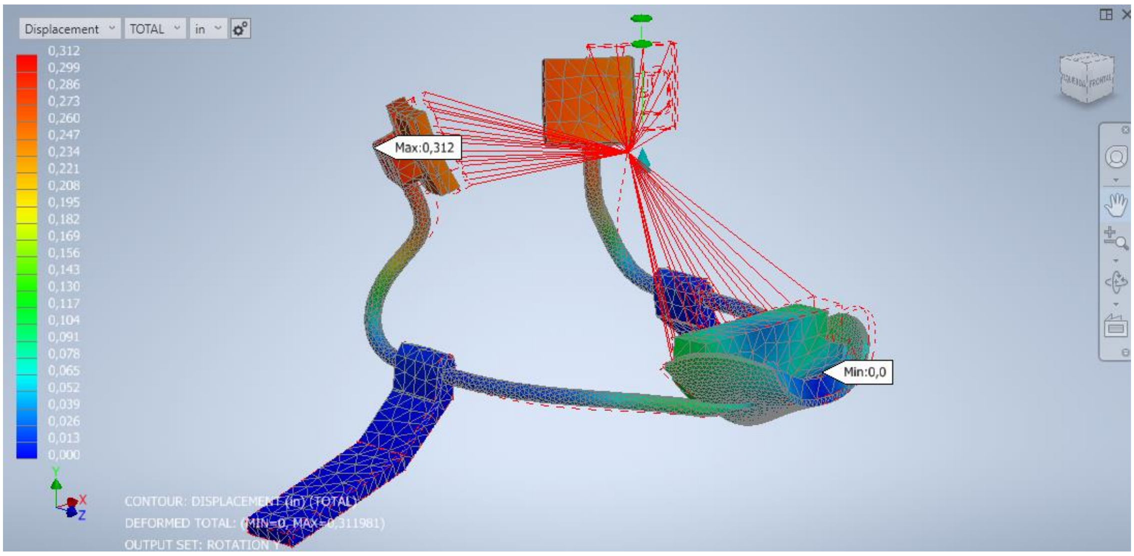
Figure 47: Von mises stress when applying a rotation about the Y axis of 3 degrees. New design.



Element: 10543
SOLID VON MISES STRESS (psi) = 2869,98
Total Translation = 0,0981839
Translation : X = -0,0679313, Y = 0,031031, Z = 0,06371

Figure 48: High stress areas, for y axis rotation

The maximum displacement occurs in the rear support pad of 0.312 in.

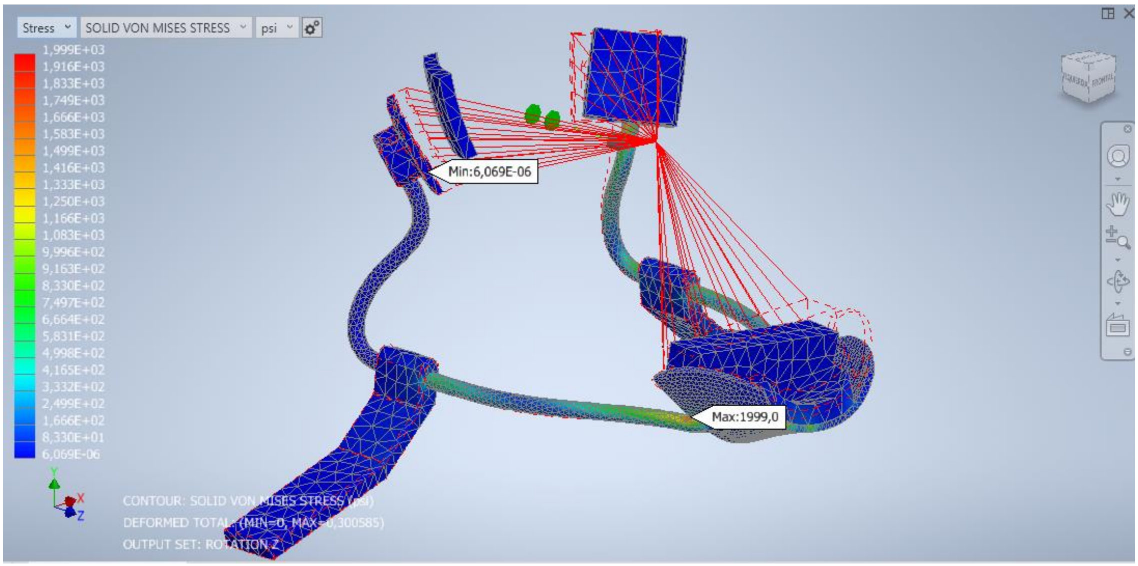


```
CONTOUR: DISPLACEMENT (in) (TOTAL)
DEFORMED TOTAL: (MIN=0, MAX=0,311981)
OUTPUT SET: ROTATION Y
```

Figure 49: Displacement when applying a rotation about the Y axis of 3 degrees. New design.

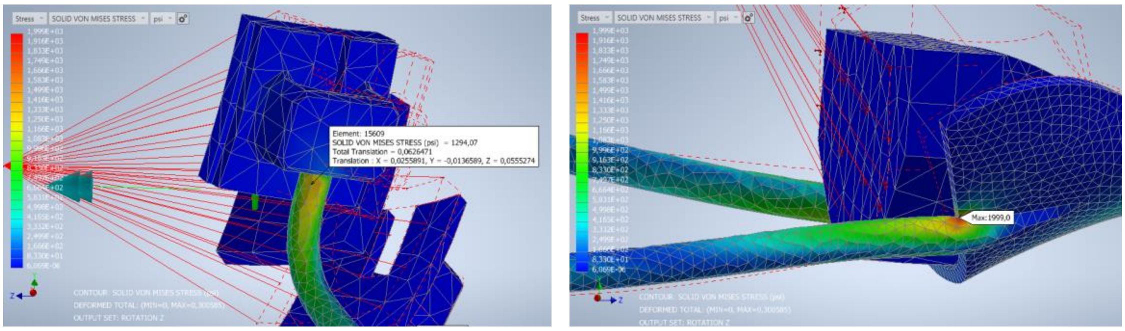
11.3.2. Z axis

A rotation of 3 degrees around the z axis is applied, simulating the lateral flexion movement of the head. The point of greatest stresses occurs where the connection between the piece that holds the chin and the struts, of 1999 psi.



```
CONTOUR: SOLID VON MISES STRESS (psi)
DEFORMED TOTAL: (MIN=0, MAX=0,300585)
OUTPUT SET: ROTATION Z
```

Figure 50: Von mises stress when applying a rotation about the Z axis of 3 degrees. New design.



Element: 15609
SOLID VON MISES STRESS (psi) = 1294,07
Total Translation = 0,0626471
Translation : X = 0,0255891, Y = -0,0136589, Z = 0,0555274

Figure 51: High stress areas, for z axis rotation

Having applied a separation constraint, the imitation skull piece on the left detaches from the holder when performing the movement while the one on the right is pressed against the head pad and moves an amount of approximately 0.12 in.

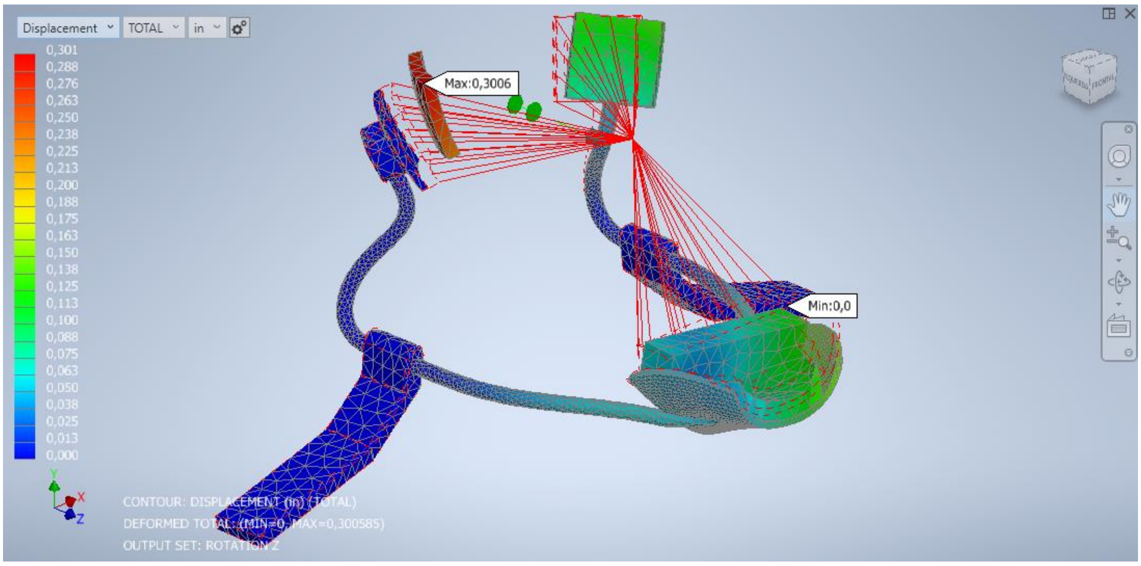


Figure 52: Displacement when applying a rotation about the Z axis of 3 degrees. New design.

11.3.3. X axis

A rotation of 3 degrees around the x axis is applied, simulating the flexion movement of the head. As for the previous design, maximum stresses occur where the connection between the piece that holds the chin and the struts, since it is the area that supports the most flexion effort, with a value of 1905 psi.

Stresses of almost similar value also occur in the struts in the base area, of 1515 psi. As shown in Figure 54.

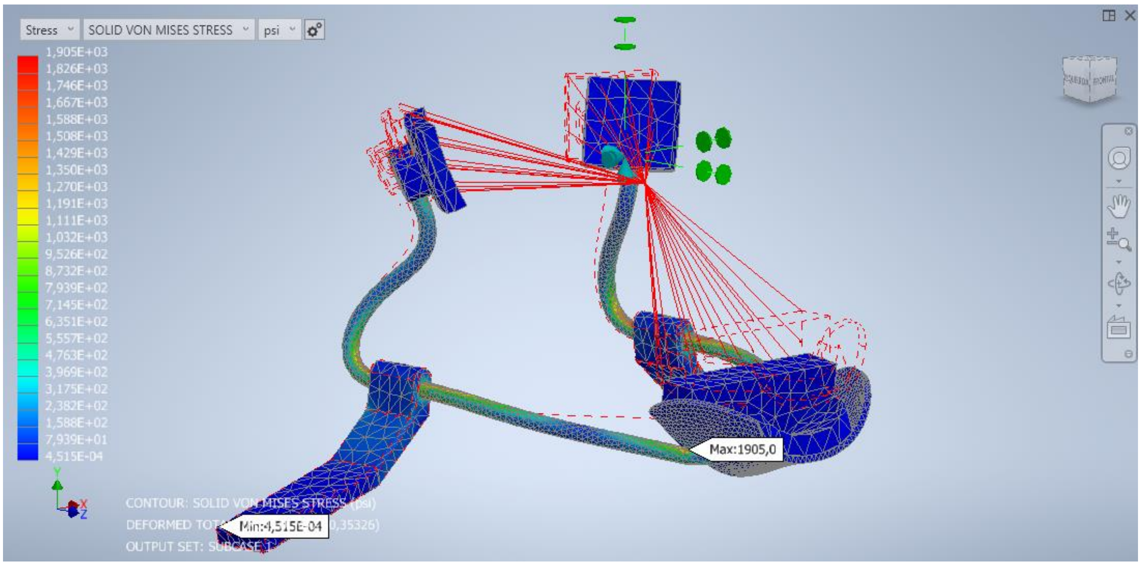
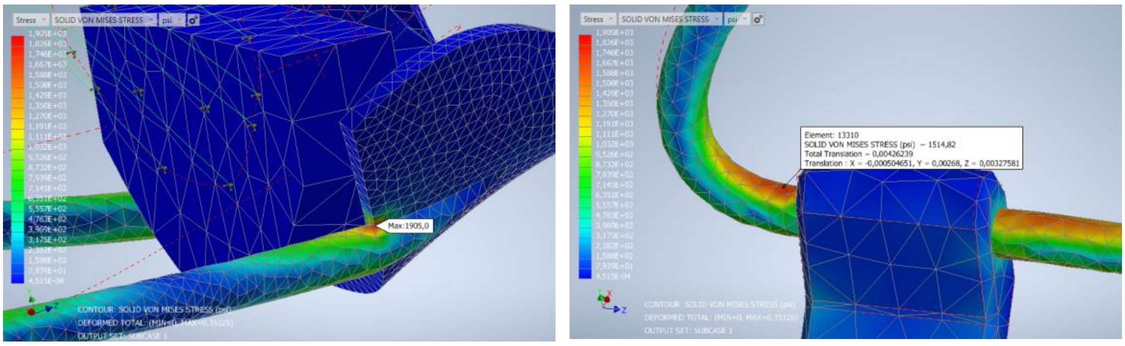


Figure 53: Von mises stress when applying a rotation about the X axis of 3 degrees. New design.



Element: 13310
SOLID VON MISES STRESS (psi) = 1514,82
Total Translation = 0,00426239
Translation : X = -0,000504651, Y = 0,00268, Z = 0,00327581

Figure 54: High stress areas, for x axis rotation

The maximum displacement is given at the chin of a value of 0.35 in.

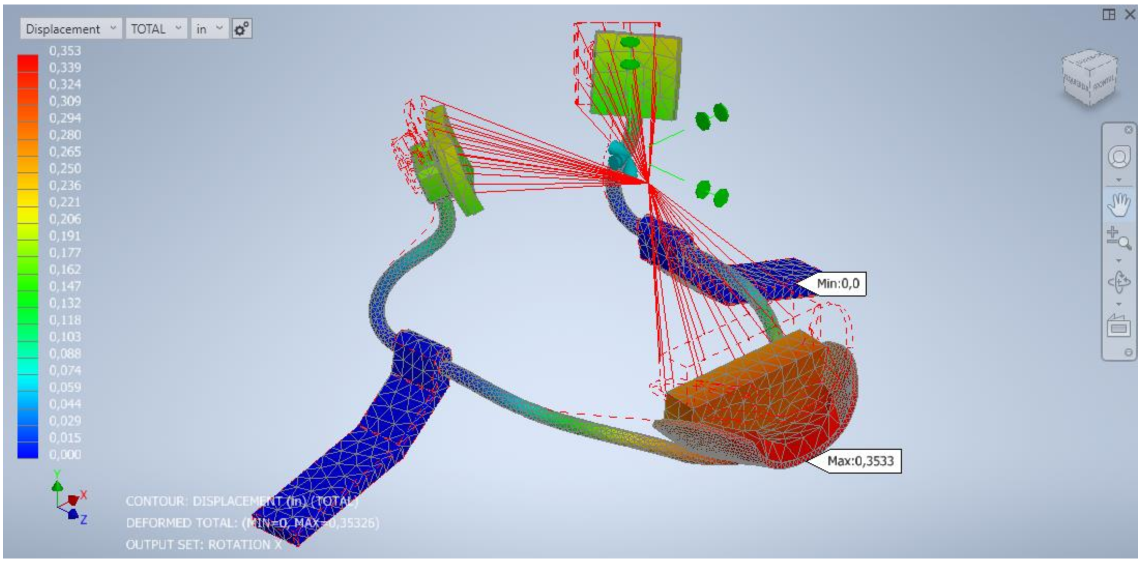


Figure 55: Displacement when applying a rotation about the X axis of 3 degrees. New design.

11.4. Conclusion

The previous design is compared with the new one, the data of the first design of values of 10000 psi are discarded, since they are considered to be errors in the design and adjustment format between pieces.

In two of the three movements analyzed, maximum stresses decrease. Also keep in mind that the section of the strut is smaller in the second design than in the first, so that by increasing the section of the struts if necessary, the stresses would decrease. The maximum tension occurs at the point of contact between the two pieces, for simplicity of analysis it does not have the fillet at that point, which would also reduce the stresses.

For this range of motion, the support would break when performing the rotational motion of the head. So even modifying the design to allow it to perform this movement would not be enough for the required functions.

For further study it would be necessary to add a mechanism in the base in order to allow the movement of the head, since without this, if we use a very flexible material, it will be able to move the head but it would not be enough to resist it and as It has been seen in the previous analysis, if the material is resistant it is not flexible enough.

Table 8:comparison of maximum stresses between the previous and new design

	Maximum stress (psi)		
	Rotation movement	Flexion movement	Lateral flexion movement
Previous Design	4276	4095	2312
New Design	4858	1905	1999

12. Disassembly mechanism proposal

For further study, mechanisms of disassembly of the head support are proposed.

One of the suggestions proposed in the article "Design of a Novel Head Support for People with Hypermobile Type Ehlers-Danlos Syndrome" by one of the patients was that the part of the chin could be easily disassembled and assembled, in order to use the rear part to stabilize the head and be able leave total freedom in the front to eat, talk etc. comfortably.

For this reason, 3 designs of easily removable mechanisms based on existing mechanisms are proposed. The first mechanism consists of a button that would be located on the chin bars and would fit into the base of the support. For disarming, it would be worth simply pressing the button and pulling the piece.

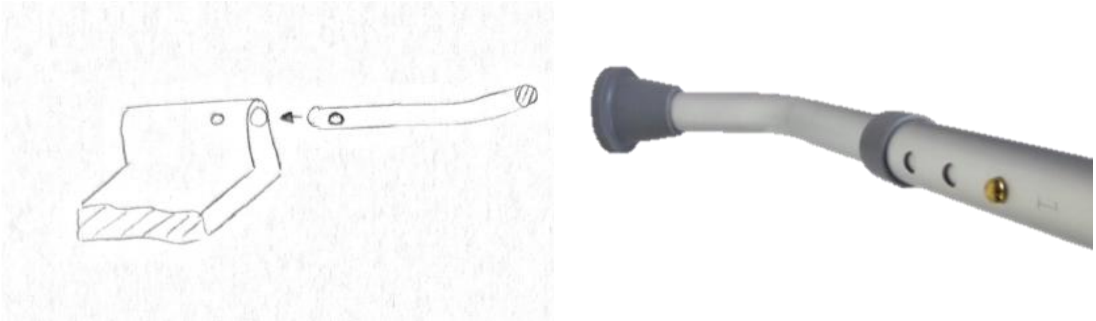


Figure 56: Mechanism proposal number 1

The second consists of a washer with a circular piece that would fit into the base and the chin bar through the holes.

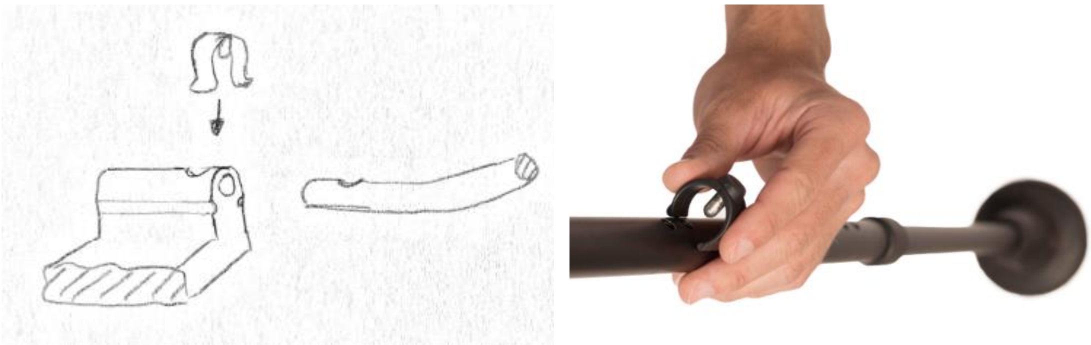


Figure 57: Mechanism proposal number 2

Finally, in the third design, a piece would be made in the part of the strut of the chin that would fit into the base and later closed by a cover.

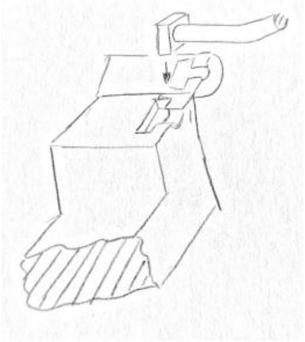


Figure 58: Mechanism proposal number 3

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