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POSTERIOR CERVICAL PLATES - DESIGNED AND FABRICATION

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Abstract: *This paper presents two implants spine (cervical area) made in 2015 in the Faculty of Product Design and Environment (in the Medical Engineering Laboratory). In the first part presents a series of issues related to the anatomy of the spine. The following are the most important diseases of the spine. The last part presents a few examples of posterior cervical plates from literature but the two models made in the Laboratory of Medical Engineering, from their design and production deal with them.*
Keywords: *spine, cervical vertebrae, plates, posterior.*

1. INTRODUCTION

The spine consists of discrete bony elements (vertebrae) joined by passive ligamentous restraints, kept separated by intervertebral discs and articulating joints, and dynamically controlled by muscular activation. The spine is broadly divided into 5 regions: the cervical spine, the thoracic spine, the lumbar spine, the sacrum, and the coccyx (Figure 1). Each has it's own unique set of kinematic functions, pathologies, and treatments. In fact, the cervical, thoracic, and lumbar regions are further divided based on kinematic and clinical considerations [1].

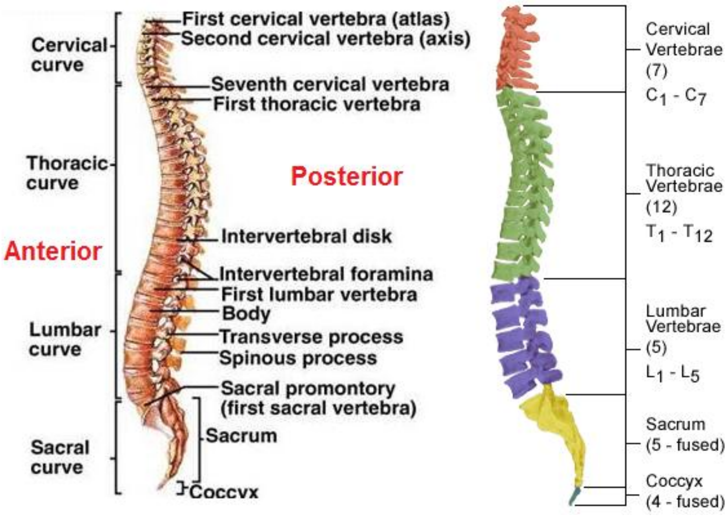

Figure 1: Anatomy of the spine. Spinal Column with vertebrae. [2]

The cervical spine (C-spine) consists of 7 vertebrae (C1-C7) in all mammals and the base of the skull, the occiput (C0) and is divided into upper (C0-C2), middle (C2-C5), and lower (C5-T1) regions. A natural, slight lordotic curve exists in the C-spine, meaning that the middle lies farther anterior than the ends. The thoracic spine (T-spine) consists of 12 vertebrae (T1-T12) and is divided into upper (T1-T4), middle (T4T8), and lower (T8-L1) regions [1]. The ribs attach to the thoracic vertebrae. A natural, slight kyphotic curve exists in the T-spine, meaning that the middle lies farther posterior than the ends. The lumbar spine (L-spine) consists of 5 vertebrae (L1-L5) in humans (some mammals, e.g., goats have 6 lumbar vertebrae). The sacrum and coccyx consists of 5 fused vertebrae each (for the coccyx, 4 or 5) - Figure 1.

2. CERVICAL SPINE DISORDERS

2.1. Degenerative Cervical Spine Disorders

Intervertebral disc herniation is also known as herniated nucleus pulposus (HNP). The intervertebral discs make up approximately one-fourth of the cervical spine's height. Over time the water content within the nucleus pulposus of the disc decreases from approximately 90% at birth to 70% by age 70 [3]. The diminished water content, along with changes due to the effects of proteoglycan, collagen, keratin sulfate, and chondroitin sulfate, results in degeneration [3]. As the degenerative process continues, the nucleus pulposus cannot generate the intradiscal force required to keep the annulus fibrosus expanded. In turn, the annulus is subjected to excessive compressive and shear forces, causing weakening and tears in its layers. The weakness puts the annulus at risk of nucleus pulposus bulging, protrusion, or herniation [3].

Spondylosis is generally defined as age- and use-related degenerative changes of the spine. This diagnosis includes degenerative disc disease and the progressive changes that occur as a result of disc degeneration, such as osteophyte formation, ligamentous hypertrophy, and facet hypertrophy (Figure 18). As the degenerative cascade continues, changes in normal spinal curvature occur [3].

Cervical spondylotic myelopathy is defined as "*spinal cord dysfunction accompanying typical age-related degeneration of the cervical spine*". Spondylosis is the most common etiology, and spondylotic myelopathy is the most common cause of spinal cord dysfunction in persons older than 55 years [3]. However, cervical spondylosis is commonplace in the aging spine, and most patients will not develop myelopathy. Radiographically, cervical spondylotic myelopathy is considered when the central canal is less than or equal to 13 mm (normal = 17 mm) or when patients have greater than or equal to 30% narrowing of the cross-sectional area of the canal with associated symptoms [3].

Cervical stenosis, classified as either congenital or acquired, is a result of either being born with a narrow spinal canal or developing a narrow spinal canal as a result of degenerative changes. Ossification of the posterior longitudinal ligament (OPLL) is a specific condition that causes cervical spinal stenosis [3]. OPLL is characterized by calcification and thickening of the PLL. This results in narrowing of the spinal canal and potential spinal cord compression as well as increased spine rigidity. With any cause of stenosis, the degree of spinal canal narrowing determines the significance of the clinical implications [3]. If spinal cord compression is evident, the patient will be counseled on operative management options, alternatives to surgery, and the risks involved with both operative and nonoperative management. Stenosis may exist throughout the cervical spine or may be limited to a few adjacent segments. In severe spinal cord compression, even with no neurologic deficit, there is a potential for catastrophic neurologic impairment [3].

Rheumatoid arthritis is a "chronic systemic autoimmune disease characterized by erosive synovitis that infiltrates and destroys multiple joints in the body" [3]. Synovitis, an acute inflammatory response,
is a result of antibody-antigen complex formation. Eventually, this can lead to complete destruction of the joint. The acute process is followed by a chronic granulomatous process of pannus formation. This produces collagenase and other enzymes that destroy surrounding cartilage and bone. The cervical spine is at risk
because the atlantooccipital (occiput and C1) and atlantoaxial (C1 and C2) articulations are purely synovial.

Ankylosing spondylitis, a seronegative spondyloarthropathy associated with the human leukocyte antigen B27, causes inflammation in the synovial joints, beginning in the sacroiliac joints [3]. As the disease progresses, ossification and ankyloses occurs in an ascending manner. The patient eventually develops a rigid, brittle, and immobile spine. This leaves the individual very susceptible to deformity (loss of normal spinal curvature) and fractures.

2.2. Neoplastic Cervical Spine Disease

More than 95% of the clinically significant spinal column tumors are metastases, and 60% of those are from cancers of the breast, lung, and prostate; myelomas; or lymphomas [3]. Approximately 8%–20% of spine metastases are in the cervical spine. In addition, 11%–17% of breast cancer patients will suffer metastases to the cervical spine; the percentage increases to 40% in patients with advanced disease [3]. Cancers of the lung, of the prostate, renal, and thyroid glands, as well as gastrointestinal and gynecologic cancers, and melanoma, in descending order of frequency, commonly metastasize to the cervical spine. Spinal involvement of metastatic cancer can lead to vertebral collapse and instability, causing pain and potential neurologic compromise. Nerve root or spinal cord compression also can be caused by the infiltration of the tumor mass, resulting in neural element compression. Although surgical intervention may not cure these patients, it may be indicated to treat tumor-induced neurologic compromise or fracture. Surgical intervention is aimed at stabilizing the spine and optimizing neurologic function.

2.3. Deformity of the Cervical Spine

Deformities develop from either anterior or posterior vertebral element disruption. This can be caused by a number of conditions, such as congenital anomalies, surgery, osteoporosis, tumor, or inflammatory or degenerative processes [3]. The underlying pathology and biomechanical imbalances it creates will determine the extent and significance of the deformity. The most common cervical spine deformity is *kyphosis*. As the deformity forms, the head is shifted forward, which increases compression on the anterior vertebral bodies. The posterior neck muscles become less effective at holding up the head. As the cycle continues, kyphosis, unfortunately, worsens over time. Common signs and symptoms are neck pain, muscle fatigue, radiculopathy, myelopathy, potentially poor posture because of looking down, and poor nutritional status because of the patient's inability to look up.

Osteoporosis, the most common metabolic bone disease, is characterized by low bone mass and structural deterioration of bone tissue. These events occur when bone resorption happens too quickly or replacement occurs too slowly. Structural deterioration leads to increased susceptibility to fractures, which are related to increased bone fragility most often seen in the hip, spine, or wrist. A current definition of osteoporosis is based on gradations of low bone mass; that is, bone mineral density (BMD) is more than 2.5 standard deviations below the peak BMD of gender- and ethnicity-matched healthy, 30-year-old Caucasian women [3]. Certain risk factors are linked to or contribute to the likelihood of an individual developing osteoporosis. Some of these factors are genetically determined and others are related to lifestyle. Increasing age plays a significant factor as the resorption of bone surpasses its formation, putting both sexes at increased risk [3]. Persons may not be aware that they have developed osteoporosis because bone loss occurs without symptoms. The first sign may be pain, spinal deformity, loss of height, or fracture.

3. POSTERIOR CERVICAL INSTRUMENTATION

3.1 Some examples of posterior cervical plates

Instrumentation used in interventions on the cervical spine has evolved alike for both types of approaches, the posterior and anterior of the basic method to strengthen interspinous processes with wires. Posterior stabilization techniques of the atlanto-axial complex historically have made use of various wiring techniques.

In 1939, Gallie described a relatively simple technique for controlling situations in which anterior instability of the atlanto-axial complex exists. The only requirement for this technique is that integrity of the C2 arch is maintained [4].

Using wires in posterior cervical column was first described by Rogers in 1942 to treat fractures and dislocations of the cervical spine. This operation involved connecting multiple law suits with wires and incorporation of bone grafts for intensifying merger. In 1959 Forsyth spoke posterior internal fixation technique cervical spine using 20 stainless steel wires to splice spinous processes [5].

In 1980 Dr. Roy-Camille was pioneer posterior cervical stabilization using lateral mass screws to the vertebrae. His technique of stabilizing the fusion induced spontaneous deck facets and therefore required no additional grafting [5].

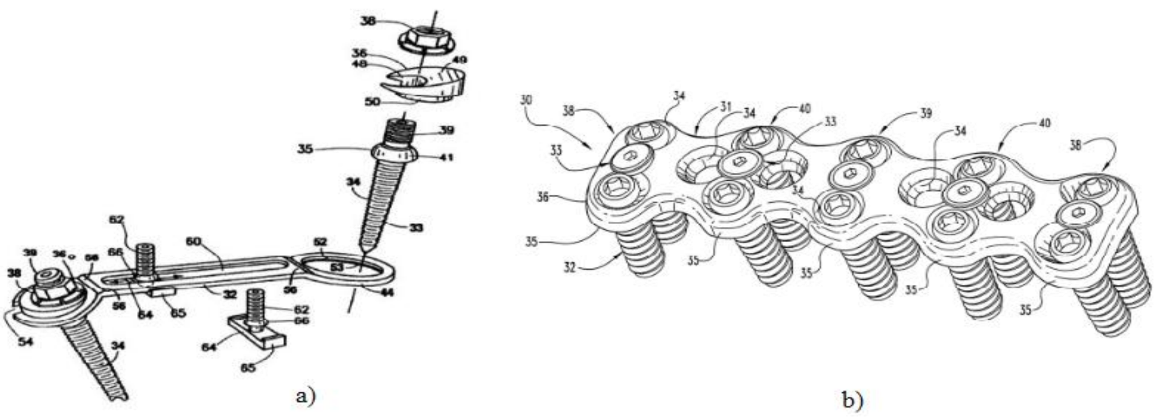

Figure 2: a) The system developed by dr. Roy-Camille; b) AME Haid Universal Bone Plate System. [5]

In 1989 Dr. Haid has developed a posterior cervical plate (AME Haid Universal Bone Plate System) made of titanium alloy to reduce artifacts in CT scans. It had a slightly concave cross-section to accommodate anatomical shapes of the articular processes (Figure 2). One of the advantages lateral mass plate fixation is independent of the integrity of the posterior elements and the fact that this positioning by normal cervical lordosis store. Fusion success rate was 98% [5].
Using anterior cervical plates provided by fusion stabilization capacity increase selective cervical segments, eliminating the need for external immobilization. A large number of anterior cervical plates have been developed and used clinically for over the years.
In 2002, Haid proposed a nomenclature for describing and labeling of anterior cervical plates (ACPs) based on biomechanical properties and load capacity of these systems graft. In order to reduce the normal stress (*stress shielding*) against graft, but also preventing unscrewing, semi-constrained plates were created. The objective was to develop nameplates takes only a percentage of uniformly distributed load and graft difference loading [5]. A system that was built for this purpose was DOC Rod (DePuy Spine, Rayham, MA). It allows translations vertical sliding bolt controlled by the over bars, a phenomenon that leads to compaction graft (Figure 3.a). This controlled slide by rigid rods implanted maintain the alignment of the anatomical structure [5]. Another example of a dynamic system is developed by Aesculap ABC plate, and presents slots and variable angle screws to reduce positioning of stress shielding. This allows the movement of translation and rotation of the screws in the screw-plate interface.

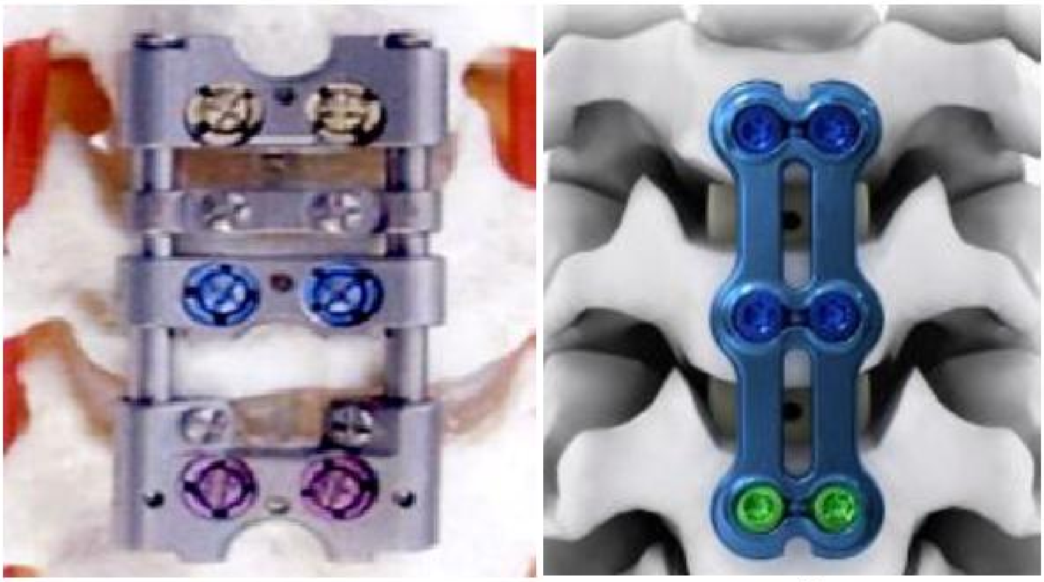
a) b)

Figure 3: a) DOC Rod System; b) Solstice NEO-SL Plate. [5]

EO-SL System of anterior cervical plate is a slim and easy to use. It has an integrated locking mechanism that allows bone screws to be securely fixed without the need for additional locking components. Its key features include plates of different lengths for procedures from level 1 to level 5. Bone screws are available that are designed for quick twist configurations in both variable and fixed angles. Moreover, the system has a locking mechanism integrated in a single step.

3.2 New models designed and fabrication in the Medical Engineering Laboratory

In the Laboratory of Medical Engineering (from Faculty of Product Design and Environment) from 2010 until now, they have been designed and produced a series of implants for hip joints, knee, shoulder and spine. In this paper are present two types of posterior cervical plates. As with Rod DOC system it allows translations vertical sliding bolt controlled by the over bars, a phenomenon that leads to compaction graft (Figure 4). This controlled slide by rigid rods implanted maintain the alignment of the cervical vertebrae [5]. The systems (posterior cervical plates) were designed using CATIA V5R19 and SOLID WORKS 2015 software. Data on the overall dimensions and aspects of strength of materials found in reference [5]. The second system (PCP-02-F) is a bit like the Solstice NEO-SL and is shown in Figure 5. The systems were produced from 316L steel in first step. Technological process to achieve systems are detailed in reference [5].

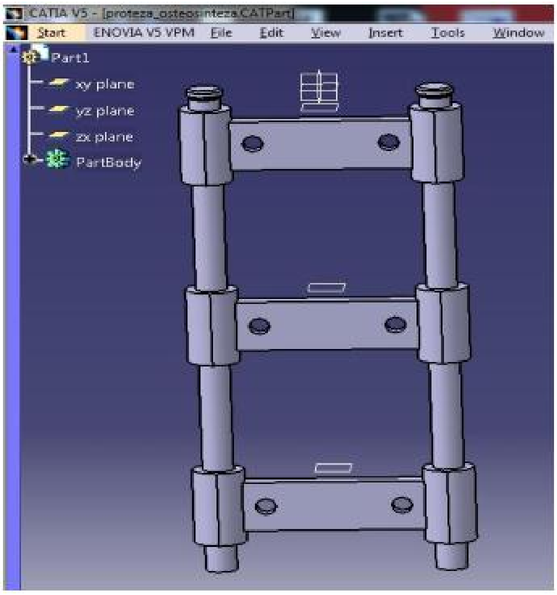

Figure 4: The first system (PCP-01-M) [5].

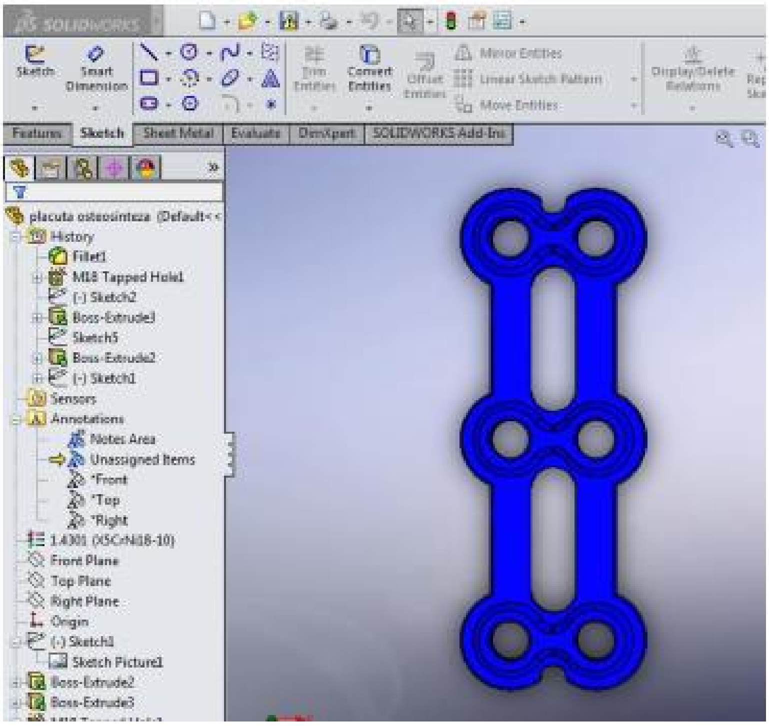

Figure 5: The second system (PCP-01-M) [5].

If the development of the first system were used for classical technologies (such as cutting, drilling, turning and welding) for the second preferred system to use nonconventional technologies (cutting water jet machine) **-** Figure 6. Cutting Water Jet Machines is at Research and Development Institute of *Transilvania* University (ICDT) in L3 Laboratory.

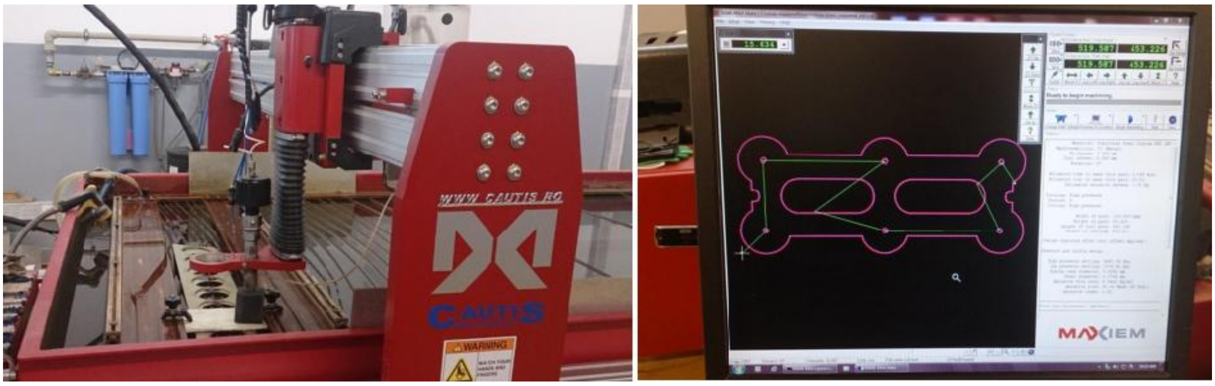

Figure 6: Cutting Water Jet Machine (*ICDT*, Laboratory –L3).


Figure 7: PCP-02-F and PCP-01-M Systems.

4. CONCLUSION

PCP-02-F device was carried out on a CNC milling of the same material (316L steel) but the time for achievement was triple. The devices were subjected to a Finite Element Analysis (FEA) using CATIA V5R19 software (only in static) to observe the behavior of the material at peak loads that occur in the cervical area; the results were good.

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