TRABAJO FIN DE MASTER EN INGENIERIA BIOMEDICA

DESIGN OF A TESTING MACHINE TO EVALUATE THE BEHAVIOR OF SPINAL IMPLANTS IN CADAVERIC SAMPLES

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Léo Fabre

Abstract

State of the art: In our evolving society, low back pain has become the first cause of years lived with disability around the world, especially in the more developed countries. When the pain is unbearable, the rising solution is to undergo a surgical operation where a spinal implant will be fixed on the patient's spine. In this context, the study of modern clinical biomechanics of the spine started four decades ago and new testing apparatus and testing conditions for the implanted spine emerged. Unfortunately, no standards are defined, and the industrial testing machine are extremely expensive.

Material and methods: The design of the structure of a new testing machine was carried out with Solidworks, based on a previous version build 18 years ago in the IBV. And the implementation of a stepper motor for the loading phase, as well as a code to synchronize the activation-deactivation of the motor with the activation-deactivation of the recording system, was achieved with Arduino. All the parts of the testing machine were meticulously chosen based on information from the scientific literature, a scientific monitoring carried out with the datasheets of the different products, and past experiences of my tutor and myself.

Results: The design of the new testing machine was achieved and presented with the assembly instructions and the test protocol. A cost analysis was carried out to estimate the necessary budget and compare the price of the designed apparatus with the ones encountered in industrial companies. This work is concluded by a list of recommendations and future improvement ideas.

Keywords: Spine, testing machine, spinal implants, design, cadaveric samples.

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CHAPTER 1. State of the art

1.1 Vertebral Column

The spine, also known as vertebral column, is the part of the human body that enables a straight standing position. It is composed of 33 vertebrae which can be classified in five different groups. Each of these five groups correspond with one region of the spine which is characterized by a specific curvature.

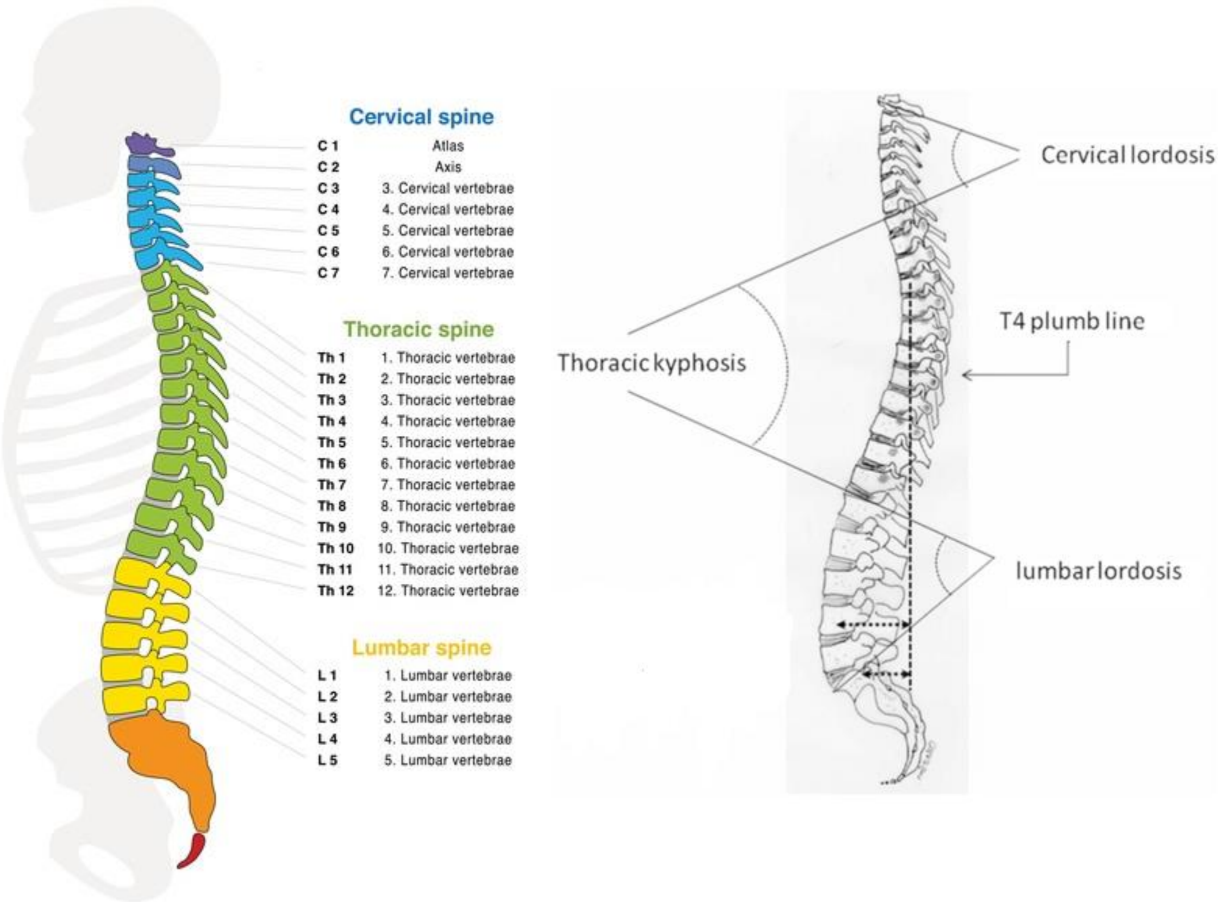


Figure 1. Left: Listing of all the vertebrae in the human body by regions. Right: Plumb line that defines sagittal balance and the three curvatures of the spine. (Clinic, 2017)

The first region is called the cervical spine which consists of seven vertebrae including the Atlas and the Axis. Directly below is the thoracic spine, the longest of the five regions, with its 12 vertebrae. As the last non-fused region, the lumbar spine is composed of five vertebrae. Finally bellow this last region is located the sacrum with 5 fused vertebrae and the coccyx with 4 fused vertebrae (Wikipedia, 2019).

The curvatures of the human spine are called, in order from top to bottom: cervical lordosis (C1 to C7), thoracic kyphosis (T1 to T12), lumbar lordosis (L1 to L5) and sacral kyphosis which can be separate in sacrum and coccyx. It can be observed that each region has curvature opposed to its previous and following regions.

The purpose of the vertebrae is to give strength and flexibility to the human spine. From C1 to L5 the vertebrae have mostly the same complex structure made of bone and hyaline cartilage with only a variation in shape, depending on the spine's region, and proportion of the two components, as shown in Figure 2. The different shapes directly influence the range of motion around one vertebra.

(a) *(b)* *(c)*

Figure 2. (a): cervical vertebrae. (b) thoracic vertebrae. (c) lumbar vertebrae (GetBodySmart, 2019).

The cavity inside one vertebra is called the vertebral foramen and is composed of the vertebra's body and the vertebral arch. It is through this opening that the spinal canal, which contains the spinal cord, goes. In this way, the nervous tissues which form the spinal cord, an important part of the central nervous system, are protected.

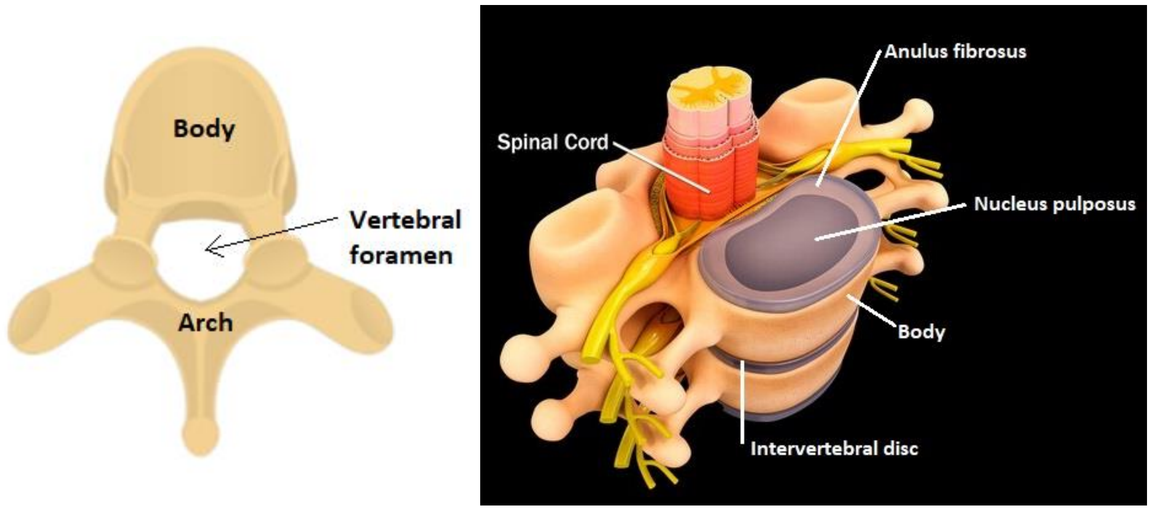


Figure 3. Left: Components of a vertebra. Right: Section of the spine.

Each vertebra is linked to others by means of the intervertebral disc which function is the one of a fibrocartilaginous joint. Like a ligament, this disc holds two adjacent vertebrae together and enable slight movements between the two. As the anulus fibrosus is mostly composed of fibrocartilage (type I and type II collagen) and the nucleus pulposus of loose fiber in gel, the intervertebral disc serves as a shock absorber for the spine.

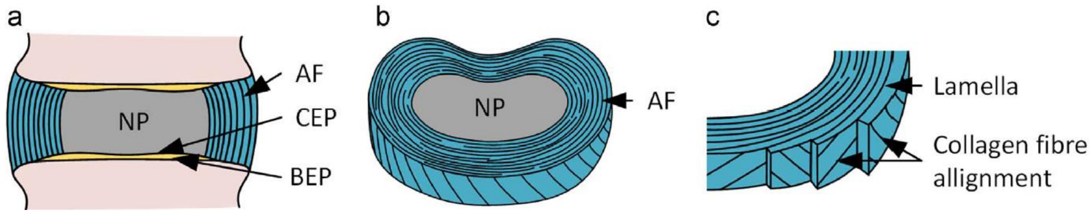


Figure 4. Gross anatomy of a disc. (a) Cross section of a disc in the coronal plane. (b) Diagram of a transversely sliced intervertebral disc. (c) Diagram showing the alternating fiber alignment in successive lamellae. AF: anulus fibrosus. CEP: cartilaginous endplate. BEP: bony endplate. NP: nucleus pulposus. (Newell, 2017)

1.2 Spine disorder

The Global Burden of Disease (GBD), which estimates mortality and disability from major diseases, injuries and risk factors around the world, published a study in 2017 showing that the first cause of disability around the world was low back pain.

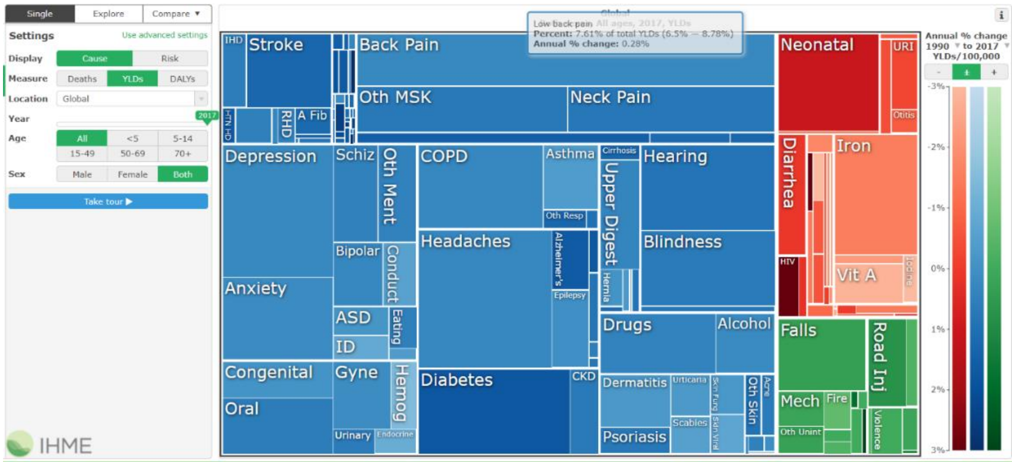


Figure 5. Treemap visualization of the causes of Years Lived with Disability (YLDs) *(Disease, 2017)*.

Figure 5 shows a treemap with all the known causes of years lived with disability around the world in 2017. With 7.61% of the total, back pain was the number one causes of YLDs around the world in 2017.

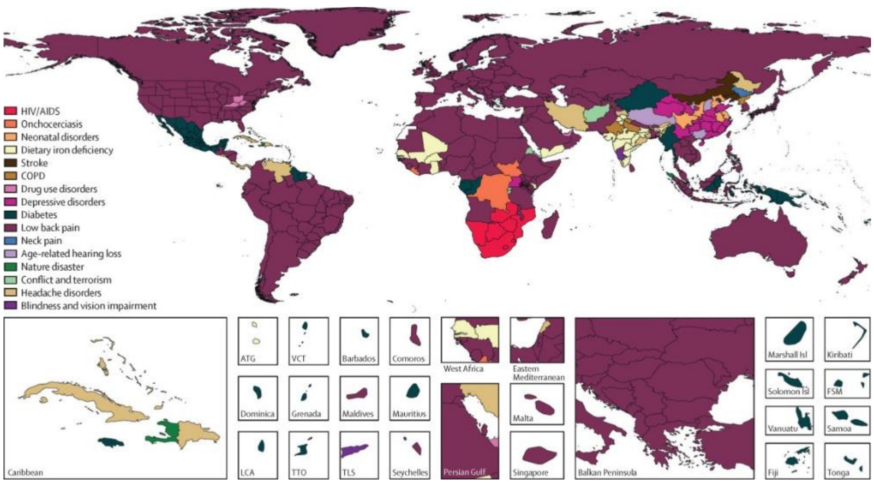


Figure 6. Leading Level 3 causes of age-standardized YLD rates by location for both sexes combined in 2017 (James, 2018)

Figure 6 shows that for most countries in the world, the first cause of YLDs is low back pain. There are two types of origin for it. The most common one is due to sprains and strains, normal wear and tear that occurred in the bones and discs, as well as sciatica (Figure 7). The second one is due to infections, diseases and tumors (Figure 7).

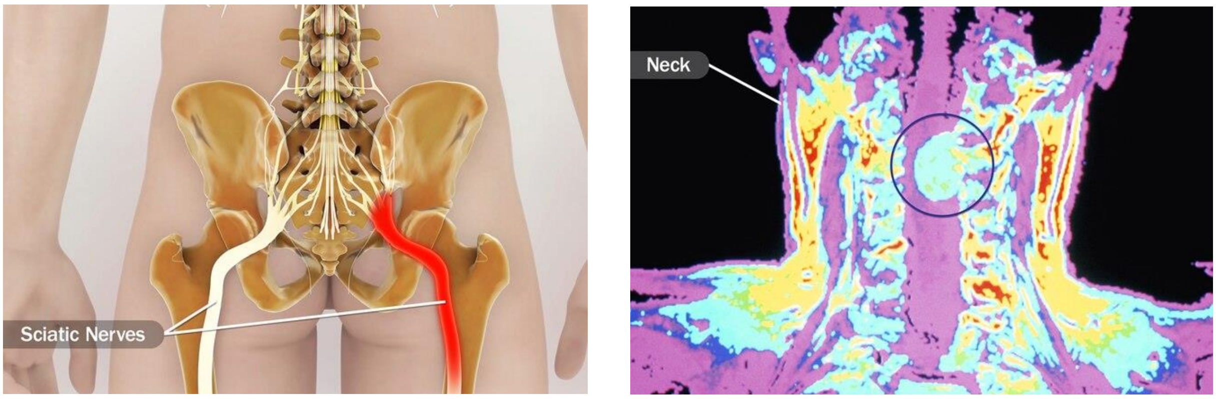


Figure 7. Left: Sciatica. Right: Cervical spine tumor.

For some cases, a simple spinal manipulation, session of acupuncture or nerve block therapy is usually enough to heal the patient. But in the more severe cases, when these therapies have failed or weren't enough, surgery becomes the best option to relieve the patient from the pain and from his/her disability.

1.3. The spinal implants

The spinal implants have three major functions, the first is to correct important deformities of the spine, the second is to strengthen and improve its stability, and the last is to facilitate the fusion of 2 vertebrae. They can later be categorized in several groups:

- Rods, which are used with screws and hooks in the aim of immobilize involved spinal levels and to contour the spine into a correct alignment. They are strong but can be shaped to contour the patient's spine.

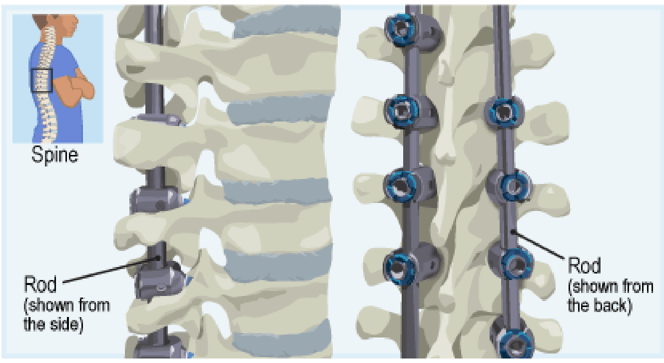


Figure 8. Fixed Rods on the thoracic spine (Shah, 1995)

- Pedicle screws, which are implanted into the pedicles of the spinal vertebrae. They enable the rods to be fixed and to contour the spine.

Figure 9. Fixed pedicle screws on the lumbar spine.

- Hooks, which play the role of anchor to the vertebrae for other implant’s parts

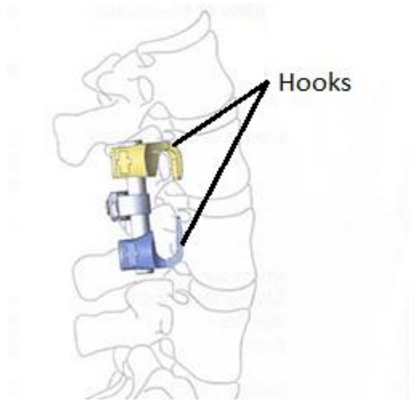


Figure 10. Example of hooks on the lumbar spine.

- Plates, which are mostly used in cervical spine and contour the patient’s spine

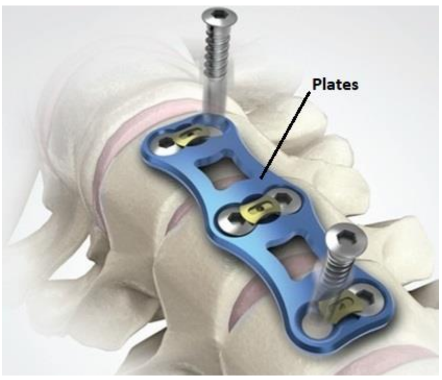


Figure 11. Fixed plates on the cervical spine.

- Cages, which are placed between 2 vertebrae and packed with bone graft to promote bone growth between these 2 vertebrae.

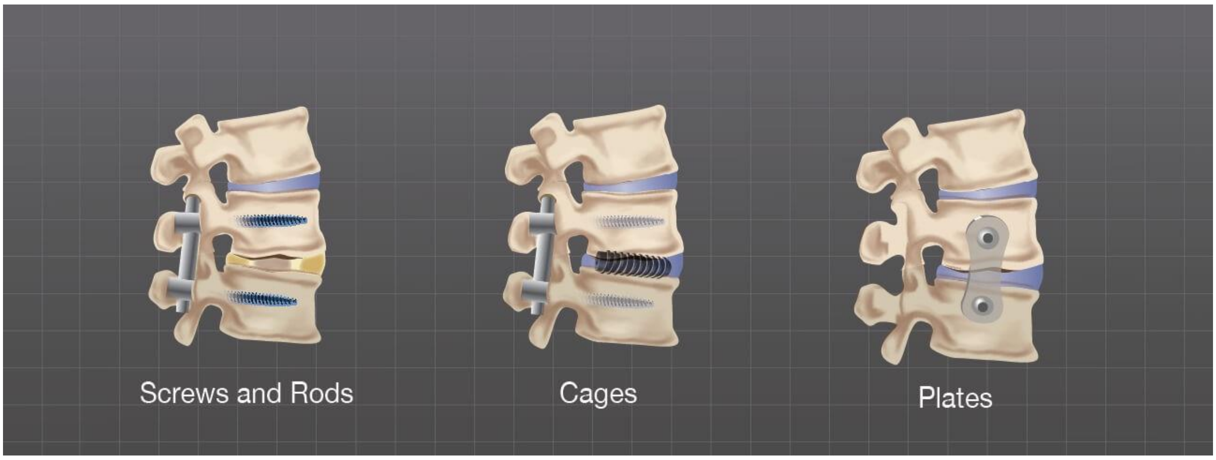


Figure 12. Comparation of three different types of lumbar spine implants.

In the last 10 years, the spinal implants market increased drastically to reach US$ 14 billion in 2018 (MedSuite, 2019) and is expecting to keep rising at a 7% compound annual growth rate (CAGR) to exceed US$ 19.5 billion by 2024, according to a recent Market Research Engine Report (ResearchEngine, 2018). Worldwide it is North America which dominates the spinal implants market in 2018 with more than 40% share, followed by Europe. The growth in these regions can be explain by three major factors:

- an increase of spinal disorder, due to an aging population and the development of a society which incite to gain weight and minimize physical efforts.
- the development of new technologies for the treatment of spinal disorder.
- the increasing awareness of these technologies.

The Asia-Pacific region, which still represents a small share of the spinal implant market, is forecasted to grow with the higher CAGR in the next 5 years. This is driven by the largest patient population, and an increase in healthcare expenditures and coverage.

In the US and Europe regions, the leading companies on the market are Medtronic and DePuy Synthes, followed by Stryker, Zimmer Biomed and others (MedSuite, 2019). Even though Medtronic had the strongest lead since its acquisition of Kyphon in 2007, DePuy Synthes rose just behind since the company creation in 2011.

1.4. Biomechanical testing of the spine

1.4.1 Major trajectory of scientific papers

The first significant publication on the study of the biomechanics of the vertebral column date back to 1978 and is called "Clinical Biomechanics of the spine" by Augustus A. White and Manohar M. Panjabi (Panjabi & White, 1978). In this book, they meticulously described and explained physical properties, function and kinematics of the spine; as well as different types of trauma, diseases and implants for each region of the spine. This publication was widely used around the world as a groundwork for following studies, reviews and books about the biomechanics of the spine.

Following this work, Panjabi and White kept studying this subject and published dozens of scientific articles. They also published a second edition of "Clinical Biomechanics of the spine" in 1990 where they added new materials adapted to the change of our society: the impact of vibration (road driving), the study of kyphosis deformity and updates of their first work (Panjabi & White, 1990). In the meantime, inspired by these two versions of Panjabi and White's book, the number of studies and publications about biomechanics of the spine rose drastically in the following years up until today.

Using the website Word of Science and the software Pajek, I created the major trajectory of scientific articles about the testing machine and conditions of the biomechanics of the spine. To do so, I chose the following keywords: spine, testing, biomechanical; and download all the 11382 articles found with the search browser of Word of Science. I then used CitNetExplorer to create a mapping of all the citation between the scientific papers. Finally, thanks to the software Pajek, I was able to model the major trajectory of scientific articles based on the three chosen keywords:

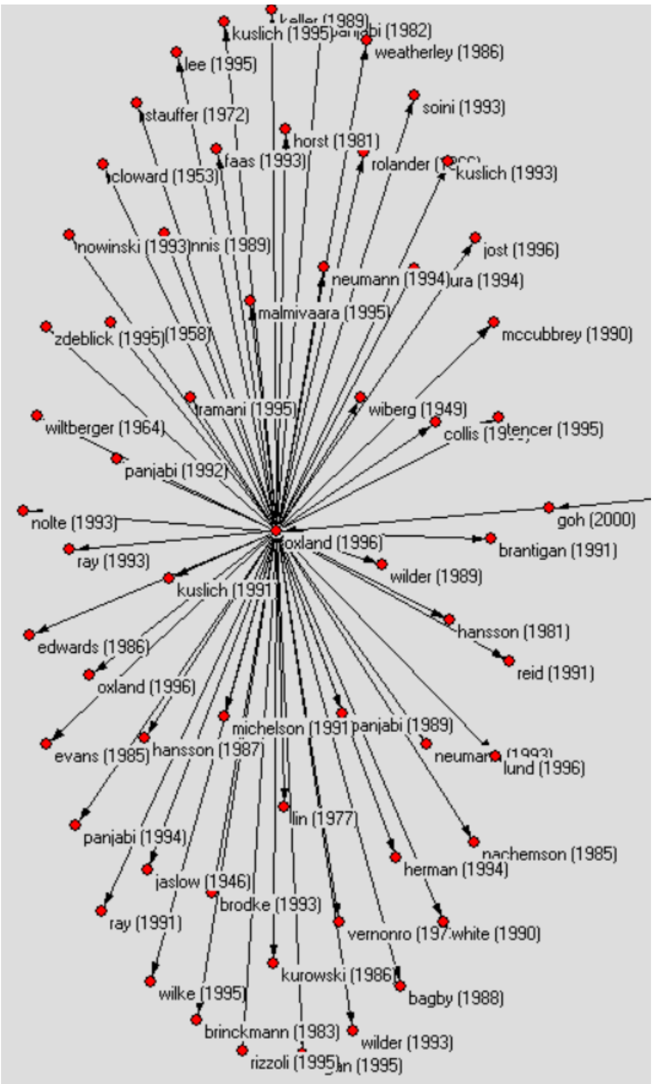


Figure 13. First part of the major trajectory of scientific articles about lumbar spine testing. From 1946 until 2000.

The first part of this trajectory forms a star with at its center, the article published by Oxland et al. in 1996. This article was a turning point in the study of spinal implants, the flexibility of an implanted spine, the testing conditions and the biomechanics of the spine (Oxland, 1996). Indeed, the star-shaped trajectory means that before this point, even though a lot of studies had been conducted and published, there was not enough significant connections between them to really make major progresses on this field. In all those significant scientific articles, the presence of four publications from Manohar M. Panjabi in 1982, 1989, 1992 and 1994, as well as on publication from Augustus A.

White in 1990, can be underlined. These two authors are considered to be the fathers of modern clinical biomechanics of the spine. In fact, in the first of its four most significant studies on this field, Panjabi explained that the knowledge of the biomechanics of all the components of the spine is essential to understand and characterize the mechanical causes of low back pain. In this publication, he focuses on the lumbar spinal ligament and created the first biomechanical model of it (Panjabi, 1982). Later, in 1989, his focus will be on the muscle forces (subject that had rarely been mentioned and studied), their role, importance and modeling, to improve the in vitro study of the biomechanics of the spine (Panjabi & Oxland, 1989). He was associated with Oxland on this work. In the continuation of these two publications, Panjabi published "The stabilizing system of the spine" in two parts in 1992. The first part was focused on its function, dysfunction, adaptation and enhancement (Panjabi, 1992); while the second part concerns the neutral zone and instability hypothesis (Panjabi, 1992). Finally his last major contribution to this trajectory of scientific articles was achieved in 1994 when he studied the "Mechanical behavior of the human lumbar and lumbrosacral spine as shown by three-dimensional load-displacement curves" with the help of Oxland (Panjabi & Oxland, 1994). The same year, Wilke et al. published their work on "a universal spine tester for in vitro experiments with muscle force simulation", which contains a description of the developed apparatus:

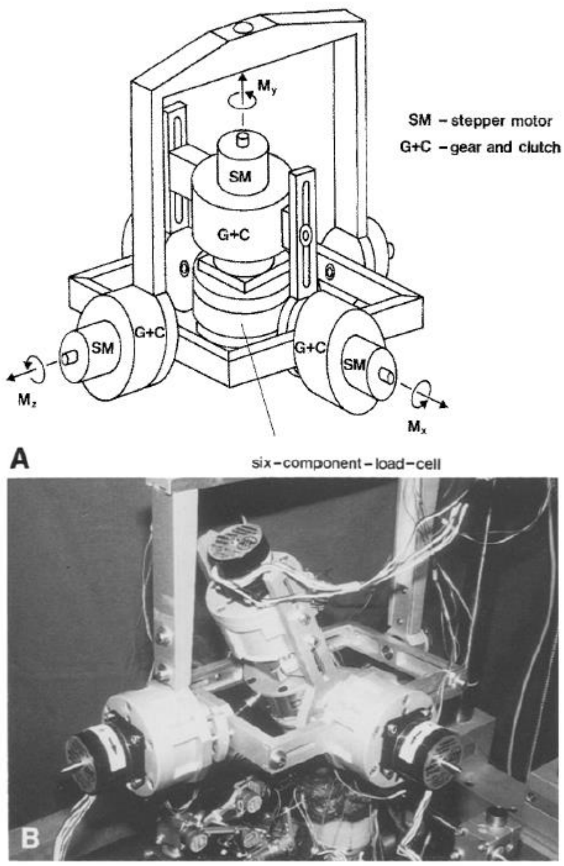


Figure 14. (A) Schematic diagram of the gimbal for external moments with stepper motor (SM) and gear and clutch (G+C) in each axis. The six-component load cell is adjusted in the center of the three axes. (B) Photograph of the gimbal with drive (Wilke, 1994).

This testing machine is capable of applying loads of pure momentum in the six directions: flexion-extension, right and left lateral bending, and clockwise and anti-clockwise torsion. It is one of the first test bench, designed for the biomechanical testing of the spine, to be described in a scientific paper.

These publications, as well as all the others present in the star-shaped representation, lead Oxland et al. to published in 1996 the article that will be the foundation of the major trajectory of scientific paper of this field: "The relative importance of vertebral bone density and disc degeneration in spinal flexibility and interbody implant performance. An in vitro study." (Oxland, 1996). In this article the author focused on the relationships between bone density and disc degeneration to characterize the biotechnical performances of interbody fixation techniques.

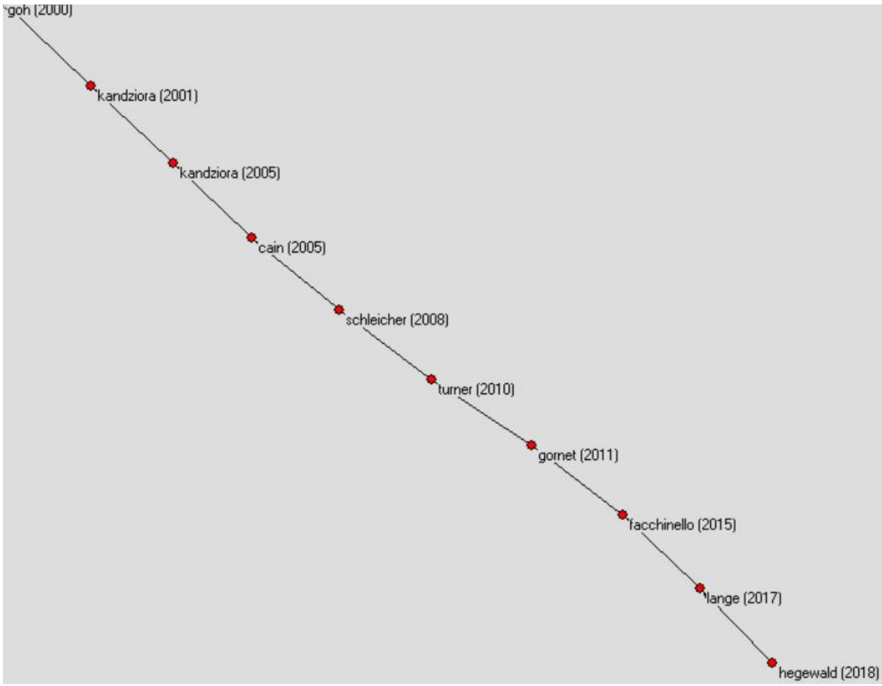


Figure 15. Second part of the major trajectory of scientific articles about lumbar spine testing. From 2000 until 2018.

Following the publication by Oxland et al. in 1996 and out of more than eleven thousands of publications, ten stand out from the rest in the last few years:

- The first one from Goh et al. is the "Influence of PLIF cage size on lumbar spine stability" published in 2000 where the author is looking "to determine the influence of increasing cage size on the restoration of spine stability after total facetectomy" (Goh, 2000). It was concluded that the cage size had a deep impact on the lateral bending and torsional stability of the lumbar spine.

- In the following year, Kandziora et al. compared "the anatomic, radiographic, computerized tomography, and biomechanical data of human and sheep cervical spines to determine whether the sheep spine is suitable for human spine research" and concluded that even though differences were obviously encounter, the sheep cervical spine (especially C3-C4) can be used for human cervical spine research (Kandziora, 2001). This helped develop a number of experiments, which were cheaper and more accessible, to characterize the stability of the lumbar spine.

- Four years later, in 2005, Kandziora et al. reviewed the biomechanical properties of the new Lumbar Facet Interference Screw (Kandziora, 2005). This was achieved by a meticulous review and comparison of established fixation techniques, leading the following authors to base their experiments on this work.

- The same year, Cain et al. published “A new stand-alone anterior lumbar interbody fusion device: biomechanical comparison with established fixation techniques” to support their hypothesis of a comparable stability between a new stand-alone device and old cage and screw devices (Cain, 2005). Again, a meticulous review of established cage and screws technique was carried out.

- In 2008, Schleicher et al. realized a “Biomechanical evaluation of different asymmetrical posterior stabilization methods for minimally invasive transforaminal lumbar interbody fusion” to understand that, even though they encountered differences, all tested methods could achieve the desired stability (Schleicher, 2008).

- Two years later, Turner et al. studied the “Spinal cord stimulation for failed back surgery syndrome [and the] outcomes in a workers’ compensation setting” (Turner, 2010). This is the only significant study in the major trajectory of scientific articles to focus on the outcomes of failed surgery following an injury.

- The following year, in 2011, Gornet et al. published the “Biomechanical assessment of a Polyetheretherketone (PEEK) rod system for semi-rigid fixation of lumbar fusion constructs” to demonstrate its durability, stability and strength (Gornet, 2011). In this study, we can observe one hand-made test bench for compression testing of the lumbar spine:

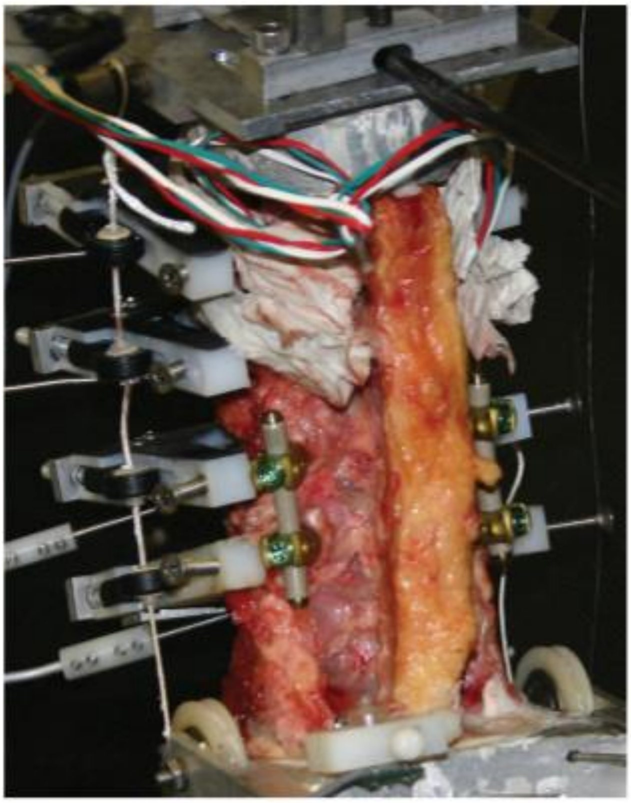


Figure 16. Cadaveric biomechanical testing of a lumbar spine with L4-L5 instrumentation.

- In their publications of 2015, Facchinello et al. find that “the differences in rod properties had a moderate impact on the biomechanics of the instrumented spine when only pedicle screws were used.” The only noticeable difference appeared when “transverse process hooks were used as proximal anchors” (Facchinello, 2015). During their study, they developed a test bench capable of applying flexion-extension and lateral bending load. This apparatus could reach a speed of 1degree/s, keep a constant rotation speed for all the duration of the experiment, but was not able to apply torsion loads.

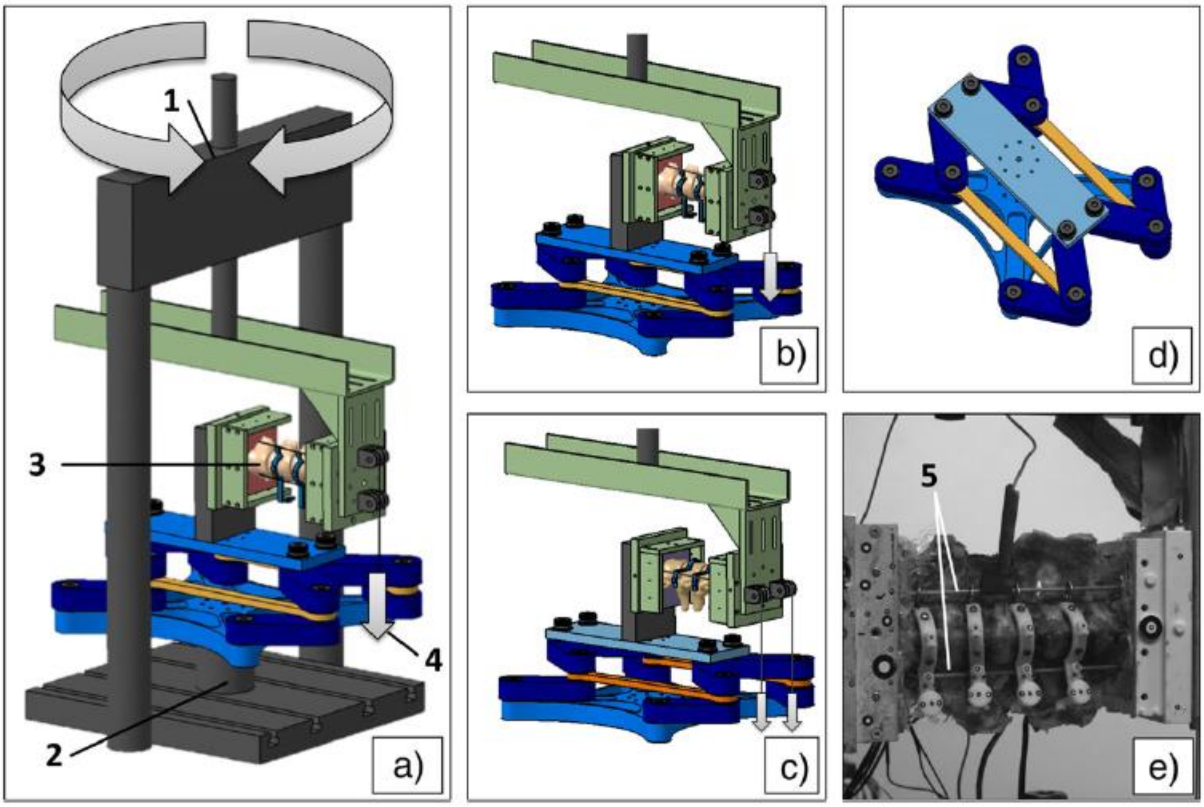


Figure 17. a) Spinal testing apparatus used to apply continuous loading with (1) axial and torsional actuators, (2) load cell, (3) specimen and (4) follower load. Specimens can be loaded in flexion-extension (b) and lateral bending (c). Translation table (d) and specimen with markers installed (e), ready for flexion-extension loading with (5) cables defining the follower load path (Facchinello, 2015).

- In their biomechanical study two years later, Lange et al. compared "different proximal implants designed to gradually reduce the stiffness between the instrumented and non-instrumented spine" and found that implants-spinal bands and cerclage wires could reduce the rigidity compare to other types of implant (Lange, 2017).

- Finally, the last noticeable scientific paper was published last year in 2018 by Hegewald et al. In their "Biomechanical investigation of lumbar hybrid stabilization in two-level posterior instrumentation", they discover that this new strategy called hybrid stabilization help reduce significantly the amount of compensatory movement compare to a rigid fixation technique (Hegewald, 2018).

1.4.2 First testing machine designed by IBV

A first testing machine for in vitro spine evaluation was designed 18 years ago by Katrina West with the help of the Instituto de Biomecanica de Valencia (IBV) (West, 2001). This test bench was supposed to allow the flexion-extension, clockwise and anti-clockwise torsion as well as right and left lateral flexion of the lumbar spine by application of pure momentums by steps of 2Nm from 0 to 8Nm.

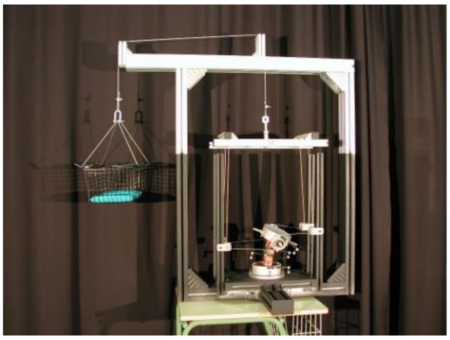


Figure 18. First version of the testing machine designed 18 years ago.

In this machine, the base of the lumbar spine needed to be fixed to the structure to be immobile while the top was connected directly to the pulley system. Once the cadaveric sample was ready, the momentums were applied by putting weights on the basket (left on the photo of Figure 17) to reach 0, 2, 4, 6 and 8 Nm and be able to analyze the evolution of the rotation angle of the lumbar spine. Indeed, once the basket contains the weight it pulls on the cable, raising the squared structure which pulls on the four cables linked to the top of the sample, allowing it to move through the pulley system.

To analyze the vertebrae’s movement and the range of motion (ROM) of the spine, they used a technique called stereophotogrammetry. It consists in estimate the position of all the points on an object in a three-dimensional coordinates system based on two or more photographs taken from different positions (Wikipedia, 2019). This technique is non-invasive, fast, reliable and was described for the first time for the lumbar spine by Morris et al. in 1985. In this study, Morris concluded that this method proved to be a useful tool for the postoperative monitoring of patients requiring fusion procedures (Morris, 1985). Because of its rapidity to collect the data and the high accuracy of the mapping, it was decided to also use this technique for the recording of the experiments.

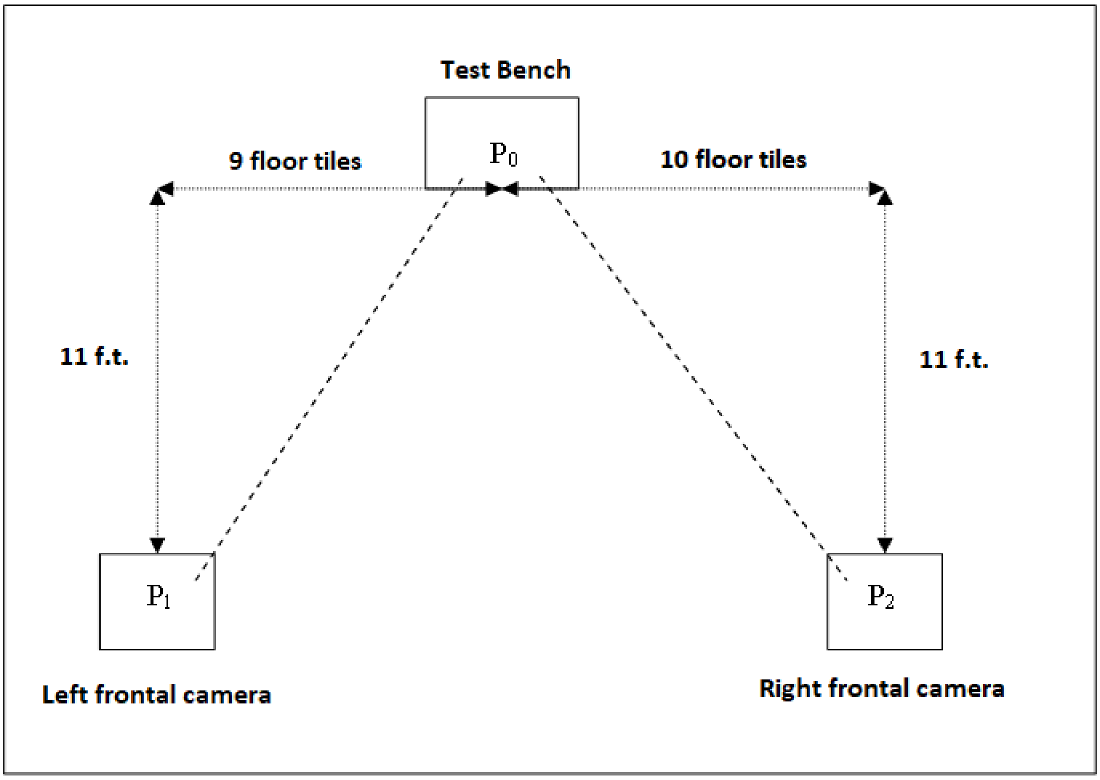


Figure 19. Disposition of the recording cameras in the first version of the testing machine (West, 2001).

During the experiments conducted with the first version of the testing machine, some problems occurred:

- The application of the loads by rounds of 2Nm made impossible the comparison of the results for the deformation angles with the existing studies. Indeed, the loads application was not continuous but rather conducted in fits and starts. Also, it made the control and application of a desired force or momentum extremely difficult.

- The structure was not stable, as the loading system was located on the left of the apparatus, during the experiments the structure was moving. The smaller legs formed an angle that reached almost 30degrees in the worst cases for loads of 8Nm. This would perturb the results and considerably changed the value of the apply loads on the cadaveric samples.

- The duration of one experiment was extremely long due to the manual loading, recording, and because the cadaveric samples were directly fixed inside the structure with PMMA, it requires a few hours of cleaning and preparing a new sample between two series of tests.

CHAPTER 2. Problem

In most cases the doctors choose the option of a surgery and a spinal implant for their patients when living with back pain is unbearable for them. Thereby, the spinal implant offer the opportunity to relieve the patient from a constant pain, stabilize his/her spine and back, as well as an alternative of long-term pain medication (a solution that both, patients and doctors, always want to avoid).
But the choice of undergoing a surgery to fix a spinal implant on a patient isn't without any risks. Other than the usual risks linked to surgery, several studies underlined the loss of motion in the torsion and flexion of the spine (Bisschop, 2013) (Landi, 2013), a recurrent pain which can appear from the leg up until the neck, a failure in spinal fusion and stabilization leading to more surgeries with of course more risks for the patient (Lee & Choi, 2015), a failure of the implant and infection at the pedicle screws location which have life damaging consequences for the patient.

Therefore, it is necessary to possessed systems that allow studying the kinematic and dynamic behavior of the column in an environment that reproduces the in vivo conditions. For this, it is necessary to use cadaveric samples in which the implants can be placed and apply similar loads to the physiological ones in a controlled way to study the deformation and rupture of the spine.

Even though such systems already exist, there is no internationally agreed model or test bench. Some of these systems have a purpose of research and investigation, such as the ones developed by Wilke et al. in 1994 (Wilke, 1994), by Gornet et al. in 2011 (Gornet, 2011) and by Facchinello et al. in 2015 (Facchinello, 2015). Each of them is extremely different from the other and there is no reviews or comparison of the results obtained with these test benches. The other existing systems are the one designed for an industrial purpose and used by companies such as Zwick Roell or Instron. These apparatuses are extremely efficient, precise and enables the testing of lumbar spine and spinal implants at a wide range of speed and loads. Their major problem is that they are extremely expensive: most of these machines cost more than 50 000€.

CHAPTER 3. Objective

Into the project, we are going to design a cadaveric spine testing machine capable of evaluate and compare against intact column the loss of motion and stabilization of the spine with different kind and brand of implants, as well as the resistance of these lasts under a normal range of motion. To resolve the problem mentioned earlier, we are going to design this testing machine so that it is simple to use, cheap and with enough precision to compare different implants/spines. The tests will be realized on cadaveric samples; therefore, the difficulty is to reproduce the in vivo conditions as well as possible.

Partial objectives:

- Update and design the elements from the first version of the testing machine to improve its use, the quality of the results and reduce the experiments duration.

- Implement the use of a motor to conduct the application of pure forces and pure momentum on the cadaveric samples.

- Design an electronic system capable of automating the process of activation/deactivation of the stepper motor and the recording cameras. The two needs to be started and stopped synchronously.

- Conduct a cost analysis of the all project to estimate the budget needed and to compare it to the price of an industrial testing machine.

CHAPTER 4. Material, method and partials results:

4.1 Design of the testing machine:

4.1.1 Design of the structure:

Starting from the pictures and leftover pieces of the first spine testing machine, I realized the design of the new version of testing machine on Solidworks 2018.

As before, I used the Bosch Rexroth library for the profiles, connectors and caps of the structure:

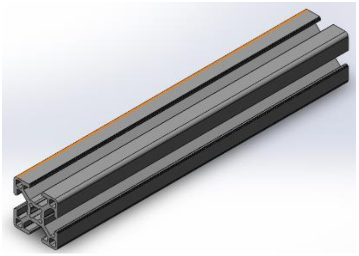


Figure 20. Profile Rexroth-3 842 990 720_200mm

The profile Rexroth-3 842 990 720_200mm was chosen for its adapted size, resistance and 360° possibility of use.

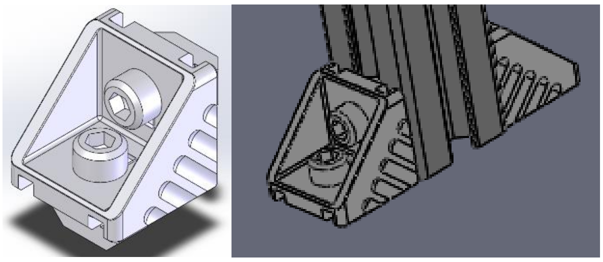


Figure 21. Connectors Rexroth-3 842 523 528_30mmx30mm

The first small connector (Rexroth-3 842 523 528) was used for the internal structure and on the moving one. It was chosen because of its strength, maneuverability, as well as its capacity to fit the selected profile. To avoid movements of the internal structure, which could false the values and make the experiments useless, I decided to double the number of connectors around the base of the internal structure. These extra connectors are put on the other side of the four legs, in the same direction as the first but looking backwards.

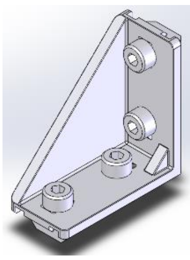


Figure 22. Connector Rexroth-3 842 523 541_60mmx30mm

The second big connector (Rexroth-3 842 523 541) was chosen for the external part of the structure which needed a better fixation to the base plate because of the height and weight it carries. As the external part only play a role of support for the motor, the cables don't affect part of this structure, the stability can therefore be obtained with only one connector on each leg.

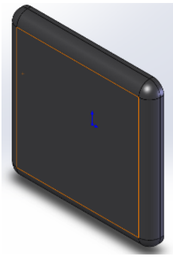


Figure 23. End cap black Rexroth-3 842 501 232

The cap was chosen to fit the selected profile.

I designed the rest of the pieces of this machine myself. One of the most important one is the part where the top of the spine is fixed. It needs to be symmetrical, so that it can make 90° turns and still be functional for the different movement constraints. It also has holes along the two symmetry plans to put the pulleys that allow flexion, extension, and lateral bending. The rest of the screw holes are for fixation. Finally, a groove was designed all around the external profile of the head piece for the cable to fit during the torsion tests:

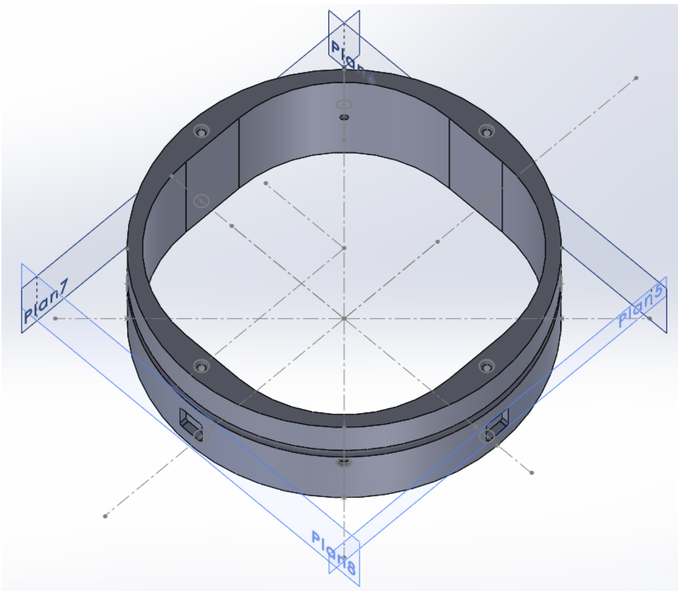


Figure 24. Head part of the structure designed with Solidworks.

In the last version, the fixation material was directly in contact with the metal of this head piece, this caused a major time consuming problem: the operator needed hours to clean the metal so that it can be used again for another experiment, it was an arduous job which left marks on the metal from scraping. And even then, small bites of the fixation material were still visible, leaving the head piece scratched and dirty after hours of cleaning process. To solve this problem, I created an inner piece inside the head one:

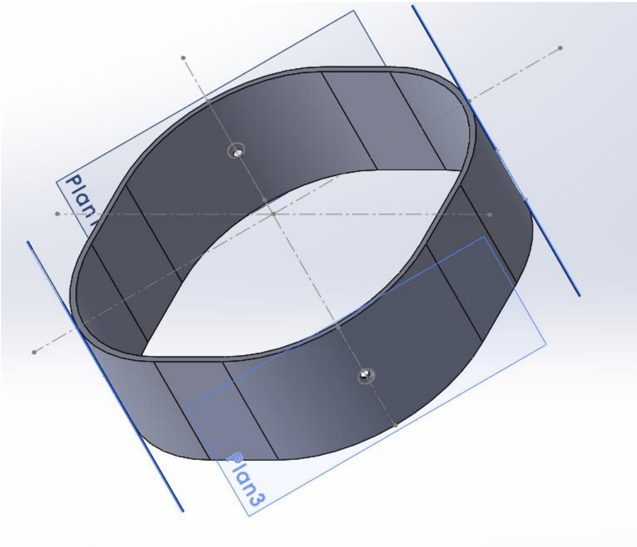


Figure 25. Inner piece which fits inside the head part and the bottom part. Designed with Solidworks.

Thanks to the production of multiple inner pieces, it is possible to do a series of experiments without stopping and clean the used inner parts at the same time, which save time and keep the head piece clean and hundred percent functional during all the experiment.

To finish the head part, I created four metal sticks that can be fixed on four different sites along the two symmetry plans. They are designed to receive the two pulleys on which the cables will be fixed during the flexion, extension and lateral bending tests. Because of the symmetry of our components, to realize all tests on one sample, we simply have to take the pulleys out, do a 90° turn of the inner head and inner bottom, and put them back in. Like that we can go from flexion/extension to lateral bending quite easily:

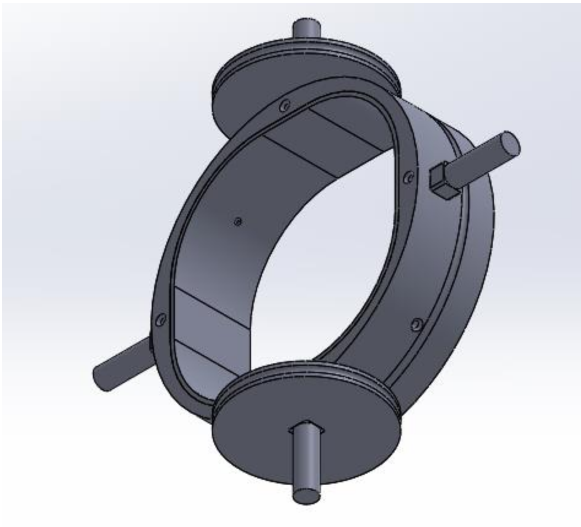


Figure 26. Head part with the four metal sticks and the two pulleys.

For the base piece, where the bottom of the cadaveric sample is fixed, I also used the same inner part to solve the problem of the first version. Furthermore, to offer a better stability and improve the measures, I decided to combine it with a bigger pedestal which is then screwed to the base plate. Thanks to the thickness of this pedestal, we get rid of the slight movements observed during the first experiments with the old version of the testing spine machine:

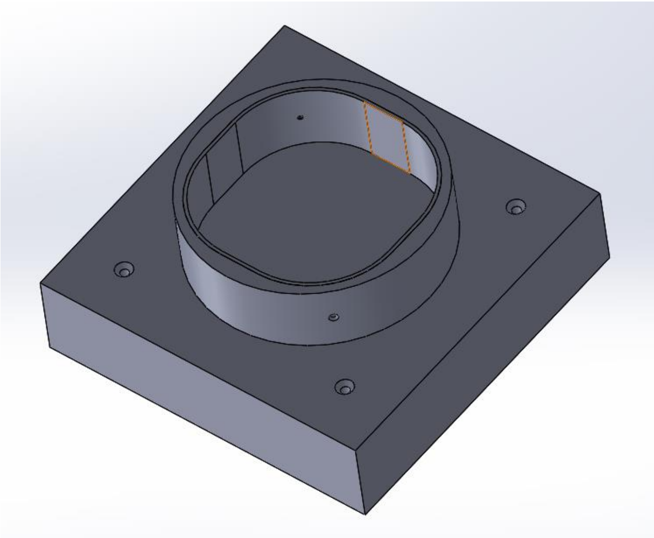


Figure 27. Bottom part of the structure designed with Solidworks.

To surround the lumbar spine once it is fixed inside the two last pieces, I designed four legs which are directly screwed to the base plate and equipped with small pulley where the cables fit from the head piece to the moving part. In the last version one of the problems encountered was that the legs only had one fixation at their base and during the experiments, because of the forces and momentum applied, they were moving up until doing an angle of 30 degrees. This results in a loss of force and momentum on the spine and makes the estimation of the values we apply on the cadaveric sample very difficult. To resolve this problem, I decided to use some stronger and larger connectors, and to put two of them at the base of each leg, in the same direction of the cables.
At 20cm from the bottom of the leg, I fixed two plates on each side to hold the small pulley where the cable fit. The distance 20cm was chosen for cadaveric samples of lumbar spines, but it can easily be shortened in case we want to experiment on cervical or thoracic spines, which are usually shorter samples.

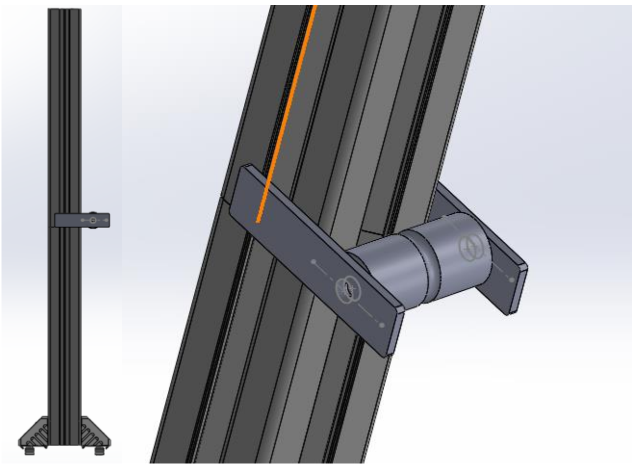


Figure 28. Smaller leg of the structure with a small pulley at 20cm from the bottom. Designed with Solidworks.

On top of those four legs, we can find the moving part of the test bench. After the cables pass around the pulleys attached to the legs, they go up and are fixed to this moving part. Then there is only one cable linking the motor and the rest of the test bench. This piece has a rectangular shape and is blocked with connectors to avoid any deformation during the experiments. It possessed two aluminum bars which are grooved on each side for the cable to be attached. In the center of the part, a thicker and stronger bar is placed to hold the hook which is linked to the motor by a unique cable. While the bars holding the cables are assembled thanks to a small connector I designed, the center one pierces the profiles on each side and is fixed by using two bolts. As it is only moving vertically, the possible rotations are prevented once all the cables are taut.

4.1.2 Design of the moving part and deformation calculus:

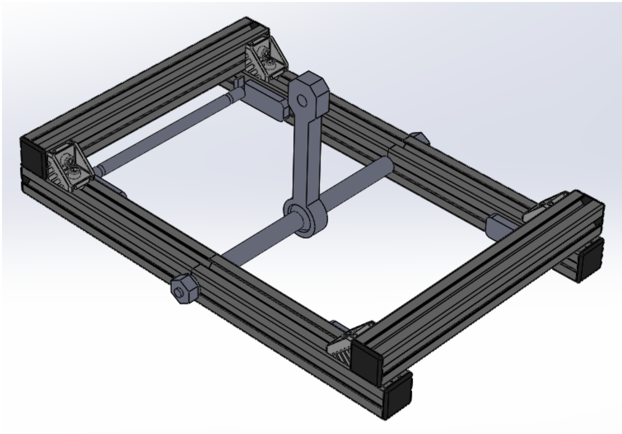


Figure 29. Moving part of the testing machine designed with Solidworks.

The only deformation that could be problematic is a bent in the profile at the center bar's level. Indeed, being pulled down at the four extremities by the cables connected to the samples and pulled up at the center of the profile by the cable connected to the motor, a deformation occurs. To estimate this deformation, first I calculated the force that the motor applies on the cable:

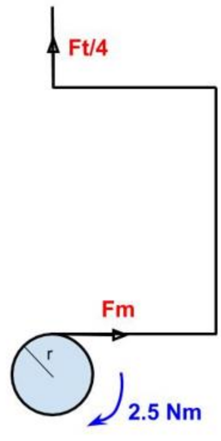


Figure 30. Schema of the momentum and force applied by the stepper motor on one cable and one pulley.

As I designed the pulley, the radius r is known and equal to 33mm. The maximum value of the pure momentum applied to the cadaveric sample was chosen at 10Nm as it is the highest recommended value for testing lumbar spine in Lange et al. (2017), which means that each of the four cables applies a pure momentum of 2.5Nm (Lange, 2017). Other studies decide to stop at 7.5Nm (Wilke, 1996) (Hegewald, 2018). We stay far from the deformation and instability values described by Oxland in his study "Fundamental biomechanics of the spine", which are 80Nm for the lumbar spine and 12Nm for the cervical spine (Oxland, 2016), but by choosing 10Nm we make sure to have the wider range of

tests possible without causing permanent deformation to the cadaveric samples.
To calculate Fm, we use the momentum formula:

$$M = rFsin(\theta) \qquad \textit{Equation 1}$$

Which gives us directly the formula to calculate the force:

$$F = \frac{M}{rsin(\theta)} \qquad \textit{Equation 2}$$

As the cable is attached to the pulley and taut, the value of the angle θ is 90°, as a result the sinus of θ is equal to 1. We can them calculate the force Fm applied on the cable when the cadaveric sample is subjected to a pure momentum of 10Nm, as there are four cables pulling in the same way and the structure is symmetrical, this represents a pure momentum of 2.5Nm per cable:

$$Fm = \frac{2.5}{0.033} = 75.8N \qquad \textit{Equation 3}$$

We suppose that the cable retains its shape during the experiments and that it is tense at all time. By the principle of force conservation, we can claim that:

$$Fm = \frac{Ft}{4} \qquad \textit{Equation 4}$$

Indeed, as there are four cables joining the moving part, following the principle of force accumulation, we obtain the total force induced by the motor in the case of a pure momentum of 10Nm on the lumbar spine:

$$Ft = 4Fm = 4 * 75.8 = 303N \qquad \textit{Equation 5}$$

The total force induced by the stepper motor on the cable is 303N. To avoid a loss in rotation speed of the motor by using it to close of its maximum capacities, it is recommended to adopt a security coefficient of 4. Therefore, the chosen motor will need to have the capacity on applying a maximum force of 1212N. In a second time, I assimilated this moving part to a pair of simple girders immobilized at their extremities (cables pulling down) and receiving a force in their center from the motor.

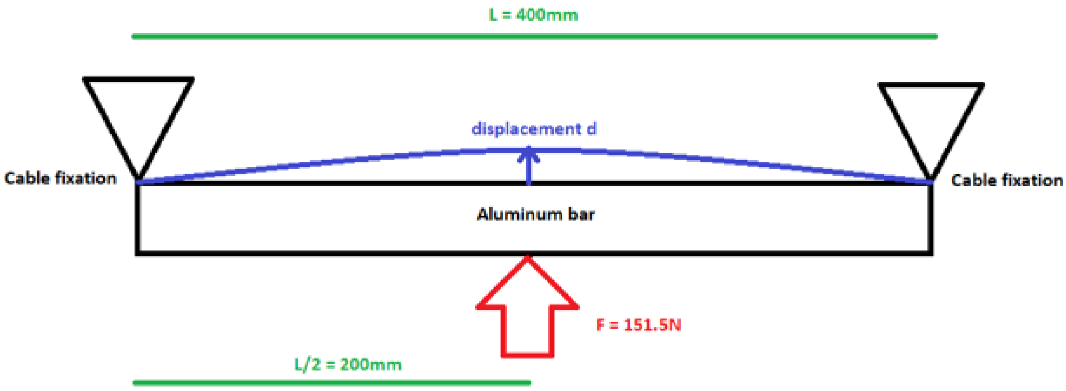


Figure 31. Representation of the applied force on the aluminum bar and the displacement generated.

In this case, as the shearing displacement is overlooked, the curvature and its radius are directly dependent of the flexion momentum, the quadratic momentum (I) and the Young's modulus of aluminum (E). By the resolution of a differential equation, we obtain the following formula:

$$d = \frac{FL^3}{48EI}$$ *Equation 6*

Here for a maximum pure momentum on the cadaveric sample of 10Nm, we need a force of 303N which equates to 151.5N per aluminum bar due to the symmetry of the design. Each bar of the moving part is 400mm in length and has a squared profile of 30mmx30mm. According to the literature, the Young's modulus of aluminum is 69GPa (Wikipedia, 2019). And the quadratic momentum I is given by the following formula:

$$I = \frac{b^4}{12}$$ *Equation 7*

The calculation of I and d gives us:

$$I = \frac{0.03^4}{12} = 6.75 * 10^{-8} m^4$$ *Equation 8*

$$d = \frac{151.5 * 0.4^3}{48 * 69 * 10^9 * 6.75 * 10^{-8}} = 4.34 * 10^{-5} m$$ *Equation 9*

This deformation at the center bar's level is 43µm which represents around 0,01% of the center bar's length. With such a small value we can considerate this deformation as negligible and estimate that the profiles stay rectilinear during all the duration of the experiment.

Finally, the global design of the structure with Solidworks was achieved:

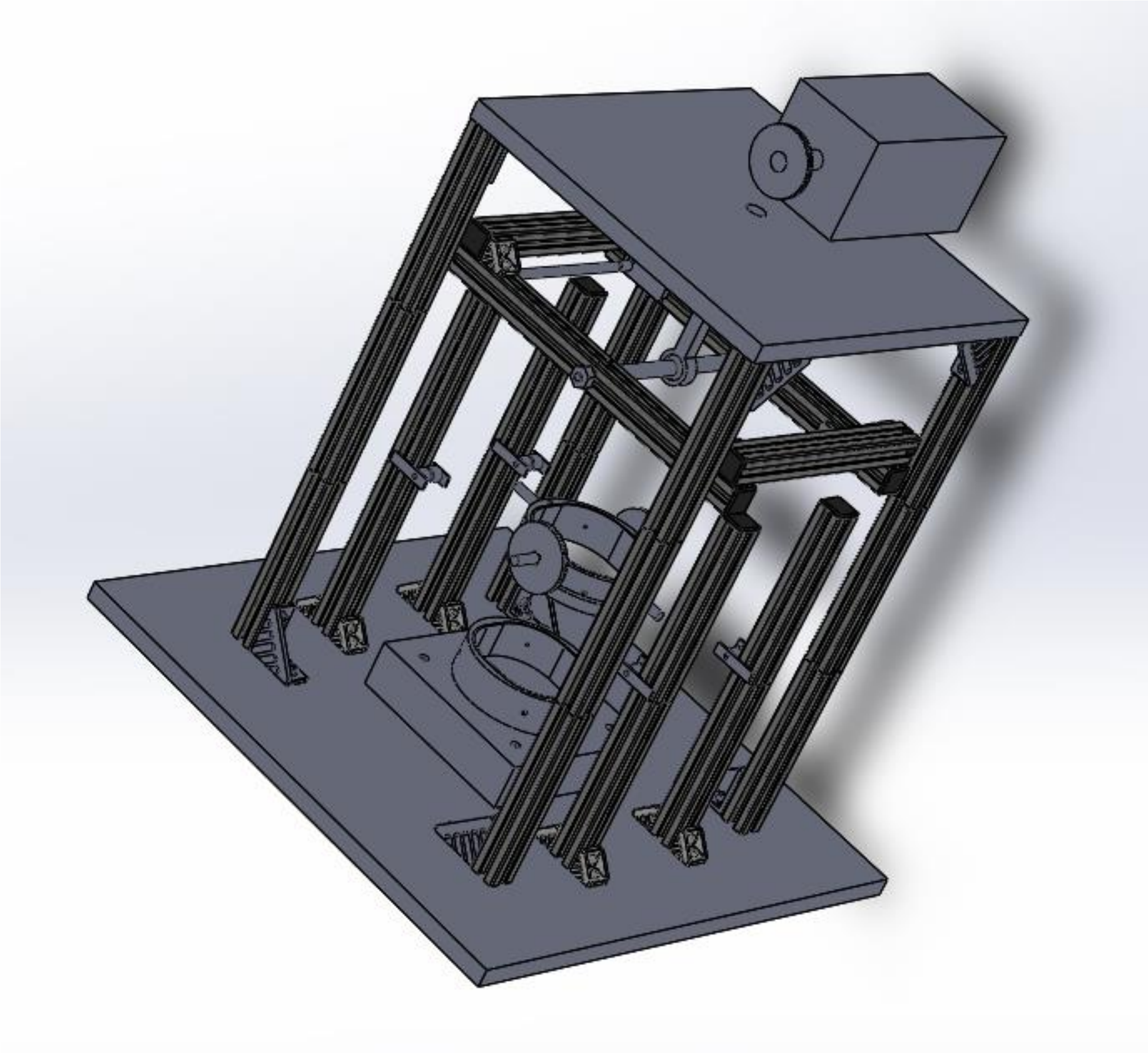


Figure 32. Structure of the new testing machine.

4.2 Electronics:

4.2.1 Motor:

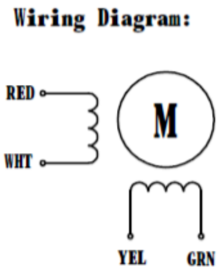
In the design of this test bench I decided to use a stepper motor that will be fixed at the top of the test bench, with the shaft centered with the cadaveric sample of the spine and the moving part to avoid any loss of force and momentum. The choice of a stepper motor instead of a simple basket with weights inside is justify by the need to follow, record and analyze the behavior of the cadaveric sample of the spine from the beginning, where no momentum and force are applied, to the end, where a pure momentum of 10Nm is applied on the implanted spine, without interruptions. Thanks to a stepper motor, it will be possible to record the deformation angles of the lumbar spine in a linear manner from 0Nm to 10Nm. Another advantage of a stepper motor is that it allows the experimenter to choose and control the rotation speed of the shaft, which is essential in the case of quasi-static experiments (Gonzalez-Blohm, 2015) (Oxland, 2016) (Lange, 2017) (Hegewald, 2018), as well as moving from quasi-static experiments to high-speed ones without any changes on the test bench. Due to the technologic improvements over the last few years, the size of the stepper motors diminished drastically as well as their weight, which gives more freedom to center it and fix it on top the machine without creating any destabilization of the structure.
To function correctly during lumbar spine experiments, the stepper motor needs to be suited for the

temperature, pression and humidity conditions that characterize the laboratory. This will not be a problem as these conditions are standards and the immense majority of stepper motor function perfectly under those.
Apart from these basic and essential characteristics, the stepper motor needs to be able to operate at a constant and quasi-static speed during all the duration of the experiment. The definition of a quasi-static speed differs from one study to another, for example Wilke et al. in 1998 defines it as being a rotation of 1.7 degree/s (Wilke, 1998). In a more recent publication, Gonzalez et al. in 2015 realizes all his experiments with a quasi-static loading ranging from 1 degree/s to 3degrees/s (Gonzalez-Blohm, 2015). Finally, in one of the latest studies about testing spine, Hegewald et al. meticulously described the quasi-static loading as being 0.7 degree/s for flexion, extension and right and left lateral bending; and 0.5 degree/s for axial rotation (Hegewald, 2018). To be the more efficient possible and keep a room for manoeuvre, I decided to opt for one stepper motor capable of operating at the lowest quasi-static speed encountered in the literature: 0.5 degree/s. Like that it will be possible to study the impact of different quasi-static velocities on the cadaveric sample of a lumbar or cervical spine.
After doing some research, I found that for stepper motor, the best value for money are the High Torque Stepper Motor NEMAXX which can range from 0.01 to 50Nm (JVL, 2019). As I calculated before and with the security coefficient of 4, the desired motor needs to be able to apply a force of 1212N on the cable that will be attached on its shaft. By using the momentum formula, I estimated the maximum force each motor could apply depending on their shaft diameter and maximum momentum:

Motors Characteristics			
Model	Shaft diameter (mm)	Maximum Momentum (Nm)	Maximum Force (N)
NEMA08	4	0,03	7,5
NEMA11	5	4	800
NEMA17	5	0,8	160
NEMA23	8	2,6	325
NEMA24	10	3	300
NEMA34	14	9	642,8571429
NEMA43	**19**	**24**	**1263,157895**
NEMA51	19	50	2631,578947

Table 1. Comparation of motors characteristics: Shaft diameter, maximum momentum and maximum force.

This table shows that only the NEMA34, the NEMA43 and the NEMA51 can produce a force superior than the 303N needed for the testing of implanted lumbar spine. To avoid any loss in rotation speed by using the motor close to its maximum force value, it was decided to take a security coefficient of 4. This means that the motor chosen will need to be able to apply a maximum force of 1212N. Thus, the NEMA34 is eliminated. Furthermore, the NEMA43's dimensions are 110mmx110mmx150mm while the NEMA51's dimensions are 130mmx130mmx280mm, this last one would require a larger top plate and a wider gap between the legs supporting the structure, which would induce a bulkier machine. The weight was also an issue, as I wanted to make the test bench as light as possible, the NEMA43 is more suited with its 8,4kg than the NEMA51 with its 26kg. By choosing the NEMA43 it would become easier for the experimenter to move the test bench around due to a lighter weight. Also, as I carried out the calculus of the maximum force for the highest momentum value encountered in the literature, there is no need to buy a motor capable of applying a higher force than 1200N. Furthermore, the NEMA43 wiring system is easier than the one for the NEMA51 due to 5 branches in this last one, instead of four in the other, which makes the connection with the controller more difficult.



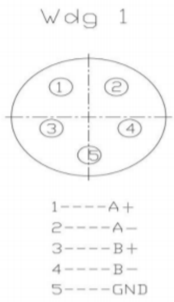


Figure 33. Left: 4 branches wiring diagram of the NEMA43 (JVL, s.d.). Right: 5 branches wiring diagram of the NEMA51 (JVL, s.d.).

Finally, as the objective was to design a testing machine for cadaveric samples of lumbar spine as cheap as possible, the difference of prices played its role in the final decision. Indeed, the NEMA43 can be found without controller at 40€ while the NEMA51 is three time more expensive at 120€. Therefore, I opted for the stepper motor NEMA43 MST432.

4.2.2 Controller:

Now that the motor is chosen, one important part of the design of this test bench is the controller. Indeed, the controller is used by the experimenter for choosing and fixing the rotation speed of the shaft, giving the possibility to conduct all experiments at the same rotation speed, at a quasi-static speed, or even at different rotation speed on the same sample. This is primordial to be able to then compare the results, obtained from the experiments, with the one that can be found in the literature. To keep the design of the testing machine as cheap as possible, I decided to buy and program a simple controller myself. Indeed, the literature shows that for quasi-static experiments on cadaveric samples of lumbar spine, the speed rotation of the stepper motor should be constant and between 0.5 and 3 degrees/s. The simplicity of the speed profile comfort me in my choice.
My experience oriented me to opt for an EasyDriver. The EasyDriver is a stepper motor driver created by Brian Schmalz and is built around a microstepping motor driver A3967 IC. It is simple to program with an Arduino and enable the control of the step angle, the rotation speed, the direction of rotation, as well as the creation of a threshold to stop the stepper motor at a desired value.

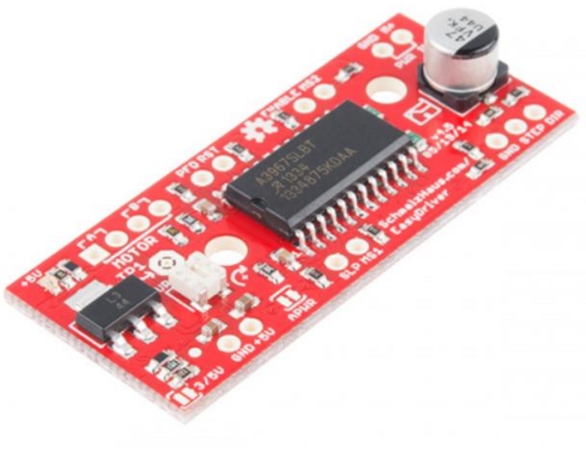


Figure 34. Stepper motor controller EasyDriver designed, developed and sold by Sparkfun.

The EasyDriver is directly connected to the stepper motor with, in this case for the NEMA43 MST 432, four cables. It is important to connect the wires pair in the same Coil A or B; the pairs are indicated in the datasheet (Figure 29) where RED and WHT form the first pair and YEL and GRN form the second one. In case there is a doubt about the pair during the connection process, it can easily be resolved by testing the resistance between one cable and the free others. The cable showing less resistance is the second member of the pair. Once the pair are determined, one is connected to the coil A and the second is connected to the coil B.

Figure 35. Top left corner of the EasyDriver, where the stepper motor is connected.

The EasyDriver is fixed on a PCB breadboard to facilitate the connection with the stepper motor, the Arduino, the power supply source and a start button.

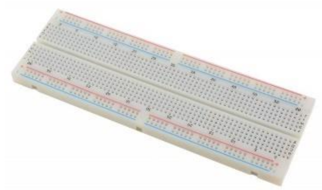


Figure 36. PCB Breadboard sold by Banggood.

The power supply source is connected to the GND and M+ ports, the first one being the ground and the second one the actual power supply ranging from 6V-30V. The range of rotation speed reachable directly depends on the voltage of the power supply source. For testing cadaveric samples of lumbar spine, it will be easy to reach the desired speed rotation as the experiments need to be conducted under a quasi-static regime. The NEMA43 MST 432 datasheet range the voltage from 0V to 80V for full speed rotation, it will be easy to obtain a speed of 0.7 degree/s with less than 10V as a power supply.

Figure 37. Top right corner of the EasyDriver where the power source is connected.

To carry out the coding and programing part, I have chosen to use an Arduino UNO REV3 which is, from my experience, the cheapest and most efficient way to realize small coding parts. As it the Arduino will only be use for one task: the determination and control of the speed as well as the activation of the threshold to stop the motor, the UNO REV3 is enough to provide us the desired results and there is no need for a more powerful Arduino.

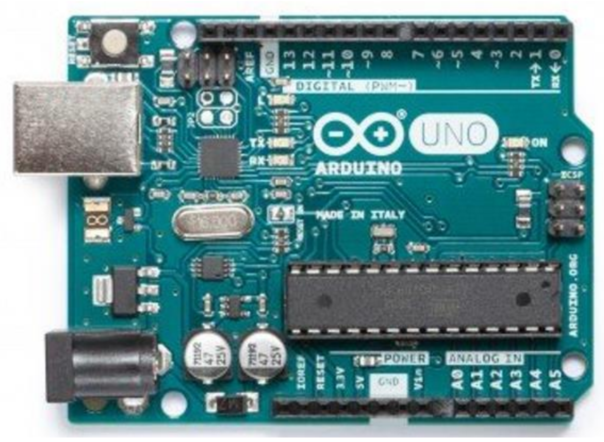


Figure 38. [Arduino](#) UNO REV3

The Arduino UNO REV3 is connected to the EasyDriver by the three following ports: GND for ground, STEP which is used to trigger the motor to advance one step and DIR for the direction of the stepper motor rotation. The GND from the Arduino goes to the GND of the EasyDriver, and the STEP and DIR, as they are logic input, are connected to one of the 14 digital I/O pins present one the Arduino. As there are only two wires, I usually like to connect them to the 4 and 5 pin of the UNO REV3. There will also be a wire connected to the load cell display, which will act as a threshold for the motor: once the decided maximum force will be reached, the motor will stop. The highest maximum force is calculated, as shown before, by means of the maximum momentum found in the literature, which was defined by Lange et al. at 10Nm, giving us a maximum force of 303N. Finally, one digital pin will serve as an output to send a signal to the cameras and starts the recording synchronously with the stepper motor. There will also be a push button connected to the Arduino on one of its digital ports, enabling the experimenter to start the all system in one push.

Figure 39. Bottom right corner of the EasyDriver where the Arduino is connected.

To facilitate the work of the experimenter, there is the possibility to implement a starting button in the circuit. Thanks to that button it will be possible to start the code without having the motor starting, which provides time to the experimenter to launch the cameras and recording software and in a second time push the button to have the motor starting to rotate. It will then require a small post-processing to quit the immobile part of the cadaveric sample from the data. This button simply needs to be connected to the ground of the Arduino, to a resistor which is connected to one of the pins 3V3 or 5V, and to one the 14 digitals pin.

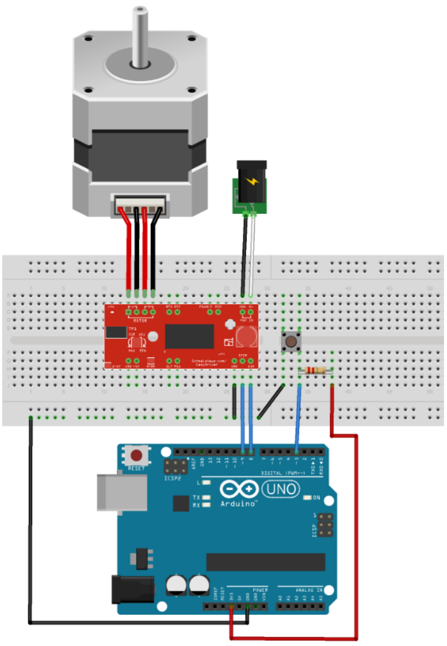


Figure 40. Example of the connection of all our components. From SparkFun.

From there, the Arduino code is basic. The digital pin connected to STEP, responsible of triggering the motor and make it advance one step, has two position: High and Low. The motor will rotate when the digital pin passes from the Low position to the High position, in the code between the two positions I implemented a delay which enables to control the velocity of the change of position. Thanks to the NEMA43 MST 432 stepper motor, I know that it functions at a rate of 1.8degrees/step. The default setup of the EasyDriver is the 1/8thmicrostep mode, which means that instead of having 200 steps per revolution, it works with 1600microsteps per revolution. From there we can calculate the delay needed to obtain the desired rotation speed. Indeed, if *dl* is the delay between each position, then *2dl* is the duration between two microsteps. As the step angle is equal to 1.8 degrees and the EasyDriver is used in its 1/8th mode, this represents 0.225degree per microstep. For the minimum rotation speed for a quasi-static experiment on a cadaveric sample of a lumbar spine described by Hegewald et al., which is 0.7degree/s, the motor needs to execute 3.11microstep/s (Hegewald, 2018). As there is 1000ms in one second, the following formula is obtained:

$$1000 = 3.11 * 2dl \qquad \text{Equation 10}$$

By isolating our variable *dl,* we get the following equation:

$$dl = \frac{1000}{3.11 * 2} = 161ms \qquad \text{Equation 11}$$

The delay between the change of position must be equal to 161ms to obtain the desired speed rotation of 0.7degree/s.
With the same process, I calculated the minimum rotation speed for a quasi-static experiment on a cadaveric sample of a cervical spine described by Hegewald et al., which is 0.5degree/s (Hegewald, 2018), and I obtained as expected a longer delay between two change of position:

$$dl_{0.5} = 225ms$$ *Equation 12*

I also calculated this delay for the highest rotation speed for a quasi-static experiment on a cadaveric sample of a lumbar spine described by Gonzalez et al., which is 3degrees/s (Gonzalez-Blohm, 2015), and obtained this time a way shorter delay:

$$dl_3 = 37.5ms$$ *Equation 13*

Once the rotation speed is decided and the delay is known, it can be implemented inside the following code I wrote:

```
const int APin = A1;
const int ForceValue = 1.5;
int MicroStepCount = 0;
int Stepping = false;

void setup() {
  pinMode(4,OUTPUT);
  pinMode(5,OUTPUT);
  pinMode(7,OUTPUT);
  digitalWrite(4,LOW);
  digitalWrite(5,LOW);
  digitalWrite(7,LOW);
  pinMode(2,INPUT);
}
```

Figure 41. First part of the Arduino code wrote for the stepper motor and cameras activation/deactivation.

The first part of the code contains the definition of four variables, two of them being constants. The first one APin contains the value of the analog port number 1 of the Arduino, this port being connected to the force display which is the value received by the load cell. The second ForceValue is the maximum value of this force tolerated before shutting down the motor. I put 1.5 in this example because the connection between the load cell display and the Arduino is analogical. This means that the force in Newton is converted into an electrical signal between 0 and 10V. As the load cell can measure forces from 0 to 2000N, a simple conversion gives a maximum electrical signal of 1.5V received by the Arduino is case of an applied force of 300N. The third one MicroStepCount contains the number of microsteps carried out by the stepper motor during the experiment, it is changing linearly and can be display using the commands Serial.begin(9600) and Serial.print(MicroStepCount). The last one Stepping serves as a coding switch which enable or not the motor to do a microstep.

In the setup part, I defined the digital pin number 4, 5 and 7 as output, 4 being use for the rotation direction of the stepper motor, 5 being the one responsible for the microsteps and 7 being the one activating and deactivating the recording cameras. I then put the three in the Low position to start the experiment. Finally, I added the digital pin number 2, the one connected to the button, as input.

```
void loop() {
  int AValue = analogRead(APin);
  if (digitalRead(2) == LOW && Stepping == false)
  {
    Stepping = true;
    digitalWrite(7,HIGH);
  }

  if (Stepping == true)
  {
    digitalWrite(5,HIGH);
    delay(161);
    digitalWrite(5,LOW);
    delay(161);
    MicroStepCount = MicroStepCount + 1;
   }
   if (AValue > ForceValue && Stepping == true)
   {
    Stepping = false;
    digitalWrite(7,LOW);
   }
}
```

Figure 42. Second part of the Arduino code wrote for the stepper motor activation/deactivation.

Inside the loop of this code, the first step is to read the force value from the analog pin chosen earlier. In a second time, the program checks if the button is pressed and if the steps are blocked, if this is the case, then the stepping is activated, and the signal is send to the camera to start recording. Following that, when the stepping is activated, the order is given to the stepper motor to do a microstep with the calculated delay (161ms for a rotation speed of 0.7degree/s) between each change of the pin position, and the MicroStepCount is incremented by 1. Finally, at the end of the loop, the program verifies if the value of the force recorded by the load cell is not higher than the calculated ForceValue. If it is indeed higher, the stepping is blocked, and the motor stops as well as the recording cameras and the code. If not, the loop starts again.

4.3 Load cells:

To control the force which is applied to the center cable and as a result control the value of the pure momentum the cadaveric sample is undergoing, it was decided to put a load cell between the

moving part and the motor. As it will be electronically connected to a display, the value of this force will serve as a threshold for the stepper motor, once the maximum value is reached, the motor will be automatically stopped.
A lot of different types of load cells can be used in the case of a test bench for cadaveric samples of lumbar or cervical spine. In the idea of keeping this testing machine as cheap as possible, the chosen load cell for this experiment is one that is already present in the workshop, as well as its display and the output cables. The model of this load cell is SM-2000N sold by PCE instruments, a manufacturer and seller of test equipment. With this, it is possible to record forces up to 2000N, which is way higher than our safety value of 1200N. The display enables the experimenter to see the evolution of the force in real time, but also allows the Arduino to receive this value thanks to its output in voltage. The conversion ratio for the output stays simple: the force is ranging from 0 to 2000N and the output from 0V to 10V, to calculate the force from the voltage value it is enough to multiply it by a coefficient of 200.

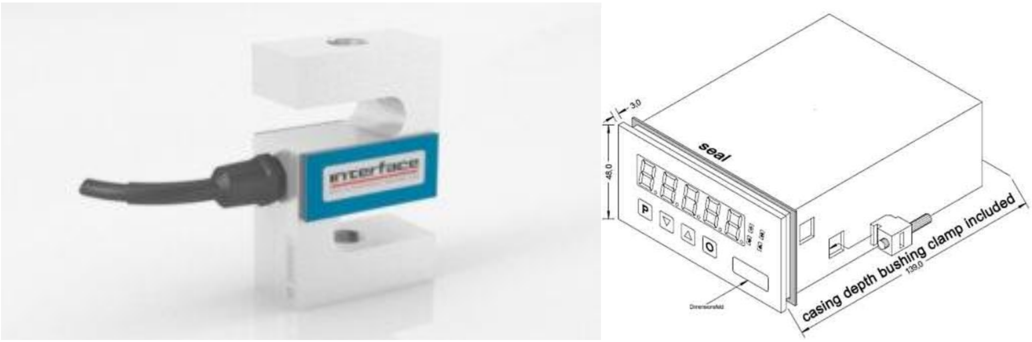


Figure 43. Load-cell SM-2000N and its display. Sold by PCE instruments.

4.4 Camera:

To record the movements of the cadaveric sample during the experiment, it is essential to use a system of cameras to be able to apply the technique of photogrammetry. This technique, as it was developed earlier in this paper, consists of creating a 3D mapping of an object based on 2D datasets. The system of cameras is already implemented and positioned in the workshop, the software that enables the calibration, recording and analysis is called Kinescan. It is very adaptable to any kind of objects and movements, that is why it is used for most of the experiments at IBV.
The 3D movement analysis system Kinescan consist of eight state-of-the-art digital cameras with a frequency of 250 frames per second. They are sensible to IR and carry a visible light filter which enables them to work with artificial light. There is no need to synchronize them with an external input as they are already synchronized. Furthermore, each one of these cameras contains an IR beam which role is to reflect on the reflective markers.

Figure 44. IR Sensible cameras present in the IBV workshop.

For the experiments on cadaveric samples of lumbar or cervical spine, two or three cameras are enough to record the movements during the application of pure momentum. The images recorded are directly sent to the computer and the software Kinescan/IBV is where the calibration, visualization, and analysis are possible.

4.5 Software:

The images recorded are directly sent to the computer and the software Kinescan/IBV is where the calibration, visualization, and analysis are possible.

Datasheet Kinescan/IBV	
Maximum n° of cameras	Unlimited
Camera resolution	1280x1024 pixels
Frequency at maximum resolution	30-240 FPS
Shutter	Global
Shutter speed	Minimum: 1/100 000s and Maximum: 1/256s at 240 FPS
Synchronization	Ethernet
Image processing	Build-in the camera
Masking of reflection	Yes (automatic)
Video previsualization	Yes
Illumination	IR (wavelength: 850nm) 62 LEDs
Filter	Yes (switching electromechanic)
Connexion	Ethernet (GigE)
Alimentation	Ethernet (PoE)
Camera's dimensions	68.6mm (H), 68.6mm (W), 53mm (D)
Camera's weight	0.320 kg
Camera's body	Anti-reflective anodised aluminum
Reflective markers	Sphericals: 9.5mm, 15.9mm and 25.4mm
Camera's support	Fixed on a bar around the room
Adjustement and Calibration tooling	Included

Table 2. Datasheet of the Kinescan/IBV

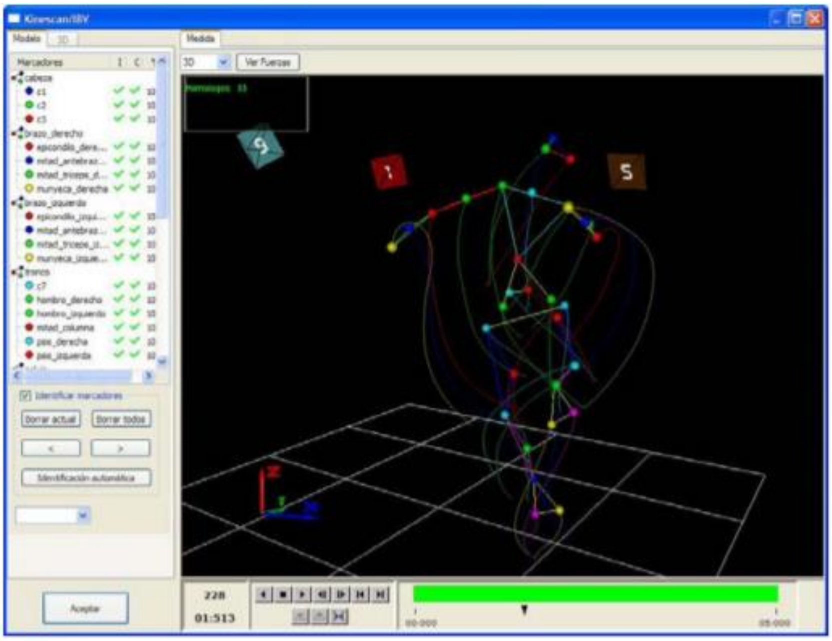


Figure 45. User screen of Kinescan/IBV

4.6 Protocol and test:

For the purpose of comparing the results obtained from the designed testing machine with the ones encountered in the literature, one of the most important aspect of the experiments is the protocol. Indeed, by studying different reviews and scientific papers, I implemented a protocol adapted to the study of cadaveric samples of lumbar and the cervical spine. This protocol needs to be strictly followed and consistent through all the set of experiments to justify the validity of the obtained results.

4.6.1 History and importance of the protocol and testing conditions for lumbar spine:

One of the first scientific paper describing a meticulous study of different testing condition was presented by Wilke et al. in 1998 (Wilke, 1998). During their work, they studied a total of three major parameters and published their results as an antecedent to the development of a universal protocol:

- The first parameter taken in account was the moisture conditions, to estimate the best way to moist or not the cadaveric samples of lumbar spine, they conducted three different type of experiments: one where the specimens were wrapped inside a saline-soaked gauze and to maintain a constant level of moisture, the gauze was sprayed with saline during all the duration of the experiments. The second group of specimens was directly exposed to the air of the testing room and let to dry out during the testing period. The last group was irrigated with saline at a rate of 2L/min. After analyzing the results, Wilke and his team concluded that the group with the more stable Range of Motion (ROM) was the wrapped in gauze one. Indeed, after loading accumulation, the ROM of this group would only increase by 10% while in the two other groups it would increase by 30% (Wilke, 1998). Keeping a constant moisture is therefore the best option to obtain results close to in vivo conditions.

- The second parameter studied was the time of ambient temperature exposure of the specimens and its influence on the ROM during the testing period. The conclusion of Wilke's work contradicted the previous publication of Panjabi et al. in 1985 where he affirmed that the cadaveric spine samples could be tested for a duration of 14 days, if between each test they are kept in a 4°C environment, without any significant changes in their ROM (Panjabi, 1985). In this new study, Wilke and his team demonstrated that by following the method of Panjabi, after two to three days of loadings and refrigeration, the samples began to change color, smell and moisture, which affected directly their ROM. They concluded that for a period of 72h of testing, with refrigeration between each test, the ROM in each direction was increased by 30% to 50%. The lateral bending being the most flexible and adaptable direction of the spine, the increase of the ROM was less than the ones in flexion/extension and torsion. This paper also underlines that after 10h to 20h of loading and refrigeration, the increase of the ROM in all direction was less than 10% (Wilke, 1998). This information can be useful in the case precision isn't the major concern of an experiment. Conducting only one experiment on each sample or conducting various as close as possible without exceeding 10h between the first and the last experiment is the best option to obtain results close to in vivo conditions.

- The last major parameter considered in this study was the angular deformation rate. Wilke and his team conducted their experiments at different speed, ranging from 0.6degree/s to 5.1degree/s. Their method was to start with a load cycle at 1.7degree/s at the beginning of the experiment, then realize the test at a determined and constant speed, and finally end with another load cycle at 1.7degree/s to check the repeatability of the measures. Their conclusion was that the angular deformation rate didn't have any impact on the ROM or the Neutral Zone (NZ), but the spine stiffness was sensitive to it, as described in Myers et al. in 1991 (Myers, 1991). This explain why, in the following years, each study had its own angular deformation rate, depending on the testing apparatus, the experiments conducted, or the parameters studied.

In 2015, Gonzalez et al. published a scientific review where they studied the currently used protocols for the testing and evaluation of lumbar spine implants (Gonzalez-Blohm, 2015). They defined and described three different types of protocols:

- The first one is called flexibility protocol and was first explained by Panjabi et al. in 1976, it is the most used for in vitro studies of the lumbar spine (Panjabi, 1976). The idea behind it is to apply a known force or pure momentum to the altered segment of the spine the experimenter wishes to analyze. This alteration can represent an injury, a deformation or an implant. The analyze of the displacements and ROM enables the experimenter to characterize the effectiveness of the treatment.

- The second protocol is called stiffness protocol and is rarely used for the testing of lumbar spine. Opposed to the flexibility protocol, this one is based on the analyze of the loads for a fixed and determined displacement. This analysis provides the experimenter with a way to improve the treatment of the patient by a better repartition of the loads. Indeed, the idea behind this protocol is that after an injury, deformation or implantation, the patient wishes to recover completely and be able to have the same freedom of movement than before. The displacement is then determined and fixed, and it is the loads values and repartition that are studied to find the best way to support them.

- Finally, the last protocol is a hybrid protocol, inspired from the two previous one. It is the most recent one and starts to be more and more used for the testing of lumbar spine. It consists in applying a known force or pure momentum to a control intact spine and measure its displacement. After that the spine the implanted, and a force or pure momentum is applied until the observed displacement matches the one measured on the control spine. The analysis is then done on the biomechanical parameters on the spine such as ROM or NZ. This protocol faces one major problem: a lack of knowledge about the appropriate values for the force or pure momentum applied to the control spine to avoid any spine instability in case of too high values.

As described by Wilke et al. in 1994, the muscle forces play a significant role in the in vitro testing of lumbar spine (Wilke, 1994). But instead of creating a modelling of this muscles by fixing taut cables to the cadaveric samples, Gonzalez et al. noticed that the most common method to solve this problem is by conducting a series of compressive preload. The best and most common preload used is a force of 400N in flexion and extension of the lumbar spine.
Finally, Wilke et al. in 2001 justify the use of pure momentums to better reproduce in vivo behavior when conducting in vitro experiments (Wilke, 2001). This is due to the transmission of a uniform momentum in the cables from the stepper motor to the sample.

4.6.2 Our protocol and testing conditions:

From all the literature and existing studies, I created a protocol and set of testing conditions inspired from Wilke et al. and improved thanks to the most recent publications and my own experience of laboratory testing of cadaveric samples. This protocol includes:

- A project title and a number. Typically the title should gives a glimpse of what the project is about, for example "Strength and mobility comparation of lumbar spinal implants", and the number should enable to find it again easily, for example characterizing the experimenter, the company which ordered it and a chronological number retracing all the projects done for this company.

- A purpose. Typically, the question or hypothesis the experimenter is trying to answer, such as "Which of these four spinal implants is the best to treat a low back injury", with a description.

- The materials. In this case it will be the description and design of the test bench, the software and versions used for analysis, recording and coding, as well as all the recording material such as the cameras, switches, computers, etc.

- The method. In here the number of experimental groups, samples, and an explanation on how the experimenter will set up the testing phase.

- The control groups. In case there is one or more, otherwise the literature used as a reference.

- The samples' references. Which are the origin of the sample, its age, sex, weight, cause of death, condition (injured, intact, deteriorated …etc.), social situation and place of residence.

- The conservation methods until arrival. This is useful when someone wants to reproduce the experiments by buying or using samples from another company.

- The storage conditions. This includes the storage temperature, time, humidity and pressure; as well as all preparation processes conducted before the experiments (scrap of muscles and nerves, pretesting moisture, …etc.).

- The experimental conditions. In this case the temperature, humidity, pressure and test duration are enough.

- The studied parameters. In this case it will be the ROM, NZ, and fracture apparition.

- The preparation methods. This part contains the determination of the rotation speed, the moisture technique, the pretesting compressive loads, the type of protocol chosen (flexibility, stiffness or hybrid) depending on the experiment, the calibration process, the recording and analysis instructions as well as safety measures.

CHAPTER 5. Results

5.1 Assembly of the test bench:

The complete assembly of the test bench will be a crucial step before the use of the machine. Indeed, one of the objectives of this work was to design it as cheap as possible, but some pieces, because of the quality needed and the fact that they were invented, are expensive to produce. To avoid any problems during the assembly process and to limit the risk of errors, an instruction guide was created. It covers all the different steps, from the first order to the last click on the computer, of the assembly process. After meticulously following this guide, the experimenter will obtain a testing machine ready to be used.

- The first step is the order of the different parts composing the structure designed with Solidworks. There are two groups of pieces, the first consists of all the existing ones, which are sold by BOSCH REXROTH, such as the profiles, the connectors, the screws, the caps and the small fixing plates. These parts are directly ordered to the website of BOSCH REXROTH and the price is fixed. The second group consists of all the pieces directly designed with Solidworks, these ones needs to be tailor-made by the company Mipesa, except for the base plate and the top plate which will be order at Metalaladecoupe. In both cases, the waiting time is higher, and the price of these parts is what make most of the total cost.

- The second step is the order of all the electronic components. This includes the stepper motor NEMA43 MST 432, the microcontroller Easydriver for the control of the rotation speed, the Arduino UNO REV3 for the code and the programming, as well as all the connecting parts: jumper wires, USB cable, PCB breadboard, the button and the resistor.

- The third step is the order of the cables that will be used to apply the pure momentums and forces to the cadaveric samples of the lumbar spine. As the structure is made of aluminum and steel, to limit the friction of the cable during the experiment, I opted for nylon-coated stainless-steel cables. They provide the solidity of regular stainless-steel cables but reduce the friction thanks to the nylon protection coat.

- Once all the orders are made, the assembly phase can begin. It starts with the metallic structure, and more specifically, the inner small structure on the bottom plate. Firstly, the bottom piece, where the cadaveric samples will be fixed, needs to be screwed at the center of the bottom plate. Then the four smaller legs will be assembled one by one with the BOSCH REXROTH's components and later set to form a rectangle of 400mmx200mm around the bottom piece, centered on it. After that, the longer legs will be assembled with the BOSCH REXROTH's components and set to form a square of 400mmx400mm around the bottom piece, centered on it. Once the base of the structure is fixed, the top plate will be connected on top of the longer legs, it will support the motor. As described before, the head piece, which contains the top of the cadaveric sample in PMMA, is only connected to the testing machine by the cables. These cables will be put at the end, once the cadaveric sample is placed in the bottom and head part. Finally, the moving structure needs to be assembled with the BOSCH REXROTH's components, and some parts that are present in the workshop: the metallic rods and the hook. To avoid the swinging of this part, it will only be connected to the structure, with cables, once the cadaveric sample is ready.

- The next step consists in assembling the electronics for the control of the rotation speed and the cameras. It starts by connecting the EasyDriver, the Arduino, the button and the resistor to the PCB breadboard. Once all are connected and powered, the Arduino needs to be connected to the load cell display to receive the value of the force, as well as with the computer running Kinescan/IBV (by USB cable) to control the recording of the cameras. At last, the Arduino will be connected to the stepper motor to control its activation as well as the rotation speed.

- The sixth step is the preparation of the cadaveric samples. Following the determined protocol, the lumbar spine must be fixed in PMMA inside the inner metallic pieces. Once it is correctly immobilized, the inner pieces are put inside the bottom part and the head part and screwed to avoid any undesired movement.

- Now that the sample is ready, the experimenter needs to put the cables in place to immobilize the head part and the moving part. It starts with the unique cable going down from the stepper motor and attached to the hook which is on top of the moving part. Then the four cables will be tied around the metallic rods of the moving part, they will go down around the four pulleys fixed on the four smaller legs and will be finally attached to the 2 pulleys on the side of the head piece.

- The last step is the calibration of the cameras which will be achieved with Kinescan/IBV and a set of reflective markers, each put at a known distance from the others.

Once all these steps are done, the experimenter will be able to put the different parameters in the Arduino code, run it and push the button to start the recording and the rotation of the stepper motor.

5. 2. Cost analysis:

In this chapter, I am going to present the cost analysis of this project. I divided it in three categories: Structure, Motor and Controller, Staff. This cost analysis was meticulously achieved because one of the objectives of this work was to design the test bench as cheap as possible. To reach that goal, I favored quality and prices rather than delivery time or company location.

Structure

Product	**Seller**	**Reference**	**Price per Unit (€/u)**	**Number of unit**	**Total (€) (TVA exc.)**
End cap, black	BOSCH REXROTH	3 842 501 232	0,8	12	9,6
Profile, Aluminium (1m)	BOSCH REXROTH	3 842 990 720	12,15	6	72,9
Connectors (30mmx30mm)	BOSCH REXROTH	3 842 523 528	4,58	12	54,96
Connectors (30mmx60mm)	BOSCH REXROTH	3 842 523 541	6,24	8	49,92
Nylon coated cables	GSPRODUCTS	TGYM080	2,23	5	11,15
Steel wire grip	GSPRODUCTS	814 391 404	3,7	5	18,5
Head piece	Mipesa	N/A	520	1	520

Bottom piece	Mipesa	N/A	400	1	400
Inner piece	Mipesa	N/A	120	4	480
Base aluminum plate (600mmx600mm)	Metalaladecoupe	N/A	122	1	122
Top aluminum plate (400mmx400mm)	Metalaladecoupe	N/A	56	1	56

TOTAL (€) Struc.(TVA exc.)	1795,03
TVA (20%)	359,01
TOTAL (€) Struc.(TVA inc.)	**2154,04**

Table 3. Cost analysis of the apparatus structure.

As explained earlier, four types of pieces were not designed during this project: the cap, the aluminum profiles and two types of connectors. They are designed, fabricated and will be order at BOSCH REXROTH.
The number of caps needed is 12: one on the top of each smaller leg (4), and one at each end of each profile in the moving part (8).
The profiles are sold by meter, therefore an estimate of the total length of the structure is needed. The four smaller legs are 0,4m high while the four higher legs are 0,6m high. The moving part is forming a rectangle of 0,4mx0,2m, which gives us a total of 5,2m of aluminum profile, number that is round up at 6m.
The small connectors (30mmx30mm) are present on two side of each smaller leg (8), as well as on the moving part to maintain the rectangle (4). In total, 12 of those are needed to build the structure of the apparatus.
The big connectors (30mmx60mm) are used to fix the higher leg at the bottom plate and at the top plate, therefore, 8 will be needed.

For the cables, as Wilke et al. first expressed in 1994, the best way to avoid any loss of force and momentum by friction during the tests is to use coated cables (Wilke, 1994). Wilke recommended to use a plastic coating, but I found out that Nylon coating is five times more resistant than normal PVC coating. As the diameter of these cables is 3mm and the force applied can be superior to 300N, I opted for the Nylon coating. In total, 5 different cables will be needed: one to connect the stepper motor and the moving part, and four others to connect the moving part to the four pulleys on each of the smaller leg. After comparing the quality and prices from two other companies (Tianlisteel and tddlcable) I chose to buy them from GSPRODUCTS because they were cheaper and delivered faster for the same quality. On one end of each cable, a steel grip is needed to prevent undesired movements of the cable, this gives us a total of 5 steel grip, also bought at GSPRODUCTS.

The rest of the pieces will be tailor-made as they don't exist of the market. For the two plates, I chose a French company with which I already worked, there prices are extremely competitive, there after-sales service is irreproachable, and the delivery times are shorter than for most companies.
For the head piece, the bottom piece and the inner pieces, I followed the suggestion of my tutor Carlos Atienza Vicente and opted for a company the IBV is used to work with: Mipresa. The estimation of the price of each part was based on the complexity of their design. Although one bottom piece and one head piece is enough for the testing machine, to offer more freedom and rapidity to conduct series of experiments without stopping, I decided to make four inner pieces. That

way, when two are used for an experiment, the two others can be prepared with another sample. Once the first test is finished, the inner pieces are taken out and the new ones directly put inside with the new sample. The second test can begin, and while it is performed, the first two inner pieces can be washed and cleaned.

All these components of the apparatus structure are making a total (TVA included) of 2154,04€.

Motor and Controler

Product	**Seller**	**Reference**	**Price per Unit (€/u)**	**Number of unit**	**Total price (€) (TVA exc.)**
Nema 43 Stepper motor	alibaba	MST 432 C213-X1AA9.0	36,16	1	36,16
EasyDriver	SparkFun	ROB 12 779	13,51	1	13,51
USB micro-B Cable	SparkFun	CAB 10 215	4,47	1	4,47
Jumper wires	SparkFun	PRT 11 709	5,38	2	10,76
Arduino Uno Rev3	Arduino	A 00 00 66	20	1	20
PCB breadboard	Banggood	MB 102	4,2	1	4,2
Resistor 3k3	Mouser electronics	594-5043ED3K320F	0,17	1	0,17
Button	BricoGeek	CPM 0039	0,5	1	0,5

TOTAL (€) M&C (TVA exc.)	89,77
TVA (20%)	17,95
TOTAL (€) M&C (TVA inc.)	**107,72**

Table 4. Cost analysis of the electronic components.

The second category consist of the electronic components. Once the stepper motor was elected, I compared different companies such as Amazon, JVL, Alibaba, LeBonCoin … to find the cheapest one. It is on Alibaba that the delivery time was the shortest and the price the lowest.
The EasyDriver is developed by SparkFun, I directly opted for this website because of the after-sales service. I also put a USB cable to connect to the computer, as well as two sets of 10 long jumper wires in the same order to save money.
It was decided to buy the Arduino UNO REV3 from the Arduino website to make sure of its quality and provenance.
The PCB breadboard was chosen from the Banggood catalog because of its size and price.
For the resistor 3K3, one of the leading companies on the market was chosen: Mouser electronics.
And finally, the election of the button was done by following a recommendation on the Arduino website: the CPM 0039 from BricoGeek.

All the electronic components are making a total of 107,72€

Staff

Name	**Company/University**	**Role**	**Salary per hour (€/h)**	**Number of hours**	**Total cost (€)**
Carlos Atienza Vicente	IBV	Supervisor	25	36	900
Léo Fabre	EC Lille	Designer	12	360	4320
Technician n°1	IBV	Assembler	12	6	72

TOTAL (€) (TVA inc.)	**7553,76**

Table 5. Cost analysis of the staff for the duration of the project.

Finally, I estimated the cost of the staff for the realization of this project. The supervisor, Carlos Atienza Vicente, spend approximately 36 hours on the project, while I spent 360 hours over 3 months on the design of the testing machine. I estimated the time of assembly at 6 hours.

The total cost of this project is 7553,76€. To put this number into perspective, a testing machine developed by companies such as Element or Admet cost around 50 000€. Of course, these apparatuses can conduct different types of tests, at different speed, and not only for cadaveric samples of lumbar or cervical spine. Nevertheless, the objective of a cheap testing machine was achieved by reducing the original cost of 85%, while keeping the quality and precision needed to compare the results with those from Wilke et al., Gonzalez et al., Hegewald et al. and others (Wilke, 1998) (Gonzalez-Blohm, 2015) (Hegewald, 2018).

CHAPTER 6. Conclusions

To conclude, the overall aim of this work was to design a testing machine to evaluate the behavior of spinal implants in cadaveric samples. The partial objectives were to design all the parts of the new apparatus by improving the existent ones and create new ones to make its use easier for the experimenter and solve the problems encountered with the first version, and to implement an electronic circuit with a code to make the load process automatic, linear and synchronized with the recording system of cameras.

The **first partial objective** was achieved by designing all the parts of the apparatus' structure and assembled them together with the software Solidworks. The major improvements created are:

- The creation of an inner piece which fits inside the head and bottom piece and where the cadaveric sample is placed inside a PMMA solid. This allows the experimenter to considerably reduce the time of the experiments by simply changing the inner pieces, instead of cleaning them between each sample. It also protects the head and bottom piece, which are the most expensive pieces of the structure, from wear, tear and erosion. This enables the experimenter to obtain more stable results and delay the process of changing these pieces.

- The use of nylon coated steel cables which limits the friction during the tests and therefore gives a better transmission of the pure force and momentum along the cables. It also protects the cables and the aluminum parts of the testing machine from the wear, tear and erosion while conducting the experiment. This also enables the experimenter to obtain more stable results and lengthen the service life of the pulleys and the head piece.

- The new disposition and weight of the apparatus. Indeed, during the design I constrained the pieces in such a way that the testing machine was smaller than the previous version. By removing some parts of the structure and equilibrated it thanks to a symmetry in the design, I was able to decrease the weight of the machine and better distribute it on all the structure.

- The new sets of connectors used. They were chosen to resolve the problem of moving legs during the experiments with the previous version of the machine and offer a better stability to the structure. I doubled the number of connectors on the more unstable parts (the smaller legs) and change the model of them to use new ones that are more resistant.

The **second partial objective** was achieved by using a stepper motor, a rotation speed controller and an Arduino for the coding part. The major improvements created are:

- The use of a NEMA43 MST 432 stepper motor, which enables the experimenter to conduct all the tests at a constant and determined speed, instead of in fits and starts as with the previous version. This makes possible the linear recording of the deformation angle as a function of the applied force on the first cable. It will then be possible to compare the results with other studies. The use of a stepper motor also provides a symmetry in the structure of the apparatus and helps equilibrated it. Finally, due to its powerfulness, the experimenter will be able to change the test protocol without changing the testing machine: the rotation speed and applied force and momentum will be completely controlled.

- The use of an EasyDriver and an Arduino UNO REV3 to control the rotation speed, the starts and stops of the stepper motor, as well as the start and stop of the recording system. The control of the rotation speed was one of the most important point to be able to conduct the experiments in a quasi-static mode and obtained comparable results. The EasyDriver enables the experimenter to obtain a minimum rotation of 0,225degree/microstep, which, thanks to the delay between each microstep, allows to control the rotation speed at low rates and reach the lowest values, as well as the highest ones, found in the different studies (Hegewald et al.). The code developed in this work, and run by the Arduino, enables the experimenter to chose the rotation speed value by changing the delay between each microsteps, to determine the maximum force applied on the structure, and to control the synchronized activation of the stepper motor and the recording system simply with the push of a button.

The major problem faced during concerns this project was the scientific monitoring and supportive bibliographic research, and the Solidworks design and assembly. Indeed, these two parts were more time-consuming than expected, and the fact that no official test criteria are defined to evaluate the stability of an implanted lumbar spine forces me to compare the different published studies to create a new method and a new protocol adapted to the project. Due to lack of time, the assembly of the testing machine couldn’t be performed, but I am confident that once the order will be placed and the machine assembled, it will be functional and efficient for the following reasons:

- The first version was functional and enables the experimenter to analyze the deformation angles with the recording system. As the same technique of analysis will be used with the same recording system, and the same system of pulleys will be applying the pure momentum on the sample, this part is guaranteed to work.

- The EasyDriver chosen was designed and conceived to control stepper motor. And as the control is the most basic one: a constant rotation speed and stopping the motor once the threshold is reached, the code is simple and functions (it was compiled and debugged without any errors).

- The activation of the recording system by the Arduino was the more difficult part. But one of the technicians at IBV explained to me that he wrote a C++ program which is able to start the recording from the software Kinescan/IBV once it received the signal from one of its USB ports. The system is functional and has already been used for other experiments. By sending the signal from the Arduino, it will be simple to start and stop the recording of the experiment.

CHAPTER 7. Future improvements and recommendations

To complete and achieve this work, I put together a list of recommendations and future improvements to follow.

- The first recommendation is to conduct a complete material study for the structure of the apparatus. Indeed, the choices of materials were made based on the previous design, the literature and scientific papers such as Wilke et al. in 1994 (Wilke, 1994), Stokes et al. in 2002 (Stokes, 2002), Gonzalez et al. in 2015 (Gonzalez-Blohm, 2015), Hegewald et al. in 2018 (Hegewald, 2018) and others, and their prices. But a complete material study could reveal the existence of other materials which will be cheaper, stronger and more resistant than the elected ones. This concerns the following materials:

  - PMMA, used to fix the cadaveric samples inside the inner pieces, which as great properties but has a poor impact resistance, a poor wear and abrasion resistance and can crack in case of a force or momentum value too high.

  - Aluminum, used for the profiles of the structure. In my opinion it is the best material to build the machine for testing in a quasi-static mode, and the calculus shown in this work proves that there will not be any significant undesired deformation during the experiments. But if the experimenter wishes to conduct some testing at a faster rotation speed and with higher forces and momentums (in case of a rupture study for example), the aluminum might not be the best option.

  - Nylon coating stainless steel. It was chosen because of its strength and stability, but a complete study of the cables types and coating types could reveal a new option better adapted to the designed apparatus.

- The second recommendation is to write a program capable of using the recorded data and analyze them automatically after the tests. This can be achieved once the tests, protocols, parameters of interest and methods of analysis are defined. The idea is to take a weight of the experimenter: Once the starting button is pushed, all the experiment is conducted automatically from the start until the display of the results, analysis and comparations. From my experience, MATLAB is a great tool for such experiments, and I recommend it to write this program.

- The third recommendation is to keep improving the design of the structure so that it is easier to move around. Indeed, even though the new version is lighter than the previous one, it still is quite heavy and bulky. A change of materials, or a better support for the structure could resolve that problem. The challenge will be to improve that design and keeping the same precision, efficiency and stability at the same time.

- Finally, one last recommendation is to continue the scientific monitoring and supportive bibliographic research, because as described earlier, the fields of low back pain treatments, spinal implants and testing apparatus and conditions, are constantly evolving and a lot of discoveries and improvements are to be expected in the following years.

CHAPTER 8. Bibliography

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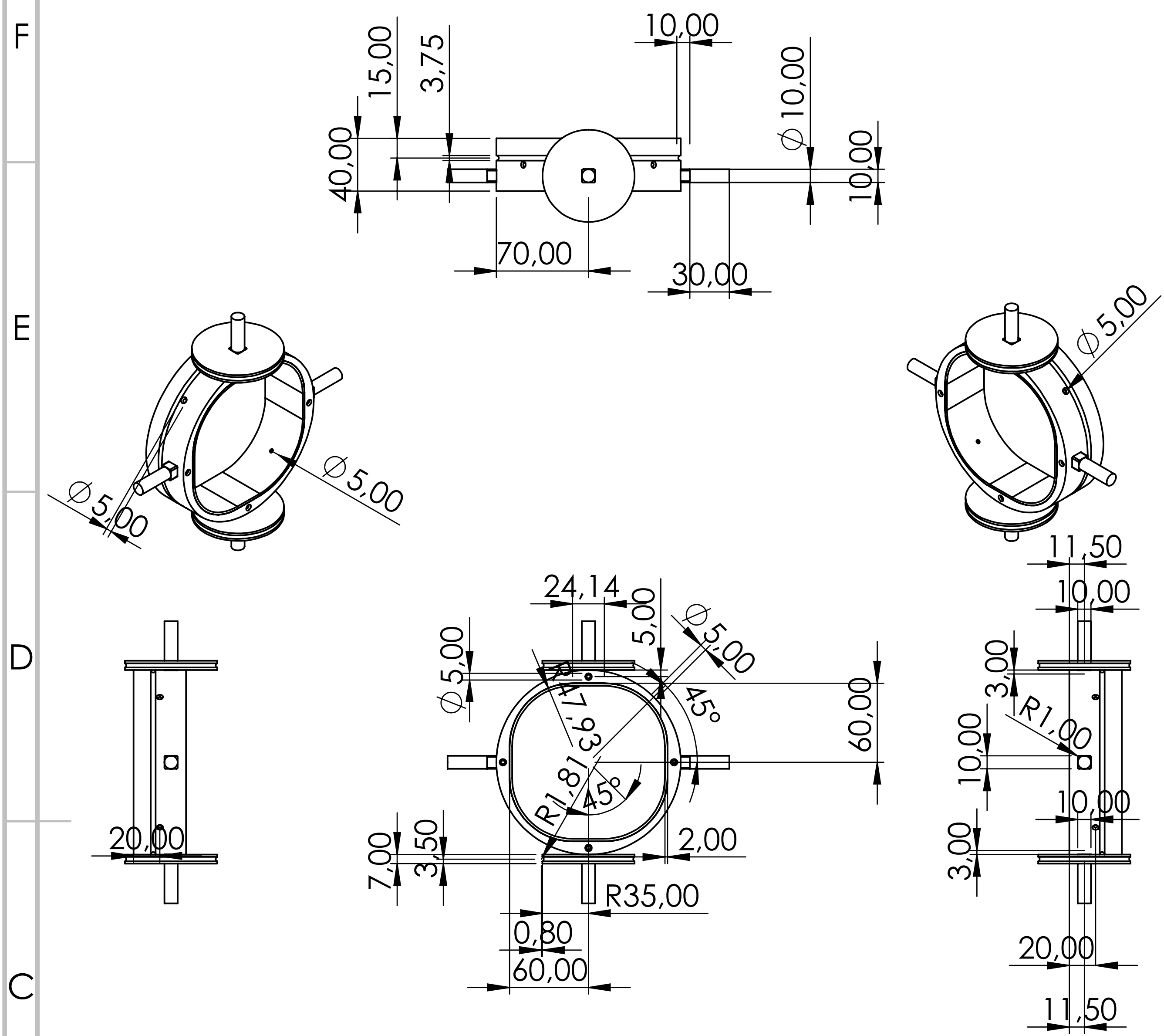
CHAPTER 9. Blueprints Document

Blueprints Index



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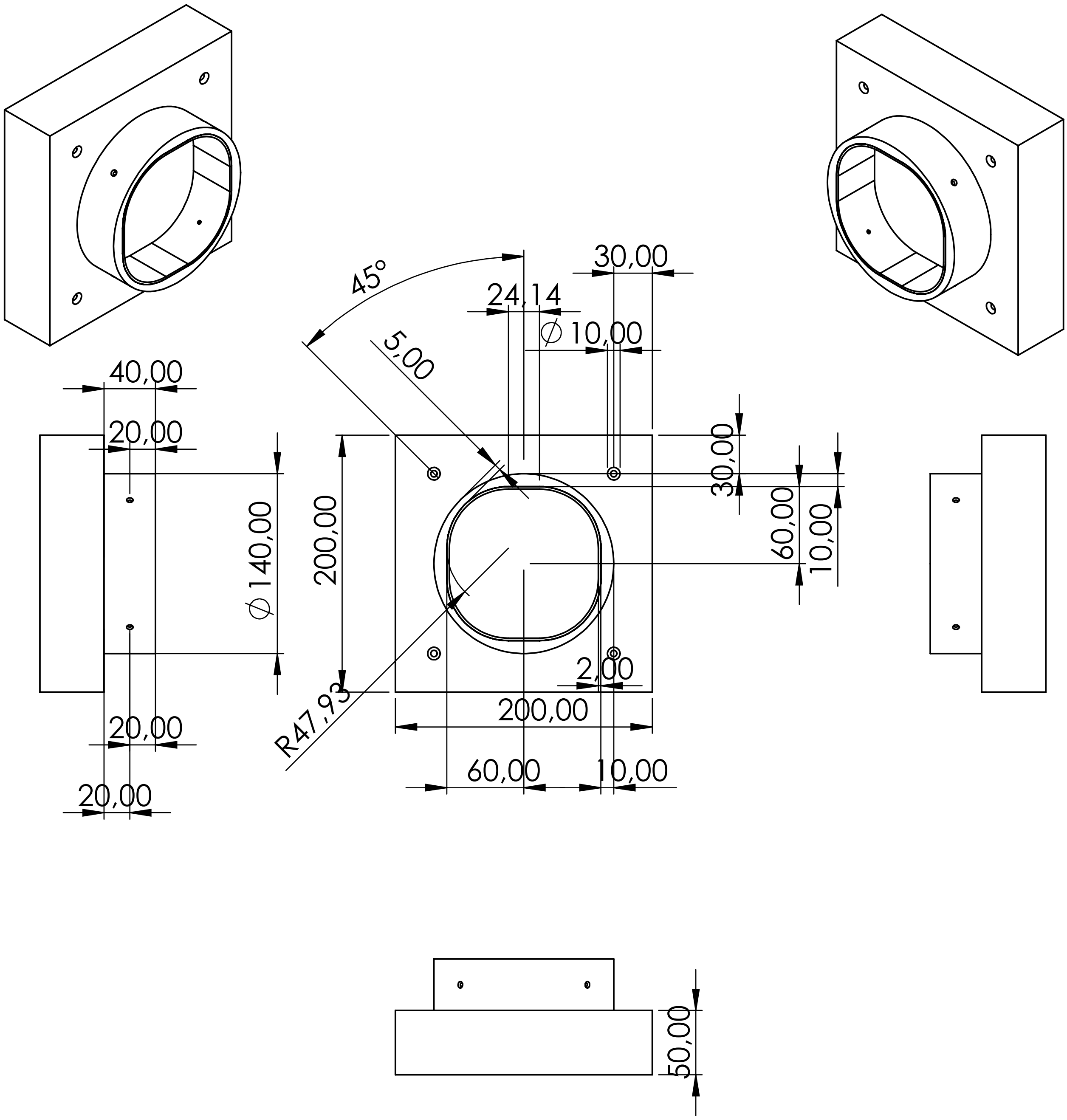

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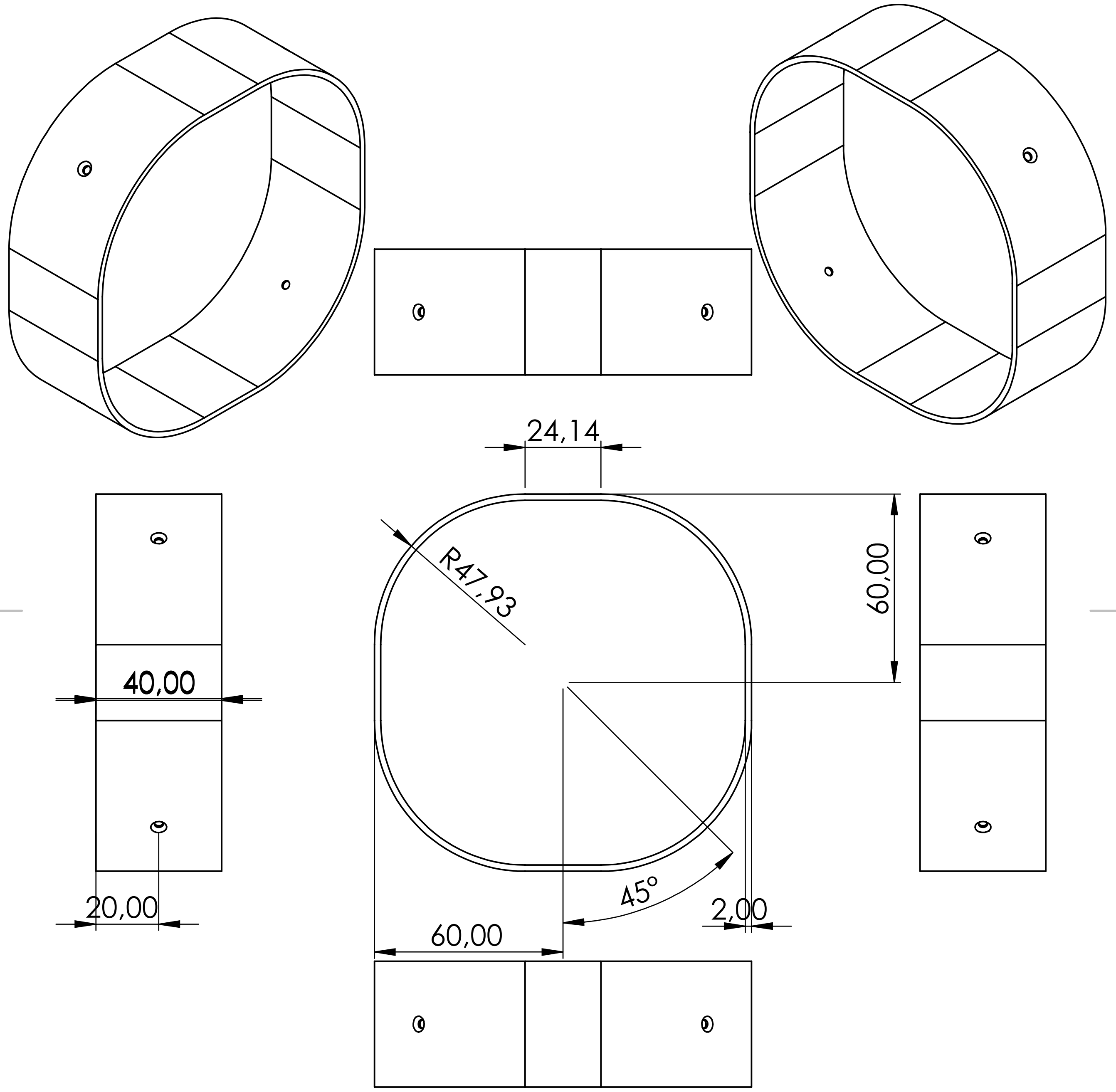

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