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Școala Doctorală de Inginerie Industrială și Robotică

SUMMARY OF THE DOCTORAL THESIS

RESEARCH ON THE DESIGN OF A DEVICE FOR THE TREATMENT OF VERTEBRAL COMPRESSION FRACTURES

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Cuprins

SUMMARY

In the present summary are presented the main aspects of the thesis as they are composed in the structure of the work, for this purpose presenting the Table of Contents, the numbering of chapters and figures, as well as the bibliography of the thesis in the original format for easier follow up of the presentation.

GENERAL ASPECTS

Medical implants are devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetic, meant to replace missing body parts. Other implants provide medication, monitor body functions or provide support to organs and tissues.

Some implants are made from skin, bone or other body tissues. Others are made of metal, plastic, ceramic or other materials.

Implants can be placed permanently or removed once they are no longer needed. For example, stents or hip prostheses are intended to be permanent. But chemotherapy ports or screws to repair broken bones can be removed when they are no longer needed. [1]

Hartmut F. Hildebrand, in one of his works on the beginnings and antiquity of implants (prostheses), makes the following (briefly) statements:

Prosthetic devices appeared at the dawn of human medical thought. The earliest evidence of human recognition of deformity and the need for rehabilitation is difficult to establish, as many ancient civilizations had no written records and historical accounts were recorded orally in songs, poems and sagas. To discover the beginnings, we must rely on anthropologists and archaeologists to interpret the myths, artworks and surviving fragments.

The making of dental implants and dentures dates back over 7000 years and is as old as the beginning of the invention of tools and tools, as old as the beginning of materials science in ceramics and metallurgy.

The most common surgical operations were bone repair, tooth replacement and skull drilling. A wide variety of materials were used from the very beginning: wood, mother-of-pearl and ivory were the first natural materials to appear, as well as allogenic bone for orthopedic construction. In terms of tooth replacements, ancient dentists used animal teeth, mainly from dogs, calves, seals and narwhals.

Later, with technological progress, surgeons and "scientists" - mostly the same person - introduced metal as prosthetic and implant material, in particular gold, silver, copper and lead with a more or less high degree of purity. The success, at least physically, of such medical devices is confirmed by the many archaeological finds, which clearly show that the operated patients survived the surgery.

Improvements have been made possible thanks to new surgical techniques, advances in prosthetic components and creative engineering ideas. [2]

Over time, due to the accumulation of surgical and anatomical knowledge, surgical procedures and orthopedic implant design have advanced. [3]

Recently, there has been accelerated progress in the manufacture and use of implants.

Today there is a wide variety of implants and prostheses. Thanks to technological development, it has been possible to obtain prostheses that are increasingly adapted to medical needs.

Advances in materials science have led to the identification and creation of biocompatible materials.

All this, coupled with medical breakthroughs, has led to the diversification and continued refinement of implants and their widespread use in a multitude of medical specialties.

This paper presents an implant-based therapeutic solution for the treatment of vertebral compression fractures.

In the INTRODUCTION Chapter, aspects related to the thesis research are presented. Some general aspects related to the specific terminology and references to the long-standing interest in implant issues and their evolution are presented. The motivation for the chosen topic is then presented, as part of the field of work from a certain period of professional activity. The objective and aim of the thesis are then established.

The thesis is then structured in four parts.

Part I presents the issues, current status and research direction. Thus, an overview of the problem of vertebral compression fracture is given, including aspects related to anatomical concepts, VCF itself, causes and symptoms, and epidemiology. This is followed by a review of the current status of VCF treatment and instrumentation. At the end of the first part the research direction is presented.

Part II is dedicated to the determination of the method and the choice of the implant technical solution. By going through the steps used in determining the optimal method the method used is determined. After an analysis of the mode of action of already commonly used treatment methods in treating VCF, a technical implant solution is determined, which can solve some shortcomings of already existing methods.

Part III presents Implant Design. It starts with the design requirements used in the design of this type of implant. Select the material from the list of recommended materials to meet the specific requirements. For the proposed mechanism concept, the structural scheme and stresses for each individual element are determined. Then, based on these values, the shape and dimensions of the elements of the assembly will be determined, depending on the role and function of each element within the mechanism. At the end of this part the strength verification of each component will be done by FEM.

Part IV covers the design of the instrumentation used to manipulate and operate the designed implant. Depending on the role of each tool, the shape and dimensions of each part are determined. The stresses for the identified critical elements are determined and after material determination, the FEM checks are made.

In the **Annexes** are presented the results of the verifications carried out as well as the technical drawings (of execution and overall) necessary for the realization of the implant.

The main objective of this PhD thesis is to design an implantable medical device to treat vertebral compression fractures. In addition to the effects usually obtained by other similar devices, i.e.: compensation of bone density loss (by providing cement), stopping vertebral damage (by reinforcing it with an implant), the following objectives will be emphasized, which are to be achieved with this type of technology, namely: restoration of vertebral height, by actuation as close as possible to the fracture site, use of a lower actuation force, and robustness.

The aim is, using a minimally invasive surgical method, to improve the quality of life of patients with vertebral compression fractures by relieving pain, restoring as much mobility as possible and preventing the fracture from recurring.

It is based on the intention to design an implant that works more effectively in treating this type of fracture.

In the treatment of vertebral compression fractures there are two main directions:

1. Conservative treatment where patients are prescribed medication, bed rest, medical recovery procedures, etc.

2. Minimally invasive surgical treatment - based on:

- "Classic" technologies (Vertebroplasty and Kyphoplasty).
- Combined technology (uses implant and cement in the treatment method).

Considering both the negative consequences on the quality of life of a patient with VCF, as well as the complications arising from such a condition, the following arguments are natural to justify the research activity in this field:

- any research activity aimed at improving the quality of life of a patient with a vertebral compression fracture is welcomes
- taking into account the disadvantages and complications that may arise from conservative treatment, especially in elderly patients who require prolonged bed rest, we can conclude at this point that in treating vertebral compression fractures, we should also look at other treatment directions and a natural direction of research is minimally invasive surgical treatment;
- after the period when gradually and naturally there were concerns about the elimination of certain shortcomings of the existing methods at that time, research directions were developed that led to the first innovative implants or so-called combined technologies.

3 REMARKS

In an attempt to establish a hierarchy (ranking) between devices in the combined technologies category (implant and cement), no studies or papers were found that addressed such a topic.

But analyzing the effects obtained by kyphoplasty and combined technologies, we compared the performance of *combined technologies* in relation to *classical technologies*, according to certain criteria.

- For example, some studies have shown that height restoration was significantly better in the **SpineJack** group compared to the balloon kyphoplasty group. Clinical implications include a better restoration of sagittal spinal balance and a reduction in kyphotic deformity, which may be related to the clinical outcome and the biological healing process. [40], [41], [42]
- In the comparative study [30], conducted to compare the performance of the Osseofix® system with that of kyphoplasty, it was found that like kyphoplasty, the method is easy to use and can be used effectively also in cases involving the posterior margin of the vertebral body. Compared to kyphoplasty, the **Osseofix®** System provides significantly less increase in vertebral body height and less correction of the mean Cobb angle without affecting the clinical outcome. On the other hand, it provides a significant improvement in pain intensity and activity level and has clinical results comparable to established cement cement reinforcement methods (kyphoplasty, vertebroplasty). It is a safe and effective method with a low complication rate (0% cement leakage rate, 2.2% adjacent fracture and height loss rate) compared to established cement methods.
- In a comparative study between **TEKTONA** and kyphoplasty, using cadaver vertebrae, the height restoration of two different augmentation procedures used to treat osteoporotic vertebral compression fractures was examined. The protocols for creating wedge fractures led to reproducible results and effects. The study showed that anterior and central restoration and volume was significantly improved with both techniques. Tektona® was shown to lead to comparable results. Force can be applied directly to the endplates, leaving more trabecular bone intact. [27]
- To compare the performance of the **V-STRUT** system with that of vertebroplasty, in one of the studies, it was shown that vertebrae that were implanted with the V-STRUT© device were at least as fortified as vertebrae treated with vertebroplasty alone. [43]
- Other studies have analyzed only the performance of the procedure itself, such as **VerteLift**, where the study concluded that spinal augmentation with the nitinol implant is an effective procedure that produces immediate and long-term pain relief, significant improvement in quality of life, and durable restoration of height with a good safety profile. [44]

***** *From the above we can conclude that preliminary results from several studies have demonstrated the feasibility, efficacy and safety of using these above-mentioned devices for rehabilitation or prophylactic treatment of pathologic VCF.*

5 CONCLUSIONS

By analysing the devices within the combined technologies as well as the directions of action in treating VCFs, some observations can be deduced about the trends in the field.

Emphasis is placed on the following benefits of a device used to treat VCFs by combined technology:

- The device allows height restoration in a controlled (adjustable) manner.
- The device decreases the potential for cement leakage.
- The device allows increased control of cement viscosity and lower pressure injection.
- The device maintains vertebral height while the cement hardens to prevent further damage to the vertebral body.

Also, by analysing existing data, general requirements of the implant concept can be extracted:

- Extensible implant that can be inserted into the vertebrae.
- The surgical instrumentation will allow the implant to extend to reduce fracture.
- Possibility to orient and adjust the implant opening.
- Combination with cement.
- Available in different sizes (desirable).

Under the Intellectual Property of Kyphon-Medtronic, vertebral compression fracture was an under-utilized market for many years until 2010, when the Kyphon patent expired.

For some time, innovative companies have focused on developing new products to treat vertebral compression fracture.

A shared vision is that there are now still truly significant opportunities for companies to be able to develop innovative products based on a combined technology.

The aim of this research is to design an implantable device that fulfills the above requirements. This device will be designed to restore the height of the vertebrae as effectively as possible by acting on the most affected area.

6 RESEARCH DIRECTION

6.1 ANALYZING THE OPERATING AREA OF VARIOUS DEVICES

Making an initial analysis of how the devices presented act to restore vertebral height, the following observations were made regarding the position where they act within the vertebra.

It can be seen that they all act on the endplates, in directions (black line) located up to midway up the vertebral body (red line).

Of these, the Kiva system and the Tektona system seem to be able to act closer to the collapsed edge of the vertebra.

The other three, SpineJack, Osseofix and VerteLift, act in areas close to the center of the vertebral body.

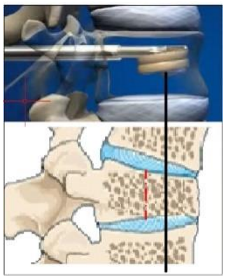


Figure 6.1- *Kiva [33], [48]*

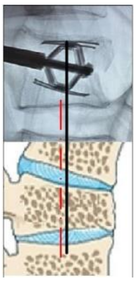


Figure 6.2 - *SpineJack [49], [48]*

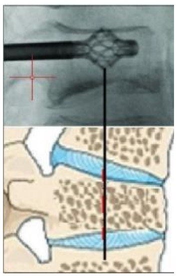


Figure 6.3 - *Osseofix [50], [48]*

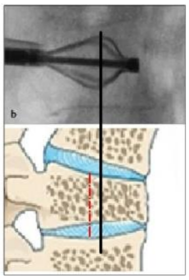


Figure 6.4 - *VerteLift [50], [48]*

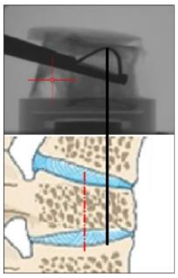


Figure 6.5 - *Tektona [27], [48]*

The V-strut system cannot be analysed from this point of view due to its proximity to the vertebroplasty principle.

The Vertebral Body Stenting System by the hydraulic action of the balloon, it acts on the walls of the cavity created by controlled perforation of the vertebra, and covers a fairly wide area of action, with a maximum positioned relatively towards the center of the vertebra.

6.2 ANALYZING HOW DIFFERENT DEVICES WORK

So far, both Kyphoplasty and SpineJack have proven their effectiveness in treating VCF both in rehabilitating vertebral height and relieving patients' symptoms.

Given their widespread use and demonstrated results, the two methods Kyphoplasty and SpineJack can be considered as a reference in the field of VCF treatment. Thus, it is only natural that any new method that may emerge should relate its results to these last two methods.

In brief, the description of the two methods has been presented previously in paragraphs 2.2.1.2 and 2.2.2.1 respectively

An analysis of the behaviour of the vertebra during the use of KP and SJ is performed for an understanding of the kinematics of the movement of the vertebral fragments during the actuation on them of the forces generated in the use of the two methods.

Only the principle of mechanical actuation of the vertebral fragments is analysed, without addressing other aspects such as: method of cement introduction, type of cement used, PMMA curing times, duration of the operation, patient recovery time, etc.

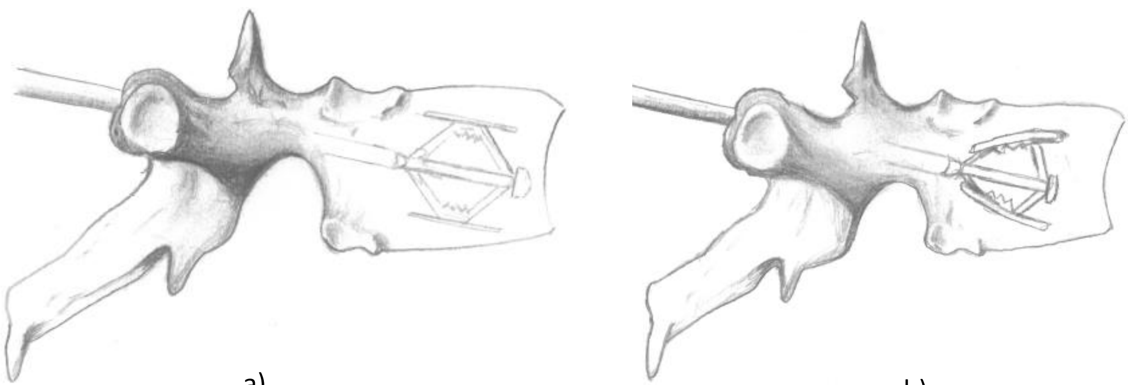
6.2.1 ANALYSING HOW THE SPINEJACK WORKS

The procedure using the Spine Jack system promises to restore the height of the vertebra "like never before" by inserting an expandable implant (much like a car jack) into the body of the vertebra, which in turn creates a cavity by the expanding action of the two arms to push the two bone plates of the vertebra back to their original position; this time, the cavity is created by mechanical action in a controlled (up-down) direction, given by the orientation of the implant. [28]

If only reinforcement of the weakened (demineralized) vertebral structure without displacement of bone fragments is desired, when using the SpineJack system, it is observed that the implant thrust soles remain approximately parallel.

If, however, a restoration of the vertebral height is attempted, it is observed that, after the expansion element (SpineJack or balloon) is inserted and actuated to create a cavity for the purpose of restoring the vertebral height, a cavity with a certain, quite pronounced taper is produced in the body of the vertebra (in *sagittal* view). These cavities were created both due to damage to the internal bone structure (under the mechanical action of the balloon or implant) and due to displacement of the upper and lower plates of the vertebra. Analyzing these cavity shapes, it can be observed that they have a larger opening towards *the anterior* part of *the vertebra*.

In the case of the SpineJack, it can be observed that, from the moment the device is opened, the soles of the device tend to act uniformly on the *top* and *bottom* fragment due to the constructive parallelism. Eventually, however, these soles lose their



a) b)

Figure 6.6– Schematic representation of the SpineJack action; a) Theoretical actuation of the device; b) Deformed appearance of the device in the action of restoring the vertebral height.

parallelism and end up in inclined positions with a pronounced taper (Figure 6.6). This aspect is easily observable in the works [51] ÷ [56]

6.2.2 ANALYSING HOW KYPHOPLASTY WORKS

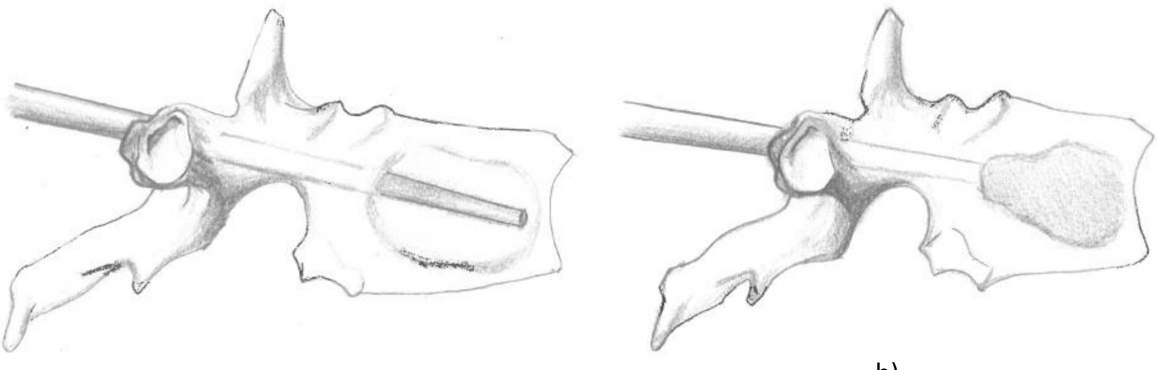
The same is observed for Kyphoplasty (Figure 6.7).

Recall that kyphoplasty consists of inserting a balloon into the body of the vertebra, inflating it and creating a cavity by displacing bone fragments back to their original position or by yielding cancellous bone tissue (especially if the cause of the fracture is osteoporosis); the creation of the cavity is somewhat random, following the principle of minimum pressure resistance inside the balloon. The resulting cavity is filled with cement. [11]

When only reinforcement of the vertebra is desired (for cases of immobile fractures) the shape of the balloon is approximately symmetrical along its length. Thus, the resulting cavity has a relatively constant height when viewed from the side.

In the case of mobile fractures, when the bone fragments are to be displaced, being pneumatic, the pressure in the balloon is constant and generates equal pushing forces through the balloon walls in all directions. And here, finally, a cavity with a variable opening is created.

In other words, under the action of a relatively uniformly distributed force toward the surfaces of the two end plates (upper and lower) of the fractured vertebra, they do not move linearly but (as expected) have a rotational motion (reverse to that produced at the time of fracture). This is observed in papers [57] ÷ [63].



a) b)

Figure 6.7 – Kyphoplasty action: a) Theoretical shape of the cavity created by the balloon action; b) Shape of the cavity obtained in an attempt to restore the height of the vertebra.

Kinematically, it seems that during the process of restoring the shape (height) of the vertebra, it behaves like a joint that has loose ends towards the anterior and the point of rotation somewhere in the posterior area of the vertebral body. This explains the greater *anterior* displacement of the vertebral plates.

In one case and in the other (SpineJack or Kyphoplasty), part of the energy (the force developed by the system) is dissipated in the *entrance* area of the SpineJack or balloon. In this portion, where the cavity created is small in shape, close to the diameter of the hole created for access into the vertebral body, the thrust forces, however great, do not produce significant displacements in geometric or anatomical terms. The conclusion being that the force required is in the anterior part of the vertebra, i.e. in the collapsed area, not in the posterior, uninjured area. However, both systems act both on the areas affected by the fracture that need to be displaced and on the uninjured (non-fractured) area that does not require displacement.

6.3 RESEARCH DIRECTION APPROACHED

This suggests that in order to effectively utilize the energy used in pushing the two plates of the fractured vertebrae in the cranio-caudal direction, it is useful to use a method of pushing them in the portion near the anterior edges as far as acceptably far from the "point of rotation". One solution is to use a mechanism consisting of articulated arms that have little or no displacement at one end (the posterior one, at the entrance of the hole drilled for the implant insertion) and maximum displacement at the opposite end, towards the anterior.

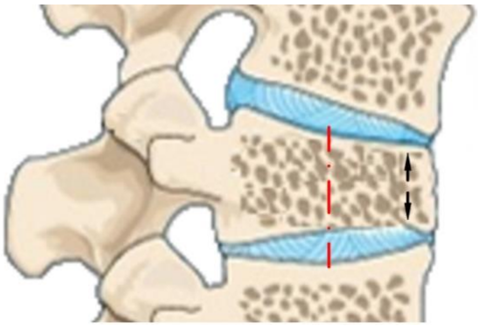


Figure 6.8 *- Actuating the end plates in the collapse zone*

Compared to the methods presented so far, with the technical solution proposed in this paper, the implant acts in the area of collapse of the vertebral body (in the anterior area). By doing so, it restores the height of the vertebra in the affected area, maintaining the integrity of the vertebral territory not affected by the fracture (posterior area). This is an advantage since bone fragility due to osteoporosis affects the entire vertebral body mass (Figure 6.8).

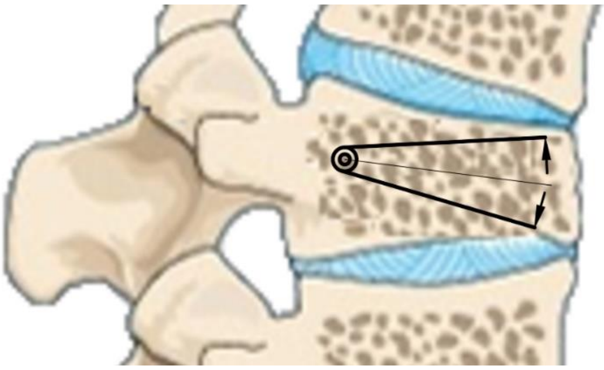


Figure 6.9 *- How the implant works*

At the same time, its mode of action can maintain around it (especially on the lateral sides) access to the uncut (and therefore still permeable) trabecular bone over a sufficiently large area to benefit from the interpenetration of the cement with the existing bone tissue (Figure 6.9).

10 DETERMINATION OF THE PRINCIPLE SCHEME OF THE DEVICE

Once the mode of actuation has been determined for the chosen method, the number of actuating arms will be determined. Because of their small size, the number of arms cannot be very large, as they will not be of sufficiently robust construction. A three-arm mechanism will be compared with a two-arm mechanism.

10.1 ANALYZE THE ACTION OF MECHANISMS ON VERTEBRAE

On the basis of some proposals to use for implantation a mechanism with arms that extend only at one end, we will perform a comparative analysis between a solution that involves using an extensible mechanism consisting of three arms that extend at one end and articulate at the other (Figure 10.1) [64] and another solution that involves using a mechanism with two arms articulating at one end and extending at the other (Figure 10.2).

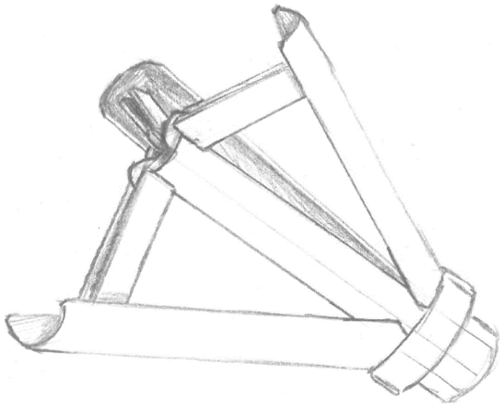
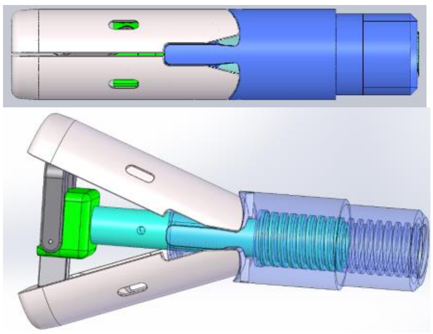


***Figure 10.1** – Implant with 3 articulated arms*

In both cases the arms are obtained by dividing the circular crown into three and two sectors respectively. In the version with three arms, they can be divided identically or with different sections by varying the angle at the center. In the version with two arms, they are obtained by equally dividing the circular crown from which they originate.



a)

b)

***Figure 10.2 –** Implant with 2 articulating arms (Two-Arm Device): a) Closed; b) Open*

Next, we will present an analysis of how the two mechanisms are stressed, then an analysis of the most sensitive element of the mechanism, and finally a method to improve the performance of this type of mechanism is presented.

10.1.1 ANALYSIS OF ARM SOLICITATION

10.1.1.1 SOLICITATIONS OF THREE-ARM VARIANT

The three arms may or may not be arranged equidistantly around the axis.

We do not discuss issues related to the practical possibilities of orienting the implant for correct positioning in the body of the vertebra. We only analyze mechanical and kinematic aspects of the mechanism.

We will start from a simplified schematic (Figure 10.3) to understand what happens during operation.

After insertion of the implant, it can orient itself in two characteristic positions:

- the situation in which one of the three arms is in contact with one of the vertebral endplates and the other two will also (both) be in contact with the other vertebral endplate, so that the full force developed by the mechanism is utilized (Figure 10.3 a).

- situation where not all three arms are in contact with the vertebral endplates but one is in contact with one plate and of the remaining two, only one pushes into the other plate, the other one relaxing, pushing laterally, depending on the angle between the arms (Figure 10.3 b).

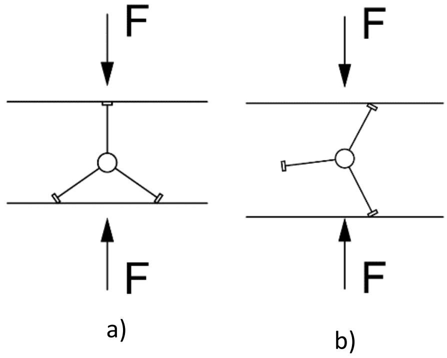


Figure 10.3 – *Implant 3 brate*
a) Full contact; b) Incomplete

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- situation where not all three arms are in contact with the vertebral endplates but one is in contact with one plate and of the remaining two, only one pushes into the other plate, the other one relaxing, pushing laterally, depending on the angle between the arms (Figure 10.3 b).

The second situation, in which all three arms do not work, being an undesirable situation and considered as meaning incorrect functioning, will not be analyzed (the reasons are obvious: instability during expansion, risk of damage to the vertebra by lateral thrust, etc.).

The first situation involves loading the three arms according to the loading scheme shown in Figure 10.4.

By denoting by F the force required to move the bone fragments, through the associated plate, force F acts on arm 1. Through the other plate, force F is transmitted to both arms. Due to the assumption that is accepted (that of the symmetry considered), each arm that comes into contact with this plate transmits the force F/2. As it can be seen, one of the arms is loaded by the whole force F, which makes it the most vulnerable if we refer to the loading aspect. It is subjected to the bending stress generated by the force F.

At the same time, the other two arms, although they are each loaded with only half of the force to be developed, due to the action of this force at a certain angle on the arm, in addition to the bending stress, these two arms are also subjected to a torsional moment, i.e. we are dealing with a compound stress for each of them.

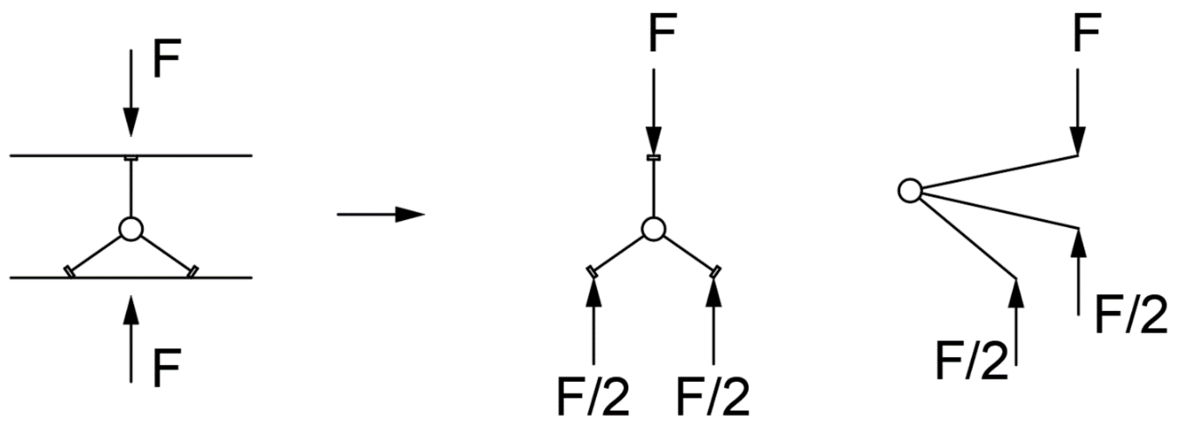


Figure 10.4 – *3 arms loading scheme*

Obviously, the stress on each arm becomes more complex if all the existing stresses specific to the assembly are taken into account (interaction with the other elements, friction between the elements of the mechanism, friction with the fabric, etc.).

The resistance of the whole mechanism is given by the resistance of the weakest element (the one that fails first). Therefore, constructively and/or kinematically, a solution can be found to balance the stress on the three arms

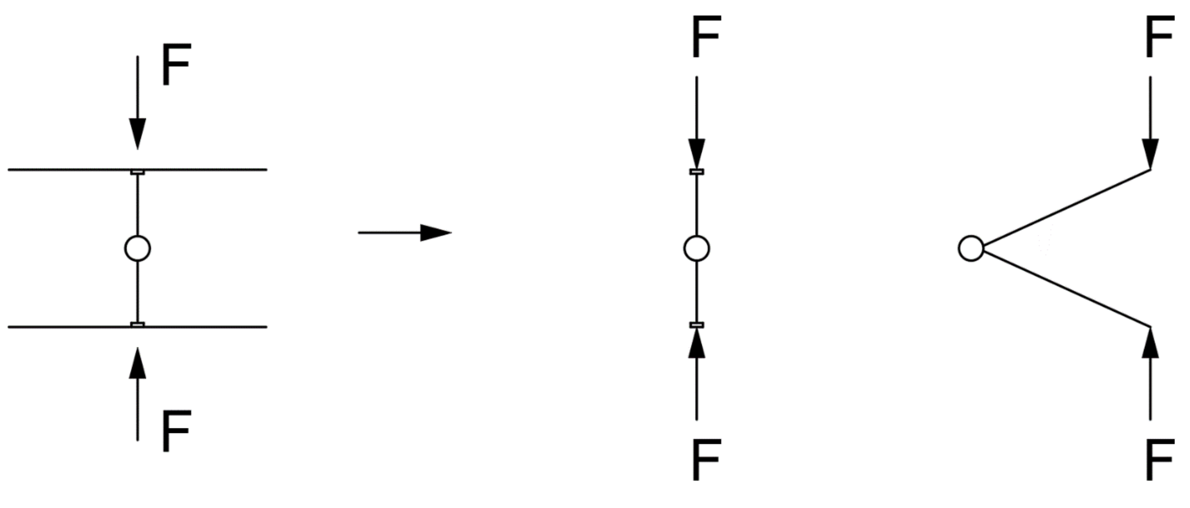


Figure 10.5 – 2 arms loading scheme

10.1.1.2 SOLICITATIONS OF TWO-ARM VARIANT

If there are only two arms, then the loading scheme is as in Figure (Figure 10.5). The two arms are identical. Consider only the situation when the mechanism is correctly positioned i.e. when each arm contacts one plate and acts in the (cranio-caudal) direction.

It can be seen that each arm is loaded by the same amount of force, F. According to the direction of the force, both arms are loaded in bending.

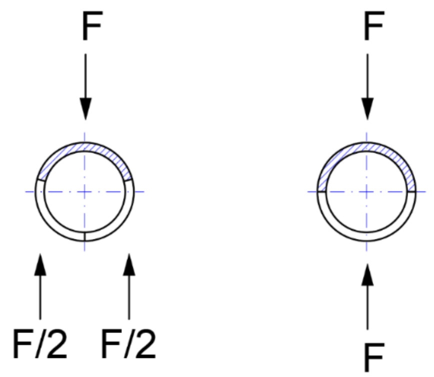


Figure 10.6 – The appearance of the arm with the highest load

10.1.1.3 REMARK 1

Comparing the two solutions with each other and analyzing the arms that are subjected to the force F, it can be observed that the arm in the 2-arm solution has a more robust structure (Figure 10.6) and therefore the amount of stress it can be subjected to will be higher.

10.1.2 ANALYZING THE ACTUATION OF ARMS (SOLICITATION OF LEVERS)

Analyzing how the arms that push towards the endplates are actuated, the following observation was made in [65]:

10.1.2.1 REMARK 2

It can be observed that both for the pushing force (actuating force and lever tension) the highest values are at the beginning of the actuation of the mechanism, when the device is in the closed position. This implies that, in order to have the lowest values for the axial force acting on the levers (and indirectly for the actuating force of the mechanism), it is necessary that the angle α (the angle made by the lever with the axis of the device) has the largest values. This will result in lower stresses for other components of the assembly.

10.1.3 ÎMBUNĂTĂȚIREA PERFORMANȚEI MECANISMULUI

Starting from the previous observation, in an attempt to minimize the stresses in the levers, in other words to decrease the initial value of the lever actuation force (from the closed position), taking into account three kinematic variants possible to implement, the following observation was reached [65]:

10.1.3.1 REMARK 3

The advantage offered by the solution in which the joints of the two levers are located on either side of the rod axis (but each in the opposite semi-plane to the joint at the other end) is very difficult to exploit by the 3-arm variant, but accessible to the 2-arm variant in various constructive variants (Figure 15.5 c).

11 CONCLUSIONS

A. In terms of actuation principle, compared to the SpineJack system, the tapered opening system allows less force to be used for restoration.

The tapered opening system also avoids pressure stress on the integral portion of the vertebra.

Since the force required is a very important limitation in the construction of such a small mechanism, in this respect the tapered opening system offers a greater variety of constructive solutions leading over time to an optimized solution.

Even the SpineJack system can be adapted to have such kinematics that the opening of the arms is no longer plane-parallel but angular, in order to reduce the force required to push the bone fragments.

B. One of the arguments tempting to consider such a configuration (three-arm) is that of the stability of the system.

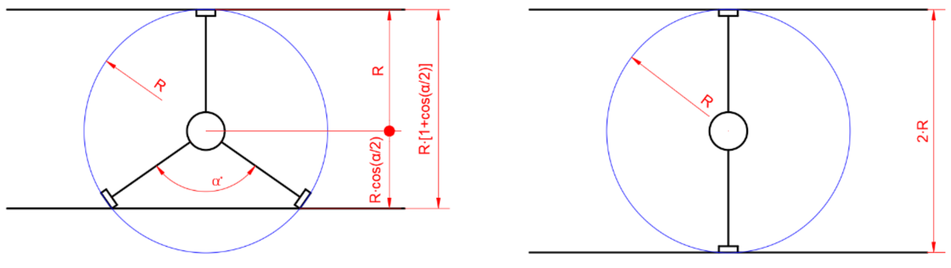
As far as the stability aspect is concerned, it should be noted that there is bone tissue, of a certain consistency, inside the vertebra. It is true that it is of a much sparser consistency in relation to the vertebral wall and even damaged by osteoporosis. But whether we are talking about SpineJack or other mechanisms, after expansion of the arms, the arms will themselves damage the bone tissue of spongy consistency. By moving, the arms, they cut the tissue. They will generate channel-like cavities (grooves) that deepen to a certain point depending on the direction of the force. The walls of these channels will also play a role in preventing the deflection of the arms moving towards the upper and lower plates of the vertebral body.

From the literature reviewed with research data on SpineJack utilization, it does not appear that a mechanism with two-directional action would be unstable under these specific conditions of use. In other words, an alleged instability cannot be an argument for increasing the number of arms.

Referring to the behaviour of the Spine Jack system inside the vertebra, those deformations that appear in the radiological images are not due to the instability of the system but to the uneven distribution of the force acting on the blades (arms), as previously presented.

C. A comparison between the two tapered opening solutions (the three-arm and the two-arm) shows that the two-arm variant allows for more robust mechanism construction solutions that can withstand higher forces.

Another advantage of the two-arm system is that it develops equal and symmetrical stresses on each end plate of the vertebra, due to the constructive symmetry and kinematics.



a) b)

Figure 11.1 *– Maximum arm opening: a) 3 arms and b) 2 arms*

At the same time, geometrically, the double-arm variant has a larger opening (stroke) of the arms, which allows for greater displacement of the vertebral endplates (Figure 11.1).

Also, inside the vertebra, the positioning of the two-arm device is less restrictive, so that even for slight deflections, both arms will continue to have the same loading and behaviour, which provides greater system stability compared to the multi-arm.

The superiority of Two-Arms Device is that:

a) it is more robust than a multi-arm device and

b) it acts more efficiently on the bone fragments both in terms of function (place of force action, how the fragments move, etc.) and in terms of force required (less force is required than in the SpineJack).

On the one hand because of the lower force required, this will result in an easier operation of the mechanism. As less actuating force is required, the focus will be on the smoothness of the movement.

On the other hand, due to the robustness, it is hoped to restore the height of the vertebra more efficiently and thus improve the patient's symptoms.

18 CONCLUSIONS

The need for continuous improvement in treatment methods has led to the design of a combined technology implant with the aim of improving the quality of life of patients with vertebral compression fractures.

In this Part, the design of the implant was presented, starting from the kinematic analysis of the concept, determining the stresses which in turn determined the shape and dimensions of the component elements.

To this end, for each part, the functional role, the functions it has to fulfill, were analyzed, and then it was shown how these requirements were implemented. Throughout the design, numerous FEM analyses (simulations) were carried out in order to determine the optimal parameters, in terms of dimensions and loads.

The final simulation reports for each part show that the implant can fulfill its functional role at the required stresses, working in pairs (two simultaneously).

23.1 FINAL CONCLUSIONS

In this work an implantable medical device was designed to treat vertebral compression fractures.

It is a type of fracture that has long been surgically untreatable, but recently, thanks to technological developments and the use of new materials in the field of implants, it has been possible to treat it by percutaneous surgery, with increasingly better results.

This type of fracture frequently occurs in people affected by osteoporosis (a condition that is also present in elderly patients), which often leads to further complications if left untreated.

The implant solution was determined following a multi-criteria analysis, taking into account specific criteria. After analyzing the agreed solutions, a mechanical solution was chosen as the optimal solution.

Although during the course of the research presented in this paper a team of researchers from Taiwan [64] presented a similar technical solution a year ago, in contrast to the proposal presented by that team, the device designed in this paper, presents advantages that make it more efficient both in use and in treating the type of fracture for which it was intended. These advantages have been demonstrated and highlighted throughout the paper.

Thus:

- the designed mechanism requires less force to move the bone fragments and therefore less actuating force;

- is more robust than a multi-arm mechanism;

- the implant acts closer to the fractured area, i.e. at a greater distance from the "pivot" point of the bone fragments, which makes it more efficient in pushing them back to their original position, giving them a trajectory similar to the one they traveled during their collapse.

On the one hand, due to the lower force required, this will result in an easier operation of the mechanism. As less operating force is required, the focus will be on the smoothness of the movement.

On the other hand, due to the robustness, a more efficient restoration of the vertebral height is obtained and consequently an improvement of the patient's symptoms. [65]

The implant was designed starting from the conditions that it must fulfill. After establishing its kinematic and structural scheme, both the shape and dimensions of the constructive elements were determined, taking into account the role (functions) of each component, analyzing the stresses that occur.

In designing the device, SolidWorks software versions 2022 and 2023, standard module, was used. For the checks and simulations performed by FEM, within the same software, the SimulationXpress Analysis Wizard function was used for simpler analysis, and the SolidWorks Simulation module for static analysis.

In terms of Instrumentation, each designed tool fulfills one or more functions throughout the implantation process. Thus, the shape of some is more complex and others are simpler, depending on the role and the demands they have to fulfill. They are customized or adapted to the specific implant situation.

From the FEM analyses performed for the critical areas, it appears that the instrumentation behaves appropriately so that the implantation process can be mechanically safe.

They have been designed in such a way that their sterilization and preservation (storage) can be easily done.

23.3 FUTURE RESEARCH DIRECTIONS

This paper opens new research perspectives based on observed aspects that can be improved. By highlighting and analyzing these aspects, improvements of existing methods and the emergence of new solutions can be achieved.

Further developments will take into account technological progress (processing and heat treatment possibilities) as well as new developments in the field of materials science, in particular in the field of biocompatible implant materials. Of the latter, particular attention will be paid to those which will give increased mechanical strength to small parts, but also to those which, once implanted, will create a symbiosis with human tissues.

Thus, a first research direction will be realized in the technological field, taking advantage of the current possibilities, in order to simplify the structure of the mechanism, with the aim of making the mechanism itself more efficient and the way it acts on bone fragments.

A second direction for future research may be the use of materials in the structure of the mechanism that would exclude the use of currently used cements and the reinforcement (strengthening) of the vertebral structure after implantation would be achieved by the interaction between the vertebral structure and the structure of the implant material.

Obviously, these approaches have consequences for the shape and dimensions of the implant elements, which must be designed in such a way that the implant can be made and fulfill its functional role in accordance with the rules in force at the time.

Last but not least, the appropriate instrumentation for the use of the implant must be considered.

A third line of research concerns instrumentation regardless of the type of implant. In addition to the purely mechanical approach to its functional role, the realization of an intelligent device is envisaged, which by electronic control, depending on the mechanical load detected and the limitations imposed as input data, it will control the opening of the implant at optimal parameters.

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