ANALYSIS OF THE LOADING MECHANISM OF AN IMPLANT USED TO TREAT VERTEBRAL COMPRESSION FRACTURES

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In the context of a significant number of cases of vertebral compression fracture, implants are beginning to be used as treatment methods in recent times. In the present work, to achieve the most appropriate strength verification for an implant, an analysis of its mode of action inside a vertebra fractured by compression is performed. The influence of various parameters on the stresses of some implant components is studied. It is thus verified that the hypotheses adopted for the analysis to be carried out by the finite element method are pertinent. It then identifies which measures can be adopted for future optimization of the device.

Keywords: force analysis, implant.

1. Introduction

Vertebral compression fractures (VCFs), common in older people, occur annually in about 1.5 million in the United States alone [1]. A characteristic feature of this type of fracture is that it is primarily caused by osteoporosis, a condition that occurs with advancing age and consists of bone demineralization and loss of bone density. [2].

Fig. 1. Vertebral compression fracture [20]

Vertebral compression fracture consists of a collapse of the vertebral body, which occurs in the anterior part of the vertebra (Fig. 1.).

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Surgical methods of treatment have their beginnings in Galibert's first realizations in 1983, being the basis of vertebroplasty (insertion of cement into the vertebral body for reinforcement) [3].

Regarding the used cements, usually, two types of cement are used in kyphoplasty or vertebroplasty, namely, acrylic bone cement or calcium phosphate bone cement,

For the acrylic cement used the specifications are found in:

ASTM F451-2021: Standard Specification for Acrylic Bone Cement

ISO 5833:2002 - Implants for surgery - Acrylic resin cements

These specifications describe the composition, physical performance and biocompatibility, and packaging requirements.

There are companies that offer the complete solution (implant, instrumentation, cement with a plant for its preparation and use). There are also companies that produce only cement for fixation of orthopedic surgical implants, including spinal implants.

Implant cement involves an amorphous PMMA powder and a liquid methyl methacrylate (MMA) component which in combination with the powder creates a mixture that begins to harden after mixing. This is introduced into the cavity using a syringe or special device. The curing process can take several minutes.

In general, these cements are classified according to their viscosity, i.e. low-viscosity, medium-viscosity and high-viscosity cements. [4]

The use of kyphoplasty (inserting a balloon into the vertebral body, creating a cavity by inflating the balloon and filling the cavity with cement) follows. [5]

After 2009, combined methods of treatment using both cement and implants appeared. For these combined methods of treatment (implant and cement), the cement is intended to fill the void created by the insertion and action of the implant. Thus, the implant, once it has achieved its objective (to move the bone fragments of the vertebra away from the vertebra) is fixed in that position, flooded by the cement inserted. In this way, implant and cement form a common block, which will prevent further displacement of the vertebral fragments.

From the category of these used implants, we mention the following.

Osseofix Spinal System produced by Alphatec Company [6]. Referring to this system, in the study conducted by Dheerendra Sujay et al [7], it was concluded that "Stabilization of VCF with OsseoFix system is associated with a short hospital stay and a low complication rate. Initial results for minimally invasive VCF therapy with the OsseoFix system show that it is a safe and effective alternative."

Stryker's SpineJack implant [8]. 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 [9], [10], [11]. Also, one of the most recent studies, highlight that the use of bilateral expandable titanium SpineJack implants, followed by vertebroplasty, is a safe and effective procedure for the treatment of vertebral fracture from pathological compression secondary to Multiple Myeloma, allowing an adequate restoration of the vertebral height and a correct distribution of the craniocaudal load forces on the vertebral column. [12]

Izi Medical's *Kiva System* [13], a former utilized in the care of clinical experiences that demonstrated significant improvements in back pain and function with minimal and clinically insignificant leakage of procedural cement. [14]

The *V-Strut* device produced by the Dawa Medical company [15], for which, along with other implants used, a study concluded that percutaneous vertebral fixation of cancer-related FCV is feasible and safe, regardless of the intravertebral implants used. [16]

The *Vertelift* implantable device from SpineAlign [17] has also been studied in this series of patients and it was concluded that vertebral 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. [18]

This category of (combined) treatment methods include the implant designed by one of the authors, following the study carried out and presented in another paper [19]. It is the Two Arm Device - TAD (Fig. 2.).

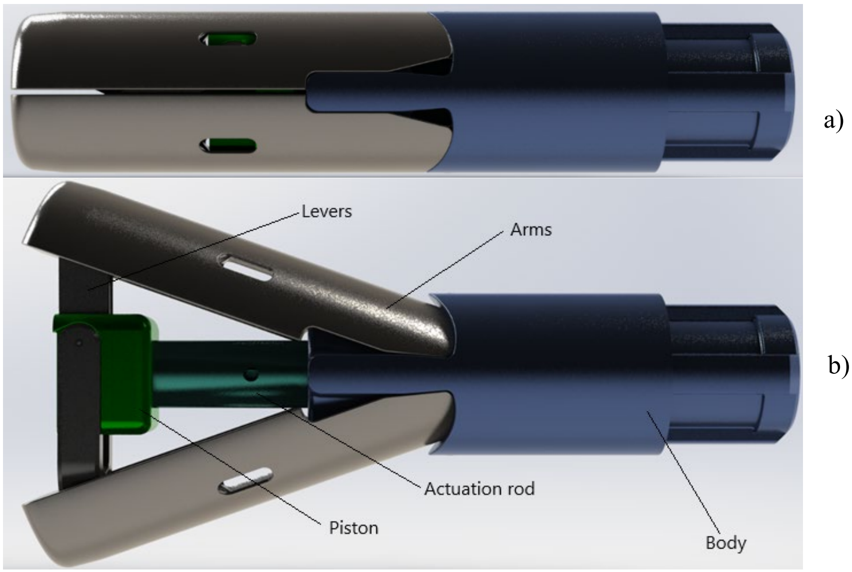


Fig. 2. TAD Implant: a) Closed; b) Open.

It consists of a Body through which passes an Actuating Rod threaded at one end and connected at the other end to a Piston. Hinged to the Piston are two

Levers which, with opposite ends, push outward the ends of two Arms. The Arms are in turn connected to the Body by a joint.

The connection between the Actuating Rod and the Body is provided by a screw-nut threaded coupling. By means of the instrumentation, through rotation, the Threaded Rod is imparted a translatory motion, and by means of the Piston, the Levers are pushed. These, by a rotational movement around the joint in the Piston push the Arms outward with the other end.

In the present paper the calculation hypothesis used for the strength verifications that were carried out by a finite element method analysis is argued.

2. Paper contents

After insertion of the implant into the vertebral body by one of the methods of approach adopted surgically, the mechanism is actuated to produce displacement of the vertebral parts towards original positions. The mechanism acts in the cranio-caudal direction on the end plates of the vertebra (Fig 4) by means of arms articulated at one end and which are disengaged when the Implant is operated from the outside by means of instrumentation.

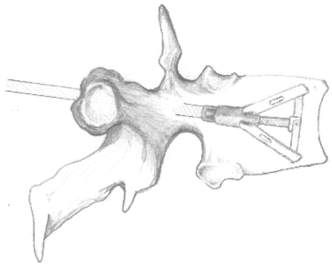


Fig. 3. TAD implant mode of action

The structure of the vertebral body in the implant actuation zone is shown in Fig. 4. The vertebral body is made of trabecular (cancellous) bone on the inside

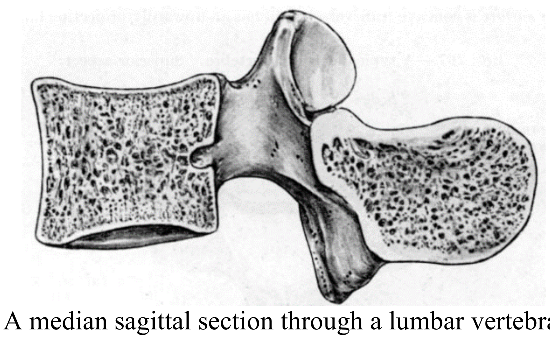
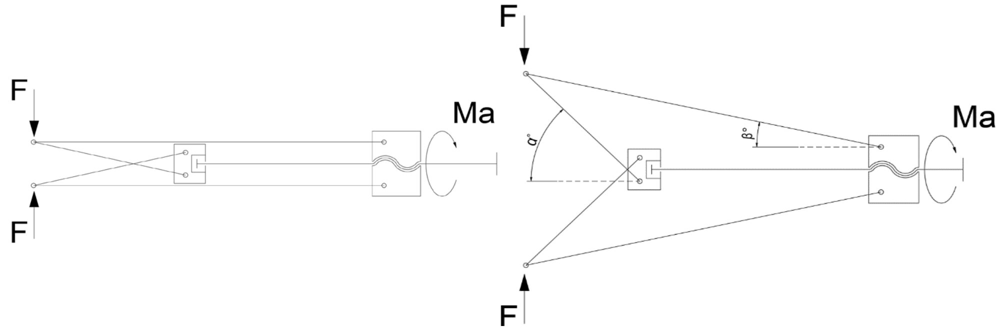


Fig. 4. A median sagittal section through a lumbar vertebra [20]

and has a cortical bone sheath on the outside. At the top of the vertebra is the superior endplate and at the bottom is the inferior endplate.

The kinematic scheme of the device is shown in Fig. 5.



a) b)

Fig. 5. TAD kinematic scheme: a) Closed; b) Open

For this type of mechanism, it is known that the maximum stresses occur in the actuating rod when the mechanism opens.

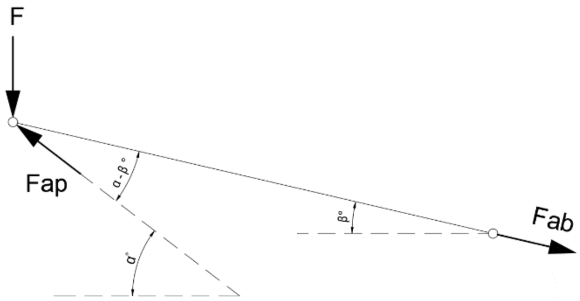
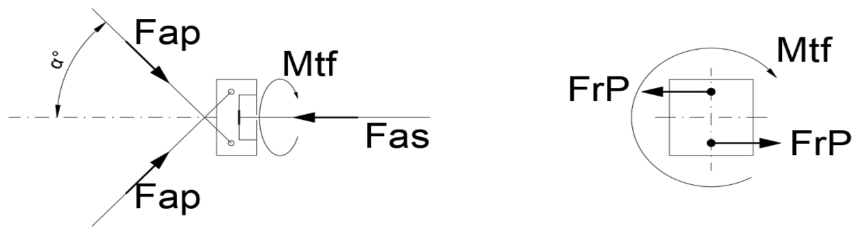


Fig. 6. Arm loading scheme

For the mechanism of the implant (Two Arm Device - TAD), some elements were isolated to determine the relation between the stresses occurring in these elements and the external force (Fig. 6 - stresses in the arm and Fig. 7 - stresses in the piston).

It was noted with Fap the axial stress in the rod, with Fab the axial stress in the arm, with F_{as}, the axial stress in the Actuating Rod and with F the external force. We have isolated only these two elements to have a calculation formula for F_{as} and F_{ap} as a function of F. For this purpose, we will use only the calculation relations that give us this information.

Thus, from one of the equilibrium equations for Piston (Fig. 7) we have



a) *b)*

Fig. 7. Piston loading scheme

$$2 \cdot F_{ap} \cdot \cos\alpha = F_{as} \tag{1}$$

By writing the equilibrium equations for the arm loading scheme (Fig. 6), we obtain:

$$F - F_{ap} \cdot \sin\alpha + F_{ab} \cdot \sin\beta = 0 \tag{2}$$

$$F_{ap} \cdot \cos\alpha = F_{ab} \cdot \cos\beta \tag{3}$$

$$F \cdot l \cdot \cos\beta = F_{ap} \cdot l \cdot \sin(\alpha - \beta) => F_{ap} = F \cdot \frac{\cos\beta}{\sin(\alpha-\beta)} \tag{4}$$

By integrating in equation (1) F_{ap} with relation (4), we obtain:

$$F_{as} = 2 \cdot F \cdot \frac{\cos\beta \cdot \cos\alpha}{\sin(\alpha-\beta)} \tag{5}$$

Constructively, for the closed position of the implant β=0 and so cosβ=1 and sin(α-β) = sin(α), which makes relation (5) to become:

$$F_{as} = 2 \cdot F \cdot \frac{\cos\alpha}{\sin\alpha} \rightarrow F_{as} = 2 \cdot F \cdot \text{ctg}\,\alpha \tag{6}$$

The value of F_{as} is maximum for minimum values of sinα. The value of sinα is minimum for the minimum value of α. Thus, we will have the maximum value of F_{as} when the device starts to open, as can be seen in the centralizing table Table 1, used to draw the graphs.

Note that the force F represents the force with which the implant pushes the end plates of the vertebra when the arms of the device come into "contact" with them.

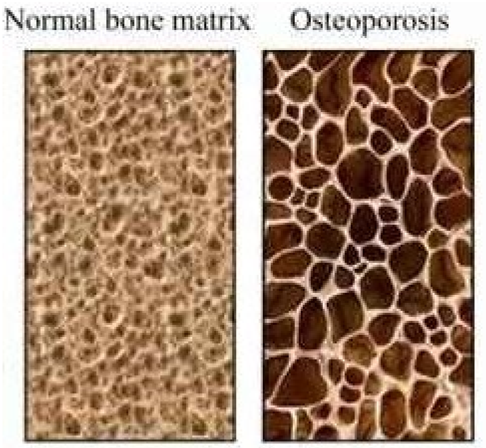


Fig. 8. The effect of osteoporosis [21]

In fact, taking into account that the arms act in the vertebral body, which is made of trabecular (cancellous) bone affected by osteoporosis (i.e. even more rarefied) - Fig. 8, when the implant starts to open, it will levitate a portion of cancellous bone in the direction of action, until the tissue becomes compact enough to transmit the thrust force given by the implant arms to the end plates by means of subsidence.

At this point the force opposing the displacement of the arms increases significantly and continues to increase up to the maximum value considered.

Basically, at that time, when the opening of the arms begins, the force acting on the arms is minimal, given by the resistance opposed to deformation by the cancellous tissue.

The resistance opposed to deformation is given by both the architecture of the bone and the composition of the bone trabeculae (very fine linear structure of cancellous bone), the latter depending on biochemical (degree of mineralization), anatomical, pathological factors. [22]

The conditions under which the implant acts are:

- the fracture is generally produced in a tissue affected by osteoporosis;
- the resistance to deformation of the trabecular bone is difficult to assess;
- it is difficult to assess to what degree of subsidence the trabecular bone had to reach in order to transmit the action of the implant arms to the end plates.

Taking into account, all these aspects it will be considered that the maximum force is acting on the device from the beginning.

Although this maximum value is generated when opening the implant arms.

In order to have a picture of the stresses in the components of the system, in particular the axial force in the drive rod (the one with the highest value), a study of the variation of this stress (F_{as}) as a function of the opening of the arms will be carried out.

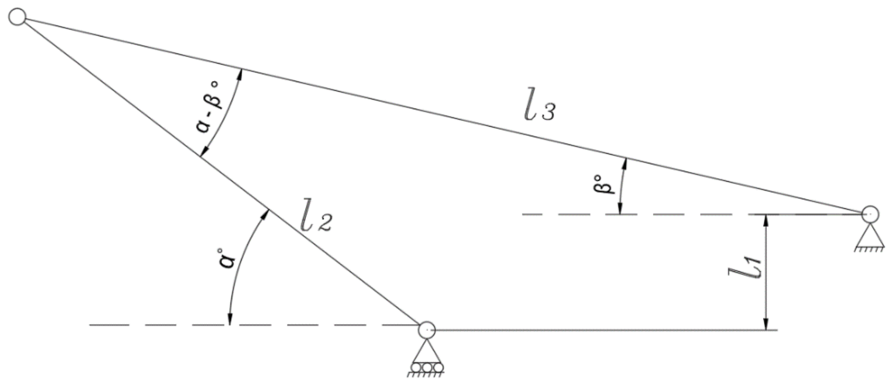


Fig. 9. Positional scheme between lever and arm

Analyzing the geometry of the device (Fig. 9) the following relations are obtained:

$$l_2 \cdot \sin\alpha = l_3 \cdot \sin\beta + l_1 \quad (7)$$

Thus, depending on the variation of the angle β, we determine the formulas by which we can obtain the values of some parameters in order to study the variation of these parameters on whose value depend other demands on the elements of the mechanism.

$$\sin\alpha = \frac{l_3 \cdot \sin\beta + l_1}{l_2} \rightarrow \alpha = \arcsin\left(\frac{l_3 \cdot \sin\beta + l_1}{l_2}\right) \quad (8)$$

$$\sin(\alpha - \beta) = \sin\left(\arcsin\left(\frac{l_3 \cdot \sin\beta + l_1}{l_2}\right) - \beta\right) \quad (9)$$

Substituting relations (8) and (9) into equation (5), we obtain the expression of F_{as} as a function of β:

$$F_{as} = 2 \cdot F \cdot \frac{\cos\beta \cdot \cos\left[\arcsin\left(\frac{l_3 \cdot \sin\beta + l_1}{l_2}\right)\right]}{\sin\left[\arcsin\left(\frac{l_3 \cdot \sin\beta + l_1}{l_2}\right) - \beta\right]} \quad (10)$$

As stated, the relation (6) was obtained for the particular position of the device, when the angle β=0 (closed position of the device), when the value of F_{as} is maximum and if the device is loaded by the maximum value of the external force F.

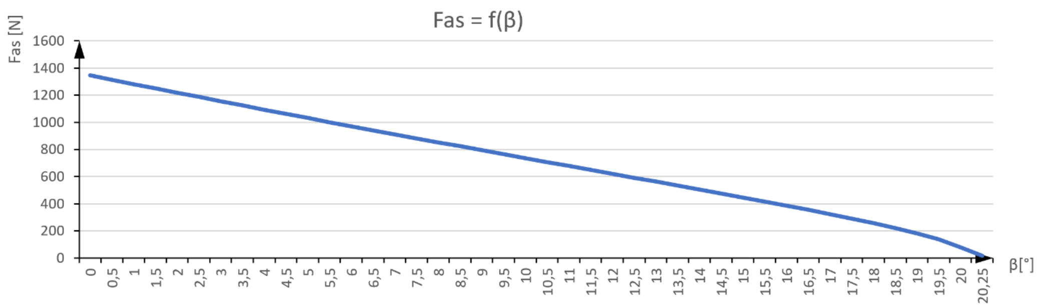
For variations from 0.5° to 0.5° of the β angle are presented in Table 1 the corrective values for the displacement of the extremities of the arms as well as the value of the F_{as} force.

Table 1

Variation of the force F_{as} as a function of the variation of angle β and displacement

β [°]	α [°]	depl [mm]	F_{as} [N]	β [°]	α [°]	depl [mm]	F_{as} [N]	β [°]	α [°]	depl [mm]	F_{as} [N]
0	24,00	0.00	1348	7	37,99	1.58	914	14	55,20	3.22	504
0.5	24,94	0.11	1315	7.5	39,07	1.7	882	14.5	56,68	3.33	475
1	25,89	0.22	1283	8	40,17	1.82	853	15	58,22	3.45	446
1.5	26,84	0.33	1250	8.5	41,29	1.93	823	15.5	59,83	3.56	416
2	27,80	0.44	1218	9	42,43	2.05	794	16	61,51	3.68	386
2.5	28,78	0.55	1187	9.5	43,59	2.17	765	16.5	63,29	3.79	355
3	29,76	0.66	1155	10	44,76	2.29	736	17	65,18	3.9	323
3.5	30,75	0.77	1124	10.5	45,96	2.41	707	17.5	67,20	4.02	291
4	31,75	0.88	1093	11	47,19	2.52	678	18	69,41	4.13	257
4.5	32,76	0.99	1062	11.5	48,44	2.64	649	18.5	71,86	4.24	221
5	33,78	1.1	1032	12	49,72	2.76	620	19	74,68	4.35	181
5.5	34,81	1.22	1002	12.5	51,03	2.87	691	19.5	78,12	4.47	136
6	35,86	1.34	971	13	52,38	2.99	562	20	83,05	4.58	76
6.5	36,91	1.46	942	13.5	53,77	3.10	533	20.25	88,55	4.63	15

Plot a graph of F_{as} versus angle β using the formula given by equation (10).



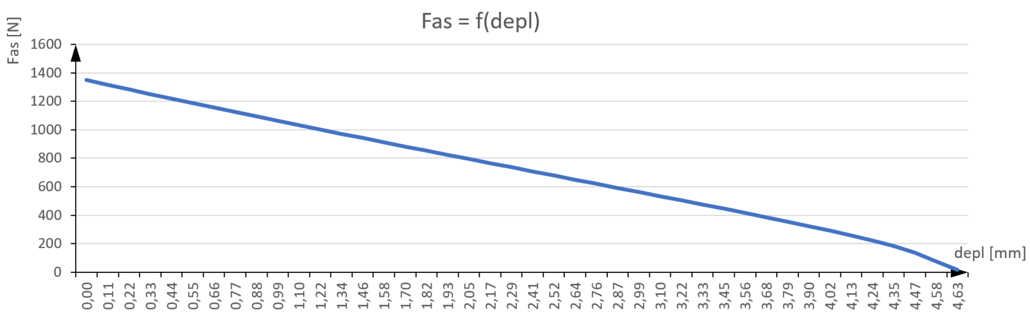


Fig. 10. Variation of the F_{as} force as a function of the angle β and of the displacement of the arm extremities.

In order to obtain the variation of F_{as} as a function of the displacement of the tips of the arms, measurements will be made of the position of these extremities, for sufficient values of angle β.

The graphs in Fig. 10 with the two variations are obtained.

The plotting was done by points imposing on β increasing values from half to half a degree starting from the initial value, β=0, and up to the maximum value, determined from the calculation formulas and confirmed by measurements on the device.

Also, for further analysis the variation of the angle α as a function of β as well as the variation of the displacement of the extremities of the arms as a function of the same angle β were plotted. These variations are presented in Fig. 11 as two graphs.

From Fig. 10 we see a relatively linear variation of F_{as} until near the end of the stroke, both as a function of β and as a function of displacements.

It can thus be observed that for small increases of the angle β (Fig. 10.), or more suggestively, for relatively small displacements of the arm tips, the value of the stress, F_{as}, decreases by quite large values. Thus, taking into account the relatively linear aspect of the variation of F_{as} over the starting area of the graph, it can be seen that there is a decrease in F_{as} by ~30 N for each 0.5° deflection of the

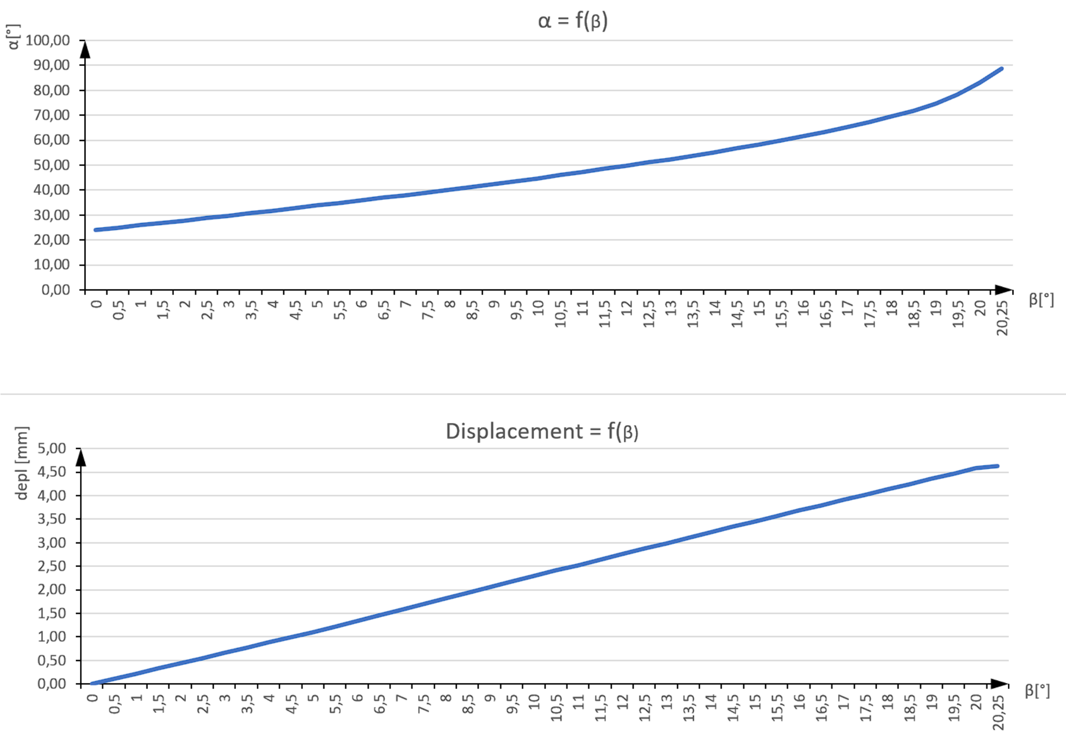
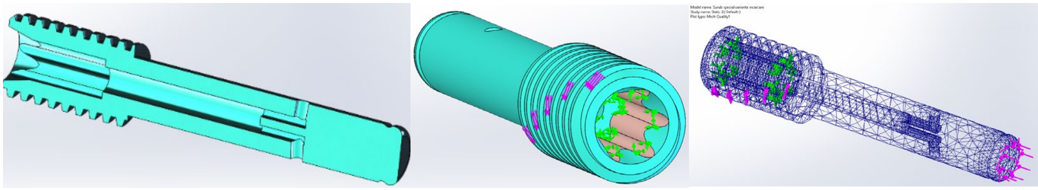


Fig. 11. Variation of the α angle and respectively displacement of the arm extremities as a function of the angle β.

arms or, equivalently, for an opening of the arms by ~0.11mm. For a displacement of the tips by ~0.5mm each (an angular opening of ~2.5°), a decrease in F_{as} by ~150 N is observed.

Proportionally the stresses on the other components of the device decrease. Thus, near the end of the stroke, where, in fact, there is the external Force at the maximum value, the stresses on the components are much lower (some tending to 0 - the F_{as} case) than in the situation for which the calculation assumption was made that the maximum Force is acting from the beginning.

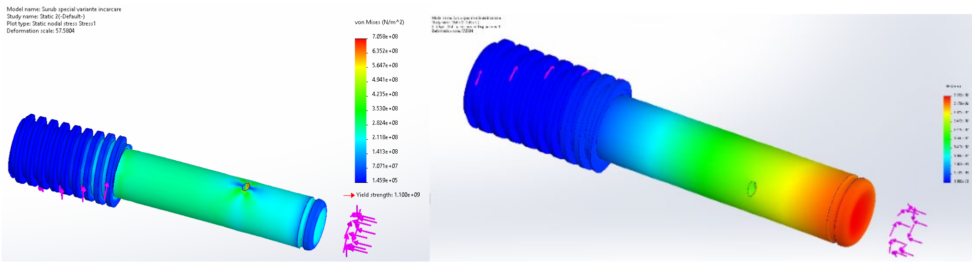
Taking into account all the stresses to which it is subjected during operation, (F_{as} - axial stress, Torsional moment due to friction between the rod and the piston and screwing moment), a check is made by a finite element method (FEM) analysis of the actuation rod (Fig. 12.).



a) b) c)

Fig. 12. Actuation rod a) Longitudinal section; b) Considered embedding mode (green arrows); c) Discretization

For this, the SolidWorks Simulation module of Solid Works 2023 software was used for static analysis. The used material Ti-6Al-4V STA (characterized by Elastic Modulus: 114GPa, Tensile Strength: 1170N/mm^2, Mass Density: 4430kg/m^3, Poissons Ratio: 0.33 [23]), the embedding mode (surfaces considered fixed), the loading mode of the rod, the loading values were indicated. An automatic discretization suggested by the software was used.



a) b)

Fig. 13. Actuation rod a) $\sigma_{vonMises}$ distribution; b) displacements;

In Fig. 13. a) it can be seen that the maximum value of $\sigma_{vonMises}$ = 705.8N/mm^2 is below the allowable value of yield stress, σ_{ac} = 1100N/mm^2.

Table 2

Variation of $\sigma_{vonMises}$ with device opening

depl [mm]	$\sigma_{vonMises}$ [N/mm^2]	depl [mm]	$\sigma_{vonMises}$ [N/mm^2]	depl [mm]	$\sigma_{vonMises}$ [N/mm^2]	depl [mm]	$\sigma_{vonMises}$ [N/mm^2]
0,00	705,8	1,10	539,6	2,29	384,4	3,45	232,8
0,11	688,6	1,22	523,9	2,41	369,2	3,56	217,1
0,22	671,6	1,34	507,6	2,52	354,0	3,68	201,5
0,33	654,3	1,46	492,4	2,64	338,8	3,79	185,3
0,44	637,5	1,58	476,7	2,76	323,9	3,90	168,6
0,55	621,2	1,70	460,9	2,87	308,7	4,02	151,7
0,66	604,2	1,82	445,7	2,99	293,5	4,13	134,0
0,77	587,9	1,93	430	3,10	278,3	4,24	115,3
0,88	571,6	2,05	414,8	3,22	263,2	4,35	94,38
0,99	555,4	2,17	399,6	3,33	248,0	4,47	70,91

It has been shown theoretically that for any other position of the arms, different from the initial position, the stresses are lower. This is proved if we make a check of the Rod for each value of the displacement (the parameter called depl) determined previously and presented in Table 1.

Thus, for each value of the parameter depl in Table 1 we obtain for $\sigma_{vonMises}$ the values in Table 2.

For a graphical interpretation of the results in Table 2, the variation plots in Fig. 14 were plotted.

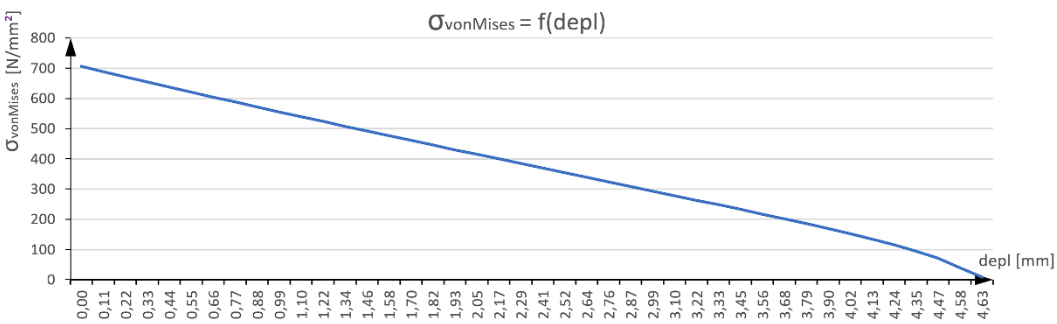


Fig. 14. Variation of $\sigma_{vonMises}$ with device

3. Conclusions

In this paper, an analysis of the working conditions specific to the type of mechanism designed has been carried out and by studying the variation of the main parameters, the critical situation, the most dangerous one that can occur in the operation of the device, has been identified.

Thus, making the verification of the elements under the most disadvantageous conditions assumed, it is observed that during operation, as the arms open, the stresses decrease to values up to values much lower than those considered in the verification calculations.

Also, for the optimization of the device, an action in this direction can be determined experimentally in the body of vertebrae affected by osteoporosis (or prepared to imitate the behavior of a vertebra affected by osteoporosis), the positions at which the external stress reaches significant values for the strength calculation of the device components.

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