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CHECKING THE CRITICAL AREAS OF TWEEZERS IN THE INSTRUMENTATION OF AN IMPLANT TO TREAT VERTEBRAL COMPRESSION FRACTURES

Abstract: *In the use of implants, a particularly important role is played by the instrumentation. It is primarily designed to fulfill its functional role. During its design phase, an important step is the strength verification calculation. For this, frequently a finite element method analysis realized with one of the established software is used. In the present work, a verification of the component identified as the most stressed is performed for the critical areas in terms of stresses*

Key words: *Implant, Instrumentation, FEM analysis*

1. INTRODUCTION

A vertebral compression fracture is a compression of a vertebra that occurs in the anterior part of the vertebral body.

Common causes of this type of fracture are:

- Osteoporosis - (a bone condition that develops when bone mineral density and bone mass decrease or when the structure and strength of the bone changes; this can lead to a decrease in bone strength which can increase the risk of fractures) [1];
- Trauma;
- Malignancies (cancerous tumors).

The treatment methods used so far are divided into two broad categories, namely, conservative treatment methods (consisting of prescription medication, bed rest, medical rehabilitation methods) and minimally invasive surgical methods. The latter are further divided into two other categories of methods: non-implant methods and implant methods.

The category of non-implant methods includes Vertebroplasty [2] and Kyphoplasty [2, 3], with derived methods [4] and the Tektona VFR system developed by Spine Art.

Vertebroplasty is the method that consists of inserting, by means of a needle, a cement inside the vertebral body to reinforce the trabecular bone tissue.

Kyphoplasty consists in inserting a balloon inside the vertebral body and inflating it to create a cavity inside the vertebra by compressing the trabecular bone. After removal of the balloon, the space is filled with cement.

These methods are effective for reinforcing the vertebra to stop vertebral damage.

The Tektona vertebral fracture reduction system consists of a device which, once inserted into the vertebra, acts in the direction of the end plates to displace the bone fragments by means of an elastic blade. The cavities created by the action of the blade are then filled with cement. [5]

From the category of methods using implants, we list the "OsseofixR Spinal System" [6] developed by Alphatec Spine, the Kiva system [7] developed by Izi medical, the V-STRU system [8] developed by Dawa Medical / Hyprevention, the Vertelift system [9] developed by SpineAlign as well as the SpineJack system [10], developed by Stryker.

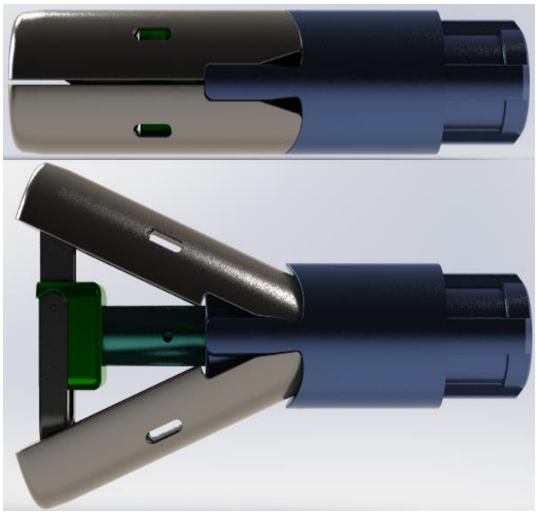
Although each implant idea mentioned is particularly valuable in itself, some of them have behind them quite complex instrumentation, sometimes more complex than the implant itself. With the help of this instrumentation the implant is helped to fulfill its intended function.

In the present work we present the proposed instrumentation for implant actuation called TAD (Two Arm Device), shown in Figure 1 [11]. Using this instrumentation the implant is manipulated, positioned, and actuated.

2. PRESENTATION OF THE INSTRUMENTATION – TWEEZERS

Following the entire medical protocol analyzes the steps that impact mechanical design:

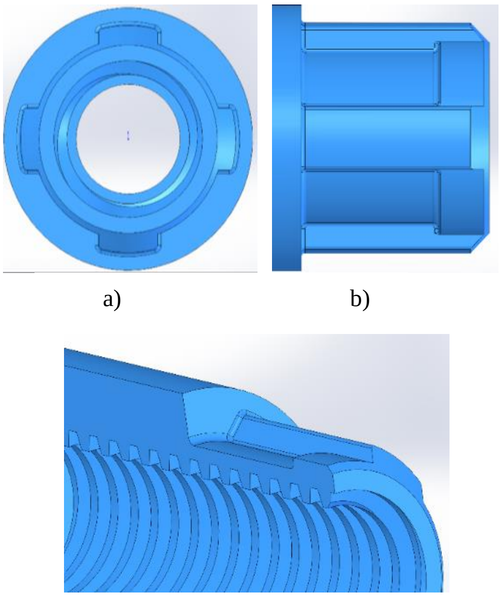
- connecting the instrumentation to the implant and its manipulation;
- insertion of the implant into the vertebra;
- correct positioning of the implant;
- implant actuation;
- cement insertion;
- removing the instrumentation.



a)

b)

Figure 1 Implant: a) Closed; b) Open [11]



a) b)

c)

Figure 2 The interface provided in the implant body: a) Frontal view; b) Lateral view; c) Longitudinal section represented in three dimensions

The tweezers is the instrument that will connect to the Implant and then, by forming a common body with it, will allow its manipulation and actuation.

The tweezers used to grasp the implant must allow easy connection with it, then form a common body with it to ensure the rigidity of the created system, allow insurance against accidental undoing, ensure throughout the process the implant is maintained in the established position, and can be easily disconnected.

For the connection with the implant, two constructive solutions were considered, one of them involves a threaded assembly, the other involves an assembly by means of special recesses, 4 in number, radially arranged on the circumference of the implant body.

The threaded assembly is simpler. However, taking into account the type of existing stresses, more specifically taking into account the torsional stress introduced by the screwing moment during actuation, there is a tendency for rotation to be prevented by this connecting piece. The threaded variant would imply an additional stress on this assembly either in the sense of tightening the assembly or in the sense of loosening it. In the first case, there is a risk that it will be impossible to undo at the end of the process, due to over-tightening. In the second case there is the risk of early loosening (detachment) of the interface piece, which hinders implant control.

These disadvantages mean that this solution has to be abandoned, even if it is possible to use constructive devices to reduce or eliminate these disadvantages. However, these improvements in functionality would complicate the constructive solution.

For a quick and secure connection, an interface was used which involves assembly by means of special recesses, 4 in number, arranged radially on the circumference of the implant body as shown in Fig. 2.

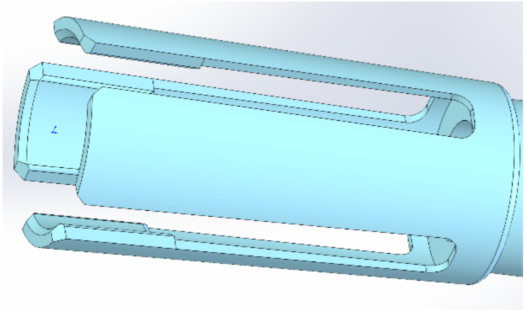


Figure 3 Tweezers - End for implant connection

These recesses prevent the tendency to rotate around the proper axis of the implant (Figure 2. a) and due to the thresholds located towards the outer end of the body (Figure 2. c), prevent the longitudinal displacement of the connecting piece with respect to the implant body.

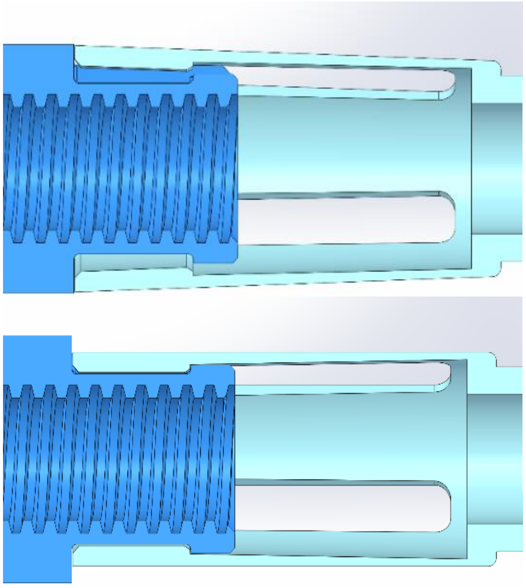
For the connection to this interface, a piece with 4 arms at one end, called Tweezers (Figure 3), was designed.

For coupling, the Tweezers must be able to engage in the correct position in the recesses made in the implant body (Figure 2a).

This implies that the connecting piece must be able to guide itself along the grooves made in the body in the connection area, move forward to the coupling position and then seat itself in the existing recesses.

For this purpose, the tweezers shall have a tubular shape to allow it to pass through the trocar but also to allow access for other tools through its interior.

The coupling end shall have the shape shown in Figure 3. It shall have the termination of a resilient sleeve, with a number of segments (arms) corresponding to the number of canals in the body of the implant, separated from each other by a notch. These segments come from a frusto-conical portion, so that in the normal (free) position, when the Tweezers are open, the arms are spaced apart, the shape of this end of the part being that of a truncated cone as in Figure 4. a)



a)

b)

Figure 4 The positions of the Tweezers in relation to the slots in the Body: a) Open; b) Closed

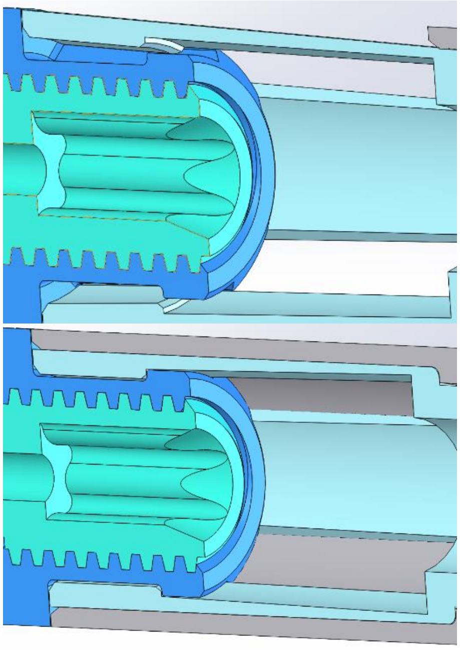


Figure 5 Positions of the Tweezers: a) Open; b) Closed, locked by the Sleeve

By pressing them towards the axis of the tube, they will seat in the recesses in the body, after correct positioning as in Figure 4. b).

The connecting piece is coupled to the body by an axial movement and its arms guide themselves into the channels in the implant body.

The connecting piece is pushed until the free end of the arms contacts the front wall at the end of the channels in the body.

The opening of the Tweezers doesn't have to be too big for many reasons:

1. By squeezing the arms, the deformations must remain in the area of the elastic deformations to allow return to the initial position.

2. In the open position, the maximum size per circumference should not exceed the inside diameter of the trocar cannula, firstly, for easy extraction through the inside of the cannula, and secondly too large an opening would cause the Tweezers to go beyond the limit at which they must stop.

The Tweezers also act as the basic piece of the instrumentation, as they will be used to control the implant and provide access to the other tools.

The Tweezers are operated by means of a tubular part, hereafter referred to as the locking bush, which, by moving longitudinally from the outside inwards, grips the Tweezers arms and places them in the correct position in the conjugated recesses.

Its displacement is made by transforming the rotational movement into a translational movement due to the threaded assembly between the Sleeve and the Tweezers. Thus, by rotating the outer Sleeve around the connecting piece, the forward movement of the Sleeve is imparted. Its advance will be constructively limited so that the movement will stop, when the arms of the Tweezers have reached the coupling position.

Once the Tweezers are fully clamped onto the implant body, the arms placed in the recesses are prevented from protruding out by the outer socket wall.

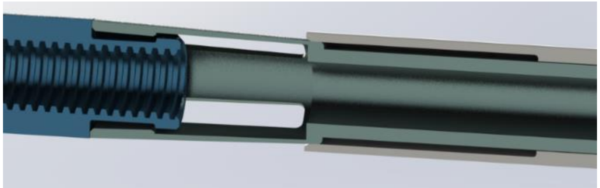


Figure 6 Detail: Tweezers - Sleeve - Implant Body

At this point, the Implant Body, the Tweezers, and the Sleeve form a rigid assembly that can be safely manipulated (Figure 5b).

In Figure 6 shows a detail of a section made by the assembly formed by the Tweezers, the Sleeve and the Implant Body, in the open position.

The material of the Tweezers is Ti-6Al-4V STA, the same as the implant material.

The instruments are made of stainless steel X20Cr13 (1.4021) according to ISO 7153-1:2016 (Surgical instruments - Materials).

The material of the Tweezers however, is Ti-6Al-4V STA, the same as the implant material, due to the mechanical properties of this material.

Table 1

Physical and mechanical properties of Ti-6Al-4V STA [12]

Physical properties	Value	U. m.
Density	4.43	g/cc
Mechanical properties		
Tensile Strength, Ultimate	1170	MPa
Tensile Strength, Yield	1100	MPa
Modulus of elasticity	114	GPa
Poisson Ratio	0.33	-

3 CHECKING THE MOST STRESSED AREAS

Since the arms of the Tweezers are the most stressed areas, a check will be made.

It is taken into account that the instrumentation is disposable and that it is used only once. Therefore, concepts of fatigue stress, reliability, etc. are not taken into account.

The elastic deformation of the arms will be checked in order to demonstrate their return, as this plays an essential role in the correct functioning of the assembly.

Then check their resistance to the lateral stress that occurs when the torsional moment is locked during implant operation.

Loading1

The verification of the elastic deflection of the arms shall be based on the design condition that a displacement of 0,425 mm is allowed at the end of the Tweezers arm in the closed position. A check shall be made to ensure that, during operation, the Tweezers' arms can withstand a deflection at the specified displacement.

As a loading scheme, the Tweezers rod is considered fixed and the force acts uniformly distributed on the outer surface of the Tweezers arms. The load is given by the action of the Sleeve on the Tweezers arms.

After the analysis carried out, it is found that this displacement is obtained at the action of a deformation force F_d=12.5N (1.25daN).

For this force, the stresses occurring in the Tweezers arms result in a safety factor of 1.7 as shown in Figure 7.

Loading 2

From the technical data of the implant, it can be noted that the actuation moment of the implant Rod is:

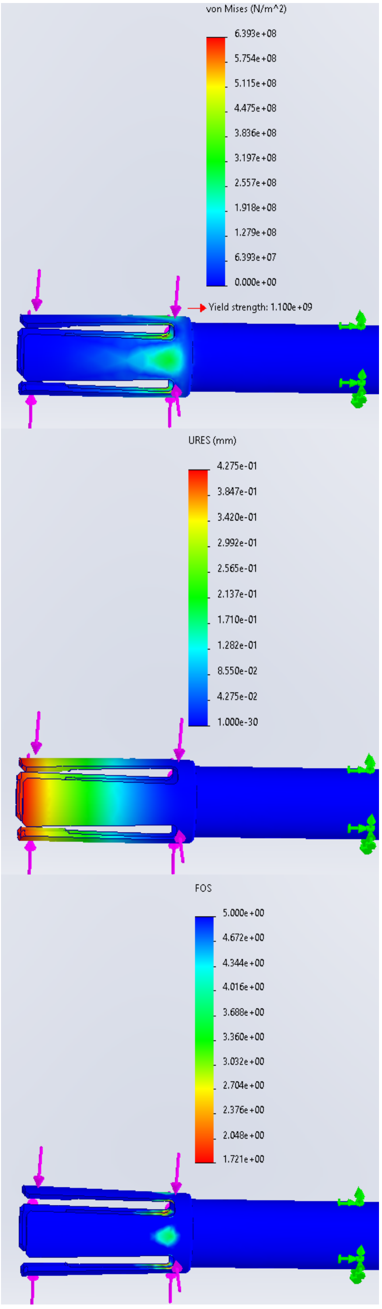


Figure 7 Results of analysis Tweezers - Loading 1

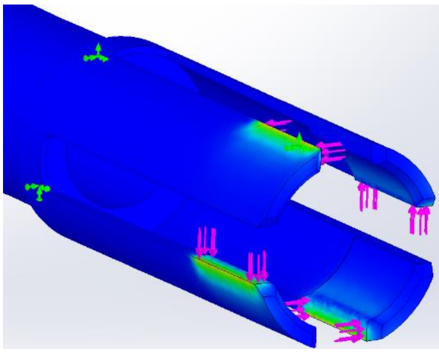


Figure 8 Tweezers detail - Loading implant rotation lock

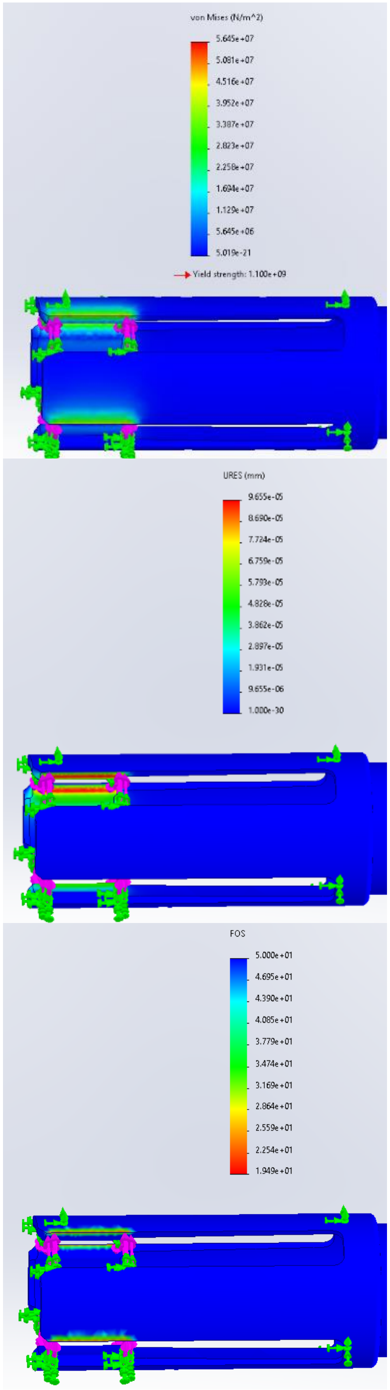


Figure 9 Results of analysis Tweezers - Loading

$$M_a = 0{,}49N \cdot m \quad (1)$$

To lock it, this moment is taken up by the lateral side of the four arms of the Connecting Piece Tweezers.

Noting with R the mean radius of the cylinder where the locking force F will act on the sides of the arms, we have:

$$M_a = R \cdot F = 0{,}49N \cdot m \quad (2)$$

Constructively, R= 2.625mm.

This results in force F:

$$F = \frac{M_a}{R} = \frac{0{,}49 \cdot 1000}{2{,}625} = 186{,}7N \quad (3)$$

This force is distributed evenly over the four arms so that each arm is acted by a force F1=F/4

So, the force acting on the side of an arm is

$$F_1 = \frac{F}{4} = 46{,}7N \quad (4)$$

As a loading scheme, the arms of the Tweezers are considered to be fixed on the outer cylindrical surface (fixation given by the Sleeve) and are acted by the force F on the sides that come into contact with the walls of the special grooves in the Implant body (Fig. 8).

The results are shown in Fig. 9.

It can be seen that the displacements are extremely small (9.665 x10-5mm) and the factor of safety is 19.

The SolidWorks Simulation module, a component of SolidWorks 2023 program SolidWorks 2023, was used for static analysis for the checks performed by FEM.

4 CONCLUSIONS

To drive the implant, the Tweezer is the part that takes most of the stress.

It was found that this part is properly sized to allow the arms to move in the elastic range so that they can return to their original shape after removal of the Tightening Bush (i.e. it allows the decoupling of the instrumentation from the implant).

Also, the coupling system, by alternating the four pairs of Tweezers arm - body rib, allows the decomposition of the moment into fractions which makes the stress on each Tweezers arm to be minimal and therefore the action to be performed safely.

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