DESIGN OF AN ADJUSTABLE TORQUE DEVICE FOR XS-TOR IMPLANT

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ABSTRACT: Scoliosis is a deformity in three dimensions of the spine, which consists of a lateral deviation and an axial rotation. The XS-TOR implant is designed to correct the curve by rotating the middle vertebrae while allowing for growth. Currently, the XS-TOR is not able to provide an adjustable torque output that can be tuned to the individual scoliosis curve and spine stiffness. Also, it is not possible to lower or increase the torque output after implantation. This could introduce an under or over-correction. An extra element called the torque adjustment device (TAD) was designed to adjust the torque output after surgery. The device can be operated in a minimally invasive surgical procedure. Hand calculations, simulations, and experiments using 3D printing are performed to verify the concept. It is expected that the addition will improve the correction capability of the implant which could improve the life quality of patients with idiopathic scoliosis. In the future, the TAD should be produced and clinically tested to verify the operation. If required, the design could be adapted to decrease the height, reducing the risk of the occurrence of pressure spots.

Key words: Idiopathic scoliosis, XS-TOR, adjustable growth-friendly implant

1 INTRODUCTION

The spine is a considerable part of the skeleton of the human body. It contributes to 40% of the length and when upright, holds the upper half of the body.[1]. Scoliosis is a deformity in three dimensions of the spine, which consists of a lateral deviation and an axial rotation [2]. The severity of scoliosis is measured by determining the Cobb angle [3]. The Cobb angle is the angle between the vertebrae that have the steepest slope in the spine [3]. Scoliosis which does not have a clear underlying case is called idiopathic scoliosis (AID) [2]. This is the most common type and affects 1-3% of children between 10-16 years [4] [2]. Available treatments are for example serial casting, wearing a brace, or performing surgery [5, 4, 2]. In surgery, the spine is fused or an implant is used. Various implants have been used in surgery, but have considerable drawbacks. One of which is the big instant correction force [6]. A new implant called the XS-TOR is developed to treat AID which applies a rather small constant torque to correct the spine gradually [6]. A downside of this method is the inability to adjust the spring tension. A first version of a tensioning device was developed to adjust the spring tension, but this method is not capable of adjusting the spring tension without minimal invasive surgery and high stresses are expected inside the device [7]. Therefore, the XS-TOR is (still) not able to provide an adjustable torque output that can be tuned to the individual scoliosis curve and spine stiffness. Also, it is not possible to lower or increase the torque output after implantation. This could introduce an under or over-correction. Therefore, the design assignment is formulated as: 'A mechanism/solution must be developed to make it possible to increase and decrease the torque output of the XS-TOR, ideally without the need for surgical intervention.'

2 METHOD

To develop the TAD, the design loop is followed. First, a stakeholder analysis is performed after which the requirements are set up. The functions and subfunctions of the TAD are formulated and solutions are developed for these sub-functions and grouped in a morphological overview. These solutions are integrated into various concept designs. These are rated to determine the ideal candidate for the final concept. In the development of the final concept, the design loop is followed multiple times. Through rapid prototyping of the design, additional information is gained to further improve the design. By showing the solution to prof. dr. M.C. Kruijt, additional feedback is

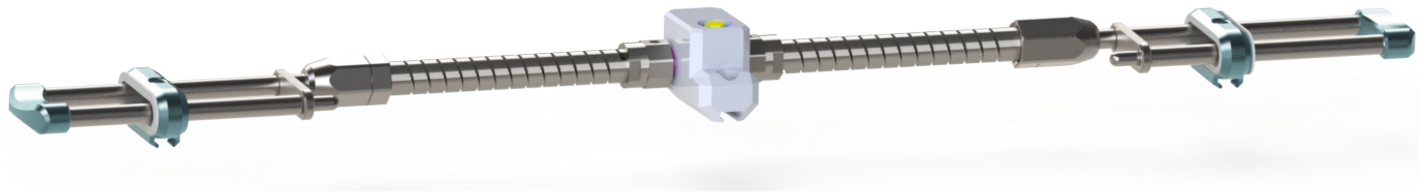

Figure 1: XS-TOR implant in combination with TAD

gained from the medical field, which developers lack. This feedback is used for adjusting the design. To test the prototype, a test rig was made, which simulates the springs of the XS-TOR. This is done to test the capability of the TAD to adjust the torque output and verify the calculations.

3 SELECTION OF CONCEPT

Various concepts were developed and rated for categories like footprint and cost. The chosen concept had the highest score due to the limited number of components and small footprint. In addition, off-the-shelf components can most likely be used which lowers cost. Also, the energy in the TAD can be released in a controllable manner. A downside of the concept is that a minimally invasive operation is needed to adjust the torque output which increases the impact on the patient.

4 DESIGN OF TAD

The TAD in combination with the XS-TOR implant is shown in Figure 1. To tension the torsion springs of the XS-TOR implant, a worm drive is designed. The (calculated) parameters are shown in Table 1 where standard equations are used [8]. A standard metric module and pressure angle are chosen.

The outside dimensions of the TAD are shown in Figure 2. To actuate the TAD, the wind-up tool is inserted on the top of the implant. The top of the implant is made flat to decrease the pressure on the back of the patient. Worm drives can be made to self-lock, but it is unclear if the TAD is self-locking. Due to vibration or other unexpected movements of the patient, slip could occur. Also due to the long implantation time, it is unclear if the system can hold the tension angle. Therefore a lock was designed which is unlocked by inserting the wind-up tool.

Table 1: Gear parameters worm drive [8]

Parameter	Value
Metric module	0.5
Amount of gears of (full) worm gear	24
Amount of threads of worm	1
Pressure angle	20°
Pitch diameter worm	5.68 mm
Circular pitch	1.57 mm
Lead angle	5.03°
Center distance	8.84 mm
Face width worm gear	4.7 mm
Pitch diameter worm gear	11.99 mm
Theoretic tooth thickness	0.78 mm

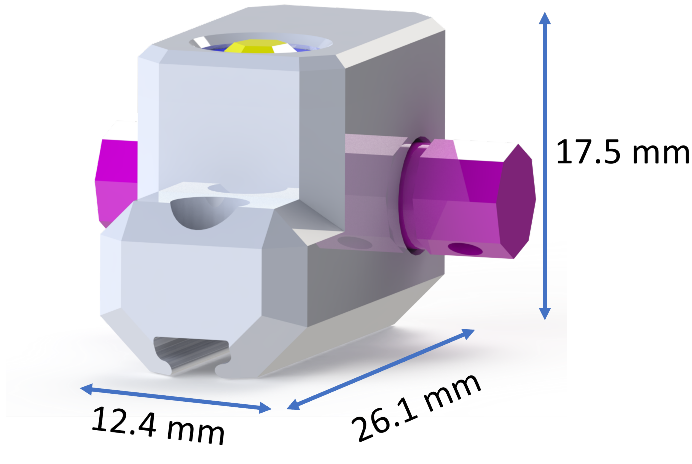

Figure 2: Outside dimensions of TAD

In Figure 3 a sliced view of the TAD is shown in which the lock can be seen. The lock consists of a lock nut slider which is locking the TAD in the shown position due to the hexagon and octagon form slots. In addition, it can be seen that the worm gear has a limited number of gear teeth. This is done to lower the outside dimensions of the TAD and minimise the impact on the patient. Furthermore, a single-enveloping worm gear is used. This is done to increase the contact area between the worm and worm gear which im-

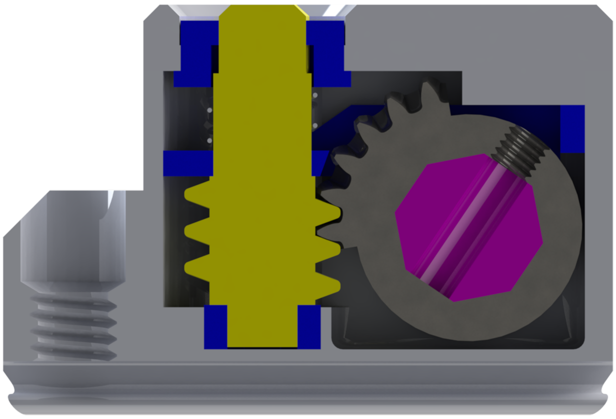

Figure 3: Sliced view in the locked position of TAD

proves the power capacity of the worm gear drive [8].

4.1 Manufacturing

It is expected that all the parts can be manufactured using standard techniques like milling, drilling, and tapping. To manufacture the attachment rail where the TAD is secured to the bridge of the XS-TOR implant, wire EDM could be used [9].

4.2 Stress analysis and materials

Hand calculations and simulations were used to calculate the stress in various components. This was done to verify the concept design. In most simulations, $2\,\mathrm{Nm}$ was put on the axle to simulate the load of the torsion springs. The maximum calculated stress in the worm and worm gear tooth was equal to $438\,\mathrm{MPa}$. For the axle, the maximum stress in the smallest cross-section was equal to $139\,\mathrm{MPa}$ and in the interacting surface between the axle and worm gear $353\,\mathrm{MPa}$. The maximum stress inside the bearings was in the simulation equal to $25\,\mathrm{MPa}$. For the axle, worm, and worm gear Biodur 108 is selected [10]. For the bearings, PEEK is selected and for the outside casing stainless steel, austenitic AISI 316H, annealed [11]. It was concluded using the relevant properties of the materials, the components will withstand the load. Nevertheless, it is expected that the PEEK bearings will experience creep due to the long constant load which could lead to misalignment.

4.3 Strength experiment

To verify the hand calculations and simulations, a 3D-printed version of the TAD is tested in a test rig which can be seen in Figure 4. On the string, a measurement cup with water is hung to simulate the torsion of the springs. The 3D print material (PLA+) is different from the final material [12], but it is argued that if the design can withstand the calculated maximum load, the hand calculations and stress analysis are reliable. The calculated maximum sustainable torque load is equal to $0.36\,\mathrm{Nm}$. In the experiment, the maximum stainable torque load while actuating was equal to $0.5\,\mathrm{Nm} \pm 0.03\,\mathrm{Nm}$. Therefore, it seems that the hand calculations and simulations are reliable and can predict if the gears withstand the load.

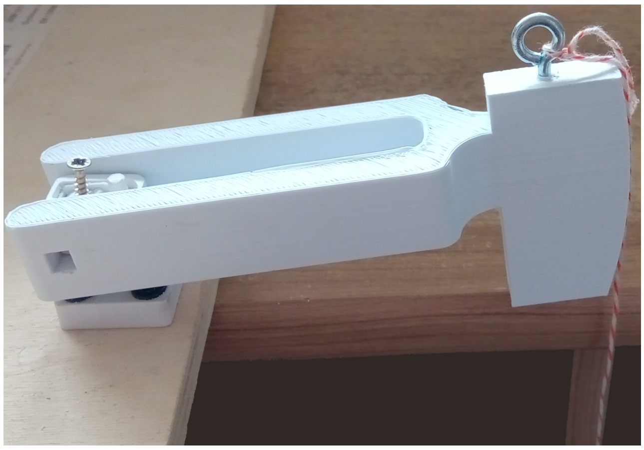

Figure 4: Test setup for testing maximal sustainable torque load while actuating

4.4 Visual prototype

A final (visual) prototype was fabricated to evaluate the design and provide recommendations for further improvements to the design. Also, it is a visual aid in explaining the design to an audience. An existing XS-TOR implant was used to limit the necessary parts. In Figure 5, the prototype is shown.

5 DISCUSSION

Although the investigation is done as thoroughly as possible, some aspects could have been improved. Overall these aspects are expected to have little influence on the overall result. The stress simulations could have been more thorough and a program like Abacus could have been used. Also in the strength experiment, PLA+ is used which is different from the final material. Also, creep is expected in the PEEK bearings which could lead to the failure of the TAD.

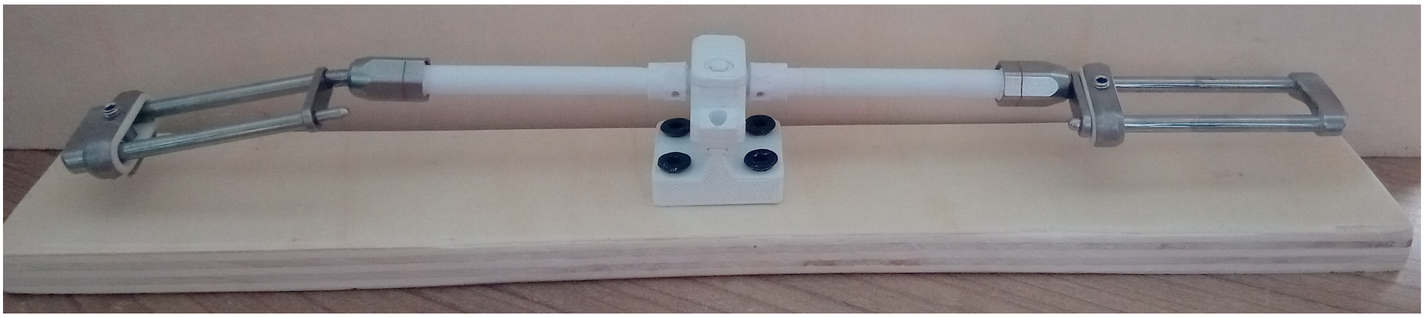

Figure 5: Visual prototype in combination with XS-TOR implan

6 CONCLUSIONS

The TAD is designed to make it possible to modify the pre-loading of the XS-TOR implant. The device can be operated in a minimally invasive surgical procedure. Although a small incision is needed, it is expected that the addition will improve the correction capability of the implant which could improve the life quality of patients with idiopathic scoliosis. Hand calculations, simulations, and experiments are done to verify the concept.

6.1 Recommendations

In the future, the TAD should be produced and (clinically) tested to conclude if the calculations are reliable. Also, the self-locking properties of the TAD should be verified. If the worm and worm gear can hold the tension without the need for the lock-nut slider, the design can be made lower, reducing the risk of the occurrence of pressure spots. In addition, it could be investigated if the height of the design could also be lowered by putting the rail on the side of the TAD. It could also be investigated if the PEEK bearings can be made from steel due to the limited actuation and therefore eliminate creep.

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