2022 44th Annual International Conference of
the IEEE Engineering in Medicine & Biology Society (EMBC)
Scottish Event Campus, Glasgow, UK, July 11-15, 2022

2022 44th Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC) | 978-1-7281-2782-8/22/$31.00 ©2022 IEEE | DOI: 10.1109/EMBC48229.2022.9871068

A Toggling Resistant In-Pedicle Expandable Anchor: A Preliminary Study*

Esther P. de Kater*, Cornel F. Weststeijn, Aimée Sakes, Paul Breedveld

***Abstract*—**
Loosening of pedicle screws after spinal fusion surgery can prevent the desired fusion between vertebrae and may be a reason for revision surgery. Especially in osteoporotic bone, toggling of pedicle screws is a common problem that compromises the fixation strength of these screws and can lead to loosening or axial pull-out of the screw. In this study, we explore the use of an in-pedicle expandable anchor that shapes to the pedicle to increase the toggling resistance of the anchor by increasing the contact area between the anchor and the dense cortical bone of the pedicle. A scaled-up, two-dimensional prototype was designed. The prototype consists of a bolt and ten stainless steel wedges that expand by tensioning the bolt. During the expansion, the wedges are required to compress the cancellous bone. Based on the first preliminary experiment, it was found that the expansion of the wedges resulted in successful compression of 5 PCF cancellous bone phantom (Sawbones). This preliminary study shows that an expandable in-pedicle anchor could be a feasible option to increase the toggling resistance of spinal bone anchors, especially in osteoporotic bone.

***Clinical Relevance*— Toggling of pedicle screws is a major cause of screw loosening. In this preliminary study, the use of an in-pedicle expandable anchor to increase the toggling resistance of spinal bone anchors is explored.**

I. Introduction

A. Pedicle Screw Fixation

Spinal fusion surgery is commonly performed to restore stability to the spine in case of deformity, fractures or pain. During spinal fusion surgery, two or more adjacent vertebrae are fused by eliminating all motion between the vertebrae using pedicle screws and rods. The strength of the construct and thus the success rate of spinal fusion surgery relies on the purchase of the screw in the vertebra [1]. Vertebrae have a shell of dense cortical bone that surrounds the porous cancellous bone. Each vertebra has two pedicles that connect the vertebral arch to the vertebral body (Figure 1). The pedicle has an hourglass shape with a smaller cross-section in the middle of the pedicle and a larger cross-section more anterior and posterior.

Pedicle screws are placed through the pedicle into the vertebral body. A larger screw diameter increases the fixation strength as it increases the contact surface between the screw and the dense cortical bone. The pedicle is surrounded by delicate anatomical structures such as the spinal cord and spinal nerve roots [2]. To avoid damage to these structures, it is advised to use a screw with a diameter of 80% of the diameter of the pedicle at the most narrow location [3]. The limited diameter of the screw and the hourglass shape of the pedicle result in limited contact between the screw and the dense cortical bone layer. This contact is even more limited due to the oval cross-section of the pedicle.

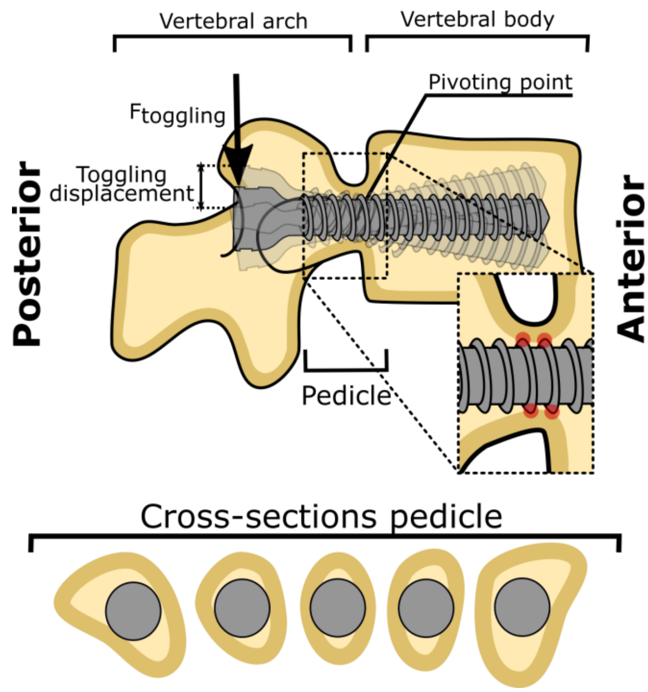

Figure 1: Schematic representation of pedicle screw toggling. The toggling force ($F_{toggling}$), results in a pivoting motion of the screw around the pivoting point causing compression of the cancellous bone and compromising the fixation strength. The oval cross sections of the pedicle show the hourglass shape of the pedicle. The red dots indicate the contact points between the pedicle screw and the cortical bone layer of the pedicle.

The fixation strength of pedicle screws is often indicated by the screw's pull-out strength which is the force necessary to axially pull the screw from the vertebra. The pull-out strength relies for 60% on the fixation of the screw in the pedicle as this is the location where the screw has purchase in the dense cortical bone layer [1], [2]. The pull-out strength can be compromised due to small rotations of the screw around the pivoting point, which is known as toggling [4]. Toggling is caused by a cyclic loading that is exerted on the screw, for instance during walking or bending of the back, and is especially a problem in caudocephalad (from tail to head) direction, due to the oval cross-section of the pedicle. A toggling force $F_{toggling}$ of 200 N applied on a single pedicle screw placed in a vertebra that is not connected to a rod, can result in a large toggling displacement of 8 mm [5]. During toggling the cancellous bone that surrounds the screw is compressed which compromises the fixation strength of the screw [1], [5].

Due to the aging of the population, more patients undergoing spinal fusion surgery suffer from osteoporosis.

Osteoporosis is characterized by the resorption of mainly the porous cancellous bone. This decrease in bone density of the cancellous bone decreases the provided resistance to toggling and compromises the fixation strength [1], [6].

B. State-of-the-Art: Spinal Bone Anchors

The success rate of spinal fusion surgery could be improved by using spinal bone anchors that have an improved fixation strength compared to the conventional pedicle screw, especially in osteoporotic bone. Different methods have been developed to improve the fixation strength of pedicle screws in osteoporotic bone. The use of cement augmented screws can almost double the pull-out strength [1] but has as a drawback the heat generation during curing of the cement which can result in bone necrosis [7]. Furthermore, leaking of cement out of the vertebral body, via veins or cortical defects, often occurs and can, in rare cases, result in serious complications such as pulmonary embolisms [8]. Lastly, cement augmented anchors are difficult to remove which can be required during revision surgery. During removal of the cement augmented anchor, the vertebra is often damaged [1].

A second means to increase the fixation of spinal bone anchors is the use of a bone ingrowth inducing coating such as hydroxyapatite. Such a coating can successfully increase the fixation strength but as a drawback, also makes it more challenging to remove the anchor in case of a revision surgery [9], [10].

In patent and scientific literature, expandable anchors are also proposed as a solution to increase the fixation strength of bone anchors. The anchors often have an expandable distal tip that anchors inside the vertebral body by creating a shape-lock which significantly increases the fixation strength [11], [12]. This explored method to increase the fixation strength of spinal bone anchors relies on increasing the fixation within the cancellous bone of the vertebral body. Although the contact area between the screw and the cortical bone layer is slim due to the cylinder shape of the screw and the oval and hourglass shape of the pedicle, the pedicle accounts for 60% of the pull-out resistance and 80% of the toggling resistance [13]. The increase in the contact area between the cortical bone and the bone anchor in the pedicle could, therefore, be more beneficial than an expandable section within the cancellous bone of the vertebral body. In osteoporotic patients, the advantage of increasing the fixation strength by increasing the contact area with the cortical bone could be even greater, as the cortical bone layer is often less compromised than the cancellous bone [6].

C. Research Goal

To ensure a long-term fixation of the screw within the vertebra, toggling of spinal bone anchors should be avoided. The goal of this study is to design an in-pedicle expandable anchor to increase the toggling resistance by increasing the contact area between the anchor and the cortical bone layer of the pedicle.

II. Method

A. Design Direction

The in-pedicle anchor should deform to the pedicle to increase the toggling resistance, which will be achieved by expansion. The current bone anchors use screw thread for fixation in the vertebra. This requires the anchors to have a circular cross-section in order to screw the anchor into the vertebra. Since the proposed in-pedicle anchor uses expansion to fixate within the vertebra, the screw thread is not required and thus is the anchor not limited to having a circular cross-section. Designing the anchor with an oval cross-section, similar to the cross-section of the pedicle, increases the contact between the anchor and the cortical bone layer. This in combination with expansion in the caudocephalad direction could make the anchor more resistant to toggling as toggling is most severe in this direction.

We expect that, in clinical use, a tunnel is made through the pedicle before the in-pedicle bone anchor is placed. The anchor is placed in the collapsed state and once in the correct position, the anchor can expand to deform to the cortical bone layer of the pedicle (Figure 2).

The proposed in-pedicle bone anchor consists of ten wedges with one bolt through the center. Tightening the bolt presses the wedges together and, due to the slanted edges, causes the wedges to expand (Figure 3A). The idea is that the resistance of the cancellous bone is slim and will thus not prevent the expansion of the wedges. The much denser cortical bone wall is expected to prevent further expansion upon impact. This way the anchor will deform to the cortical bone layer of the pedicle and increase the number of contact points with the cortical bone layer, making the anchor more toggling resistant compared to the conventional pedicle screw.

B. Expansion Working Principle

Wedges have an inclined side that can be used to convert a force. In this design, a compressive force will result in an angulated normal force which will cause the wedge to expand (Figure 3B). Besides the normal force that is generated, friction forces will be induced. These friction forces will

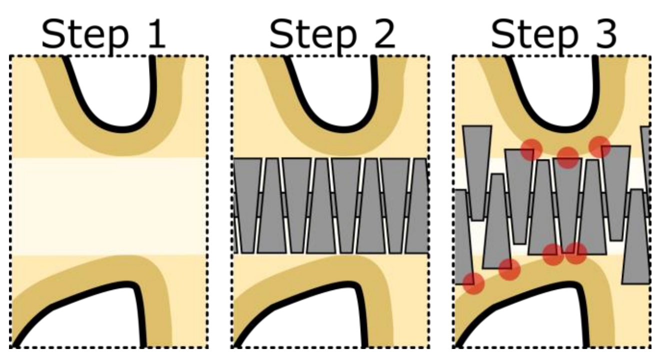

Figure 2: Schematic visualisation of the working principle of the in-pedicle expandable anchor. The first step is to make a tunnel through the pedicle (Step 1) after which the anchor is placed in the collapsed state (Step 2). After correct placement, the anchor can expand (Step 3). The expansion results in multiple contact points between the anchor and the cortical bone layer (indicated with red dots).

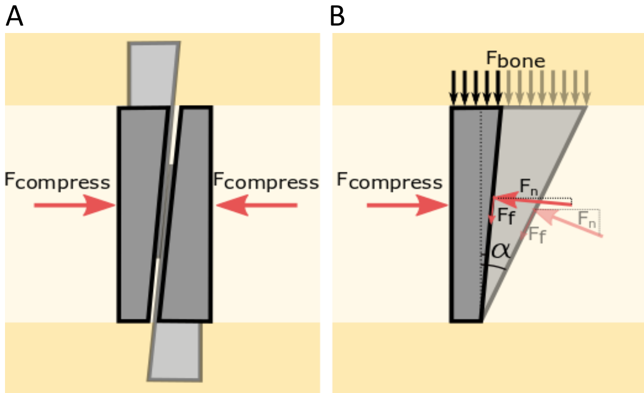

Figure 3: Wedge principle. A) A compressive force $F_{compress}$ results in expansion of the wedges. B) Free Body Diagram of the forces acting on a single wedge during expansion. The compressive force results in a normal force F_n which is dependent on the inclination angle α, and friction forces F_f. When the wedges expand the wedge will compress the cancellous bone by overcoming F_{bone}.

oppose the expansion and are highly dependent on the friction coefficient between the two wedges.

The wedges of the prototype are intended to expand within the pedicle. This requires the wedges not only to overcome the friction force between the wedges but also to exert enough force to compress the cancellous bone. Wedges with a larger inclination (larger angle α) require a smaller compression force to obtain the desired expansion, which is advantageous. However, the larger the inclination, the wider the wedges will become, and thus the more cancellous bone must be compressed to allow the wedges to expand. This will increase the forces opposing the expansion. Besides this, the pedicle has a limited length, thus an increasing width of the wedges would also decrease the number of wedges that fit within the pedicle and thus result in fewer contact points between the anchor and the cortical bone layer of the pedicle. Therefore, a smaller inclination is beneficial as long as the inclination is large enough to allow the wedges to expand when exerting a limited compressive force.

C. *Prototype*

To explore the idea of increasing the toggling resistance using an in-pedicle expandable bone anchor, a two-dimensional (2D) prototype was designed. This 2D prototype should be able to deform to a 2D cross-section of the pedicle.

The prototype comprises a stainless steel M8 bolt and ten stainless steel (316L) wedges made by electrical discharge machining (EDM) (Figure 4A). The bolt is flattened at the sides to avoid rotation of the wedges around the bolt during insertion and expansion. To prevent the wedges from expanding before insertion, two alignment pins are used. After placement of the anchor, these alignment pins are removed such that the wedges can expand. The eight wedges in the middle have two slanted sides such that from both sides compression will cause the wedge to move outwards. The first and last wedges have one slanted side where the wedge is in contact with an adjacent wedge to allow for expansion. The other side of the wedge, where it is in contact with the nut or the head of the bolt, is straight to increase the contact area to avoid peak forces that could damage the prototype.

The anchor is scaled up (~200%) to ease the fabrication and allow for visual observations during the validation process. The prototype has a width of 10.8 mm, a height of 20 mm and a length of 33.7 mm when in the collapsed state, and a height of 30 mm and a length of 21.8 mm when in the expanded state (Figure 4B).

D. *Preliminary Experiment*

The main function of this in-pedicle expandable prototype is that tightening of the bolt must result in the expansion of the wedges which causes compression of the surrounding cancellous bone. In this preliminary experiment, the expansion of the wedges through the cancellous bone will be investigated.

For this experiment, the prototype will be placed between two plates of 5 Pound-force per Cubic Foot (PCF) solid foam cancellous bone phantom (Sawbones) which has similar mechanical properties as osteoporotic cancellous bone [14].

The bolt will be tightened to 7 Nm. The initial state of the wedges and the expanded state after tightening the bolt up to 7 Nm will be captured by a camera (Sony A6000). This test will be repeated three times in a new block of 5 PCF cancellous bone phantom.

Photographs of the wedges were analyzed using Matlab 2019b to determine the displacement of each of the wedges in the x and y-direction.

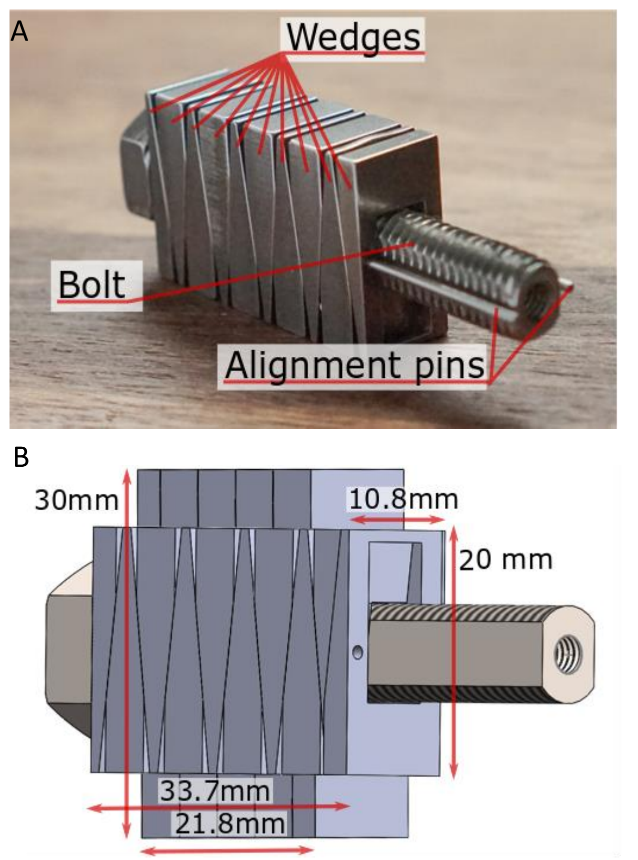

Figure 4: Prototype design. A) Photograph of the prototype consisting of ten wedges, a bolt that runs through the center and two alignment pins. B) Dimensions of the prototype in the collapsed and expanded state.

III. RESULTS

Figure 5 shows the expansion of the wedges when tightening the bolt to 7 Nm. The red indicated wedges show the collapsed position and the blue wedges show the expanded position of the wedges. The white arrows indicate the expansion path of the wedges. Figure 6 shows the mean displacement and the standard deviation in the x and y-direction for each of the wedges.

IV. DISCUSSION

A. Main Findings

This preliminary study presents the idea of using in-pedicle expansion to increase the toggling resistance of spinal bone anchors. A prototype was developed consisting of ten wedges with a bolt that runs through the center of the wedges. Tightening of the bolt results in expansion of the wedges. The first preliminary experiment showed that the wedges were able to successfully expand within 5 PCF solid foam (Sawbones), which corresponds to osteoporotic cancellous bone [14]. Due to the slanted sides of the wedges, expansion of the anchor also leads to shortening of the anchor. It can be observed that the wedges tend to contract to the center of the anchor.

B. Limitations and Future Research

The preliminary experiment shows that the use of wedges to expand through cancellous bone is a possible option to create an in-pedicle expandable anchor to prevent toggling. In future research, the abilities of the anchor to deform to the pedicle must be investigated as well as the toggling resistance of the in-pedicle expandable anchor.

After validation of using in-pedicle expansion to increase the toggling resistance, future research should be conducted

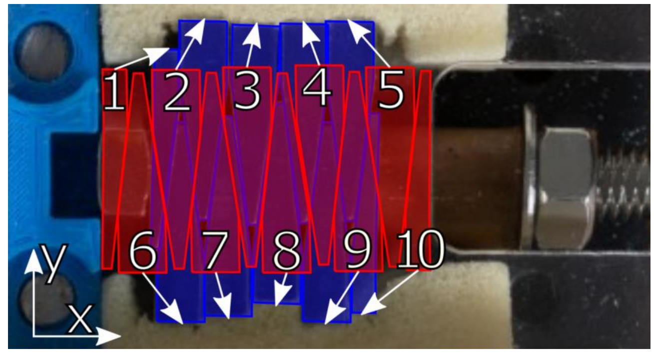

Figure 5: Expansion process when exerting a force of 7 Nm. The numbered wedges in the collapsed state (red) and the expanded state (blue) with the expansion path indicated with the white arrow.

such that the anchor can be used in a clinical setting. The current prototype is scaled-up and made in 2D, as this allowed for better visual observations during the preliminary validation. Future experiments will be carried out such that they are closer to the clinical setting in which the anchor is intended to be used. For these experiments, a new prototype must be designed that is scaled to the required size and works in 3D. Furthermore, the current is made of stainless steel prototype, and although stainless steel is listed as a biocompatible material, it is not used for long term implants. For clinical use, the prototype should be redesigned in a material suitable for long term implants such as titanium.

The tests presented in the study are performed using Sawbones 5 PCF solid foam and although this is a good alternative to real bone as it has similar mechanical properties, the phantom is very homogeneous while real bone has a more heterogeneous character which could influence the expansion of the prototype. Furthermore, the pedicle shape is different from person to person and from vertebra to vertebra. Both *ex-*

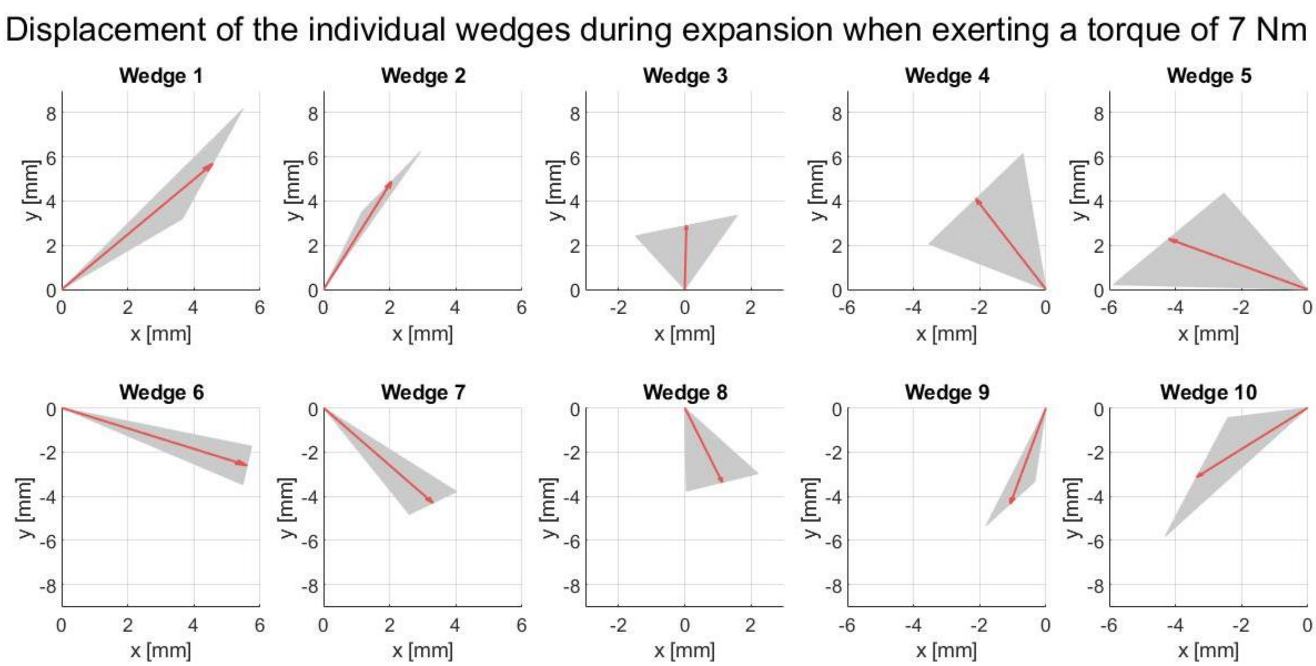

Figure 6: Displacement of the wedges during expansion in the x and y-direction. The mean is indicated with the red arrow and the standard deviation is indicated with the grey triangle.

vivo and *in-vivo* tests will give more insight into the adaptability of the anchor for these different pedicle shapes and bone characteristics.

In this preliminary study in-pedicle expansion is investigated as a single means of anchoring. It would be interesting to look into combining in-pedicle expansion with currently used spinal bone anchors, such as the conventional pedicle screw. This preliminary study presents a first step in using in-pedicle expansion to increase the toggling resistance and could in the future serve as a means to increase the fixation strength of spinal bone anchors, especially in osteoporotic bone.

V. CONCLUSION

The use of in-pedicle expansion to increase the toggling resistance of a spinal bone anchor is explored in this paper. A scaled-up prototype was manufactured consisting of a bolt running through the center of ten wedges. After placement of the anchor in a premade cavity, the bolt can be tightened which will cause the wedges to expand. The wedges were able to successfully compress a cancellous bone phantom during expansion. The presented prototype is a promising step to explore the use of expandable structures within the pedicle to increase the fixation strength and the toggling resistance of spinal bone anchors.

ACKNOWLEDGEMENT

The authors would like to thank David J. Jager for his help in fabricating the prototype. This research is supported by Netherlands Organization for Scientific Research (NWO), domain Applied and Engineering Sciences (TTW), project number 17553.

REFERENCES

[1] M. R. Zindrick *et al.*, ‘A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine’, *Clin Orthop Relat Res*, vol. 203, no. 99–112, p. 2, 1986.

[2] J. N. Weinstein, B. L. Rydevik, and W. Rauschning, ‘Anatomic and Technical Considerations of Pedicle Screw Fixation’:, *Clinical Orthopaedics and Related Research*, vol. NA;, no. 284, pp. 34–46, Nov. 1992, doi: 10.1097/00003086-199211000-00006.

[3] G. F. Solitro, K. Whitlock, F. Amirouche, A. I. Mehta, and A. Mcdonnell, ‘Currently Adopted Criteria for Pedicle Screw Diameter Selection’, *International Journal of Spine Surgery*, vol. 13, no. 2, pp. 132–145, Apr. 2019, doi: 10.14444/6018.

[4] M. Aycan and T. Demir, ‘Toggling effect on pullout performance of pedicle screws: Review’, *International Advanced Researches and Engineering Journal*, vol. 4, pp. 161–172, Dec. 2020, doi: 10.35860/iarej.722229.

[5] M. Law, A. Tencer, and P. Anderson, ‘Caudo-Cephalad Loading of Pedicle Screws: Mechanisms of Loosening and Methods of Augmentation’, *Spine*, vol. 18, no. 16, pp. 2438–2443, Dec. 1993.

[6] S. Wray, R. Mimran, S. Vadapalli, S. S. Shetye, K. C. McGilvray, and C. M. Puttlitz, ‘Pedicle screw placement in the lumbar spine: effect of trajectory and screw design on acute biomechanical purchase’, *Journal of Neurosurgery: Spine*, vol. 22, no. 5, pp. 503–510, May 2015, doi: 10.3171/2014.10.SPINE14205.

[7] M. Stańczyk and B. van Rietbergen, ‘Thermal analysis of bone cement polymerisation at the cement–bone interface’, *Journal of Biomechanics*, vol. 37, no. 12, pp. 1803–1810, Dec. 2004, doi: 10.1016/j.jbiomech.2004.03.002.

[8] J. S. Yeom, W. J. Kim, W. S. Choy, C. K. Lee, B.-S. Chang, and J. W. Kang, ‘Leakage of cement in percutaneous transpedicular vertebroplasty for painful osteoporotic compression fractures’, *The Journal of bone and joint surgery. British volume*, vol. 85, no. 1, pp. 83–89, 2003.

[9] T. Hasegawa, A. Inufusa, Y. Imai, Y. Mikawa, T.-H. Lim, and H. S. An, ‘Hydroxyapatite-coating of pedicle screws improves resistance against pull-out force in the osteoporotic canine lumbar spine model: a pilot study’, *The Spine Journal*, vol. 5, no. 3, pp. 239–243, May 2005, doi: 10.1016/j.spinee.2004.11.010.

[10] B. Sandén, C. Olerud, C. Johansson, and S. Larsson, ‘Improved extraction torque of hydroxyapatite-coated pedicle screws’, *European spine journal*, vol. 9, no. 6, pp. 534–537, 2000.

[11] Z. Wu *et al.*, ‘A comparative study on screw loosening in osteoporotic lumbar spine fusion between expandable and conventional pedicle screws’, *Arch Orthop Trauma Surg*, vol. 132, no. 4, pp. 471–476, Apr. 2012, doi: 10.1007/s00402-011-1439-6.

[12] S. Vishnubhotla, W. B. McGarry, A. T. Mahar, and D. E. Gelb, ‘A titanium expandable pedicle screw improves initial pullout strength as compared with standard pedicle screws’, *The Spine Journal*, vol. 11, no. 8, pp. 777–781, Aug. 2011, doi: 10.1016/j.spinee.2011.06.006.

[13] T. Hirano *et al.*, ‘Structural Characteristics of the Pedicle and Its Role in Screw Stability’, *Spine*, vol. 22, no. 21, pp. 2504–2510, Nov. 1997.

[14] S. Nagaraja and V. Palepu, ‘Comparisons of Anterior Plate Screw Pullout Strength Between Polyurethane Foams and Thoracolumbar Cadaveric Vertebrae’, *J Biomech Eng*, vol. 138, no. 10, Oct. 2016, doi: 10.1115/1.4034427.