Comparison of Screw loosening and pull-out resistance between a double-threaded Screw Geometry and a standard Polyaxial Screw with and without polymethylmethacrylate-augmentation

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Introduction

Screw loosening or failure is a common clinical complication of pedicle screw fixation, especially in patients with osteoporosis. Pedicle Screw augmentation is becoming a popular solution to this problem in Germany [Goost H, et., 2012].

However, this technique can cause complications such as embolism or neurologic injury, as well as allergic reactions. Aspects such as oseointegration at the screw/bone interface and the effects of the cement regarding the nourishment of the adjacent intervertebral discs haven't been at full length studied.

The objective of this study is to investigate whether a novel pedicle screw offers a better loosening and pull-out resistance than standard pedicle screws with and without augmentation.

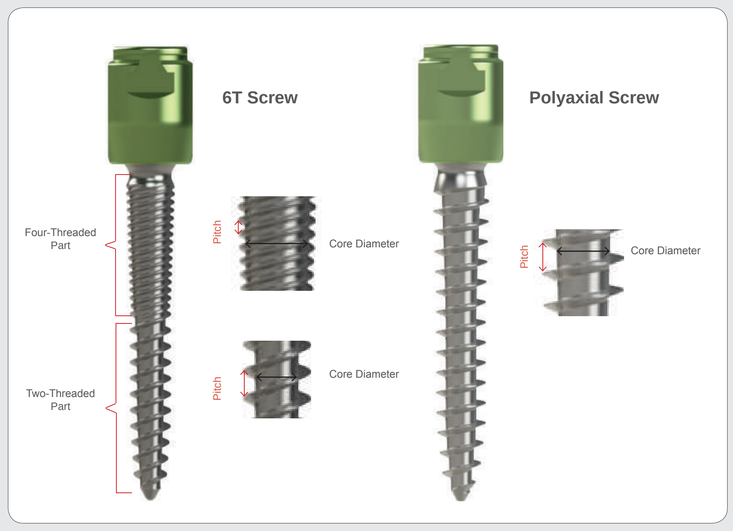


Fig.1 Geometry 6T vs Polyaxial Screw

Methods

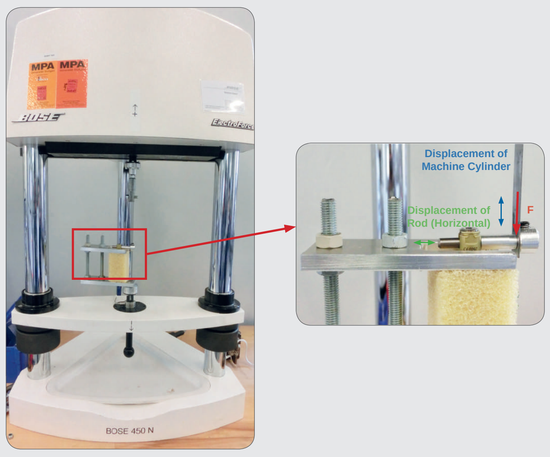


Fig.2 Set-up Fatigue Tests Polyurethan Foam

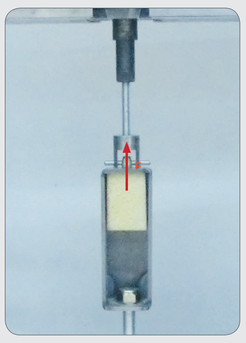


Fig.3 Set-up Pull-out Polyurethan Foam

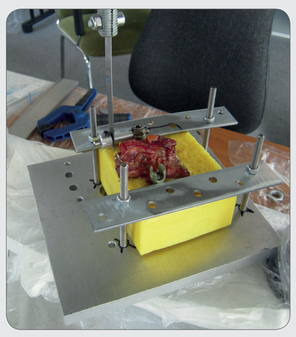


Fig.4 Set-up Fatigue Tests Cadaveric Bone

In the first part of the study the screws were inserted in rigid foam blocks that represented osteoporotic cancellous bone. The Polyurethan foam tests were divided into 4 Groups where the pull-out immediately after insertion as well as the loosening displacement and the pull-out after a cycling loading with a load range of 270N by 150.000 cycles were measured.

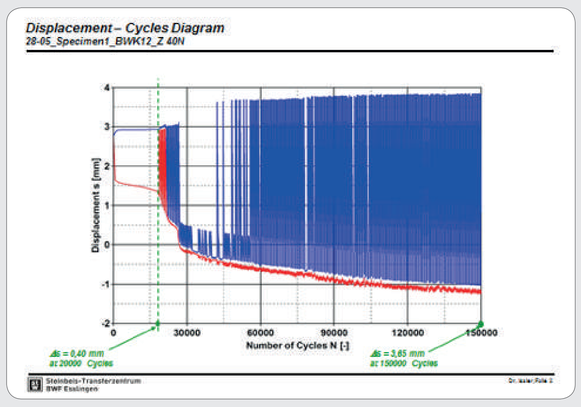
The Tests Set-up are shown in fig.2, fig.3 and fig. 4.

In the second part of the study cadaveric bone tests were performed. Two screws were inserted into each pedicle of the same vertebra. In one side a Fenestrated Screw with 2ml injected cement and in the other side a 6T Screw. The insertion torque was measured as well as the loosening displacement with a load range of 80N by 150.000 cycles.

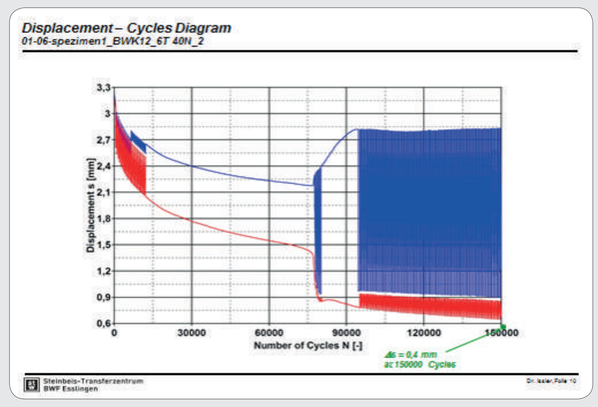
Results

Sample	Level	Max. Insertion Torque (Nm)	
		Cement	6T
3	LWK 5	0.6	0.8
3	LWK 3	0.2	0.3
1	BWK 12	0.3	0.6
1	LWK 2	0.4	0.7
1	LWK1	0.3	0.5

Table 1. Max. Insertion Torque Cement vs 6T Cadaveric Bone



Graphic 1. Displacement BWK 12 Cement Fatigue Tests Cadaveric Bone



Graphic 2. Displacement BWK 12 6T Fatigue Tests Cadaveric Bone

Fatigue Tests Polyurethan Foam								
Screw Type	Minimum Load Fmin [N]	Maximum Load Fmax [N]	Load Range DF [N]	Number of Cycles N [-]	Displacement of Machine Cylinder [mm] Mean Value	Max. Pull-out Load after fatigue F[N] Mean Value	Max. Pull-out Load after first insertion F[N] Mean Value	Comments
Polyaxial screw Φ6.5x45 without cement	-135	135	270	150.000	0.712	873.8	1372	High deterioration of the pullout and the highest displacement
Polyaxial screw 6T Φ6.5x45 without cement	-135	135	270	150.000	0.126	1321.2	1296	No significant change in pullout and low displacement
Fenestrated screw Φ6.5x45 with cement	-135	135	270	150.000	0.258	1800.2	1972	No significant change in pullout and higher displacement than the 6T without cement
Fenestrated screw 6T Φ6.5x45 with cement	-135	135	270	150.000	0.008	1681.2	2009	Low deterioration of the pullout and no significant displacement

Table 2. Fatigue Tests in Polyurethan Foam

Conclusion

Our results in Polyurethan foam confirmed that loosening of the Novel PS is significantly lower than that of the Standard PS and even lower than the one of the augmented Fenestrated PS. This may be due to the increment of fixation of the screw at the material due to its wider inner diameter that compacts the material around its threads giving a much higher fixation.
The results also confirm that the loss of maximal pull-out between the first insertion and after the cycling loading is very significant for the Standard PS and inexistent for Novel PS. However, the pull-out resistance of the augmented PS is significantly higher than the one of the no augmented Novel PS and it presented also no reduction after cycling loading.
The results in cadaveric bone show that the insertion torque of the 6T is significantly higher than that of the cement screws, however the loosening tests do not show a significant higher loosening for the 6T screws as that of the cemented ones. The cadaveric bone tests have to be concluded in order to drive the final conclusions of this study.

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