Pullout strength of anterior spinal instrumentation: a product comparison of seven screws in calf vertebral bodies

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Received: 11 January 2006 / Revised: 26 October 2006 / Accepted: 29 December 2006 / Published online: 2 February 2007
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Abstract A lot of new implant devices for spine surgery are coming onto the market, in which vertebral screws play a fundamental role. The new screws developed for surgery of spine deformities have to be compared to established systems. A biomechanical in vitro study was designed to assess the bone–screw interface fixation strength of seven different screws used for correction of scoliosis in spine surgery. The objectives of the current study were twofold: (1) to evaluate the initial strength at the bone–screw interface of newly developed vertebral screws (Universal Spine System II) compared to established systems (product comparison) and (2) to evaluate the influence of screw design, screw diameter, screw length and bone mineral density on pullout strength. Fifty-six calf vertebral bodies were instrumented with seven different screws (USS II anterior 8.0 mm, USS II posterior

6.2 mm, KASS 6.25 mm, USS II anterior 6.2 mm, USS II posterior 5.2 mm, USS 6.0 mm, USS 5.0 mm). Bone mineral density (BMD) was determined by quantitative computed tomography (QCT). Failure in axial pullout was tested using a displacement-controlled universal test machine. USS II anterior 8.0 mm showed higher pullout strength than all other screws. The difference constituted a tendency ($P = 0.108$) when compared to USS II posterior 6.2 mm (+19%) and was significant in comparison to the other screws (+30 to +55%, $P < 0.002$). USS II posterior 6.2 mm showed significantly higher pullout strength than USS 5.0 mm (+30%, $P = 0.014$). The other screws did not differ significantly in pullout strength. Pullout strength correlated significantly with BMD ($P = 0.0015$) and vertebral body width/screw length ($P < 0.001$). The newly developed screws for spine surgery (USS II) show higher pullout strength when compared to established systems. Screw design had no significant influence on pullout force in vertebral body screws, but outer diameter of the screw, screw length and BMD are good predictors of pullout resistance.

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Keywords Product comparison · Vertebral body screws · Pullout strength · Bone mineral density · Screw design

Introduction

Correction of spinal deformities can be achieved by spinal surgery using a posterior and/or anterior approach. Anterior spinal instrumentation systems have the potential advantage of preserving additional motion segments by instrumentation of fewer vertebrae.

Anterior procedures may give greater correction through a direct manipulation of the vertebral body. However, correction by fusing fewer segments may increase the stress within the instrumentation construct, particularly at the bone–screw interface. Introduced by Dwyer et al. [6], anterior spinal instrumentation has developed during recent decades to yield a variety of different systems with different product design and surgical principles [17, 21, 24, 44, 51, 58]. Newly developed screws for spine surgery—the Universal Spine System II (USS II)—were released onto the market for correction of scoliosis. These new screws have to stand up to comparison with established systems. Especially, at the end vertebrae of multilevel spinal constructs large reduction forces are transmitted and high axial pullout resistance of the screws is necessary to avoid implant loosening. The bone–screw interface can be characterized by means of in vitro pullout tests evaluating the holding power of screws in bone, which is a popular and accurate parameter for experimental study of screws used in spine surgery. Till now, there is no biomechanical study in the literature comparing the pullout force of the USS II spinal screws with other implants. In this in vitro study we (1) evaluated the initial strength at the bone–screw interface of the new Universal Spine System II (USS II) screws (Synthes, Umkirch), compared to Kaneda Anterior Spine System (KASS) screws (Depuy, Sulzbach) and universal spine system (USS) screws (product comparison). As in our department usually screws from the universal spine system (USS and USS II) are used for spine surgeries (instability and deformity), we evaluated these screws in comparison to another product, the KASS screws. The first generation of USS screws were developed as pedicle screws and were subsequently widely used also for anterior spinal instrumentation. For this reason we tested a mixture of screws, which are used only for anterior instrumentation (KASS and USS II anterior screws) respectively used as pedicle screws as well as vertebral body screws (USS, USS II posterior).

While much research has been conducted in the past concerning the stability of entire anterior device systems [11, 14, 45, 57] and pedicle screws investigating their biomechanical properties and fixation strength [4, 16, 23, 31, 43, 46, 48, 56] to the author's knowledge—only a few studies concern about singular vertebral body screws and the influence of screw design on pullout force, with partially contrary or not comparable results [3, 15, 24, 30, 44, 50]. Therefore we (2) evaluated the influence of screw design, screw diameter, screw length and bone mineral density on pullout strength in anterior spinal instrumentation.

Materials and methods

Four calf spines from 10 to 18-week-old calves were separated into 56 vertebral bodies (Th 4 to L 6), dissected free of soft tissue, sealed in double plastic bags and stored at -20°C . After thawing to room temperature the bone quality of the specimens was evaluated by measuring the bone mineral density (BMD) of the vertebral body using quantitative computed tomography (QCT) (Densiscan 1000, SCANCO medical AG, Basserdorf, Switzerland). Cancellous bone density was measured at a depth of 2 mm within 5 mm of the planned screw entrance point, which was sited 10 mm anterior to the posterior vertebral body wall (Fig. 1). Avoiding the endplates five scans of 1 mm thickness (inner squares excluding cortical bone) were averaged.

Vertebrae were grouped into seven groups of eight calf vertebrae each. The mean BMD was 0.48 g/cm^3 ($0.4\text{--}0.6\text{ g/cm}^3$) showing no difference between the groups ($P = 0.998$). Further there was no statistically significant difference between the groups with regard to vertebral body width, which was on average 37.5 mm (28–54 mm) ($P = 0.449$). BMD and vertebral body width were independent ($P = 0.733$).

Hole preparation and screw instrumentation followed the free hand procedure routinely employed during anterior spinal screw fixation, using a starter for cortex penetration followed by 2.8–3.8 mm awl insertion with penetration of the contra lateral cortex. The hole was created parallel to the coronal plane (posterior vertebral body wall) and the end plate.

Seven different vertebral screws (USS II anterior 8.0 mm, USS II posterior 5.2 mm, USS II posterior 6.2 mm, USS 6.0 mm, KASS 6.25 mm, USS 5.0 mm, USS II anterior 6.2 mm) were inserted with bicortical

Fig. 1 Inner square excluding cortical bone, placed within the vertebral body around the planned screw entrance point for determination of bone mineral density (BMD) with quantitative computed tomography (QCT)

Table 1 Technical data of implants tested

Screw design	USS II		KASS (6.25 mm)	USS II		USS standard	
	Anterior 8.0 mm	Posterior 6.2 mm		Anterior 6.2 mm	Posterior 5.2 mm	6.0 mm	5.0 mm
Thread diameter (mm)	8.0	6.2	6.25	6.2	5.2	6.0	5.0
Core diameter 1 (mm)	5.0	5.2	4.6	4.0	4.2	4.8	3.8
Core diameter 2 (mm)	4.3	4.5		3.5	3.8		
Thread pitch (mm/thread)	2.75	4 (2 × 2)	2.2	2.75	4 (2 × 2)	1.75	1.75

Fig. 2 Design of screws tested

anchorage (the thread of the screw protruded 1–2 mm out of the opposite cortex). Geometric data and screw design can be seen in detail in Table 1 and Fig. 2.

Vertebrae were embedded in a block of polymer resin (Beracryl) as shown in Fig. 3, at right angles to the screw axis, so that a precisely axial pullout force could be applied (Fig. 4). Screw necks and heads were covered with non-hardening putty, providing that there was no polymer resin intrusion to the screw neck [32].

Failure in axial pullout was tested using a displacement-controlled hydraulic universal test machine (Fig. 4) with constant velocity of 2 mm/min to a maximum load of 10 kN or a maximum displacement of

more than 5 mm. Exact axial pullout strength was defined as the force at the first peak of the force displacement curve (Fig. 5).

All data were first checked for normal distribution (Kolmogorov–Smirnov test $P > 0.2$) and homogeneity of variances (Leven's test $P = 0.067$). As both tests were not significant, parametric analysis was applied for all evaluations. Global differences among the groups were tested by univariate analysis of differences (ANOVA) and influences of screw length and BMD on the pullout strength as investigated by correlation analysis. Univariate analysis of covariance (ANCOVA) was then carried out, correcting for screw length

Fig. 3 Calf vertebra embedded in a block of polymer resin (Beracryl). Anterior vertebral body screw (KASS) inserted with bicortical anchorage **Fig. 4** Beracryl-embedded calf vertebra for exact axial pullout strength evaluation

Fig. 5 Load-displacement curve (USS II anterior 8.0 mm) showing linear region of force increase, maximum load at failure and nonlinear region of force decrease with full pitch displacement point at 2.75 mm (thread pitch)

and BMD, and differences between individual groups were worked out by post hoc testing with Bonferroni adjustment. Statistical significance throughout the foregoing text is defined as $P < 0.05$.

Results

ANOVA analysis showed, that the groups differ significantly from one another on pullout strength ($P = 0.011$) (Table 2; Fig. 6).

Correlation analysis revealed that pullout strength correlated significantly with BMD ($P = 0.0015$) and with vertebral body width/screw length ($P < 0.001$), whereby the influence of screw length was larger than the influence of BMD (mean squares 14.062 and 5.997, respectively). Thus the groups were compared after correction for both of these parameters. Estimated marginal means of pullout strength after correction for BMD and vertebral body width are shown in Table 3 and illustrated in Fig. 7. USS II anterior 8.0 mm showed significantly higher pull out strength than KASS 6.25 mm, USS II anterior 6.2 mm, USS II posterior 5.2 mm, USS 6.0 mm and USS 5.0 mm (+30 to

Fig. 6 Pullout strength of the screws tested without correction for screw length and BMD: box- plot representation

+55%, $P < 0.002$). The difference from USS II posterior 6.2 mm did not quite achieve significance (+19%, $P = 0.108$). USS II posterior 6.2 mm showed significantly higher pull out strength than USS 5.0 mm (+30%, $P = 0.014$). There were no significant differences in pullout strength between any of the other screw types.

Discussion

The objectives of the current study were to evaluate the initial strength at the bone–screw interface of newly developed vertebral screws (Universal Spine System II) compared to the former USS and another established system (KASS), further to evaluate the influence of screw design, screw diameter, screw length and bone mineral density on pullout strength. USS II anterior 8.0 mm showed higher pullout strength than all other screws. The difference constituted a tendency ($P = 0.108$) when compared to USS II posterior 6.2 mm (+19%) and was significant in comparison to the other screws (+30 to +55%, $P < 0.002$). USS II posterior 6.2 mm showed significantly higher pullout

Table 2 Pullout strength of screws tested without correction for screw length and BMD: mean values $\pm$ 1SD

USS II anterior 8.0 mm	3,159 N ($\pm$ 999 N)
USS II posterior 6.2 mm	2,737 N ($\pm$ 916 N)
KASS 6.25 mm	1,863 N ($\pm$ 267 N)
USS II anterior 6.2 mm	2,294 N ($\pm$ 447 N)
USS II posterior 5.2 mm	2,413 N ($\pm$ 553 N)
USS 6.0 mm	2,791 N ($\pm$ 995 N)
USS 5.0 mm	2,019 N ($\pm$ 587 N)

Table 3 Estimated marginal means of pullout strength by after correction for BMD and vertebral body width: mean values $\pm$ 2SE

USS II anterior 8.0 mm:	3,207 N ($\pm$ 122 N)
USS II posterior 6.2 mm:	2,701 N ($\pm$ 122 N)
KASS 6.25 mm:	2,244 N ($\pm$ 126 N)
USS II anterior 6.2 mm:	2,232 N ($\pm$ 122 N)
USS II posterior 5.2 mm:	2,345 N ($\pm$ 122 N)
USS 6.0 mm:	2,474 N ($\pm$ 124 N)
USS 5.0 mm:	2,072 N ($\pm$ 122 N)

strength than USS 5.0 mm (+30%, $P = 0.014$). The other screws did not differ significantly in pullout strength. Pullout strength correlated significantly with BMD ($P = 0.0015$) and vertebral body width/screw length ($P < 0.001$). Similar results concerning the positive correlation between BMD and pullout strength is reported by several authors [25] and was also found by Pitzen et al. [33, 34] in the cervical spine. Breeze et al. [3] evaluated the influence of bicortical anchorage of anterior vertebral body screws in human thoracic vertebrae on the pullout force. They found that bicortical anchorage of an anterior vertebral body screw increased the resistance to pullout compared to unicortical anchorage by 25–44%. However, Pitzen et al. [33] found no significant difference for pullout force between mono- and bicortical screws in human cervical vertebrae. Nevertheless we decided for bicortical anchorage of the screws as the majority of studies confirmed its positive influence on the resistance to pullout.

Calf vertebrae are used in many biomechanical studies as alternative to human cadaver spines [8, 11, 13, 26, 45, 55]. Some basic studies compared the biomechanical properties of calf versus cadaver human spine models [5, 38, 53, 54]. Compared to other animal models (deer, sheep, pig) calf spine and vertebrae show most anatomical and mechanical similarities to human specimens. Vertebrae of calves older than 10 weeks show a size 1.5–twofold of adult human vertebrae, length of the whole spine is similar between 6 and 8 weeks old calves and an adult human spine. Bone quality, distribution of cortical and cancellous bone, ash density, apparent and equivalent mineral density and compressive strength are very similar to human vertebrae of 20–50 year old people [28, 49]. Therefore singular calf vertebrae are a widely used and popular animal model, which we used in this study. However, biomechanical studies concerning spine constructs of several motion segments have some limitations regarding the range of segmental motion compared to the human spine [5, 38, 49, 53, 54]. However, in this study, only singular vertebrae, not spine constructs of several motion segments were used, so that according to data from literature the results should be transferable to human vertebrae.

In the past much biomechanic research was conducted, investigating the influence of screw outer and inner diameter, screw length; thread pitch, flat angle and other design parameters of screws in long bones [10, 19, 20, 29, 39, 52]. However, the anatomy of the vertebral body and its constitution of mainly cancellous bone with only a thin cortical shell differs strongly from that of long bones, therefore the biomechanic results

found about screws in long bones may probably not be transferable to vertebrae. There are indeed different opinions in literature about the question, whether the cancellous bone or the thin cortical shell with the periosteum are more important for fixation strength of anterior vertebral body screws [7, 12, 18, 30]. Horton et al. [18] presume, that anterior vertebral body screws may be fixed more in the cancellous vertebral body. Ogon et al. [30] in contrast presume that even in the vertebral body the main structure for fixation is the cortical shell and the periosteum of the vertebral body.

In recent years some studies examined new products and implants [1, 9, 27, 36, 40] and the additional use of special devices like staples and washers [1, 46], cramps and nuts [24, 40], suprapedicle claw constructs [1] or different types of augmentation of the anterior vertebral body (cement, calcium phosphate and others [2, 22, 35] to increase the fixation strength of screws. However, to the author's knowledge only a few studies concern about singular vertebral body screws and the influence of screw design on pullout force, with partially contrary or not comparable results [3, 15, 24, 30, 44, 50].

Like the Kaneda anterior spinal system [21], also the MACS^{TL} twin screw device [37, 41] and the MACS^{TL} polyaxial screw XL device [42] have a two screw design with specific angles of the screws to each other in one vertebra. It is to be expected that triangulated double screw/double rod systems will achieve higher pullout strength than single rod/single screw systems, as several studies showed [30, 37, 40–42, 44]. A two-rod or two-screw system however, has a high metal load for the patient and, especially in the surgery of spinal deformities in children with small and dysplastic vertebrae, is more difficult and sometimes impossible to implant. These problems also exist for the monocortical “Hollow Modular Anchorage System (MACS^{TL}-HMA) screws with a large outer diameter of 12 mm [9, 40], which can be used as rescue screws or in osteoporotic bone, but which are in most cases not suitable in the small vertebrae of children and adolescents. Additionally, these devices can be used for anterior stabilisation of fractured vertebrae, but not for correction of spinal deformities like scoliosis. In adolescents with idiopathic thoracic scoliosis the use of a pullout resistance nut is a possible solution in small vertebral bodies to increase the pullout resistance [24, 40]. However, the surgical technique to reach the opposite side of the vertebral body and to add the nut is more demanding and the risk of vessel, neural or pleural injury increases. Therefore it is still important to focus on the biomechanical properties of a single screw in anterior instrumentation.

In principle, two main categories can be distinguished: screws anchored mainly in the bone cortex and screws anchored mainly in the cancellous bone. The ratio between outer and inner diameter is small for cortical screws and is greater for screws intended for use in cancellous bone. The first generation of USS screws, which were of the typical cortical screw design, were developed as pedicle screws and were subsequently also widely used for anterior spinal instrumentation [24, 40, 47]. The new USS II screws have a so-called “dual core design” with two inner diameters, starting with a small diameter from the tip to the middle of the screw, where a larger diameter follows. Furthermore, the USS II posterior screws have a double-lined thread with a thread pitch of 2×2 mm/thread. The USS II posterior screws have a typical cortical screw design whereas the USS II anterior screws are of the typical design of screws intended for use in cancellous bone. The design of the KASS screws shows properties of both as well cortical as cancellous screws. As it has not yet been proven which screw design reaches the highest pullout forces in vertebral bodies, we also tested the USS II posterior screws, developed for transpedicular instrumentation, for pullout strength in vertebral bodies. In our study screws with similar thread diameter (outer diameter), but different thread pitch and core diameter (USS II posterior 6.2 mm, USS II anterior 6.2 mm, USS 6.0 mm and KASS 6.25 mm) showed no significant difference in pullout strength (Table 3; Fig. 7). In this study neither “cortical” nor “cancellous” designed screws showed advantages regarding initial fixation strength in anterior spinal instrumentation.

Fig. 7 Estimated marginal means of pullout strength by after correction for BMD and vertebral body width: mean values $\pm$ 2SE

Conclusion

The newly developed screws for surgery of spinal deformities (USS II) possess pullout strength that is higher than that of established systems. Screw design however, had no statistically significant influence on pullout force in vertebral body screws in this study, but the outer diameter of the screw, screw length and BMD are good predictors of initial fixation strength. In anterior spinal instrumentation the outer diameter and insertion depth of the screw (screw length) should be chosen to be as large as the anatomical structures will allow in order to achieve higher initial fixation strength. Depending on the patient and his bone quality (BMD) screws designed either more as a cortical bone screw or as a more cancellous bone screw may be preferable in anterior spinal instrumentation. Further studies including normal and osteoporotic vertebrae may be necessary to address this issue, e.g. screw augmentation or development of new devices.

Acknowledgments The authors thank Synthes, Umkirch, Germany for their support in the performance of the study and providing their screws for the experiments. Study and investigation were conducted at the AO Research Institute, Clavadelstrasse, 7270 Davos, Switzerland.

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