Long-term biocompatibility of posterior instrumentation systems in thoraco-lumbar spine surgery

B. COSTACHESCU[a,b], A. CHIRIAC[a,b,*], B. F. ILIESCU[b], C. POPESCU[b], L. PENDEFUNDA[a,b]
[a] *"Gr. T. Popa" University of Medicine and Pharmacy, Romania*
[b] *"Prof. Dr. N. Oblu" Clinical Emergency Hospital, Romania*

The spine consists of a complex bony and ligament structures designed to ensure a strong support for the body and for the back muscles but also to allow various degrees of motion. When bony tissue damage occurs (most often as a result of trauma) the resulting instability represents the main drawback in tissue and neurologic healing and recovery. Fixation of the unstable spine structures is required to insure the structural integrity and to create the proper mechanical environment for functional healing. Metallic implants are routinely used nowadays and are known to achieve good functional results. However, the long-term biocompatibility is not yet completely studied in terms of bone changes around the implant fixation screws. Here, we analyzed the imagistic bone transformation around the pedicle screws of posterior thoracic spine implants for two different commercial systems. The computed tomography images of five patients were studied in terms of osteodensitometry. Three of them had titanium alloy implants (Ti6Al4V), while the other two received hard-titanium alloy (Ti6Al7Nb) implants. The implant screw performance was monitored and the results are discussed.

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1. Introduction

Nowadays the human medicine appeals more and more to various synthetic materials to remedy, reinforce, treat or replace various living tissues [1]. Therefore, the biomaterials science became one of the most frenzy research fields, which attracts worldwide important financial and human resources, in the quest of finding or testing new implant solutions. Numerous fundamental studies concerning prospective materials for medicine are reported each year, yet only scarce evidence of their *in vivo* behaviour can be found in literature.

Due to their excellent mechanical resistance, the prominent biomaterials in use are of metallic origin. Among them, the pure titanium as well as its super-alloys passed the test of time, and due to their harmonically entwined mechanical, corrosion resistance and low cytotoxicity properties they now dominate the implant market.

Implant fixation represents a matter of great importance in medical practice. Generally, two types of fixations are known: cemented, uncemented and hybrid (e.g., endoprosthesis with cementless femur component and a cemented tibia component). The cemented solution proved its feasibility, they can be placed also in less-durable bone, but the periodic revision surgeries restrict their application to elderly patients. The most used cementless solutions are: press-fitting, biological fixation (via a bioactive coating layer) or mechanical interlocking (internal fixation using screws, Kirschner wires, pins, Kuntscher nails, etc.).

The press-fit implants require a rough surface (grit-blasted or porous-coated) to stimulate the bone formation and the *in situ* retention [2,3]. For press-fit implants a solid healthy bone tissue is necessary, and they also entail a longer healing time [4].

The biological implant fixation, perhaps one of most intriguing medical solutions, generated a frantic research in the last decade. This is achieved by applying biofunctional coatings of hydroxyapatite or other calcium phosphates [5–7], bioactive glasses [8–10] or carbonaceous materials [11,12], on the surface of bulk implant materials of metallic [5–9,11–14], ceramic [15,16] or polymeric origin [17]. This way one can exploit the superior biocompatibility of the coating layer (which can thus trigger various biological factors and stimulate the bone in-growth fixation) with the suitable mechanical properties of bulk implant substrate. The advantages and applicability of this implant fixation solution are still under debate [18,19].

The screw retention is one of the most popular implant fixations in current clinical practice, due to certain advantages such as the lower cost or the easier hygiene maintenance or revisions, making the technical and biological complications to be treated more easily [20–22]. Different studies reporting comparative performances of screw versus cement fixed implants (mainly for oral restorations) have been reported recently [20,22–24]. However, not too much attention has been given to the bone tissue changes that occur around the implant fixation screws in spinal surgery which influence directly implant retention quality and eventually the success of the medical intervention. In this study we have monitored the bone transformation around the pedicle titanium-based screws of posterior thoracic spine implants from two different

commercial systems, during the healing process. The osteodensitometry results are presented and discussed.

2. Experimental

2.1 Study plan

A single-centre, single-surgeons team, retrospective study was conducted. A group of ten patients who received posterior spinal stabilization with two pedicle screw fixation systems were analyzed in terms of osseointegration and osteoconductive properties.

Indications for surgery were both traumatic and degenerative lesions, disc degeneration that was not responsive to non-operative treatments for at least six months.

The study was restricted to patients with osteolytic lesions whose bone density may be influenced by the primary lesion. Patients with a disc abnormality (infection) at adjacent levels and patients undergoing multilevel surgery were also excluded. Other exclusion criteria were addressed to the patients who received at intervention the other types of implants besides the pedicle screw fixation system.

An informed consent was signed by each patient and/or family members.

Patients had the intervention performed in the period from January 2010 until September 2013 at Clinic Emergency Hospital "Prof. Dr. N. Oblu", Romania.

All studies have been carried out in perfect agreement with the World Medical Association (WMA) ethical guidelines of the Declaration of Helsinki: 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, and 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

2.2 Implants

Two titanium-based spinal fixation systems were investigated in this study.

The Synthes Matrix Spine System (Ti6Al7Nb) is a universal set of implants that cover degenerative, deformity, MIS and trauma indications. It is a comprehensive thoraco-lumbar pedicle screw system designed to provide flexibility, biomechanical performance and a solution to complex posterior pathological changes. The system is composed of preassembled polyaxial pedicle screws, monoaxial screws, locking caps, transconnectors, rods and polyaxial head implants. The monoaxial pedicle screw had a dual-core, double-lead thread design that is optimized to securely anchor the screw implants in both the cortical and cancellous bone anatomy. The low-profile head minimizes the implant high above the bony anatomy.

The Xia 2 Spine System (Ti6Al4V) is developed by Stryker as spine surgery products, and is a flagship line with ever-new extensions and products for the latest applications. The aim to develop better implants is represented by the patented buttress thread closure mechanism. What started as a top-loading pedicle screw system for treatment of degenerative spine pathologies has grown to include deformity solutions and a recently introduced trauma/tumour line extension. The Xia Stryker Spinal System who reached its third generation, is comprised of implants and instruments for stabilization of the spine during fusion in the thoracic, lumbar and sacral regions, with many features including: (i) reduced profile and implant volume; (ii) patented buttress thread closure mechanism; (iii) ergonomically designed instruments; (iv) available in stainless steel and titanium alloy form.

2.3 Surgical technique

A posterior spinal interbody arthrodesis with posterior pedicle screw fixation system was performed through a midline posterior approach.

Posterior transpedicular instrumentation is performed in the same fashion despite the level. The differences are the entry point of the screws according to the vertebral level. Under general anaesthesia the patient is placed in prone position. Through a midline incision the muscles are detached in subperiosteal fashion, exposing the laminae. The dissection is carried out laterally to the tip of the transverse processes. The entry point for thoracic spine T1 to T10 screws is the intersection between two lines: a horizontal line along the superior aspect of the transverse process and a vertical line 2 mm medial to the lateral border of the superior facet. For thoraco-lumbar spine (T11– L2) and lumbar spine (L3 – L5) the horizontal line is drawn in the middle of the transverse process and the vertical line passes in the middle of the superior facet. Under fluoroscopic guidance the pedicle awl is used to enter the pedicle. After that the pedicle screws are inserted and the rods are attached to the screws (Fig. 1). Finally according to the pathology to be treated we used compressions or distractions on the screws.

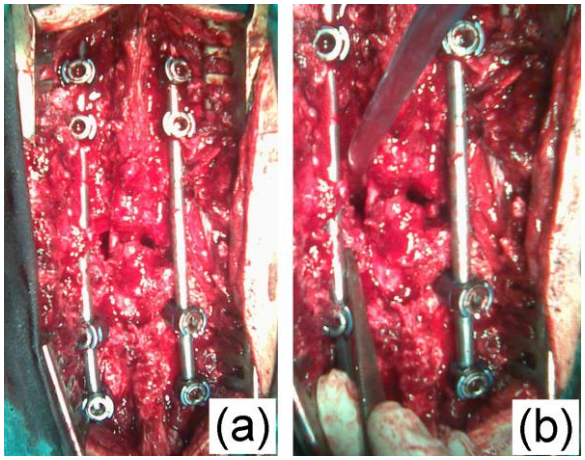

Fig. 1. Intraoperative images of spine fixation: (a) long instrumentation (8 screws, Xia 2) for a fracture-dislocation T11– T12; (b) the suction is spotting the T12 vertebrectomy.

2.4 Employed characterizations

CT images are digital images typically 512×512 pixels with a thickness described by the slice spacing of the imaging technique. The basic element of the CT image is a voxel, which has a value referred to in Hounsfield units that describes the density of the CT image at that point. Each voxel contains 12 bits of data and ranges from -1,000 (air) to +3,000 (spinal implant materials) Hounsfield units (HU). The density of structures within the image is absolute and quantitative and can characterize bone quality.

For each case, an expert operator measured the bone density, expressed in HU, using dedicated imaging software (eFilm, 2004 Merge Technologies Inc.). HU were used as an indication for differences in gray value and hence as an indication of relative density of the bone. Software allowed precise measurements of bone density around the screw implant insertion site.

The CT scans were obtained by using a 4-slice multi-detector CT scanner (Light Speed QX/I, GE Medical Systems, Milwaukee, Wis) with a mode of 1 mm thickness, slice pitch 3, and scanning time of 0.8 seconds. After scanning, Digital Imaging and Communication in Medicine (DICOM) images were then input into a personal computer.

The CT scans of the fused segments were made before surgery, 24 hours after intervention and six and twelve months postoperatively. Bone density measurements were performed in thirty points of specific areas. In order to achieve an accurate measurement of bone density in the same points for each image, a virtual model of the implant edge was created. This virtual model represents the contact area between implanted screw and bone, and was used as a measurement landmark by its superposition to each studied image (Fig. 2).

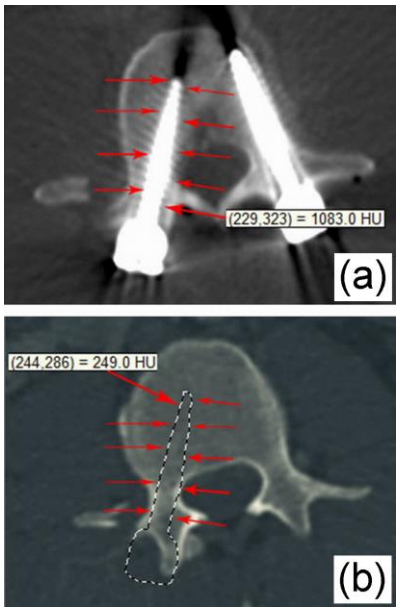

Fig. 2. (a) Imagistic analyses of implant screws in situ in the case of thoracal vertebral fracture; (b) Virtual model of the implant edge.

2.5 Statistical analysis

Statistical analysis was performed by using SPSS software (version 12.0). The means and standard deviations of bone density according to the virtual model depth at 1 mm intervals were computed for both implants: 30 points. The one-way ANOVA test was used to analyze differences in bone density according to the virtual model depth for each CT images. The paired t-test was used to compare mean bone densities between the two types of implants and the different time interval of CT images.

3. Results and discussion

Table 1 shows the means and standard deviations of bone density according to time at 1 to 12 month intervals, and the mean bone density for each type of spinal implant system. The values of mean bone density varied between 714 and 1149 HU for the Synthes Matrix Spine System, and were in the range of 581 to 1300 HU for the Xia Stryker Spine System, indicating some variability according to area.

The results (summarized in Table 1) indicated significant differences in bone density with increasing time from surgery for each type of implant. A decreasing bone density with increasing depth was more distinct in the vertebral body area compared with vertebral pedicle area. A comparison of mean bone density according to each type of implant for similar areas showed no significant differences.

The observation of a lower bone density and less trabecular bone formation, at various time intervals in the study group, was the most important finding of our study. This difference suggests that trabecular bone formation occurs at a slower rate when titanium alloys implants are used.

Donor-site pain, increased duration of surgery, and increased blood loss had no significant influence on the postoperative clinical course. The slower appearance of trabecular bone on CT scans in the study group also did not influence the clinical postoperative course. Neither migration nor subsidence of the screws was noted, suggesting that despite the obvious changes in the bone structure sufficient stability in the early postoperative stages is achieved with a good prognostic for the functional outcome.

Measurements based on Hounsfield density scale are proved to be appropriate to estimate the quality of bone. HU values measured on CT output data can be interpreted as an indicator of the differences in bone density. HU units are standardized according to the attenuation coefficient of water: water (0 HU), air (–1,000 HU), and enamel (13,000 HU). Due to their quantitative properties they are suitable for tissue identification. It has been reported that the placement site of temporary skeletal implants is strictly associated with their success [25,26]. A decreasing bone density with increasing depth was more evident in the vertebral body area compared with vertebral pedicle area. Up to now, the role of bone density in primary screw

stability has not yet been established. Published results suggest that higher bone density does not particularly affect the resistance of insertion of the screws but might result in a better stability.

On the other hand, in a different study [27] cortical thickness was not found to be correlated with maximum insertion torque but was positively associated with pull-out force. Thus, it appears that it is mainly the thickness (quantity) and not the density (quality) of the cortical bone that guarantees the stability of the screws. Clinically, this could suggest that clinicians should consider both local bone density and the thickness of the cortical plate during planning for screw placement. Moreover, the use of a torque wrench during screw placement could add more useful information in describing the bone response to temporary skeletal anchorage device insertion and primary stability as well.

Although various implants showed slightly different bone compatibility, the variability of bone alterations was not significant. However, the tolerance of the implant and the intensity of bone-implant interaction seem to be related to the location of the implant site. The amount of spongious bone in the vertebral body and the spongious/cortical bone ratio seem to be more reliable predictors for the success of the implant and, as a consequence, of the clinical stability prognostic.

Table 1. Evolution of bone density and of mean bone density for each type of spinal implant system.

	Bone density						Mean bone density
	Before surgery	24 hours after surgery	1 month after surgery	3 month after surgery	6 month after surgery	12 month after surgery	
Synthes Matrix Spine System (Ti6Al7Nb)							
Patient 1	716±268	822±284	939±266	1061±225	1134±168	924±192	933±189
Patient 2	829±179	1021±187	819±234	737±274	806±302	855±322	845±192
Patient 3	714±218	738±234	778±268	874±258	1057±170	971±195	855±168
Patient 4	978±260	1055±250	1141±191	1149±178	1178±150	999±163	1083±146
Patient 5	912±182	1006±270	1092±237	1121±265	1105±286	1113±171	1058±197
Xia Stryker Spine System (Ti6Al4V)							
Patient 1	752±287	733±288	719±253	755±239	1012±206	1241±128	869±194
Patient 2	777±246	784±273	825±278	890±295	1046±254	1142±151	911±213
Patient 3	1060±161	1063±232	1102±212	1120±281	1142±272	1132±232	1103±186
Patient 4	1300±130	1272±229	921±271	722±271	626±247	581±222	904±188
Patient 5	1003±153	1056±153	1039±176	1084±179	1116±156	1087±166	1064±138

4. Conclusions

Our studies indicated that a decreasing bone density with increasing depth was more distinct in the vertebral body area compared with vertebral pedicle area. A slower formation of cancellous bone has been observed, but did not influence the clinical postoperative course. The spongious/cortical bone ratio could be a more reliable predictor for the success of an implant.

As recent research studies suggested that bone formation in interbody arthrodesis continues beyond three years after surgery, we intend to continue our observations by performing a CT scan at three years postoperatively and to report the results in a future study.

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*Corresponding author: chiriac_a@hotmail.com