Stent-screw-assisted internal fixation (SAIF)

Chapter 10

Summary and Discussion

Vertebral fractures, caused by underlying osteoporosis or cancer, present across a wide range of severity, with stable or unstable features, and relative preservation or loss of vertebral body osseous integrity. [1–3]

These fractures pose the clinical problems of pain, bed bounding or reduced function, spinal deformity, and neurological compromise. Their treatment varies from conservative non-invasive approaches, to minimally invasive cement vertebral augmentation techniques, and to surgical interventions for anterior and posterior column stabilization. [4] In most severe fractures vertebral augmentation might not be feasible and is generally regarded as an undertreatment, and surgical stabilization is then advocated. [5] Nevertheless, surgery is a rather invasive therapeutic measure, that carries significant morbidity, especially in fragile patients, such as elderly or metastatic cancer patients. A therapeutic alternative filling the gap between standard vertebral augmentation techniques and surgical stabilization, with a less invasive profile, yet able to offer effective stabilization and pain palliation, with a favorable safety profile, would be desirable.

The overall research aim of this thesis was to assess whether a recently developed minimally invasive image-guided interventional technique, based on a reinforced or “armed” vertebral augmentation technique, called stent-screw assisted internal fixation (SAIF), could fill that gap and represent a viable therapeutic option in severe neoplastic and osteoporotic vertebral fractures without neurological impairment.

In **chapter 2**, **research question 1**, whether vertebral body stenting (VBS) could be used to reconstruct the anterior column in extreme osteolysis (EO) of the vertebral body, was addressed.

The study included 41 vertebrae (in 29 patients) with EO, featuring high degree of collapse in 22/41 and epidural mass in 21/41. VBS augmentation was performed as a stand-alone procedure in 26/29 patients (36 vertebral levels), or it was added to posterior surgical fixation, with decompressive laminectomy when deemed necessary, in the remaining cases, thereby avoiding corpectomy and grafting. The study results showed excellent feasibility, with VBS-augmentation being performed in all cases; despite some degree of cement leakage was present in 34% of treated levels, no clinically relevant intra-procedural complications occurred. Vertebral reconstruction was rated by a neuroradiologist and a neurosurgeon as satisfactory (grade 3-4 good-excellent in 90% of cases). These results were maintained throughout a mean follow-up of 15 months, and only one patient underwent new surgical stabilization due to an

adjacent vertebral fracture. The VBS seemed particularly appropriate in the treatment of these EO lesions, in fact, with their large support-surface, filled with PMMA, VBS could provide primary reinforcement of the anterior column, and their tight mesh may help achieve cement containment. This approach has then been replicated, in its version combined with surgical decompression and posterior stabilization, by Mohammed et al., in their study published in 2020, on a series of 14 patients with neoplastic spinal cord compression, thereby providing anterior column support and avoiding a more invasive corpectomy. [6] Another series, recently published, described the successful results of VBS augmentation in 78 thoraco-lumbar compression fractures of different etiologies. [7]

Nevertheless, in most severe EO, given the fact that PMMA-bone cement has no adhesive properties, in lack of containment by osseous cortical margins, the VBS-cement complex might dislodge under axial load. In fact, in one case, a ventral shift of the VBS-cement complex was noted at radiological follow-up in our study. This particular case induced us to consider a technical solution to this limitation. Stability of the construct could be further enhanced by an anchor from the VBS-cement complex in the vertebral body to the posterior elements, more rarely involved in lytic destruction than the vertebral body.

In **chapter 3**, **research question 2**, whether the VBS-cement complex could be integrated by transpedicular screws, and which applications could be addressed by this new technique, called SAIF, was addressed by a technical explanation of the procedural steps of SAIF, its rationale, and its potential clinical applications.

The issue of anchoring the cement after vertebroplasty or kyphoplasty had already been investigated in the past in patients with fractures with higher risk of cement displacement, such as those characterized by a high degree of fragmentation or avascular necrosis of the vertebral body. [8–10] However, in the absence of a definitive solution, it was suggested that a better interdigitation of cement in the trabecular bone could help, but this may be unpredictable or difficult to achieve. [11]

The pediculoplasty, which is injection of cement in the pedicles, along the needle tract, was first described in 2002 [12] as a possible solution for that purpose. However, it is somehow limited, because the PMMA bone cement is highly resistant to axial load but poorly resistant to bending forces, as those acting on the pedicles; moreover, the pediculoplasty is a technique with higher risk of cement leakage in the central canal and neuroforamina, with the risk of injury to

the adjacent nervous structures. To obviate these limitations Amoretti et al. in 2014, [13] and Pusceddu et al. in 2017 [14] have proposed a vertebroplasty technique performed through a previously inserted pedicular fenestrated screw. This technique has been presented again, in combination with balloon kyphoplasty this time, by Yonezawa et al. in 2021. [15]

Inspired by surgical techniques, the optimal anchorage to the posterior elements can be provided by cannulated surgical screws in order to obtain the highest resistance to loading and bending forces, and at the same time the safest technique due to absence of risk of cement leakage. Nevertheless, this new technique does not address the issue of vertebral body height restoration, mechanical support and cement containment faced by a standard vertebroplasty or balloon kyphoplasty in challenging fractures.

Chapter 3 describes a new technique, combining VBS kyphoplasty and pedicular screw fixation, named Stent-screw-Assisted Internal Fixation – SAIF. The VBS, besides its features that allow anterior column reconstruction, represents an ideal device for fixation to posterior elements, as it may accommodate the screw to reach the anterior third of the vertebral body within its own lumen; the other devices developed for implant-based kyphoplasty obstruct instead the central portion of the vertebral body compelling the use of shorter, and consequentially less stable and effective, pedicular screws.

From a procedural point of view, the SAIF technique presents additional advantages beyond the anchorage of the stents to the posterior elements, namely the treatment of pedicular fractures and improved support for the middle column, and is useful in multiple clinical scenarios. Generally speaking, it might be useful for comminuted fractures, fractures with loss of cortical bone integrity and for fractures with damage of the middle column and/or posterior wall involvement. For neoplastic lesions, the use of SAIF might be considered to augment extensive osteolytic lesions with dehiscent cortical boundaries (**Tomita** extra-compartmental lesions type 4–6) [16] that are fractured or at risk of impending collapse, but it could be also used to perform vertebral augmentation in severe osteoporotic fractures with crush deformity, advanced collapse (**Genant** grade 3), [17] high degree of fragmentation (**McCormack** grade 2 and 3) [18] and large osteonecrotic clefts.

The whole construct of stents, screws and cement is fully contained inside the vertebra, acting as an internal vertebral body prosthesis fixed to the neural arch and, unlike surgical

corpectomy and posterior instrumentation, do not require fixation of adjacent vertebral levels, thereby preserving the role of adjacent disc spaces and of the spinal functional units. To this regard SAIF can be regarded as a non-fusion vertebral reconstruction technique, that obtains fixation within the vertebra itself, therefore called internal fixation, as opposed to the bridging fixation of the adjacent vertebrae operated by standard surgical stabilization. SAIF can also be combined with posterior surgical stabilization, thereby at least replacing a more invasive corpectomy. Its limited invasiveness compared to surgical stabilization, makes it an interesting option, especially for fragile patients.

In **Chapter 4**, **research question 3**, whether SAIF has a biomechanical rationale in the stabilization of extreme osteolytic lesions of the vertebral body, and how SAIF compares mechanically to surgical posterior fixation, was addressed by a biomechanical simulation, on a finite element analysis (FEM) of a lytic vertebra model.

The effect of SAIF on the lytic vertebra model was analyzed biomechanically in terms of restoration of the load-bearing capacity of the vertebral body (i.e.: axial stiffness) and in terms of reduction of re-fracture risk (i.e.: principal strains).

The study revealed that SAIF effectively restored the load-bearing capability of the vertebral body to values comparable of an intact spine, while significantly reducing the strains on the superior endplate and the posterior wall (beyond 90%), and on the anterior wall (about 40%) compared with an untreated vertebra. Of even greater interest, the surgical fixation was significantly less effective than SAIF in reducing the strains, both on anterior and posterior walls, potentially indicating a greater fracture risk.

However, a further scenario which was analyzed in our model was the supplementation of the SAIF technique with posterior fixation, to understand whether the techniques could work synergistically. This model showed only a marginal decrease of the strains on the bony structures (about 5% on the superior endplate and posterior wall, 16% on the anterior wall), with such a relatively small advantage that it should be weighed against the greater invasiveness of a surgical posterior fixation technique and a potential interference with initiation of radiation treatment.

Neoplastic fractures, especially those characterized by EO, pose several treatment challenges. These fractures are unstable, cause pain and pose a risk of neurological compromise. [5,19] Moreover, radiation therapy, used to obtain local disease control in spine metastases, carries an additional significant risk of transient weakening of the bone and increased risk of collapse. Such complex fractures have been rarely managed by minimally invasive interventional procedures, as the primary goal is to treat the potential instability of the spine, a process that is thought to require surgical stabilization. Standard augmentation techniques are usually considered either unsafe, contraindicated, impossible or at least an undertreatment in these fractures [20,21].

The SAIF technique aims at treating both pain and biomechanical instability, with posterior surgical fixation being the standard treatment for comparison . In this clinical scenario the FEM study attributed a theoretical biomechanical rationale to SAIF in the stabilization of extreme osteolytic lesions, as an alternative treatment to surgical fixation.

In **chapter 5**, **research question 4**, whether SAIF is clinically safe and efficient to treat extreme osteolytic lesions of the vertebral body, is addressed by a study reporting on a clinical series of patients affected by neoplastic EO of a vertebra, fractured or at risk of fracture, deemed unstable or potentially unstable according to the Spinal Instability Neoplastic Score (**SINS**), [22] treated with SAIF.

In 36 SAIF procedures performed in 35 patients, the SAIF technique proved to be feasible and safe for vertebral body reconstruction and stabilization, confirming the biomechanical data on finite-element analysis (FEM) models, with satisfactory clinical and radiological results. Cement leakage was in fact observed in 12/36 cases, but only one was symptomatic and required surgical decompression, with no permanent sequelae. No other intra-procedural complications occurred, and despite the fact that 23/36 of the treated levels showed an epidural mass on pre-procedure MRI, no post-procedure worsening of neurological status was observed. The vertebral body reconstruction, judged independently by an interventional neuroradiologist and a neurosurgeon, was deemed good/excellent in 94.5% of cases by the two raters, with high interrater agreement. At follow-up the results were stable in all cases but one, that developed osteomyelitis, mobilization of the SAIF construct, and required surgical intervention.

The main focus of this study was on mechanical stability, through assessment of vertebral body reconstruction and spinal stability at follow-up. Although most patients with EO report some form of mechanical pain, pain palliation was not a primary endpoint of this study, as multiple studies, including a randomized controlled trial, have demonstrated meaningful pain improvement with cement augmentation in neoplastic vertebral fractures. [10] Certainly, SAIF has also a role in pain palliation, as a form of vertebral augmentation, when necessary.

SAIF procedures were performed as a stand-alone intervention and in conjunction with posterior surgical fixation, with or without laminectomy, showing the compatibility of SAIF with posterior surgical open or percutaneous stabilization techniques.

Altogether with the low invasiveness profile, SAIF appeared particularly advantageous in patients with spinal metastases, since it could be performed in day-surgery or a very short hospitalization setting. Patients receiving SAIF can in fact return promptly to daily activities, and there is no interference with chemotherapy and radiation treatment regimen. It should be underscored that these oncological patients require individualized clinical decisions for the planning of comprehensive treatment strategies. In our clinical setting this effort was undertaken by a multidisciplinary spine tumor board composed of medical and radiation oncologists, spine surgeons, neurologists and neuroradiologists with extensive experience in the treatment of oncological disease, who defined indications for and the timing of medical, radiation or invasive treatments. [23–27]

In **chapter 6**, **research question 5**, whether there is a biomechanical rationale to explain the re-fractures of the middle column after cement augmentation in osteoporotic vertebrae, is addressed by a FEM study on an osteoporotic spine model. The “bare area” concept, the lack of augmentation of the middle column after standard vertebral augmentation, as vertebroplasty and balloon kyphoplasty, is investigated biomechanically, and SAIF is compared to standard vertebral augmentation in its efficacy to stabilize the middle column.

The conventional augmentation model was effective in reducing strain both in the anterior and to a lesser extent in the middle column. The SAIF technique, however, proved superior to conventional augmentation techniques improving the results by a significant margin

and further reducing the strains both at the anterior and middle column. The improvements where particularly relevant at the superior endplate of the anterior column and at the posterior wall (-68% and -64% in upper body flexion compared to vertebral augmentation).

The distribution of the loads was also remarkably improved by promoting a higher load transfer on the anterior column compared to simple augmentation and to the untreated osteoporotic condition, while the middle column resulted to be relatively unloaded.

Standard augmentation techniques, in fact, aim at anterior column reinforcement. [28–32] The fracture of the middle column is indeed frequently cited as a contraindication to traditional vertebroplasty and kyphoplasty, because the concomitant fracture of the anterior and middle column, as in burst fractures, is considered a sign of instability. These fractures are frequently characterized by collapse and retropulsion of the posterior wall and if treated with anterior column-only cement augmentation, might undergo catastrophic splitting between the augmented anterior portion of the vertebral body and the middle column. [20,33]

Moreover, the vertebral body accesses generally used for any kind of vertebral augmentation are strongly limited in approaching a triangular-shaped area located immediately ventral to the posterior wall, and that could be named “bare area”. [34] This area is normally inaccessible to needles, and cement distribution in this area is difficult, unpredictable, or undesired because of the higher risk of leakage in the contiguous epidural space. Acting as a reinforcement of the posterior third of the vertebral body, the screws utilized in the SAIF technique were proven effective in stabilizing and protecting the middle column, despite the biomechanical simulation of the “bare area”. This biomechanical advantage of SAIF technique, compared to conventional augmentation in restoring the load bearing capacity of the anterior and middle spinal columns might lead to favor SAIF in osteoporotic fractures with crush deformity, advanced body collapse, pediculo-somatic junction fracture and large osteonecrotic clefts, since many of these fractures present with middle column involvement.

In **chapter 7**, **research question 6**, whether SAIF is clinically safe and efficient to treat severe osteoporotic fractures of the vertebral body, is addressed via a study on a series of patients affected by severe osteoporotic fractures treated with SAIF.

Eighty severe thoraco-lumbar osteoporotic vertebral compression fractures, with the majority (79%) at the thoracolumbar junction (T10–L2) were treated with SAIF. There were no intra-procedural complications and no symptomatic cement leakages. One patient experienced un-explained transient self-resolving hypoesthesia and mild motor deficits in the lower limbs. The vertebral reconstruction score was good or excellent in 98.8% of cases, with perfect inter-rater agreement. There was a statistically significant difference in VAS pain scores before the pro-cedure versus 1 and 6 months after. The patient's global impression of change (PGIC) scale indicated a very positive patient's subjective global clinical impact.

No cases of stent or screw dislocation were seen until the last available follow-up, highlighting the great reliability of the technique in obtaining a stable and durable vertebral reconstruction. Despite the presumably scarce bone quality in this elderly osteoporotic population, no screw mobilization was noted during follow-up, probably due to the minimal forces acting on the ped-icle screws in the SAIF construct, differently from the pull-out strains acting on screws of a surgical stabilization construct.

After the SAIF procedure, patients were allowed to stand and walk without spinal braces as soon as 3 hours after the procedure and commonly discharged the same day, in a day-surgery setting.

Treatment of severe osteoporotic vertebral fractures with middle column injury should aim at fracture reduction, correction of pathological kyphosis, restoration of axial load-bearing capa-bility with arrest of fracture progression and early mobilization. [21] In many clinics surgical stabi-lization is considered the gold standard, but it is invasive, carries a significant risk of morbidity in the elderly population, and carries a high risk of mechanical failure in patients with poor bone quality. [35] In this clinical scenario SAIF seemed to offer a valid minimally invasive alternative, able to fulfill the treatment requirements.

In **chapters 8a** and **8b**, **research question 7**, whether the frequently associated posterior wall retropulsion might represent a contraindication to the SAIF procedure, was addressed

by two different studies. One study (**8b**) represents a description of a technique to create a true cavity in the vertebral body, in those vertebrae with extreme osteolysis and posterior wall de-hiscence, before performing SAIF. We developed and described

a technique (“Q-VAC”) to create a cavity using intravertebral soft tissue mass fragmentation by means of a mechanical curette before vacuum suction and lavage. Associated to the SAIF technique, Q-VAC might lead to debulking of the centrally located soft-tissue tumor component in the vertebral body, resulting in the creation of a cavity that allows safer expansion of VBS and to a potentially safer and more predictable deposition of larger amount of cement, ultimately reducing the risk of central canal compromise in presence of posterior wall retropulsion or erosion.

The bone marrow “washout” or lavage has been reported in a clinical setting in a series of osteoporotic vertebral compression fractures, potentially reducing the risk of cement leakage and prevent pulmonary embolism, and in a small series of patients treated with multilevel vertebroplasty for multiple myeloma spine lesions. [36] Nevertheless, we found simple aspiration or washout attempts are only able to partially remove the fluid, necrotic, or bloody parts of vertebral neoplastic lesions, as in multiple myeloma, but cannot remove solid vertebral lesions commonly occurring in metastatic breast and lung cancer.

The use of a coaxial curettes has been previously described in case of sclerotic changes after vertebral body fractures to maximize height restoration during balloon kyphoplasty, but it has not been employed to fragment neoplastic intravertebral soft tissue in lytic lesions.

Creation of a cavity prior to cement injection or intravertebral device expansion, such as balloons or VBS, might help increase safety and avoid severe adverse events. Proposed solutions to reduce the cement migration include radiofrequency ablation and cryoablation prior to cement injection, which may result in reduction of tumor mass due to induction of necrosis, and can cause thrombosis of the vertebral and paravertebral veins therefore reducing the PMMA embolization risk. [37–41]

However, the induction of tumor cell necrosis does not correspond to an immediate void creation and their use to obtain an intravertebral cavity remains questionable, as subsequent cement injection would simply push residual tumor cells and necrosis aside. As additional drawbacks, radiofrequency and cryoablation require a safety margin with vital and nervous structures and imply adjunctive time and cost increase.

The other study (**8a**) assessed a series of 53 fractures of mixed etiology, with posterior wall retropulsion, that were treated with an armed kyphoplasty technique (AKP) using vertebral

body fracture internal distraction devices such as VBS and SpineJack®. AKP was able to obtain posterior wall retropulsion correction in traumatic, osteoporotic and neoplastic burst fractures. It was used as a stand-alone minimally invasive procedure in most cases or in combination with a posterior surgical approach, but without the need to perform any direct form of posterior wall retropulsion correction. The SAIF technique was performed in 33/53 levels.

A statistically significant difference between pre- and postoperative posterior wall retropulsion and vertebral body height was found, suggesting the biomechanical effectiveness of the technique, and showed durable results: no re-intervention was required on the target level at the end of the follow-up. Two patients presented transient new neurological symptoms, with spontaneous clinical resolution, and their imaging did not show any sign of worsening of central canal compromise No patients presented onset of new permanent neurological deficits. In two cases worsening of posterior wall retropulsion was noted, which remained uneventful.

Posterior wall retropulsion has been considered a relative contraindication for vertebral augmentation (and in particular for traditional balloon kyphoplasty) because it is unable to clear the canal and might lead to worsening of the neurological condition through epidural cement leakage or further displacement of bony fragments or neoplastic soft tissue epidural component in the central canal. [37] The inflation of balloons during balloon kyphoplasty might in fact potentially worsen a posterior wall retropulsion, while the subsequent deflation effect, [10] with loss of vertebral height restoration, does not guarantee a reliable fracture reduction and kyphosis correction. Even simple injection of cement can exert a mass effect, with displacement of soft tissue tumor mass in the central canal, as demonstrated with post-balloon kyphoplasty CT-myelograms by the study of Lis et al. [42]

Traditionally, open surgery is considered the best treatment to obtain indirect fracture reduction, kyphosis correction, central canal decompression by laminectomy and posterior wall fragment impaction, accomplished by ligamentotaxis of the posterior longitudinal ligament. Nevertheless, stabilization of the anterior column is crucial in burst fractures with severe fragmentation to avoid loss of correction and instrumentation failure, [43] and although surgical anterior instrumentation has proved effective in stabilizing the anterior column, it requires a more invasive approach which could be associated with increased morbidity. Some authors, on the contrary, support a conservative approach in patients without neurological deficits, claiming that spontaneous remodeling and resorption of the posterior wall fragment could eventually

occur. [35,43] The risk of spinal cord compression after vertebral augmentation is higher for fractures caused by extensive lytic lesions with erosion of the posterior wall or epidural tumor spread, either from cement leakage or from further central canal encroachment by the epidural mass**.** [44]

In recent years kyphoplasty with metallic implants like VBS and SpineJack® ("armed kyphoplasty" or "AKP") has been reported as an alternative to balloon kyphoplasty that potentially guarantee better height restoration in compression fractures by avoiding height loss due to deflation effect, and is increasingly used as a stand-alone measure to reconstruct and restore axial-load capability in burst fractures, even with posterior wall retropulsion. A cadaveric study has shown the ability of SpineJack® to reposition a retropulsed posterior wall of a burst fracture model and substantially maintain this gain after cyclic recompression. This ability rests on fracture distraction and kyphosis correction allowing reduction of posterior wall retropulsion through ligamentotaxis. In the same experimental setting posterior instrumentation alone did not maintain central canal clearance. However, the potential of armed kyphoplasty to correct the posterior wall retropulsion in burst fractures had not been investigated in vivo.

In this study the SAIF technique confirmed its potential in being a minimally invasive approach that might represent a balanced compromise between invasive surgical treatment and conservative approach for the treatment of burst fractures even with significant posterior wall deformation and retropulsion. This series gives preliminary indication that posterior wall retropulsion does not seem to be a contraindication to SAIF, which to the opposite exploits the ligamentotaxis to obtain posterior wall retropulsion correction along with vertebral body fracture reduction.

In **chapter 9**, **research question 8**, whether SAIF is non-inferior in terms of clinical efficacy and cost-effectiveness to multilevel posterior spinal fusion in patients with severe unstable osteoporotic fractures, is addressed by a randomized controlled study design. Despite promising results for SAIF in terms of safety, clinical and radiological outcomes as reported in Chapter 2 through Chapter 8, a higher level of evidence, through prospective and controlled data, is necessary to make a change for clinical practice on a larger scale. In fact, the most severe osteoporotic fractures, following the recent classification system and treatment recommendations of the German Society of Orthopedics and Trauma (DGUS), [45,46] represent an almost exclusive surgical indication for a 360° stabilization approach. Such interventions pose a risk of

morbidity in the fragile, elderly population, with high costs, prolonged hospitalizations, and the risk of delayed failures, such as pull out of implants and adjacent fractures, in case of poor bone quality. In addition, due to the fact that these fractures occur frequently in elderly patients, often with co-morbidities, a major surgical intervention might be contraindicated, resulting in patients that are left untreated, often bed-bound, or with progressively worsening kyphosis, risk of falling, pulmonary problems, chronic pain, opiate over-use, and overall increased mortality risk. [47] In case the trial should show non-inferiority of the SAIF procedure, the shorter duration of the SAIF procedure, the negligible blood loss, the shorter hospital stays and prompt return to normal activities, compared to the multilevel surgical option, should also make this procedure more suitable than the traditional multilevel surgical stabilization, even in the elderly population, allowing a safe and efficient treatment in a larger portion of those patients.

The study is designed as a multicenter prospective randomized controlled study, aiming at assessing non-inferiority of SAIF compared to multilevel surgical fixation in terms of QUALEFFO, a specific quality of life metrics in osteoporotic patients, and in terms of radiological vertebral height restoration and kyphotic correction in patients suffering from unstable osteoporotic vertebral fractures. Study follow-up duration will be 12 months. Additionally, complications, blood loss, length of hospital stay, and cost-effectiveness will be measured. The control group, undergoing control surgical stabilization, comprises multilevel posterior fixation, with or without cement screw augmentation, with or without index level augmentation with vertebroplasty of kyphoplasty, with or without index level corpectomy and grafting, based on the treating physician's decision and individualization of approach.

While this multiple technique control group may be regarded as a methodological weakness, it takes in consideration the lack of consensus on the most appropriate surgical technique to treat these fractures, and thus closely adheres to clinical practice. The study might face difficulty in recruiting patients due to randomization between two treatments with different invasiveness profiles; to minimize this risk SAIF procedure will not be offered to eligible patients as a standard procedure outside the trial. The trial aims at enrollment of 140 patients and will be preceded by a 12 months feasibility trial supposed to enroll 20 patients.

Simultaneously, we will pursue an observational study in which we will include patients that fulfill the inclusion criteria but are not eligible as they are considered not fit enough for major invasive surgery, but still can undergo the less invasive SAIF intervention.

The observational cohort is not part of the randomized controlled trial, but outcomes will be assessed during one year of follow-up, in order to assess if the SAIF intervention can offer an effective treatment to a fragile population that cannot be treated by multilevel fixation surgery.

The study protocol has been examined and accepted by the Ethical committee of Canton Ticino (Switzerland).

Conclusions

This thesis investigated a novel minimally invasive percutaneous image-guided technique to treat severe thoraco-lumbar vertebral fractures of neoplastic or osteoporotic nature. This technique, called Stent-screw assisted internal fixation (SAIF) was tested by biomechanical simulations and clinically by assessment of large patient series. The SAIF technique seemed to be able to fill the gap between standard vertebral augmentation, that can be considered an undertreatment in severe fractures, and multilevel spinal fusion techniques with posterior and anterior approaches, that are invasive and carry a high risk of morbidity in fragile patients.

SAIF seems to offer safe, effective, and durable treatment of severe neoplastic and osteoporotic vertebral fractures with no neurological deficit. The technique can be performed in an outpatient day-surgery setting or with a short hospital stay, and when deemed necessary, SAIF can be combined with posterior spinal fusion, thereby avoiding a more invasive anterior approach with corpectomy. In neoplastic patients the SAIF technique does not interfere with chemo- or radiation-therapy regimen. However, more robust, prospective data need to be acquired through a randomized controlled trial to gather high level evidence for clinical efficacy and cost effectiveness of SAIF in order to improve current clinical practice on a larger scale.