Stent-screw-assisted internal fixation (SAIF)

Valorization of Research

In this chapter, we will translate the findings of this thesis in terms of 'knowledge valorization'. Knowledge valorization of research refers to the process of creating value from knowledge, by making it available for social and or societal utilization.

Spinal disorders are common and have a substantial impact on both patients and society, affecting more than 1.7 billion people worldwide. With aging of our population, the burden of spinal disorders on society, in terms of decreased quality of life and an increase in costs, is expected to further rise.

Low bone mass by osteoporosis affects a steadily growing number of people in the economically developed countries.[1] The number of older adults with osteoporosis is expected to increase by about 30% from 2010 to 2030.[2] Fragility fractures present major medical and socio-economic challenges and it has been estimated that approximately 76,000 new fragility fractures occurred in the Netherlands in 2010, of which 12,000 were vertebral fractures.[3]

New vertebral fragility fractures occur in approximately 500,000 patients per year in Europe. Fragility fractures can be life-changing and bring pain, isolation and dependence. Vertebral fragility fractures can lead to a downward spiral of symptoms and morbidity, from pain and disability to impaired pulmonary and respiratory function. There are also associated mortality risks, with up to 72% mortality rate at 5 years and 90% at 7 years.[4–6] The economic burden of fragility fractures is huge (approximately 37 billion euros in 2010 for Europe) and the costs are expected to increase by 25% in 2025.

Another rising healthcare problem related to the spine is spinal metastases. Spinal metastases affect more than 70% of terminal cancer patients.[7] Advances in medical treatment for systemic disease have improved survival rates among patients with cancer, which has contributed to an increased incidence of spinal bone metastases. Spinal metastases can cause skeletal-related events such as a pathologic fracture or spinal cord compression, with necessity for radiation therapy or surgery (for pain or impending fracture), with potential adverse impact on quality of life. The occurrence of a skeletal-related event contributes significantly to the cost of care.[8] Data from a large study across four major European countries showed that all types of skeletal-related events are associated with considerable health resource utilization and costs of up to €12,082 per event.[9]

Narcotic analgesics, back braces, and immobilization are common non-surgical means for treatment of vertebral fragility fractures, but may be poorly tolerated in elderly patients with side effects, such as constipation and increased risk of falls.[10,11] In most severe cases patients are bed bound and might require hospitalization, thereby increasing risks of complications, comorbidities, and healthcare costs.

Even after best conservative medical management, these fractures not infrequently lead to poor recovery of health condition, spinal deformity, sagittal imbalance, poor balance and gait, increased risk of falls. In such cases, surgical vertebral augmentation intervention with vertebroplasty or balloon kyphoplasty can provide improved pain relief, functional recovery, and health-related quality of life.[12–15] Furthermore, lower mortality risk and a higher probability of being discharged to home instead of a nursing facility have been reported for augmentation over non-surgically managed patients in the majority of claims-based studies.[6,16–20] Additionally, a randomized trial on more acute and more painful vertebral fragility fractures reported earlier discharge from hospital and less tendency to progressive kyphotic deformity in patients treated with vertebral augmentation compared to those in the sham placebo group.[11] A recent meta-analysis[21] reported that invasive treatment of osteoporotic vertebral fragility fracture is superior to non-surgical management with regard to pain palliation, without affecting quality of life nor causing more subsequent vertebral fractures.

Although these are encouraging data regarding vertebral augmentation techniques in the treatment of patients with painful osteoporotic vertebral fractures, in severe, unstable fractures, such as those classified OF 3 to OF 5, patients will need to be treated not only to palliate pain, but also to regain spinal stability and axial load capacity. In these situations, standard vertebral augmentation techniques may be regarded as unsafe, not feasible or at least as an undertreatment. In such severe cases, surgical fixation is considered.[22] However, operative treatment can be complex in these often fragile patients because of physical deconditioning, medical comorbidities, balance and gait problems with subsequent risk of falling, and poor bone quality with concomitant risk of poor operative fixation and new fractures. Spinal fusion in such cages carries in fact high rates of mechanical failure and proximal junctional failure, for which low bone mineral density because of osteoporosis is an important determinant.

When the vertebral body has lost its structure and ability to bear the axial load, vertebral body resection and cage grafting might be considered, with a 360° surgical approach,[23,24]

which, despite its biomechanical efficacy, is highly invasive surgery, carrying high rates of complications, high costs, and long hospitalization and recovery times, especially in fragile and elderly patients.[25,26]

The need to balance potential risks and benefits in clinical practice requires a patient-tailored assessment and decision making. Moving between the hurdles of this delicate balance causes some patients to be undertreated with conservative treatment or a standard cement augmentation where a more powerful stabilizing technique would have been required, while other patients will be treated with an invasiveness that their clinical condition cannot withstand, and thus a large portion of patients may be left untreated because there is no suitable treatment that can be offered to them.

The percutaneous surgical technique Stent-screw-assisted internal fixation (SAIF), subject of this thesis, could fill this treatment gap, offering a minimally invasive yet efficient tool in case of severe osteoporotic and neoplastic vertebral fractures, to palliate pain and restore axial load capability.

Biomechanical studies in this thesis showed how SAIF can be used to reconstruct the anterior column on simulation models of osteoporotic and neoplastic vertebral body lesions, favorably comparing to surgical posterior stabilization and to standard vertebral augmentation. The biomechanical simulations showed that the vertebral bodies treated with SAIF recovered their axial load biomechanical capabilities. In addition, the middle vertebral column, generally left untreated by standard vertebral augmentation techniques was reinforced by the SAIF construct. This may expand the list of indications for SAIF treatment to unstable fractures with middle column involvement. Very satisfactory results were then confirmed clinically in patients with neoplastic extensive osteolytic destruction of the vertebral body, where SAIF was shown to offer an alternative to more invasive corpectomy. By providing an internal scaffold of the destroyed vertebral body, filled with bone cement and anchored to the posterior osseous vertebral elements, SAIF could be considered as an internal non-fusion means of 360° vertebral stabilization. Such an “armed concrete” approach proved to be efficient and safe also in complex unstable osteoporotic vertebral fractures. Exploiting the ligamentotaxis mechanism, the fracture reduction achieved with SAIF can also lead to indirect central canal decompression in those challenging fractures presenting with posterior wall retropulsion. Combining percutaneous curettage, lavage and vacuum suction of the vertebral body, even extensive neoplastic

vertebral lesions with central canal involvement, in neurologically intact patients, can be treated with SAIF. All these biomechanical, technical, and clinical results, pose the basis for the application of SAIF in vertebral fractures traditionally representing exclusive indications for surgical fusion. In the clinical series of both osteoporotic and neoplastic cases, SAIF was combined with posterior surgical stabilization, as a means of vertebral body reconstruction, thereby avoiding at least the most invasive surgical part of vertebral body resection and grafting in selected cases.

Technically, the SAIF procedure can be performed in an angiography suite and does not necessarily require an operating room. It can be performed in day-surgery setting, with hardly any blood loss, and with greatly reduced operating times as compared to spinal fusion. Early yet unpublished results of SAIF across centers have shown its reproducibility and consistency. Obviously, training of operators is crucial to endure a standard level of performance. SAIF is likely to speed up recovery and discharge, minimizing days of hospitalization, and also minimizing the post-intervention interval for radiation treatment in patients with neoplastic lesions. The costs of this procedure are in between those for standard vertebral augmentation (vertebroplasty or balloon-kyphoplasty) and those for standard surgical fixation. Dedicated appropriate reimbursement policies are at present lacking, but should be considered and should take into account all the potential benefits of this procedure.

Patients with severe vertebral fragility fractures or extreme neoplastic osteolytic vertebral lesions, who could benefit from SAIF, are typically fragile, because of age, comorbidities, and oncological treatment. Management of these patients cannot be limited to the surgical treatment of their vertebral lesion, but should consider a multidisciplinary approach for their multidimensional problem, including pharmacological treatment for low bone mass, a comprehensive pain treatment, physical therapy, fall prevention, and rehabilitation. In case of metastatic spinal lesions, SAIF has to be considered solely as a means for stabilization of the vertebral injury, while the local and systemic disease control strategy has to be left to the oncologist.

As a next step, we designed a protocol for a prospective randomized controlled trial with the aim to gather level I evidence to ascertain whether SAIF is not inferior to surgery in treatment of severe unstable osteoporotic fractures, and to better ascertain its cost-effectiveness. The same level of evidence should be pursued for complex extensive lytic neoplastic lesions of the spine, causing fracture or posing the risk of impending collapse.

Such level of evidence might lead to an additional option in the treatment paradigm of severe pathologic and osteoporotic vertebral fractures, that should be accompanied of course, by training of surgical operators toward this new technique, and by parallel development of health policies for reimbursement.

These factors may ultimately lead to the possibility to offer patients a minimally-invasive effective treatment for severe osteoporotic and neoplastic spinal fractures, with a positive impact on their quality of life, and a potential to save healthcare resources when compared to standard surgical treatment.

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