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# Osseoplasty: Review and Analysis of 1081 Cases in the United States and Europe

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## SUMMARY

This report is a retrospective analysis of 1081 reported clinical cases performed by 206 physicians in the United States, UK, Italy and Spain from November 3<sup>rd</sup>, 2008 through November 2<sup>nd</sup>, 2010, using the Osseoflex and Osseoperm vertebral augmentation system in the treatment of symptomatic vertebral compression fractures. As cases were performed by numerous clinicians in multiple sites, and without the structures of a clinical trial, some data are necessarily unavailable. It is, however among the largest reviews performed to our knowledge for any commercially available system for percutaneous treatment of compression fractures.

Response data was collected from over 50 patients among the first 300 procedures. This confirmed substantial pain reduction in the vast majority of patients that at least equals the relief produced by all other currently available balloon or straight needle systems.

Technical issues initially included clogging of the needle, and isolated instances of device failure largely due to violation of recommended procedure parameters by individual physicians. Redesign of the tip effectively eliminated clogging, and only 4 cases out of 428 since the new release experienced device failure.

No adverse clinical sequelae resulted from any of these events. Cement extravasation was documented in 5.7% of the 1043 US levels for which data are available.

No new or severe complications unique to the Osseoflex system were recorded. The reported experience from 206 physicians, 39 states and three European countries demonstrates the Osseon system to be effective, safe, and more efficient than any commercially available system in the world.

## BACKGROUND

More than 700,000 osteoporotic compression fractures are seen in the US annually<sup>36</sup>, with similar numbers seen in Europe. Tens of thousands more sustain painful compression fractures associated with metastatic malignancies. Clear decrements in function and predicted survival can result from this process<sup>21</sup>, particularly in populations with co-morbidities. The personal and societal cost of this is enormous, in terms of physical pain, lost work for patients or caregivers, medications and direct medical care.

Percutaneous vertebral augmentation for the improvement of function and symptoms was first described in a solitary case in France in 1987<sup>1</sup>. The procedure was gradually adopted and utilized by orthopedic surgeons, neurosurgeons, and ultimately by interventional radiologists who now perform the majority of vertebroplasties in the United States<sup>28</sup>. In the 1990's a variant of this procedure was introduced using a balloon, inflated within the vertebral body to develop a cavity, filled thereafter with cement (i.e., balloon kyphoplasty). This system was proprietary and, until quite recently cavity-creating systems were limited largely to the Kyphon™ devices. Other groups have subsequently developed and marketed systems that produce an intravertebral cavity by alternative means, while some recently have developed balloon-based systems of their own.

Vertebroplasty, also known as percutaneous

Every attempt has been made to ensure the accuracy of the statistics and statements in this monograph. Any errors or misstatements are the sole responsibility of the first author (ML), and neither the subsidiary authors nor Osseon Therapeutics.

vertebral augmentation or PVA, involves introduction of cement without establishing a defined location within the vertebra where cement will go beyond locating the tip of the introducer needle. Kyphoplasty, also known as vertebral augmentation with cavity creation or PVACC in contrast involves formation of a cavity by mechanical means, prior to introduction of cement. Authorities have argued strongly for and against fundamental differences in efficacy or safety between the two basic approaches. Clear differences exist, although few dispute the clinical benefit from both approaches. Two articles<sup>18,19</sup> published last year in NEJM suggested no difference in outcome between vertebroplasty and a placebo, or sham procedure. Multiple professional societies and clinicians in contrast have strenuously questioned the methodology and structure of the studies which, in their opinions (and in the opinion of the authors of this review) render the conclusions suspect, if not entirely invalid.

## PURPOSE

While all commercially available vertebral augmentation systems (both PVA and PVACC) are at least partially effective, they vary in the ease of access, cement delivery control, and procedural time as well as the range and frequency of complications. Most of these variables are intrinsic to the design of each discrete system. The goal of the founders and engineers of Osseon was to build upon the established efficacy of vertebral augmentation, while enabling more precise delivery of cement and thereby improving fracture stabilization. This goal was to be achieved via the following:

1. Subjective pain relief at least equivalent to the best commercially available systems in the United States or Europe.
2. Decreased complication rates. The complications most commonly described include cement extravasation; subsequent adjacent vertebral fractures thought to be associated with some types of vertebral augmentation; device failure; cement-related issues, including problems with preparation, delivery or manipulation, and; lastly, failure of the procedure itself after initiation.

3. Shortened procedure time, defined as the time in minutes from initial skin incision to the time of device and cannula removal.
4. Prevention of new or rare but catastrophic complications with the introduction of new technology.
5. Better cost effectiveness: both primary, via competitive pricing through efficient design and production, as well as secondary cost effectiveness by minimizing the need for redundant or incidental equipment.
6. Commercial release and distribution of a true PVACC system that does not rely upon a balloon, or otherwise inflatable device.

It should be specifically noted that height restoration was never a goal, and to our knowledge never a finding either in preclinical development nor in our experience in over 1000 reported clinical cases. It is uncommonly attained to any significant or long lasting degree. It is the opinion of the clinical and engineering staff at Osseon, and largely the opinion of the physicians using the system that radiographic height restoration carries little or no relevant mechanical nor clinical benefit. Assertions of height restoration<sup>22</sup> seem to rely upon fluoroscopic measurements before and after cement introduction with balloon kyphoplasty systems, rather than under standard weight bearing conditions. There is also no established correlation to our knowledge between purported height restoration and improved analgesia or function. Further, at least one study suggests that the goal of anterior vertebral height restoration produces load transfer onto the adjacent levels, themselves already osteoporotic by definition, thereby facilitating the increased rate of adjacent vertebral fractures reported in several published series<sup>9, 11,14,37</sup>, ranging as high as 25%<sup>14</sup>.

The system was designed by a team of engineers and clinicians, and design parameters were finalized through two serial cadaver studies conducted by Osseon and advisory clinicians prior to live clinical application. Refinements of the system were incorporated with the input of practicing clinicians familiar with both the Osseon system and other commercially available systems.

## MATERIALS AND METHODS

The Osseoflex® Steerable Vertebral Augmentation Needle is a device which, by steering and channeling through the bone creates a void within the vertebral body. Following this, polymeric bone cement is injected through the steerable needle to fill the previously created void. The device package contains: (1) Osseoflex steerable needle, (1) straight/biopsy needle, (1) bevel tip stylet, (1) 4-point diamond tip stylet, and (2) cannulas.

Since inception, the Osseoflex has been updated with continuous design improvements and innovations:

- Tubing and cement gun threads were optimized to improve strength
- Chevrons were condensed from 26 to 19 to improve columnar strength
- The outer diameter of the needle was increased to further improve columnar strength
- The thickness of the inner liner was increased to prevent potential cement leakage through the chevrons
- Depth markers were added to the needle shaft to facilitate guidance by clinicians
- The needle tip was redesigned to reduce any risk of clogging. The cement port was relocated away from the main axis to void cancellous particulate coring. Additionally, interior contours were optimized to provide smooth flow
- The articulation knob was redesigned to incorporate a positive stop, to reduce the potential for over-articulation by users
- Additional proprietary modifications further improved overall device strength.

Since the Osseoflex/Osseoperm system can be used for either vertebroplasty (PVA) or vertebral augmentation with cavity creation (PVACC), the decision to perform one or the other variant of vertebral augmentation is left to the discretion of the treating physician. Many of the first 100 cases were described as PVAs. With increasing experience and a more thorough understanding of the ability to create directed channels within the vertebral body, subsequent cases were performed as PVACCs, where

a branching series of cavities and channels within the vertebral body were created prior to cement introduction.

All patients in this retrospective series were selected by the treating physicians. All had radiographically confirmed compression fractures along with substantial pain that in the opinion of the managing clinician required intervention and should respond to PVA or PVACC. Participating physicians included interventional radiologists, orthopedic surgeons, neurosurgeons and anesthesiology/pain specialists.

Information regarding the demographics, the procedure itself and observations were provided by the treating physician or physician staff, and was forwarded by the local Osseon representative no later than 48 hours after each procedure.

Information from the European cases was forwarded on a weekly/semiweekly basis. Specific pre-treatment and post-treatment pain scores were obtained for the 31 Limited Market Release (LMR) patients; thereafter, a series of 25 patients embedded in the subsequent 250 cases was also queried to garner additional information regarding analgesic efficacy.

Any adverse events or perspectives from the treating physicians were forwarded, and clinical review by the chief medical officer and/or medical advisory board participants was obtained along with discussion with the treating physician as deemed appropriate.

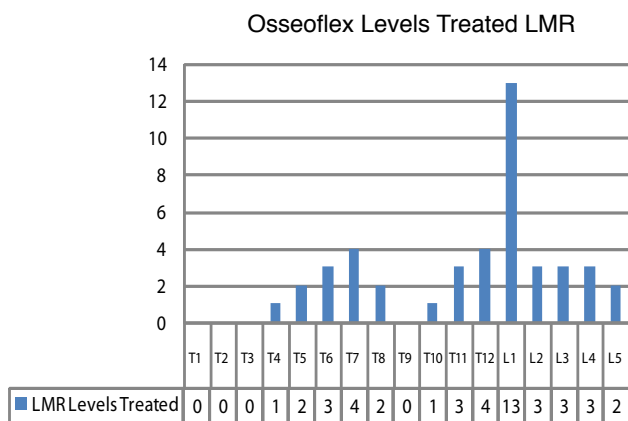
## RESULTS

Clinical observations are subdivided into three groups. The first is a brief discussion of the first 31 (LMR) patients treated at a total of 44 levels between November 3, 2008 and January 21, 2009. The second and third will be the subsequent 950 cases performed in the United States between January 21, 2009 and November 2, 2010, parallel with the 131 cases performed between February 16th 2010 and September 28<sup>th</sup>, 2010 in Italy, the United Kingdom and Spain. European release was delayed until sufficient clinical experience was accumulated in the United States, along with CE Mark approval for the Osseoflex system in September 2009. Differing

data collection between US and EU cases render conclusions less refined in the European clinical experience. It can be stated that European clinicians describe pain relief similar or identical to that reported in the US, treating a similar distribution of patients.

In the 31 patient LMR, 19 women and 12 men were treated. Ages ranged from 41 to 103. The median age was 77; 24 lumbar and 20 thoracic levels were treated, as depicted in Table 1. The median pain level on a 10 point scale pretreatment was 8.0; this fell to a median of 1.0 post-procedure. Only one patient failed to experience improvement in pain scores. Problems experienced during the initial 31 cases included shearing of one device in the vertebral body, caused by the clinician twisting the needle when curved within the vertebral body. Upon jamming the device, an attempt was made to dislodge it forcefully rather than removing it with the introducer as a unit, leading to separation at the introducer tip. The remaining fragment was embedded in cement and caused neither acute nor late sequelae. This was the 15th case ever performed, and subsequent physician education focused heavily upon refining the procedural steps, which were in evolution at that time. No symptomatic complications were reported by patients or clinicians.

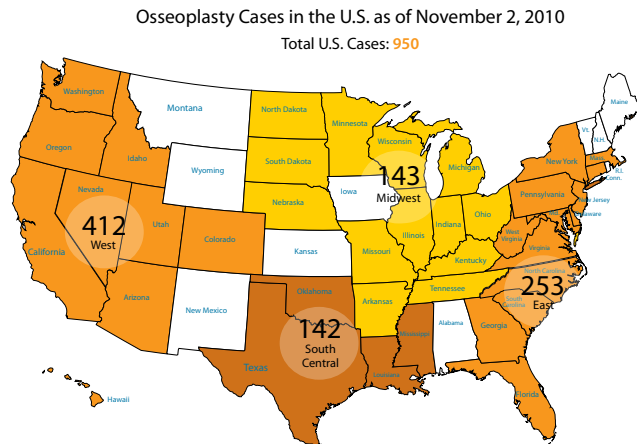
Table 1



## POST LIMITED RELEASE EXPERIENCE

As of September 2010, Osseoplasty procedures have been performed in 39 states including Hawaii. A regional breakdown is depicted in Figure 1 below.

Figure 1



The distribution of treated levels has been consistent from the first 44 levels, through interim analyses performed after 331 and 501 cases, and is also similar to the distribution seen to date in cases from Europe (Figure 2). A strong female predominance in treated patients has been evident since inception, and accurately reflects clinical experience in osteoporotic fractures in Europe and the US. The vast majority of symptomatic osteoporotic fractures occur in women over 65, whose statistical risk for this exceeds the general population by 100 fold. While median ages are similar, a larger proportion of male patients are younger than 60, and many of these are traumatic rather than malignant or osteoporotic fractures associated with employment in building trades or recreational trauma.

## EUROPE

From February 16<sup>th</sup> through October, 2010, 131 patients were treated in Europe, representing 12.1% of all Osseoplasty cases to date. Demographics were available for most but not all patients. At least 69 females (56.3%) and 46 males (38.4%) were treated, a relatively even distribution. In the United States, the early proportion was nearly 2:1, and moved toward a greater female proportion over time.

Figure 2

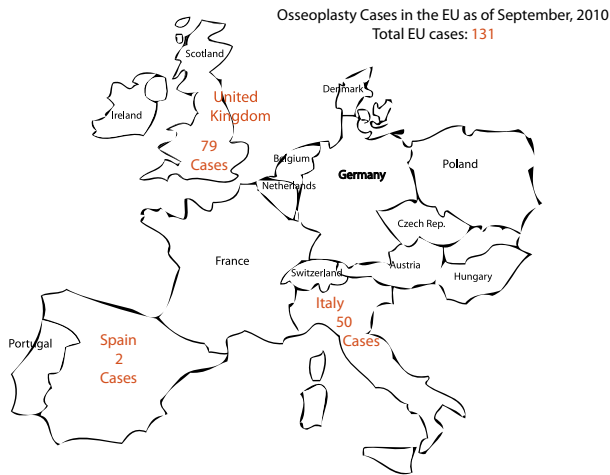
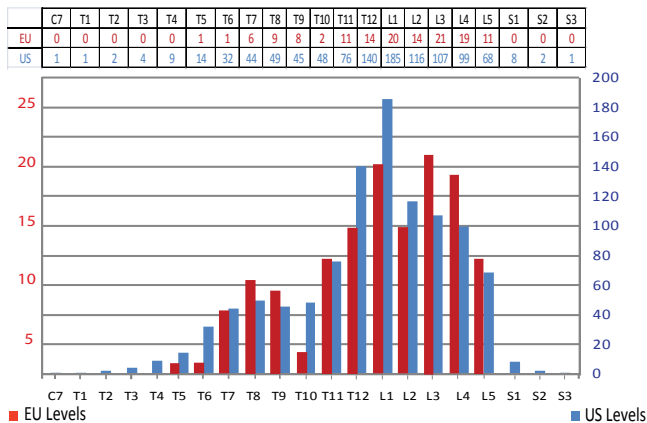


Table 2

EU and US Levels Treated



**EXTRAVASATION: EU versus US experience**

Until approximately the 400<sup>th</sup> case performed, reports of extravasation were sporadic, as clinicians and Osseon representatives tended to assess minor extravasation as insignificant and thus unreported. At that time, we directed all users and reporting individuals to make note of any degree of extravasation whatsoever. Analysis of these cases reveals a correlation between thoracic versus lumbar level risk, and furthermore a correlation between extravasation frequency and cement volumes >4.5 cc in thoracic levels above T12. We recorded 8 extravasations in the lumbar, and 9 in the thoracic spine from case 442 through case 950.

Extravasation rates in cases reported from EU are

difficult to assess with precision. In the US, specific attention was directed to collecting this information by case, level and cement volume after case 442. As such, very accurate figures are available in the US. Less information is available from the EU, as only a minority of users specifically note the presence or absence of extravasation. We can only state that extravasation has occurred in 5 thoracic and 3 lumbar cases in Europe and the United Kingdom, depending upon reported cases to date. This broadly flanks the established rate in the US. Given the similarity of both patient populations, we have no reason to expect that extravasation rates will differ significantly, with increasing experience. We note that extravasation rates, which exceeded 10% as recently as March, 2010 fell precipitously to less than 5% soon thereafter due to a variety of factors, including recognition that extravasation rates in the thoracic spine above T12 rise significantly when more than 4.5 cc of cement is used at a single level. Each 100 cases from that time to date are associated with consistent rates of 4.3 to 4.9%, and we anticipate that the overall reported rate of 5.7% will steadily decline with larger case volume. Regardless of decreasing or stable rates, this is, to our knowledge the lowest rate reported for any percutaneous vertebral augmentation system commercially available.

It bears noting that extravasation rates for typical vertebroplasty range from 15 – 30%, while rates reported for balloon kyphoplasty range from 9 – 12%. Our experience in this area serves to highlight the intrinsic difference of the steerable vertebral augmentation procedure from typical straight PVA, and in the opinion of the authors’ one of the advantages over balloon PVACC.

**OSSEOPLASTY IN MALIGNANT COMPRESSION FRACTURES**

Treatment of symptomatic compression fractures associated with malignancy is a highly heterogeneous area, due to the wide variation of anatomical defects and coexistence of sometimes bulky malignant tissue.

Of the more than 1000 patients reported, no less than 11 were treated for malignant fractures. Subtypes included myeloma (7), breast cancer (1), along with

individual cases of prostate cancer and unknown primary tumors (3). To date, Osseoplasty has been performed on 6 patients known to have myeloma and 4 with forms of cancer of an unspecified type.

The risk of extravasation is higher in these patients due to abnormal anatomy associated with tumor infiltration. Of the 11 known cases treated for malignancy, only 2 reported extravasation.

## SACROPLASTY

To date, 12 sacroplasty procedures have been performed for stabilization and clinical relief of painful sacral fractures or insufficiency. Fewer studies have been published in this area<sup>29, 30, 32-34</sup>, and few studies have examined the use of balloon devices in this area due to the complex anatomy<sup>35</sup>.

None of these cases were associated with procedural complications, and all cases were described by the clinician as technically successful and associated with meaningful pain relief. Long-term follow-up information is not yet available. We anticipate a controlled, non-randomized trial by experienced clinicians to be initiated no later than 2011 to definitively evaluate this application.

## CLOGGING

The initial Osseoflex device incorporated a distal port for cement introduction that was offset from the actual tip, in order to avoid cancellous bone coring and consequent luminal obstruction. In most patients, particularly those with highly osteoporotic bone, this design was effective in achieving tissue penetration and cavity creation, followed by cement delivery without incident.

The ability to turn the Osseoflex while deployed in the vertebral body also, allowed the potential for bone fragments or marrow to enter the lumen. On a few occasions, these bone shards could not be extricated from the device, and another Osseoflex needle or straight introducer was substituted. The procedural technique initially taught to clinicians incorporated flushing of the needle after cavity creation, reducing the frequency of clogging events. Patients with relatively dense bone, among others, remained a recurring challenge.

Among the first 500 cases, we recorded a total of

23 clogging events. Of these, 6 were corrected with flushing of the needle and re-introduction. In a few (<10) cases, use of the steerable device could not be achieved for cement delivery, but rather for cavity creation only. In fewer than 5 cases, the procedure itself could not be successfully completed by these means.

The distal lumen design was re-engineered, and from February 2, 2010 (case 522) onward, the modified tip reduced the incidence of clogging substantially to 2 of 428 cases overall. Of all cases recorded, only 9 cases required substitution of a second Osseoflex or a straight needle for completion of cement delivery, or 1.7% of all 535 levels since February 2, 2010. Ongoing design modification is likely to reduce this to a rate below 1%.

## TRAUMATIC NEEDLE SHEARING/FAILURE

The Osseoflex needle is steered using two integral design mechanisms: a laser-welded internal pull wire, and a series of accurate laser-cut chevrons distally, allowing for a clinician directed arc of up to 100 degrees from the main device axis. Accurate positioning is maintained by the introducer, which maintains the transpedicular channel.

If the Osseoflex, while deployed in a curved position, is twisted radially, shear is produced at or distal to the tip of the introducer. This in turn can produce either binding at the introducer tip, or if even greater (and inappropriate) force is exerted, structural failure at the point of greatest shear within the chevrons.

Clinicians are all instructed specifically not to exert undue retraction force, to never radially twist the Osseoflex when in curved deployment, nor to attempt to remove the Osseoflex without also removing the introducer if binding is encountered. Despite this, five devices during five separate procedures sustained traumatic failure in association with one or more of the above procedural events. In 3 cases, the distal most tip of the Osseoflex remained embedded within the vertebral body, encased by PMMA cement.

As the device is sterile and entirely encompassed within bone and cement, the risk of infection or other foreign body complications is statistically equivalent to wire sternal sutures or other stainless implants

of similar mass. It is nevertheless an outcome to be avoided, and the five traumatic shearing examples are used extensively in clinical training discussions to illustrate the potential device and procedure failures associated with use of unapproved technique.

## DISCUSSION

The Osseoflex system in its current iteration meets or exceeds the goals initially set for the device in 2007, when development began in earnest. Patient and physician satisfaction have been generally high. No complications unique to the device have been encountered beyond jamming with incorrect technique. Unipedicular access in effectively all cases both reduces procedural time, and reduces the potential risk of bleeding or infection compared to bipedicular approaches. Access in complex, high level or previously instrumented vertebral bodies has been judged superior to straight needle or inflatable systems. Balloon systems cannot reach the uppermost levels of the thoracic spine and extreme vertebral collapse exceeding 62% has been cited as a contraindication to vertebral augmentation<sup>36</sup> with balloon kyphoplasty. Osseoplasty has been employed in levels through C7 and vertebral heights as small as 2.5 cm have been accessed with excellent cement delivery and infrequent extravasation. Procedural complications common to all percutaneous vertebral augmentation systems are at or below observed frequencies for Osseoplasty, including exceptionally low extravasation rates. Time for single level procedures matches that seen for the simplest vertebroplasty systems, with substantially better control of cement delivery. While acquisition and stocking costs vary by region and purchasing organization, the Osseoflex System is arguably the most cost effective PVACC system currently available when all cost and reimbursement factors are combined.

Subsequent developments will include methods and devices such as the Osseoflex DR (a steerable drill) used to expand utility and access in more difficult vertebral compressions, including those with existing instrumentation or with unusually dense or fibrotic bone.

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## NOTES: