

## Review Article

# Radiofrequency kyphoplasty for the treatment of osteoporotic vertebral fractures: A review of the literature

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## Abstract

Vertebral fractures are a leading cause of disability among the elderly people. While conservative treatment remains the mainstay of treatment, other techniques such as kyphoplasty are reserved for cases of lasting pain. However, cement extravasation has traditionally been a relatively common complication of all vertebra augmentation procedures. Radiofrequency kyphoplasty (RF-VTA) is a relatively new method, which relies on the targeted creation of minimally destructive paths, thus preserving the microarchitecture of the trabeculae. In addition, it yields comparable or superior outcomes than compatible techniques. The aim of this project is to review all the studies concerning this novel technique and provide the reader with its results and potential adverse effects.

**Keywords:** RF Kyphoplasty, Radiofrequency kyphoplasty, Osteoporotic vertebral fractures, Balloon kyphoplasty

## Introduction

Osteoporotic vertebral fractures are a leading cause of disability among the elderly population. Their incidence in Europe has been estimated to be approximately 500,000 fractures per year rendering treatment options of particular importance<sup>1-4</sup>. While conservative management remains the mainstay of treatment, minimally invasive techniques such as kyphoplasty (KF) and vertebroplasty (VP) offer valuable alternatives, especially in cases of lasting pain. Both of them have well established clinical outcomes in terms of pain relief and functionality improvement. However, concerns regarding the destruction of bone microarchitecture and cement extravasation has led to the introduction of Radiofrequency kyphoplasty, as an alternative<sup>3,5,6</sup>. It is a relatively new technique, called also radiofrequency- targeted vertebral augmentation (RF-TVA), which appears to provide comparable outcomes, while it reduces potential adverse effects. It was approved in 2007 in the USA and in 2009 in Germany for the treatment of painful vertebral fractures. RF kyphoplasty is primarily indicated for osteoporotic compression fractures, while it can be reserved in cases of an underlying bone pathology, such as multiple myeloma<sup>7</sup>. Through a unipedicular approach, a navigational osteotome is used to create specific paths inside the cancellous bone preserving to a great extent the microarchitecture of the

trabeculae. RF are used to warm the cement and transform it into an ultra-high viscosity mass, thus reducing evidently the risk of cement leakage. This article aims to provide a short review of all available published data evaluating the effectiveness and the benefits of this technique.

## Methodology

For collecting all the appropriate data for this review, a thorough search and analysis of the literature was conducted. Using radiofrequency or RF kyphoplasty as keywords in Pubmed and Google Scholar databases, all relevant articles were retrieved. Only those articles written in English were included. Out of fourteen, thirteen articles were considered to be eligible for reviewing. One article was excluded because

*The authors have no conflict of interest.*

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**Edited by:** Konstantinos Stathopoulos

**Accepted** 4 May 2018

it referred to radiofrequency ablation of metastatic lesions, which is out of the scope of our review article. Finally, twelve articles were included: ten articles referring to *in vivo* studies and two to *ex-vivo* ones.

## Results

### *Ex-vivo studies*

Krüger et al conducted a cadaveric study to assess cement interdigitation and bone-cement interface after vertebral fracture augmentation<sup>8</sup>. This study was the first to evaluate cement interdigitation on a histological basis. A fresh frozen spine was used to assess these parameters by applying four different methods of augmentation: vertebral stenting, the traditional method of balloon kyphoplasty (BK), shield kyphoplasty and radiofrequency kyphoplasty (RF-VTA). Wedge fractures were created utilizing a material testing device in 13 prepared vertebrae and divided into four groups. Each group was randomized to one of the four augmentation techniques. The scores for the distance between the cement and the bone were higher for balloon kyphoplasty, compared to vertebral stenting, and much higher than these after shield kyphoplasty and radiofrequency kyphoplasty. The differences observed among the several techniques were statistically significant. Consequently, it was observed that the methods, which did not create a void, (RF and shield kyphoplasty) demonstrated significantly better cement interdigitation. The clinical implication of this study lies in the fact, that void-assisted augmentation techniques can lead to early mechanical instability, which may be the reason for persistent pain.

In 2012, Dalton et al conducted an *ex-vivo* study in order to compare the radiographic and morphologic outcomes of both RF-VTA and traditional BK<sup>9</sup>. Sixteen cadaveric osteoporotic vertebrae were used divided into two groups (RF-kyphoplasty and BK respectively). They were evaluated for cavity restoration, vertebral height, as well as the delivery and the connection of the polymethylmethacrylate to the surrounding trabeculae. According to the results, RF-TVA group demonstrated a better restoration of the vertebral height than BK, though this difference was not statistically significant. Furthermore, BK resulted in more trabecular destruction and less created cavities than RF-TVA. Conclusively, this study reveals the potential clinical utility of RF-TVA as a better method than BK, since it provides a higher restoration of the height and a lower level of trabecular destruction. These results are consistent with those of previous studies<sup>10</sup> as for the vertebral height, while the smaller destruction of trabeculae is also being addressed.

### *In vivo studies*

In 2011, Robertson presented a new system of percutaneous vertebral augmentation, the StabiliT Vertebral Augmentation System<sup>11</sup>. This system was based on radiofrequencies and offered bone cement of high

viscosity, which derives from suitable processing before Radiofrequency warming. This offered the possibility of receiving from the osteotome a very high quantity of ultra-high viscosity cement as opposed to other techniques, such as balloon kyphoplasty and vertebroplasty. The authors suggested the use of a combination of radiofrequencies and kyphoplasty through the new system StabiliT, in order to lead to higher effectiveness<sup>11</sup>. Nonetheless, this system should be further evaluated before being incorporated in the clinical process.

Rollinghoff et al (2012) performed a study in order to assess RF kyphoplasty concerning the restoration of the vertebral height and whether this restoration can lead to a reduction in the patient's pain<sup>10</sup>. The study included 25 patients suffering from painful osteoporotic vertebral fractures, who had already received prior conservative treatment. According to the results of this study, there was a significant reduction in pain at 3 months follow-up with a tendency for further improvement. The height of the vertebral bodies and the kyphosis angle were also significantly corrected. However, a slight deterioration in the radiological parameters was noted after 3 months without any statistical significance. Asymptomatic leakage was the only complication which was observed only in 2 patients. Overall, it was concluded that RF-VTA leads to faster and continuous improvement of the clinical symptoms and restoration of the vertebral height. Furthermore, slight loss of vertebral height did not strongly correlate with patients' clinical improvement. However, limitations of this study included the relatively small sample size and the fact that the cement distribution had not been addressed by performing a CT-scan.

One year later, Rollinghoff et al (2013) tried to investigate whether a smaller amount of cement can be equally effective applying again radiofrequency kyphoplasty<sup>1</sup>. He conducted a study of 35 patients, and the system used was StabiliT. The main parameters measured were vertebral body height and pain. According to this study's findings, all the patients that went through the conservative treatment, continued to suffer pain, whereas after radiofrequency kyphoplasty, the pain and the kyphosis angle were reduced and the height of the vertebral body was significantly restored. An asymptomatic cement leakage occurred in two cases (4,1%). Additionally, a 5,7% of the sample presented new fractures after their treatment, which were treated successfully again using RF kyphoplasty. Pain relief and vertebral height restoration did not show again any correlation.

Similarly, Georgy (2013) made a retrospective study to compare balloon kyphoplasty and RF-TVA for the restoration of the vertebral compression fractures<sup>12</sup>. The whole sample consisted of 80 patients, from which 45 received RF-TVA and 35 received balloon kyphoplasty. The evaluation of the existence and the location of cement leakage was realized with the use of postoperative radiographs. According to the findings, 12% of the patients treated with BK presented

cement leakages, while the respective percent of the RF-TVA group was only 5%. In conclusion, the RF-TVA method could lead to about 50% reduction in the cement leakage rate comparatively to BK, fact that can be attributed to the low rate of cement delivery and the controlled rate of delivery of radiofrequency. This study is very important since it confirms the results of previous studies<sup>1,7,9</sup> in a bigger sample of alive people, and, therefore, suggests that RF kyphoplasty is a promising method with low percentage of cement leakage.

Georgy et al, tried to compare the effectiveness of RF kyphoplasty and BK in his study in 2013 in terms of cement extravasation, which is known to be a relatively common complication, when performing augmentation procedures<sup>12</sup>. 49 levels were treated using conventional BK, whereas in 57 cases the RF technique was utilized. The vast majority of the cases were benign fractures with only 10 patients, where a malignant etiology was identified. Cement leakage occurred in 50% fewer cases in the RF kyphoplasty compared to BK, with the corresponding rates being approximately 6% and 12% respectively. The authors attributed this fact to both cement properties injection technique.

Three years later, Petersen et al (2016) conducted a study on 80 patients with osteoporotic vertebral fractures in order to compare the methods BK and RF-TVA<sup>11</sup>. The comparisons between the two groups were performed both perioperatively and postoperatively, and after 1 year. This study found a higher improvement in the angle of kyphosis for the RF-TVA group, while the improvement of pain was significant in both groups and no difference was observed. After 1 year, the most patients had no pain. The overall improvement was higher for the patients that received RF-TVA therapy. The authors concluded that RF kyphoplasty had an obvious superiority, when referring at pain at rest. Additionally, the duration of the RF- kyphoplasty was shorter and the amount of cement was significantly lower in this technique.. No extravasation of cement occurred in any case. This study, just like the one conducted by Georgy (2013), was based on a bigger sample than previous ones and offered new data for the reduction in pain and the kyphosis angle, parameters that had been studied until then only in smaller samples<sup>1,10,12</sup>.

Ali et al (2016) assessed the safety and the effectiveness of RF-TVA for the treatment of myeloma-associated vertebral fractures<sup>13</sup>. The sample of this study included 87 patients suffering from myeloma and painful vertebral fractures, who received a RF-TVA therapy. The impairment was assessed with ODI (Oswestry - Disability - Index), kyphosis angle, vertebral height and fractures were assessed by x-rays, and pain was assessed by VAS (Visual Analogue Scale). According to the results, pain, vertebral height, kyphosis angle and impairment were significantly reduced after surgery. However, a deterioration of these parameters was noted in the late follow-up period. This could be attributed to the impaired bone structure of myelotic vertebra. As far as the negative effects are concerned, 18% of the patients

presented cement leakage, while 10% presented new fractures during the 24 months of follow up. Conclusively, both pain and quality of life were improved irrespective of the midterm deterioration of the radiological parameters. This study focused on the vertebral fractures caused after a myeloma, while it studied four basic parameters (pain, height, kyphosis angle and impairment) in a quite big sample. Though, it is noted that these results, in contrast to previous studies, indicated a relatively higher number of side effects<sup>1,10,12</sup>.

Bornemann et al (2016a) made a retrospective study in order to assess the result of posterior fixation of vertebral fractures combined with BK or RF-TVA<sup>14</sup>. The sample consisted of 44 patients, suffering from osteoporotic vertebral fractures. The augmentation of the vertebral body was achieved by either RF-TVA or BK, while a posterior fixation was performed to all patients. The sample was evaluated for vertebral height, kyphosis angle, pain and impairment. Both techniques demonstrated comparable radiological outcomes: The kyphosis angle was significantly corrected in both groups with no statistically important difference at 12 months, while the vertebral height was significantly better in the BK group both at 3 and 12 months follow-up. However, as far as pain and impairment are concerned, the results were significantly superior in the RF-TVA group. Nevertheless, the percentage of the cement leakage was a relatively higher in the RF-TVA group than the BK one. In any case, the total cement extrusion was within the reported ranges. According to these findings, the authors suggested the RF-TVA is as a more preferable therapeutic choice than BK, since it presents generally better improvement in terms of pain and comparable radiological outcomes with only an insignificantly higher percentage of cement leakage.

During the same year, Bornemann et al (2016b) published another retrospective study with the aim to assess the safety and the effectiveness of the vertebral augmentation through RF-TVA and BK for the treatment of painful vertebral compression fractures<sup>15</sup>. The sample consisted of 192 patients with vertebral fractures, a sample that is the biggest one until today used for the evaluation of Rf kyphoplasty, while the parameters assessed were the vertebral height, the impairment, the pain and the kyphosis angle. The results indicated that the two therapies both improved impairment and pain, while both of them led to a reduction of the kyphotic angle and an increase in the vertebral height. However, these two techniques both led to cement leakage in some cases, with the highest rate corresponding to the balloon kyphoplasty. Thus, RF method seems to be safer due to the smaller percentage of cement leakage and its shorter in duration and easier application<sup>15</sup>.

Last but not least, it is noted that a special group of interest is the elderly patients who suffer from painful osteoporotic vertebral compression fractures and had no progress after the conservative therapy, or even the patients

that present aggressive primary tumours or osteolytic metastases to the spine. When there are contraindications for surgery, minimally invasive methods are preferred. Mattyasovszky et al (2014) tried to assess the effectiveness of RF kyphoplasty on 44 older patients suffering from painful osteoporotic vertebral fractures<sup>16</sup>. The results showed no significant reduction in pain for the 12 months after the therapy, but their impairment was significantly improved. As far as the side effects are concerned, asymptomatic cement leakage was observed in the 27,4% of the patients studied, while one patient presented new vertebral fractures after the treatment. These findings are contracting to those of Dalton et al (2012), who recommended RF kyphoplasty for the confrontation of osteoporotic fractures in older people. Consequently, more studies are required especially on the elderly people in order to find the best, non-invasive therapeutic approach for vertebral fractures.

## Discussion

RF kyphoplasty seems to provide similar or superior results compared to BK in terms of pain relief and patient's satisfaction. Radiological parameters, such as kyphosis angle and vertebral height are effectively restored in both techniques, but the superiority of RF kyphoplasty is not so obvious as it is in patient's factors. A slight deterioration of radiological parameters has been reported by many authors without having any significant impact on patient's satisfaction. Thus, there is no strong correlation between vertebral height loss and pain. The most consistent finding of the majority of studies is the lower rate of cement extravasation. Except for one study (Bornemann 2016), all the other studies have shown significant lower percentage of cement leakage in the RF technique. The smaller targeted channels, as opposed to the large cavities, which are created in the BK, seem to be a reason for this fact. Higher cement viscosity can also account for the lower rates of cement leakage in the RF groups. In conclusion, RF kyphoplasty is a promising technique with at least comparable outcomes and lower complication rates than the BK. However, further research is required in order to establish these findings. Future studies should focus more on long term outcomes of these procedures.

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