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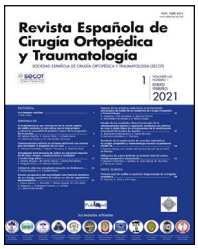

ORIGINAL PAPER

Silicone kyphoplasty (elastoplasty) versus traditional cement kyphoplasty for osteoporotic vertebral fractures. Does this new technique reduce the complications?

R. Luque*, D. Garríguez, P. Checa Betegon, M. Sanchez, J.L. Perez Gonzalez, I. Dominguez Esteban

Servicio Cirugía Ortopédica y Traumatología, Hospital Clínico San Carlos, Madrid, Spain

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KEYWORDS
Osteoporosis;
Vertebral fracture;
Kyphoplasty;
PMMA;
VK100;
Oswestry

Abstract
Introduction: Stiffness is increased in vertebrae after kyphoplasty with bone cement is performed, which cause an increase in subsequent fractures in adjacent levels. This has led to increased interest in alternative filling materials such as bioactive calcium phosphate ceramics or silicon-based polymers. This study's objective is to compare the results between kyphoplasty with bone cement and with the VK100 silicone.
Materials and methods: This is a comparative, prospective study involving 64 patients 64 patients, 23 treated using VK100 and 41 with PMMA. Clinical, radiological and functional results (Oswestry) and quality of life and (EQ-5D) were analyzed and compared between both groups, focusing on differences in subsequent fractures in adjacent levels.
Results: There are no differences between the two treatments in terms of epidemiological factors (age and sex) or hospital management. A significant difference is observed in the gain of vertebral body height, with greater improvement in those treated with PMMA. There is also a higher fracture rate in the PMMA group, the difference is not significant. Finally, both treatments show similar outcomes in pain relief and quality of life.
Conclusion: Both VK100 elastoplasty and PMMA kyphoplasty are effective treatments for vertebral fractures. VK100 has a lower rate of complications and adjacent fractures. However, long-term results in terms of pain relief and quality of life are similar, making both treatments equally valid.

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* Corresponding author.
E-mail address: doctorluque@yahoo.es (R. Luque).

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PALABRAS CLAVE
Osteoporosis;
Fractura vertebral;
Cifoplastia;
PMMA;
VK100;
Oswestry

Cifoplastia con silicona (elastoplastia) versus cifoplastia tradicional con cemento para fracturas vertebrales osteoporóticas. ¿Esta nueva técnica reduce las complicaciones?

Resumen
Introducción: La rigidez que se genera en las vértebras tras una cifoplastia con cemento óseo produce un aumento del riesgo de fracturas en vértebras adyacentes. Por esta razón, se han propuesto materiales de relleno alternativos con mayor elasticidad como cerámicas o siliconas bioactivas. El objetivo de este trabajo es comparar los resultados entre cifoplastias realizadas con cemento óseo (PMMA) y con la silicona VK100.
Material y Métodos: Se trata de un estudio comparativo y prospectivo, en el que participan 64 pacientes, 23 tratados con VK100 y 41 con PMMA. Se analizaron y se compararon los resultados clínicos, radiológicos y funcionales (Oswestry) y la calidad de vida (EQ-5D), y complicaciones tales como fracturas en vértebras adyacentes.
Resultados: No existen diferencias en los resultados clínicos ni radiológicos entre ambos tratamientos. Destaca una diferencia significativa en el aumento de altura del cuerpo medio vertebral,siendo mayor en los tratados con PMMA. También destaca una mayor tasa de fracturas en los tratados con PMMA aunque la diferencia no es significativa. Por último, ambos tratamientos tienen resultados similares en lo que respecta al alivio del dolor y la calidad de vida.
Conclusión: Tanto la elastoplastia VK100 como la cifoplastia PMMA son tratamientos eficaces para la fractura vertebral. El VK100 tiene una menor tasa de complicaciones y fracturas adyacentes. A pesar de ello los resultados a largo plazo en términos de eficacia dolor y calidad de vida son similares por lo que ambos tratamientos son igual de válidos.

Introduction

The prevalence of osteoporosis in Spain in 2022 was such that a total of 2,945,000 people were affected (79% women) causing 289,000 fragility fractures per year, the equivalent of 33 fractures per day.[1] They were typically low-energy fractures in people over 50 years of age, excluding other conditions that cause bone fragility.[2] Radiologically, a vertebral fracture is defined when there is more than 20% decrease in vertebral height or at least 4 mm compared to a previous X-ray, generally between T4 and L5.[3,4] ''Osteoporotic'' fractures can present as back pain, limited mobility, loss of height, functional disability and loss of quality of life.[5,6]

Minimally invasive procedures for the treatment of vertebral fractures were initiated in 1986 by Gallibert and Daremond,[7] through the development of vertebroplasty (VP). Garfin and Reyley subsequently designed kyphoplasty (KP) as an evolution of the cementation technique[7] for the treatment of subacute fractures to stabilise and relieve pain,[8,9] with a low complication rate.[10,11] Kyphoplasty is a minimally invasive technique used in vertebral compression fractures (anterior wall compression of no more than 60% compared to the nearest normal vertebral body), either to try to stabilise the vertebral body and prevent its progressive collapse or to reduce pain in those patients who continue to have pain after conservative treatment. The procedure consists of the percutaneous introduction through the vertebral pedicles of an inflatable balloon that allows the lost height of the upper plate to be restored. The cavity left by this balloon when removed must be filled with some material that is initially viscous so that it can be introduced through the working cannulas and that subsequently becomes solid to act as a foundation for the upper plate.

As with any surgical technique, PMMA kyphoplasty is not free from complications, such as vascular cement leaks, which is why other different materials have been developed, such as hydroxyapatite resins, calcium phosphate cement, calcium sulphate cement or even polyetherketone (PEEK). Another of these filling materials is VK100®, an elastomer from the polysiloxane or silicone family designed by the company Bonwrx (Phoenix, AZ, USA) and whose main objective would be to reduce this increased rigidity acquired by the vertebrae after a traditional PMMA kyphoplasty. This would enable a reduction in the rate of fractures at adjacent levels after the procedure. Furthermore, this material does not produce an exothermic reaction upon polymerisation, which could prevent heat injuries to adjacent structures but could also reduce the analgesic effect of the procedure, believed to derive from the stabilisation of the vertebra, the reduction of microscopic and macroscopic movements in the fracture, and the neurolytic effect (both thermal and chemical) of the cement. In the limited literature that exists on this material, the procedure has been called ''elastoplasty.''

The main objective of this study was to compare the rate of fractures in adjacent vertebrae in two treatment groups: traditional kyphoplasty with PMMA and kyphoplasty with VK100 or elastoplasty. As secondary objectives, other parameters were compared between both groups, such as pain, results on functional scales, gain and maintenance of vertebral height and associated complications, together

with a comparison of results obtained with those found in the literature.

Material and methods

Study design

This study was carried out in a tertiary hospital (level 1) of the Spanish National Health System, after approval by the Clinical Research Ethics Committee (CEIC) of the same centre. It was a comparative and retrospective study of patients from Traumatology and Orthopedic Surgery with osteoporotic vertebral fracture treated with kyphoplasty with PMMA cement vs. elastoplasty with VK100 silicone. It was a case (VK100) and control (PMMA) study. Patients who met the inclusion criteria treated in the hospital and who agreed to participate in the study through informed consent were sequentially incorporated into the sample, performing a random assignment of treatment according to the indications of the statistics service. Variables related to musculoskeletal pathology; treatment complications; pain; medical treatment, and quality of life were analysed. The main variable of the study was the appearance of new vertebral fractures in adjacent vertebrae. The rest of the variables that analysed the clinical and radiological results and complications were secondary variables.

The study duration was 6 years from the inclusion of the first patient in July 2018 until the results were obtained in April 2024. The subjects of the study were added sequentially, with the last one being incorporated in March 2022.

For the study, 64 patients were initially included, 23 treated with VK100® and 41 with PMMA. Due to dropouts or compliance with exclusion criteria, a sample of 58 patients was finally used, 22 were treated with VK100 elastoplasty and 36 with PMMA kyphoplasty.

The following criteria were taken into account when choosing the sample:

Inclusion criteria:

- Symptomatic osteoporotic compression fracture of the spine, unresponsive to medical treatment, with a minimum evolution of 3 months treated with kyphoplasty or elastoplasty.
- Maximum of 1 level of vertebral compression fractures eligible for treatment located at the T5 to L5 level and verified by MRI, CT or bone scan.
- Reduction in the height of the affected vertebra(s) with compression of the anterior wall not greater than 60% compared to the nearest normal vertebral body.
- Pain that correlates with the fractured levels requiring regular intake of analgesics and/or causing substantial disability.
- Patient with communication capacity to understand the procedure and participate in the study.

Exclusion criteria:

- Patients under 50 years of age.
- Any burst fracture.
- Unstable fractures with neurologic deficit.
- Kyphosis >30°, translation >4 mm.
- Established or suspected malignancy of the fractured vertebra. Hemangioma of the fractured vertebra.
- Currently being treated for cancer or HIV.
- High-energy trauma or clinical diagnosis of herniated nucleus polyps or severe spinal stenosis as suggested by progressive weakness.
- Have neurologic symptoms or deficits, or radiculopathy related to the fractured vertebrae.
- Patients with BMI >40.
- Previously treated with vertebroplasty.
- Patients with concomitant diseases that may be worsened by invasive treatment of the fracture, such as severe cardiopulmonary dysfunction (including aortic aneurysm), as judged by the investigator.
- Active systemic infection or local skin infection at the puncture site.
- Pregnancy or breastfeeding.
- Patients with known chemical or drug dependence or a medical history of drug abuse.
- Participation in another research study within 30 days prior to inclusion.
- Pacemaker.
- Previous or active radiation therapy affecting the spine.

Surgical technique

The surgery was performed on a radiolucent table with the patient in the prone position. Depending on the patient's comorbidities, the number of vertebrae operated on and the expected individual tolerance to the procedure, the procedure was performed under general anaesthesia or sedation and local anaesthesia. In all cases, antibiotic prophylaxis, intraoperative radiological control with fluoroscope and a minimally invasive approach were used. The surgeons were always members of the spine unit of the orthopaedic surgery and traumatology service of the same centre.

Before starting surgery, the fracture level was located and marked using fluoroscope, together with the position of the pedicles. The trocar was introduced into the vertebra using the ''battleships'' technique (Fig. 1): each half of the vertebral body was divided into four parts. In the anteroposterior projection, five vertical lines were drawn (lateral edge of the body; lateral edge of the pedicle; middle of the pedicle; medial edge of the pedicle and spinous process). Once half of the vertebral body was divided into four areas with five lines, they were named with the letters A (lateral edge of the body-lateral edge of the pedicle), B (lateral edge of the pedicle-middle of the pedicle), C (middle of the pedicle-medial edge of the pedicle) and D (medial edge of the pedicle-spinatus).

In the same way, five vertical lines were drawn in the lateral projection: posterior edge of the joint, posterior edge of the pedicle, midpoint of the pedicle, anterior edge of the pedicle and anterior edge of the vertebral body. Four areas were marked, which we called 1 (posterior edge of the joint-posterior edge of the pedicle), 2 (posterior edge of the pedicle-middle of the pedicle), 3 (middle of the pedicle-anterior edge of the pedicle) and 4 (anterior edge of the pedicle-anterior edge of the vertebral body).

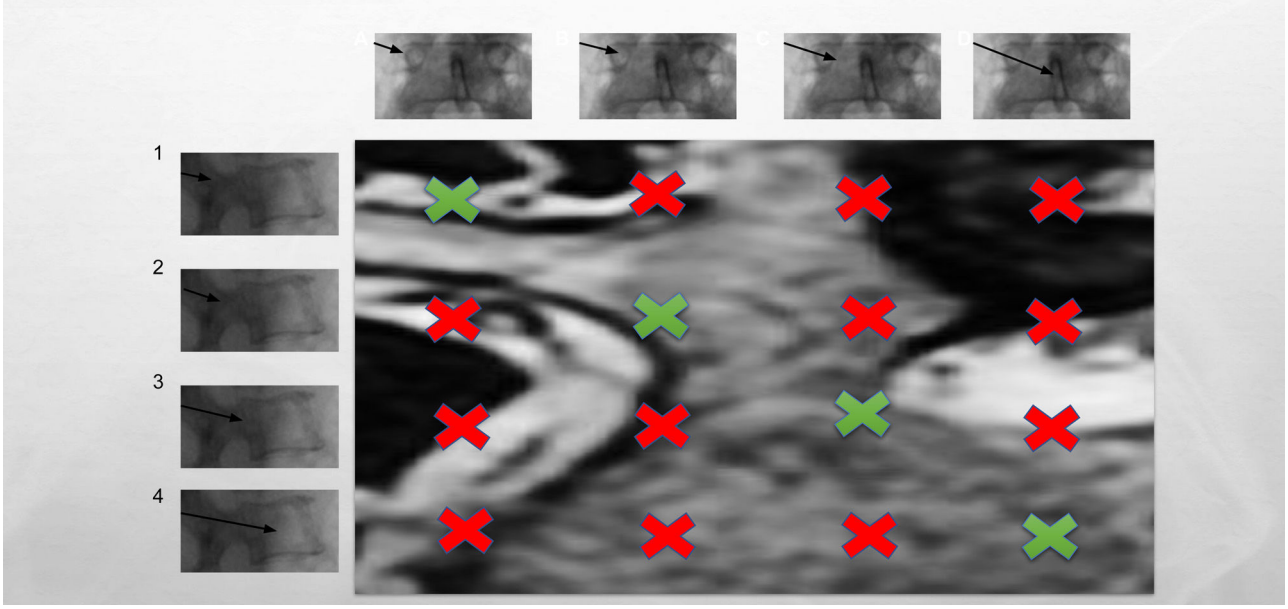

Figure 1 Visual diagram of the ''battleships'' pedicle canalisation technique.

Using this terminology, we designated the location of the trocar tip with a letter in the anteroposterior projection and a number in the lateral projection.

With ''battleships'' in mind we are able to make a 5×5 table, in which we place the anteroposterior areas in the first row and the lateral areas in the first column. To understand which positions correspond to each quadrant, we can place an image of a coronal section of the vertebra as follows: the combination of both characters will give us three possible results, pedicle: A1, B2, C3 and D4; lateral: A2, A3, A4, B3, B4, C4, and medial: B1, C1, C2, D1, D2, and D3. With this simple coordinate method, using two anteroposterior and lateral images, we can locate the tip of the trocar at any time during minimally fluoroscopically assisted pedicle canalisation.

The approach used was two 5 mm craniocaudal incisions located approximately 5–7 mm lateral to the marking of both pedicles. The instruments used for accessing the kyphoplasty were Speedtrack cannulas (Joline®) of 4.1 mm and the Allevo balloon catheter system (Joline®) with balloons of 10 or 16 mm length. In all cases, bipedicular access to the vertebral body was attempted. When this was not possible, the kyphoplasty was performed in a unipedic manner. The balloon was inflated progressively with radiopaque contrast until reaching pressures not exceeding 300 bars, and the balloon expansion and restoration of the height of the vertebral body were monitored in serial fluoroscopic images in the lateral and anteroposterior projections.

Once the appropriate working time of the filling material to be used (VK100 or PMMA depending on the group) had been reached, the balloons were progressively deflated, removed and the vertebral body was filled through the working cannulas with a volume equal to that achieved during balloon expansion. As previously, the filling was carried out with serial fluoroscopic controls in the lateral and anteroposterior projection. Once the filling material had been introduced, an obturator was placed in the working cannula and was kept without removing it until the working time of the material had ended to prevent leakage of the material through the pedicles.

After removing the cannulas, a final fluoroscopic control was carried out in lateral and anteroposterior projections and the skin was closed with staples or absorbable stitches (according to the surgeon's preference).

The standard procedure was for the patient to be discharged home the day after surgery if there were no associated complications. The follow-up visit was carried out at 1 month, 3 months, 6 months and 1 year after surgery.

Clinical, radiological and functional analysis

Clinical and radiological variables were collected retrospectively by two independent evaluators who had not participated in the surgical procedures, through consultation of the patients' electronic medical records. The clinical evaluation included demographic and epidemiological variables such as sex; age; fracture level; concomitant fractures and treatment for osteoporosis pre- and post-procedure, as well as variables related to the procedure such as uni- or bipedicular access, hospital stay and anaemia after surgery. Medical complications after the procedure were also recorded, such as deep vein thrombosis (DVT), pulmonary thromboembolism (PTE), acute renal failure (ARF) and urinary or respiratory tract infections.

Data on the patients' preoperative and current medical treatment for osteoporosis was collected, together with parameters on their quality of life and current level of pain using two scales; First, the Oswestry Lumbar Disability Scale[12] was used, which assesses the patient's level of pain and its influence on personal care; lifting; walking; sitting and standing; sleeping; sexual activity; travelling and social life. Each section has a score of 0–5 points, with a higher

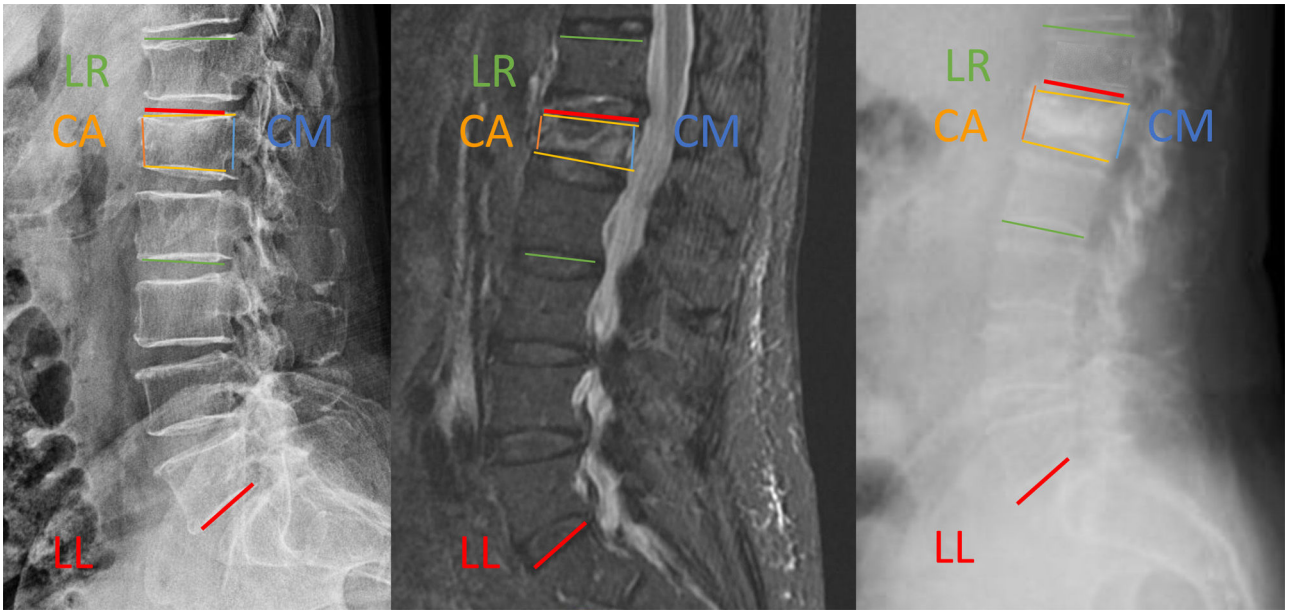

Figure 2 Rx PreQx; MRI PreQx; Rx PostQx: A. PreQx AC height: 7 mm; B. PreQx CM height: 13 mm; C. PreQx kyphosis: 28.8°. AA. Post-Qx AC height: 13 mm; BB. PostQx CM height: 18 mm; CC. PostQx kyphosis: 22.9.

score being more severe. The scores are added together and a disability percentage is obtained:

- 0–20%: Minimal disability.
- 21–40%: Moderate disability.
- 41–60%: Severe disability.
- 61–80%: Disabled.
- 81–100%: These patients may be bedridden or exaggerate their symptoms. Careful evaluation is recommended.

The EuroQol-5D scale was also used to assess the quality of life and the level of physical and mental health of patients in a more general way.

The radiological analysis included preoperative imaging tests (plain X-rays in anteroposterior and lateral projections and nuclear magnetic resonance [NMR], and postoperative (plain X-rays in anteroposterior and lateral projections on the first postoperative day and standing radiographs or teleradiographs during follow-up). The measurements taken on the preoperative and postoperative radiological images were: anterior spinal height (AC), posterior spinal height (PC), fractured vertebral kyphosis (FVK): measurement of the angle formed between the vertebral endplates, regional lordosis (RL): measurement of the angle formed between the upper endplates of the proximal vertebra and the lower endplate of the distal vertebra, lumbar lordosis (LL): angle formed between the upper endplate of L1 and the lower endplate of L5 (Fig. 2).

In cases where a cement leak was suspected by intraoperative or postoperative imaging tests, a CT scan was requested to characterise the size and location of the leak. Radiological variables included height gain in the middle and anterior columns of the vertebral body, changes in regional kyphosis and changes in spinopelvic parameters, as well as radiological complications such as cement leakage (through the pedicle, through vessels or through the fracture itself) and fractures in adjacent vertebrae.

Statistical analysis

For statistical analysis we will use the SPSS 15.0 statistical package (IBM SPSS Statistics 22, Chicago, Illinois). To evaluate the association of qualitative variables we will use the Chi-square test, or the Fisher exact test when the expected frequency is less than 5 in more than 25% of the variables to be compared.

To compare the distributions of two independent samples, whether the variables are continuous or ordinal, we will use the Mann–Whitney test.

For all the statistical tests mentioned, we will consider a power of significance of 5% as valid.

Ethics committee

This study received approval from the hospital's ethics committee, with internal code: 23/130-E, and complies with the ethical standards of the research committee and the Declaration of Helsinki of 1975.

Results

The study was conducted with a total of 58 patients, divided into two groups according to treatment, group 1 consisting of 22 patients treated with VK100 and group 2 consisting of 36 patients treated with PMMA.

Epidemiological results

Age

The average age at surgery was 77.7 years (58–88 years). There were no significant differences between the groups ($p > .05$).

Sex

Regarding sex, 41 women (76.6%) and 17 men (23.4%) took part. There are no significant differences between the groups ($p > .05$).

Treatment of osteoporosis

Overall, 61.9% of patients were taking some medication for the treatment of osteoporosis prior to surgery. Among all patients in the study, 59.5% were taking calcium and vitamin D, which was the most commonly used treatment. Nine point five per cent of patients were using bisphosphonates, 12.2% were using teriparatide, and no patients were using denosumab.

In group 1, 61.5% were receiving treatment (53.8% Ca+VitD; 15.4% bisphosphonates; 7.7% teriparatide) versus 38.5% who were not, while in group 2, 62.1% were receiving treatment (62.1% Ca+VitD; 6.9% bisphosphonates; 14.3% teriparatide) versus 37.9% who were not receiving treatment. There were no significant differences between the two groups ($p > .05$).

After surgery, 80.5% of patients were receiving some treatment for osteoporosis. 80.5% of patients received treatment with Ca+VitD, meaning that all treated patients received Ca+VitD; 10.8% received treatment with bisphosphonates; 16.2% with denosumab and 16.2% with teriparatide.

In group 1, 83.3% were receiving treatment (83.3% Ca+VitD; 25% bisphosphonates; none treated with denosumab or teriparatide), while in group 2, 79.3% were receiving treatment (79.3% Ca+VitD; 6.9% bisphosphonates; 20.7% denosumab; 20.7% teriparatide). There were no significant differences between the two groups ($p > .05$).

Approach

Overall, a bipedicular approach was achieved in 93.6% of patients. In group 1, it was achieved in 87.5% of patients; in group 2, in 96.8%. There was no significant difference between the two groups ($p > .05$).

Postoperative hospital stay

Overall, the average number of hospitalised days after surgery was 1.6 days. Comparing both groups, group 1 had an average of 1.81 days, with a minimum of 0 and a maximum of 9; while group 2 had an average of 1.41 days, with a minimum of 0 and a maximum of 8. There was no significant difference between the two groups ($p > .05$).

Complications

Among the immediate complications of surgery, a leak rate of 12.1% was notable overall. The VK100 group 1 had a leak rate of 7.7%. No embolism occurred due to silicone leakage. The PMMA group 2 had a leak rate of 14.2%. In addition, one patient in group 2 had a pulmonary embolism due to cement leakage. No patient had symptoms associated with the leakage of cement or silicone from the vertebral body. There were no reinterventions. There were no significant differences between the two groups ($p > .05$).

One patient in each group had a surgical wound infection. Both cases were resolved with medical and local treatment through dressings, with no further surgical interventions being required.

Regarding the long-term complications, a rate of adjacent vertebral fracture of 10% was recorded in the series. The average time from the operation to the appearance of the fracture was 2.5 months. Comparing both groups, group 1 had a fracture rate of 7.7%, with a mean time from operation to onset of 3 months; while group 2 had a rate of 13.1% with a mean time to onset of 2.33 months. There were no significant differences between both groups ($p > .05$). All new fractures were treated medically and also required surgical treatment in 28% of the series (kyphoplasty 12%, percutaneous fixation 10%, fixation and kyphoplasty 6%). There were no significant differences between both groups ($p > .05$).

Radiological parameters (Fig. 2)

The mean height of the anterior column (AC) before surgery was 14.5 mm and after surgery was 20.9 mm. There was a mean gain of 4.7 mm. Comparing both groups, there were no significant differences.

The mean height of the middle column (MC) before surgery was 15.9 mm and after surgery was 21.5 mm. There was a mean gain of 6.1 mm. In group 1, the mean height of the MC before surgery was 17.7 mm and after surgery, 21.9 mm. There was a height gain of 2.73 mm. In group 2, the mean height of the MC before surgery was 15.8 mm and after surgery, 25.9 mm. There was a height gain of 8.3 mm. There was a significant difference between the two groups. ($p = .05$ [2.73–7.79]).

In the kyphosis (KP) analysis a decrease in kyphosis of 3.5° was noted after surgery. Comparing by group, in group 1 the kyphosis angle was reduced by 4.2° while in group 2, it was reduced by 3.09°. There was no significant difference between the two groups ($p > .05$).

Lumbar lordosis (LL) after surgery increased by 3.5°. In group 1 there was an increase after surgery of 5.45°. In group 2 the LL increased by 2.8°. There were no significant differences between the two groups ($p > .05$).

The mean regional lordosis (RL) at the general level before surgery was 15.33° and after surgery was 16.54°, thus increasing by an average of 1.06°. In group 1 the pre-surgical RL was 20° and post-surgical RL was 23.72°, increasing by an average of 3.25°. In group 2 the RL before surgery was 13° and after surgery was 19°, also with an average increase in RL of 5.90.° There were no significant differences in the correction of regional lordosis.

Table 1 Summary of patient responses overall (SG) and by study groups (G1 and G2) and the corresponding statistical value.

	Response 1			Response 2			Response 3			Response 4			Response 5			*p*
	SC	G1	G2	SC	G1	G2	SC	G1	G2	SC	G1	G2	SC	G1	G2	
Mobility	30%	33%	29%	16%	10%	21%	20%	17%	21%	30%	35%	25%	3%	6%	4%	0.2
Self-care	40%	33%	40%	23%	0%	30%	20%	33%	17%	17%	33%	13%	0%	0%	0%	0.1
BADL	20%	17%	21%	37%	33%	38%	23%	0%	30%	13%	33%	8%	7%	17%	4%	0.2
Pain	13%	0%	17%	33%	67%	25%	20%	0%	25%	27%	33%	25%	7%	0%	8%	0.1
Depression	30%	17%	33%	40%	66%	33%	13%	0%	16%	13%	17%	16%	4%	0%	4%	0.4

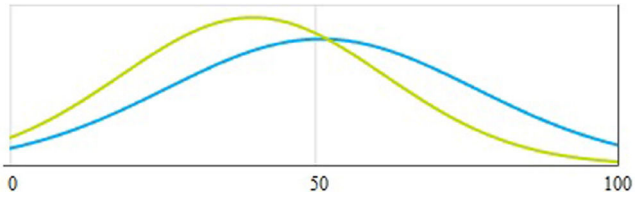

Figure 3 Dispersion of patient results: Oswestry Disability Index. The first curve (blue) represents the PMMA group and the second curve (green) the VK100 group.

Clinical results

Oswestry

Using the Oswestry scale to assess the level of pain and disability caused by it after surgery, the average value for the patients overall was 45%, which is the limit between moderate and severe disability. The minimum value of the study was 2% and the maximum 80%.

Comparing both groups, in group 1 the average disability was 52%, considered severe disability. The minimum score was 18% and the maximum 79%. In group 2 the average disability was 40.8% (moderate disability), the minimum 2% and the maximum 81%. There were no significant differences between both groups ($p > .05$) (Fig. 3).

EQ-5D

The results of the EQ-5D scale are shown in Table 1. No statistical differences were found when comparing the general series and the study groups (Fig. 3).

Subjective health level

Finally, the subjective health level of each person was assessed, with the maximum score being 100 (best possible health status) and the minimum 0 (worst imaginable health status).

At a general level, the average subjective health of the patients was 55.86, with the minimum being 10 and the maximum 90.

In group 1, the average subjective health was 56.67, the minimum 30 and the maximum 80. In group 2, the average was 55.65, the minimum 10 and the maximum 90. There were no significant differences between the two groups (Fig. 3).

Discussion

Both kyphoplasty and elastoplasty are techniques that have revolutionised the treatment of osteoporotic vertebral fractures, reducing pain, hospital stay, complications and improving quality of life. Both treatments are performed using the same procedure, with the only difference between them being the material used in each of them.

The results of the study comparing both treatments indicate a general equivalence between them in most of the parameters evaluated, with slight differences that in most cases are insignificant.

Both treatments demonstrated a similar capacity to correct spinal curvatures, being slightly longer in elastoplasty, as well as an equivalent average postoperative stay and moderate capacity and independence in both cases.

Regarding immediate complications after surgery, both treatments were similar. However, within the long-term complications, PMMA has a slightly higher rate of complications than VK100 due to a higher rate of adjacent fractures, with no statistically significant difference ($p > .05$). As regards the NNT (number needed to treat), an interesting variable existed in the context of treatments performed to replace another to avoid a complication. In our study the average value was 18.5 which meant that 18.5 patients needed to receive treatment with VK100 to avoid an adjacent level fracture.

These differences can be explained by the different modulus of elasticity of the materials used in each procedure. Cement, being more rigid, allows for a greater vertebral height to be recovered and maintained, but this increase in consistency translates into a decrease in flexibility and less load cushioning, which explains this higher rate of adjacent vertebral fractures. In contrast, VK100 silicone has properties that liken it to physiological bone, which also explains this better correction of vertebral curvatures and better transmission of loads.

Although VK100 reproduces the characteristics of the vertebra better, this improvement does not translate into an improvement in the quality of life or in the functional capacity of patients after surgery compared to the PMMA group.

The results obtained in this study are consistent and match those of other previous studies that have also compared both treatments. Bornemann et al.[13] conducted a study comparing 15 patients treated with PMMA with

15 patients treated with VK100. The correction of the height of the vertebral body was similar in both studies, with a greater correction of the height being seen in the two studies with PMMA kyphoplasty. The level of disability due to pain, assessed using the Oswestry scale, was also similar in both studies, with no significant differences between the treatments in either study.

In their study Bornemann et al.[13] reported a leak rate for PMMA of 6.7%, slightly lower than that recorded in our study (12.1%). However, their recorded rate of 33.3% of adjacent fractures in those treated with PMMA is notable and considerably higher than that of this study (10%). Regarding VK100, the leak rate was slightly higher in our study, but the rate of adjacent fractures was the same in both.

The study by Bornemann et al. analysed the loss of vertebral height after surgery, i.e. a 12-month follow-up was carried out in which the reduction in vertebral height over time was compared between those treated with PMMA and those treated with VK100, showing a greater loss of height in those treated with PMMA, but even so, the total gain in height was still greater in those treated with PMMA. However, the correction of the physiological curvatures of the spine was not analysed.

When comparing the complications of the PMMA and VK100 groups in this study with other studies specific to each treatment, concordance between the results is also present, especially with the PMMA group.

The meta-analysis carried out by Lee et al. in 2009[10] summarised all the complications of kyphoplasty. Cement leaks occurred in 14% of all cases, but only .01% were symptomatic. Also, new vertebral fractures occurred in 17% of patients. These data coincide with those obtained in our study, with the rate of adjacent fractures being lower in our study.

The study conducted by Gasbarrini et al. in 2017[14] with the start of performing VK100 elastoplasties, assessed their impact on quality of life and improvement of pain, together with complications. To assess the improvement of pain and quality of life, they used the VAS scale and its pre- and post-surgical score, reporting a 50% improvement in the level of pain at 24 h after the operation. Furthermore, the rate of adjacent fractures was 5%, lower than that presented in this study; and the rate of leaks was 13%.

This slight discrepancy in the results of complications could be due to the limit of the sample of patients in group 1 VK100, and the results could be more similar if the sample were increased.

Furthermore, in reference to what Checa-Betegón et al.[15] proposed, regarding quality of life and the impact of fractures with osteoporosis, performing a surgical procedure on the fracture has an impact by decreasing mortality at 2 years and 10 years, and improving functionality and pain in these patients. Comparing the treatment options, it seems that there is a direct relationship between recovery time for a biomechanical function with the angles of residual kyphosis and the spinopelvic balance. Notwithstanding, control studies and long-term follow-up should be carried out to verify the probable secondary events of these procedures.

In this way, by having a close follow-up in the comparison for the treatment of osteoporosis fractures, it can be pointed out, as described by Mattie et al.,[16] that management by means of vertebroplasty with PMMA, compared to conservative treatment, is shown to be superior in a period of one year. However, complementary treatments must be added in this type of patients, when they have an underlying disease. The use of cementation or augmentation techniques involves understanding the study result, since the use of PMMA directly on the treatment is an excellent tool but the aim must also be to reduce side effects.

In contrast, the treatment modality can be objective at the time of its selection. Li et al.[17] pointed out that although in osteoporosis fracture management these treatments are safe, they found that the use of PMMA is exposed to complications such as material leakage, as well as epidural haematomas. However, the desired result is directly influenced by restoring kyphotic angulation as well as the early reincorporation of the patient. Cleary, the choice of treatment functionality depends largely on technique knowledge and use, together with materials, with better results being achieved and patient follow-up verification.

Regarding treatment verification, Zhang et al.[18] showed that in the use of therapies for vertebral augmentation great debate remains regarding adverse events, since any of its presentations are recorded as safe, However, when comparing if there is any significant difference on secondary fractures this becomes insignificant, since patient type may flag up other factors which are not being observed within the study. As pointed out, both treatments are therefore safe but minor changes can directly influence long-term follow-up.

The present study demonstrates the efficacy in relation to what was established by Wen et al.,[19] when considering the functionality of kyphoplasty in elderly patients with osteoporosis, denoting that its use in comparison with conventional techniques using pedicle screws greatly improves the sequelae of kyphosis, the reinforcement of the vertebral body, and pain. However, it is reported that the use of combined techniques of both cementation and short segments reduces the sequelae of secondary fractures. In relation to our study, both components were very useful for the functionality of the treatment. To this we would add that in patients who present with an adverse event, the use of a combination of treatments can be chosen.

By having a broad review of data, Rajasekaran et al.[20]were able to show that both the treatment with kyphoplasty and with vertebroplasty are safe and greatly reduce the symptoms of patients with osteoporotic fractures, denoting that the differences vary in the cost as well as in the probable side effects. In contrast to the study, both VK100 and PMMA are shown to be safe depending on the type of fracture and the technique for their application, thus greatly improving the patient's symptoms during follow-up, with no serious complications.

For all this, it is important to point out that our study has some limitations that could have influenced the results. For example, the sample size might not have been large enough, especially in the VK100 group, to detect significant differences in some of the secondary outcomes. In addition, a small sample may affect the extrapolation of the results to the wider population. Future studies with larger samples and groups of equal size could help confirm and validate these findings.

The limited sample size must be added to the rate of patients dropping out of the study (6 patients). The main reason for dropping out was death (none as a result of this study), because in addition to the fact that the average age of the patients in the study was high (76.7 years), the duration of the study was also quite long (5 years), as patients were added sequentially.

Although this study has provided a large amount of information on the treatment of osteoporotic vertebral fractures with minimally invasive procedures (elastoplasty and kyphoplasty) and the differences between them, there are still areas to be investigated that were not possible to include in this study. These include the use of analgesic medication and its need with each of the treatments, a clinical cost-effective study to assess the cost–benefit of each treatment, together with factors which may be associated with a higher risk of adjacent fracture. This is a fairly contemporary and extensive topic on which there is still much to be investigated.

Conclusion

Both kyphoplasty and elastoplasty are effective techniques that generate rapid pain relief and an improvement in quality of life. VK100 is the most modern technique and the one that has the greatest similarity to vertebral tissue, which can be seen in better physiological parameters and a lower rate of complications. However, although objective data show a slight superiority of VK100 over PMMA, the subjective analysis of each person and the functionality, represented in the surveys, show similarity between both treatments. In general terms therefore, both have similar outcomes. Criteria cannot be established for the use of one or the other, both being equally valid for the treatment of osteoporotic vertebral compression fractures.

Level of evidence

Level of evidence III.

Ethical approval

This study was conducted with approval from the Ethics Committee of our institution in accordance with the 2000 revision of the Declaration of Helsinki.

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Conflict of interests

All the authors declare they have no conflict of interests.

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