

USE OF A NEW EXPANSIVE SCREW IN PATIENTS WITH POOR BONE QUALITY. MULTICENTER STUDY

UTILIZAÇÃO DE UM NOVO PARAFUSO EXPANSIVO EM PACIENTES COM MÁ QUALIDADE ÓSSEA. ESTUDO MULTICÊNTRICO

UTILIZACIÓN DE UN NUEVO TORNILLO EXPANSIVO EN PACIENTES CON MALA CALIDAD ÓSEA. ESTUDIO MULTICÉNTRICO

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ABSTRACT

Objective: To observe the behavior of the expansive screw in patients with poor bone quality, its safety, the technique, conduct and complications: percentage of loosening, breaks, pull-outs and pseudoarthrosis. **Methods:** Prospective multicenter study analyzing the patient's risk factors, VAS, surgery time, blood loss, location of the screws and complications due to the implant at the time of discharge, and at 3, 12 and 24 months. **Results:** 99% of the patients did not have any permanent complications related to the implant; there was only one case of unresolved radiculopathy. In 95% of the implants, the screws were placed without complications; in 5% percent of cases there were complications related to poor placement or expansion of the screw, which were resolved with the surgery. Mean intervention time per level: 56 minutes; average intervention time, 2 hours and 35 min. Average bleeding per level that received intervention, 211cc. There were three cases of "pull-out". VAS evolved favorably and significantly, with average reduction greater than four points. The study will continue until age five, these being the preliminary results. **Conclusions:** This type of expansive screw provides a new anchoring system for patients with poor bone quality; it is safe and effective, easy to insert, and provides less exposure to X-ray, and in case of removal of the screw, it leaves the way free for a new surgery.

Keywords: Arthrodesis; Spine; Bone screws; Postoperative complications; Osteoporosis.

RESUMO

Objetivo: Observar o comportamento do parafuso expansivo em pacientes com má qualidade óssea, sua segurança, a técnica, conduta e complicações: porcentagem de afrouxamento, quebras, "pull-out" e pseudoartrose. **Métodos:** Estudo prospectivo multicêntrico analisando fatores de risco do paciente, VAS, tempo cirúrgico, perda de sangue, localização dos parafusos e complicações devido ao implante na alta e aos 3, 12 e 24 meses. **Resultados:** 99% dos pacientes não tiveram nenhuma complicação permanente relacionada com o implante; apenas um caso de radiculopatia não se resolveu. Em 95% dos implantes, os parafusos foram colocados sem complicações; em 5% houve complicações relacionadas com a má colocação ou expansão do parafuso, que foram resolvidas com cirurgia. Tempo médio de cirurgia por nível, 56 min.; tempo médio por intervenção, 2 horas e 35 min. Sangramento médio por nível que recebeu intervenção, 211 cc. Ocorreram três casos de "pull-out". A VAS evoluiu favoravelmente e de forma significativa, com reduções médias maiores que quatro pontos. O estudo continuará até os cinco anos, sendo que estes são os resultados preliminares. **Conclusões:** Esse tipo de parafuso expansivo é um novo sistema de ancoragem para pacientes com má qualidade óssea; são seguros e eficazes, rápidos para colocar, proporcionam menos exposição aos RX e, em caso de retirada do parafuso, deixam o caminho livre para uma nova cirurgia.

Descritores: Artrodese; Coluna vertebral; Parafusos ósseos; Complicações pós-operatórias; Osteoporose.

RESUMEN

Objetivo: Observar el comportamiento del tornillo expansivo en pacientes con mala calidad ósea, su seguridad, técnica, manejo y complicaciones: porcentaje de aflojamiento, roturas, "pull-out" y pseudartrosis. **Métodos:** Realizamos estudio prospectivo multicéntrico analizando factores de riesgo del paciente, VAS, tiempo quirúrgico, pérdida de sangre, emplazamiento de tornillos y complicaciones debidas al implante a la alta y a los 3, 12 y 24 meses. **Resultados:** El 99% de los pacientes no tuvieron ninguna complicación permanente relacionada con el implante; sólo hubo un caso de radiculopatía no resuelta. En el 95% de los implantes, los tornillos se colocaron sin complicaciones; en el 5% aparecieron complicaciones relacionadas con la mala colocación o expansión del tornillo, resueltas en acto quirúrgico. Tiempo quirúrgico promedio por nivel, 56 min.; tiempo promedio por intervención, 2 horas 35 min. Sangramiento promedio por nivel intervenido, 211cc. Hemos tenido tres casos de "pull-out". El VAS evolucionó favorablemente de forma significativa, con reducciones promedio mayores a cuatro puntos. El estudio continuará hasta los cinco años, siendo estos los resultados preliminares. **Conclusiones:** Este tipo de tornillos expansivos aportan un nuevo sistema de anclaje para pacientes con mala calidad ósea; son seguros y eficaces, ofrecen rapidez en su colocación, una menor exposición a los RX y, en caso de retirada del tornillo, dejan el camino libre para una nueva cirugía.

Descriptores: Artrodeseis; Columna vertebral; Tornillos óseos; Complicaciones postoperatorias; Osteoporosis.

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INTRODUCTION

Due to the increased longevity of the population, it is becoming increasingly necessary to perform surgery on elderly patients with spinal pathology, and it is well-known that over the age of 25, bone quality decreases with age, and is considered poor after the age of 65 years.

The spongy bone is the most affected, with a decrease in quantity and changes in the microstructure of the bone.

It has been demonstrated that fixation of implants is less effective when the bone is of poor quality. The same applies to the vertebra, for which biomechanical studies have demonstrated higher rates of screw loosening, pull-out and pseudoarthrosis.^{1,2}

Various methods have been proposed for improving screw fixation in cases of poor bone quality: the use of longer screws with a wider diameter; the use of screws with cementation; and size of the graft inside the vertebral body. In theory, these methods enable greater fixation of the screws. However, various studies have shown that these methods are not free of complications, such as fracture of the pedicles, violation of the anterior cortex of the vertebral body, or complications arising from cementation, particularly leakage of cement.³⁻⁷ Furthermore, biomechanical studies have failed to demonstrate improved fixation of the implants or greater resistance to pull-out with some of these methods.^{3,4}

Another option is expandable screws, which have been shown, in various biomechanical studies, to increase resistance to pull-out.⁸⁻¹⁰ We present a study with an expandable screw with a new design, which doubles its diameter at the level of the vertebral body, where the pedicle ends, increasing resistance to pull-out by 30% and resistance to mechanical failure by 50% in poor quality bone, compared with the normal screw.⁸

The objective of this study is to evaluate the reliability of the expansive screw in the treatment of instrumented vertebral fusion in patients with poor quality bone, in terms of its management and safety.

METHODS

We carried out a prospective, multi-center observational study in 99 patients with different spinal pathologies (fractures, deformities, degenerative diseases) in which we placed a total of 576 expandable screws (OsseoScrew, Alphatec Spine) with a mean follow-up of 19.2 months ($\sigma=6.6$; 12-29). (Figures 1 and 2)

The main biomechanical characteristic of these titanium screws is their capacity to expand in the union of the middle and distal thirds

of the screw body itself, after it has been inserted in the vertebral body immediately anterior to the pedicle. This expansion capacity is up to double the diameter of the screw at the union of the middle and distal thirds of the screw, giving three anchorage points: at the start of the pedicle with the head of the screw, in the pedicle itself, and in the vertebral body at the point where it separates from the pedicle. (Figure 3)

We studied the reliability of the fixation technique and its management, through the analysis of surgery time, blood loss, and screw placement; security of the implant, analysis of the complications caused by it; and analysis of the evolution of postoperative VAS as an indirect value of the non-existence of complications.

We performed a study in 99 patients, with an average of 73 years (52-83) and a prevalence of females (67%) compared to males (33%).

In the parameters collected in the surveys, we investigated the presence of factors that could influence the final result: smoking habit (non-smoker 95%, smoker 5%); use of corticoids (87% yes; 13% no); body mass index (17% normal; 56% overweight; 21% mild obesity; 6% moderate obesity).

Regarding the reason for surgery, the majority of the patients were operated on due to degenerative pathology of the spine (82%), followed by traumatic pathology (11%) and deformity (7%).

The main motive for the intervention was due to lumbalgia or lumbosciatalgia, followed by claudication and/or stenosis of the canal. In a smaller percentage, the patients were operated on for paresthesias of the lower limbs, deformity and/or scoliosis, discopathy and/or chronic radiculopathy, and changes in sagittal profile.

The screws were placed mainly in the last segments of the lumbar spine (L4, L5 and S1). In one case, the screws were placed from T3 to S1, in one patient with adult scoliosis, this being an exception, due to limitation of the diameter of the screw and of the pedicle at levels higher than T10.

In 49% of cases, circumferential arthrodesis was performed (40% somatoarthrodesis with implant via PLIF, 35 via TLIF and 6% only with contribution of autograft of the iliac crest).

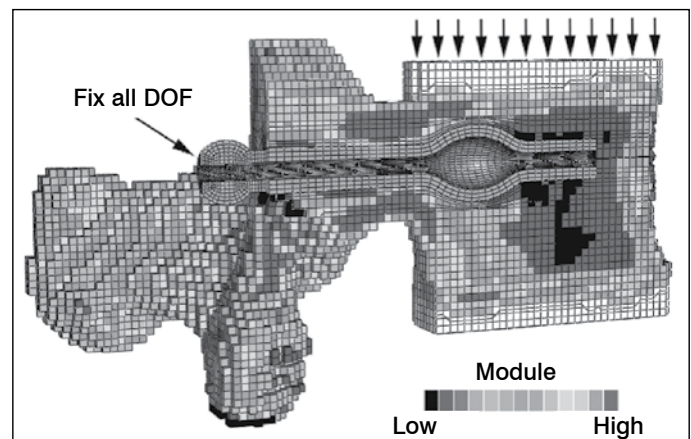


Figure 3. Titanium expandable screws.

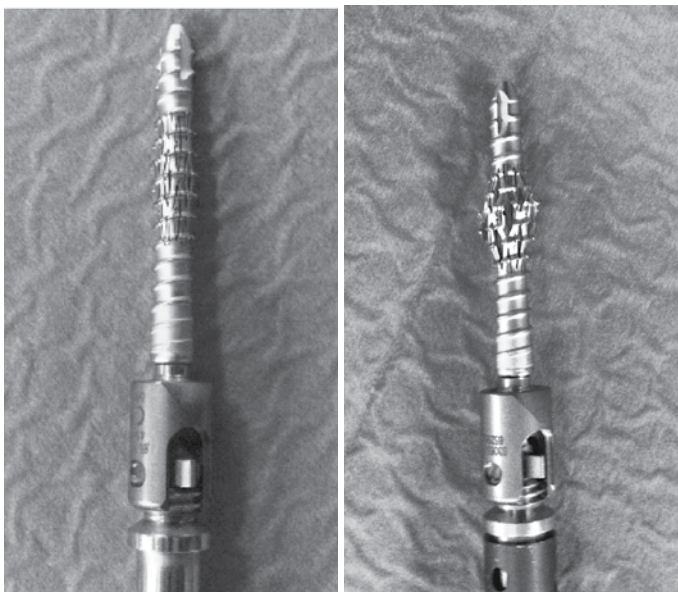
RESULTS

Surgery time

The average surgery time was 2 hours and 35 minutes, with the majority of cases lasting less than 3 hours (55%, less than 3 hours; 45%, more than 3 hours) and an average time per level of 56 minutes.

Blood loss

The average intraoperative blood loss, analyzed by measuring the volume in cubic centimeters (cc), was 652 cc per intervention,



Figures 1 and 2. Expandable screws.

and between 301 and 1000 cc in most cases (33%). This average was increased in cases of deformities. We recorded an average blood loss per instrumented vertebra of 210 cc.

Intraoperative complications

In most of the patients who underwent surgery, there were no complications derived directly from the screw (95%). There was one case of partial rupture of one of the pedicles of L4; three cases of failure of the screw to expand; one medialization of a screw in S1, which was resolved by retrieving the screw and placing a new one a month after the surgery, and one case in which a malpositioned screw had to be replaced in the same surgical procedure.

Evolution of VAS

Analyzing the evolution of pain between the preoperative and postoperative periods, in the majority of cases we found a reduction in VAS of more than 4 points, both in terms of lumbar pain and irradiated pain.

Follow-up results

In the two years after surgery, there were three cases of pull-out, in two patients.

DISCUSSION

The use of expandable screws has demonstrated, in various studies, greater resistance to pull-out and loosening than with the other implants used, with the same range of complications as normal screws, but less than cemented screws or those with greater diameter and length, in patients with poor quality bone.⁸⁻¹²

Some studies on the effect of pedicle screw fixation by bone mineral density (BMD), have shown greater resistance to pull-out and loosening than conventional screws in patients with lower BMD.^{1,2}

Subsequently, other authors have shown that in these patients with poor bone quality, the resistance to loosening using expandable screws was similar to that of normal screws in healthy bone.^{8,12}

The resistance to loosening and pull-out has also been shown to be higher with the use of cemented screws in patients with poor quality bone, compared with conventional screws. However, different studies *in vitro* have proposed the possibility of complications due to leakage of the cement. Furthermore, it has been proposed that in the long term, the occurrence of loosening was similar to that recorded with the use of conventional screws. For this reason, some authors recommend the use of expandable screws with cementation in patients with less severe poor bone quality, reserving the expandable screw and cementation for severe cases.^{4,6,7}

Regarding the grade of arthrodesis obtained, different studies have demonstrated a higher percentage with expandable screws, in patients with poor quality bone, than with conventional screws.¹¹

In general, there have been few studies in the literature on expandable screws. The majority compares them with cemented screws, and all are biochemical studies.

CONCLUSIONS

In view of the results obtained in our studied, which corroborate other studies on expandable screws, we believe that the use of this screw in patients with poor quality bone is a secure method, with few complications derived from the implant, and with a low percentage of pull-out and loosening of the screws. We therefore consider it to be a useful method for use in patients with poor quality bone.

All authors declare no potential conflict of interest concerning this article.

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