



(RESEARCH ARTICLE)



Spondylolisthesis treatment using vertaux pedicle screw system, osteobone dual threaded screw, and occipital system: A study

Vitelio Lazaro *

San Suchitoto Hospital, El Salvador.

World Journal of Advanced Research and Reviews, 2024, 22(01), 1443–1449

Publication history: Received on 04 March 2024; revised on 20 April 2024; accepted on 23 April 2024

Article DOI: <https://doi.org/10.30574/wjarr.2024.22.1.1150>

Abstract

Background: Pedicle screw fixation has its origins in Europe. Spinal screw most commonly pedicle screws, play a major role in different spinal surgeries by providing stabilization to vertebrae that promote healing, and correction of deformities. In the recent era spondylolisthesis issue is more common. So, we have retrospectively analyzed using three different spinal screws of Titanium Alloy as per EN ISO 5832-3:2021 to treat the spondylolisthesis issue in the lower lumbar spine, which were manufactured by Auxein Medical Private Limited.

Materials and Methods: Spinal screws consist of a variety of shapes and sizes. In this analysis total 45 patients with one year follow up were analyzed. The Spondylolisthesis related spinal issue of lower lumbar spine were treated by using different spine screws: VERTAUX Monoaxial Pedicle Screw with Cap (\varnothing 5.5 mm, L 35 mm); Osteobone Multiaxial Pedicle Fenestrated Dual Thread Screw (\varnothing 5 mm, L 25 mm) and VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread (\varnothing 5 mm, L 25 mm) of Ti-6Al-4V material which was manufactured by Auxein Medical Private Limited, India. X-ray was used to examine the pre and post clinical conditions. In addition, the functional outcomes were assessed with Average VAS score.

Results: X-ray showed good outcomes. Prior to the surgery the average VAS score was 8.1 and after one-year completion the average VAS score was seen 0.4 only. After 1 month, 3 months, 5 months and 9 months and 12 months the average VAS score were calculated as 6.2, 4.7, 3.3 and 1.9 respectively.

Conclusion: The treatment by using VERTAUX 5.5mm Pedicle Screw System, VERTAUX Osteobone Dual Threaded Screw and VERTAUX Occipital System showed good results with less complications.

Keywords: VERTAUX 5.5mm Pedicle Screw System; VERTAUX Osteobone Dual Threaded Screw; VERTAUX Occipital System; Titanium Alloy; Spondylolisthesis; Spinal Stability

1. Introduction

Spondylolysis has been shown to be absent at birth, and generally develops at a young age. Spondylolisthesis is the slippage of one vertebral body with respect to the adjacent vertebral body causing mechanical or radicular symptoms or pain. It can be due to congenital, acquired, or idiopathic causes. Spondylolisthesis most commonly occurs in the lower lumbar spine but can also occur in the cervical spine and rarely, except for trauma, in the thoracic spine. In the medical literature, Raymond Roy-Camille is widely credited with the first application of screws through the pedicles of the vertebrae [1-3]. Spondylolisthesis is displacement of a vertebra due to a defect in the pars. There are five categories of spondylolisthesis classified by Wiltse et al. [4] Type I is dysplastic and refers to a congenital dysplasia that results in the anterior and superior rounding of the S1 vertebrae. This rounding allows the L5 vertebrae to slip anteriorly on the S1

* Corresponding author: Vitelio Lazaro

vertebrae. Type II is isthmic and is separated into Type IIA and Type IIB. Type IIA is caused by a stress fracture of the pars interarticularis (spondylolysis) that results in anterior slippage of the vertebrae. Type II B is caused by repetitive fractures and subsequent healing which results in lengthening of the pars interarticularis leading to anterior slippage of the vertebrae. Type III is degenerative and the root cause is commonly from arthritis. Arthritis of the facet joint prevents movement of the joint leading to stress and instability which ultimately leads to the weakening of the ligamentum flavum. Weakness of the ligamentum flavum leads to degenerative instability and permits anterior slippage of the vertebrae [5] Type IV is traumatic and is caused by high energy trauma to the spine. Type V is pathologic and can be caused by lytic bone tumors, osteopetrosis, or osteoporosis. Type VI is iatrogenic spondylolisthesis and is a potential sequelae of spinal surgery. Fredrickson et al. [6] performed a prospective study on 500 first graders and found a prevalence of 4.4% at the age of 6 years which increased to 6% by the time adulthood was reached. The incidence of spondylolysis was present at a ratio of 2:1 male to female. Ciullo J.V., et al [7] Spondylolysis is generally caused by repetitive stress to the pars interarticularis, especially due to hyperextension. This injury is commonly seen in football linemen, gymnasts, and Olympic weight lifters due to repetitive hyperextension [8, 9]. Andrew K. Chan K. et al [10] reported that degenerative lumbar spondylolisthesis is a common cause of low back pain, affecting about 11.5% of the United States population. Herkowitz and Kurz et al. [11] conducted a study of a heterogeneous sample of 50 patients with lumbar stenosis and degenerative spondylolisthesis. Severity of disease varied among the patients, during 3-year follow-up, all but one patient (96%; 24/25) in the fusion group had satisfactory results, compared with only 11 (44%; 11/25) satisfactory results in the decompression-alone group. Lee CW et al. [12] conducted a comparative study of ALIF (n 5 27), LLIF (n 5 24), and PLIF (n 5 31) in the treatment of 82 patients with L4-5 spondylolisthesis. Mean follow-up ranged from 32.8 to 38.4 months. No significant differences were found with regard to length of hospital stay, blood loss, operation times, complication rates, or subsidence rates. There were no cases of pseudarthrosis requiring revision. Fusion rates were not compared. VAS back pain, VAS leg pain, and ODI clinical outcomes were similar across the 3 groups postoperatively. The various researchers provide the information for recommendations for the management/treatment of degenerative lumbar spondylolisthesis as described in Table 1.

Table 1 Treatment of degenerative lumbar spondylolisthesis along with grade for recommendations

S. No.	Author	Year	Recommendation	Grade	References
1	Weinstein JN et al.	2007	Surgical treatment of degenerative lumbar spondylolisthesis results in superior clinical outcomes compared with nonsurgical treatment.	A	[13]
2	Mummaneni PV et al. & Kotani Y, et al.	2017 & 2012	MIS to have comparable clinical outcomes with open fusion, at a reduced cost, decreased blood loss, shorter time, shorter length of stay in hospital.	B	[14, 15]
3	Kono Y, et al.	2018	ALIF and LLIF are associated with greater improvements in disc and foraminal height than posterior approaches for interbody placement.	B	[16]
4	Ohtori S, et al. and Sato J, et al.	2015 & 2017	Prepsoas LLIF is associated with radiographic and clinical improvement.	C	[17, 18]

Pedicle Screws fixation with the rods and connectors is most commonly surgical procedure to treat Spondylolisthesis problems. In the current study the Ti-6Al-4V alloy is used because of it possess many advantages over stainless steel such as highly biocompatible, less weight, highly corrosion resistance. In addition, due to the surface treatment such as sand blasting on titanium screws it improve the mechanical stability of the implant. High bioactivity and more flexibility may improve bone ingrowth and mechanical fixation, and the material also offers superior magnetic resonance imaging (MRI) and computed tomography (CT) resolution and significantly less signal interference [19-22]. Spondylolysis is a precipitating factor and can be classified as isthmic, dysplastic, degenerative, traumatic, and pathologic [23]. The lumbar spine is consisting of 5 vertebra numbered L1- L5 and each vertebra present vertebral disc. The complex anatomy of the lumbar spine is a remarkable combination of these strong vertebrae, multiple bony elements linked by joint capsules, and flexible ligaments/tendons, large muscles, and highly sensitive nerves. It also has a complicated innervations and vascular supply. For example, in a recent analysis, 95,647 Medicare patients with a diagnosis of lumbar DS, 40% were treated with corticosteroid injections, 37% were treated with physical therapy, and only 22% were treated surgically [24].

Patient Outcomes Research Trial (SPORT), 7% were treated with decompression alone, 21% were treated with non-instrumented fusion, and 71% were treated with fusion surgery. The reoperation rate is also high at 22% at 8 years after initial surgery. Nevertheless, surgical treatment of DS with symptomatic spinal stenosis has been shown to be cost-effective with gain of 0.43 quality adjusted life years (QALYs), or greater for patients with multilevel disease

[25]. Degenerative spondylolisthesis is often asymptomatic but can present clinically as symptomatic axial low back pain, radicular pain, or neurogenic claudication as it is associated with lumbar stenosis. Prevalence within the United States of America has been reported to range widely from 20–25% of females and 4–31% of males [26-31]. The biggest challenge in the surgery is accurate placement of the pedicle screws. Gelalis ID, et al. [32] Conduct a prospective clinical studies and on total 1,105 patients in which 6,617 screws were inserted. In the studies using free-hand technique, the percentage of the screws fully contained in the pedicle ranged from 69 to 94%, with the aid of fluoroscopy from 28 to 85%, using CT navigation from 89 to 100% and using fluoroscopy-based navigation from 81 to 92%. The screws positioned with free-hand technique tended to perforate the cortex medially, whereas the screws placed with CT navigation guidance seemed to perforate more often laterally.

2. Method

The data were collected electronically from the hospital's database. The data for 45 patients were collected and analysed at San Suchitoto Hospital, El Salvador, between September 2019 to November 2020. The patients were included in the study was 18-60 years of age group and those who have completed at least follow up of 9 months. Table for Inclusion & exclusion criteria are given in Table 2 below.

Table 2 Inclusion & Exclusion criteria

S. No.	Inclusion Criteria	Exclusion Criteria
1	The patient between 18-60 age group with symptomatic spondylolisthesis not relieved by conservative treatment.	The patients with severe spondylolisthesis G-IV
2	Isthmic or degenerative spondylolisthesis were only included.	Acute traumatic spondylolisthesis.
3	Spondylolisthesis b/w G I –III	Patients with failed previous lumbar surgery.
4.	Patient who have completed the follow up for at least 9 months.	

The indications for surgery were isthmic spondylolisthesis in Isthmic (lytic) 30 Cases and degenerative spondylolisthesis in 15 cases operated. Spinal System- VERTAUX Monoaxial Pedicle Screw with Cap (\varnothing 5.5 mm, L 35 mm); Osteobone Multiaxial Pedicle Fenestrated Dual Thread Screw (\varnothing 5 mm, L 25 mm) and VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread (\varnothing 5 mm, L 25 mm) of Ti-6Al-4V material were used for posterior spinal stabilization. The Myerding grading system was measures the percentage of vertebral slip forward over the body beneath. Patient physical fitness was also examine through America Society of anaesthesiologist Grade. Pain Scale record from the patient using Visual Analog Scale. Follow up of the patient were taken on 1 month, 3 months, 5 months and 9 months and 12 months Spinal Screws consists of a variety of shapes and sizes of screws. In the current study the three different categories of spine screws i.e. VERTAUX 5.5mm Pedicle Screw System: that consist of a different shape and size of rods, screws, cross-link connectors and connection components which can be rigidly locked into a variety of configuration with each constructs being tailor made for individuals. VERTAUX Osteobone Dual Threaded Screw: this Osteobone Dual Threaded Screws is designed with dual thread, upper thread is made finer to engage with bone more effectively and resist the backing out of screw while lower thread made coarser that prevent from the pull-out of the screw. VERTAUX Occipital System: Occipital System is designed to optimize the fixation to the occiput. It stabilizes and promotes the fusion of the occipitalcervical junction. The schematic diagram of all the screws used in the study is shown in Fig. 1 (a, b, c) respectively.



Figure 1(a) Actual Image of VERTAUX Monoaxial Pedicle Screw with Cap



Figure 1(b) Actual Image of Osteobone Multiaxial Pedicle Fenestrated Dual Thread Screw



Figure 1(c) Actual Image of VERTAUX - Occipital Polyaxial Pedicle Screw, Partial Thread

3. Results and Discussion

The According to ASA Grade all Paitent were felt in Grade 1 Isthmic spondylolisthesis patients were more common than Degenerative, both being common in female patients and Grade 2 listhesis for 30 patients was common then Grade 1 listhesis 10 patients and Grade 3 for 5 patients. Thereafter the physical therapy post-surgery for spondylolisthesis starts immediately. Ankle toe movements and deep breathing exercises started on the same day to prevent circulatory and

respiratory complications. Post operatively the Intravenous Antibiotics were continued for 07 days followed by oral antibiotics for a period of 12 days. Regular wound check is done with the drain being removed on 11th post-operative day and the sutures being removed on average of 13 days. Brace is to be continued for 3 months postoperatively and patient removed it in average 3 months approx. Lumbar radiographs with anteroposterior, lateral and lateral standing flexion extension films and oblique view were obtained beginning with the 1 month, 3 months, 5 months and 9 months and 12 months calculated from the day of surgery to check the stability. The fixation procedure is equally good achieving fusion and stability. The fusion status was judged, an evaluation done by an independent observer. The Average pain scale has been also calculated for the patients. Data is presented in Fig. 2.

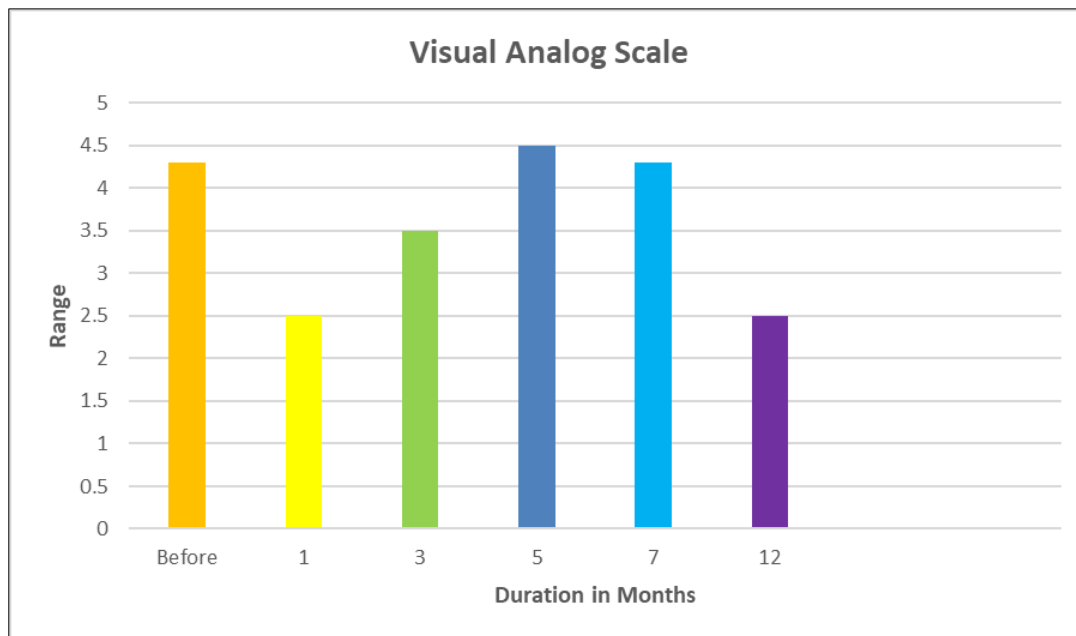


Figure 2 VAS Score that indication the range of pain

Before surgery VAS score was avg.7.1 and after 12 months it reduced to 0.5 only. The avg. VAS score after 1, 3, 5, 7, 12 months 6.1, 4.5, 3.2, 2.1 and 1.6 respectively. All the patients included in the study showed satisfactory bony fusion as judged by solid fusion at both facets joint. Radiological fusion was seen earliest on 3rd month in x- rays. Pre and post operation lateral radiograph of L-S spine showing forward displacement of L5 over S1. Dai., et al. treated 43 patients with degenerative spinal disease and osteoporosis. The radiological observation indicated no loosening or pulling out of the novel screw, and bone fusion was excellent.

4. Conclusion

On the basis of result, I believe that all the three screws are very effective for the treatment spondylolisthesis with very less complication. The fixation procedure is equally good achieving fusion and stability. However, further study with larger sample sizes would be needed to confirm the results.

Compliance with ethical standards

Author contribution

All authors whose names appear on the submission equally contributed to this work.

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