

Preliminary Clinical Experience to Assess the Use and Safety of Vivosorb® Sheet in Herniated Lumbar Disc Surgery

M.L. Ellis, MD Orthopedic Surgeon
Ziekenhuis Rivierenland Tiel, The Netherlands

Introduction

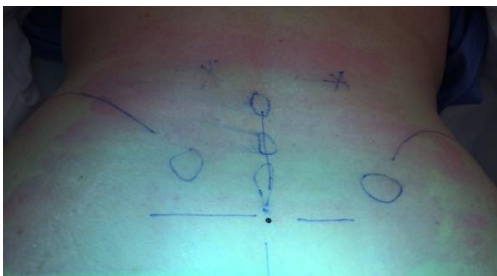
Post operative peridural fibrosis is a common late complication of spinal surgery. Vivosorb is a bioresorbable copolyester poly(DLlactide- ϵ -caprolactone) that is currently used to prevent post-operative soft tissue adhesions in tendon and nerve surgery. Due to this prior experience we wanted to explore the use and safety of this material in herniated lumbar disc surgery by placing it on the dural sac and nerve root.

Patients and methods

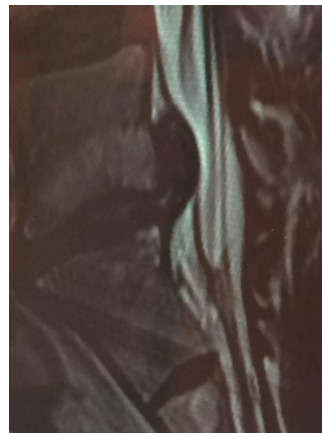
In the period May 2017 through December 2018 fifty-seven consecutive patients were operated for a single level herniated lumbar disc by the same orthopedic surgeon. Vivosorb was placed on the dural sac and nerve root as a temporary protective sheet to prevent eventual fibrosis.

The operative technique was the same in all patients and can be described as follows. After general anesthesia, the patient was placed in a knee chest position. Localization via fluoroscopy and methylene blue dye injection was used to confirm the level. Then a mini-open procedure was performed using an approximately five to eight centimeter incision and tissue spreader.

Following removal of the herniated disc material, a five- by seven-centimeter Vivosorb sheet was cut to the appropriate size and inserted to cover the exposed nerve root and dural sac, without suture fixation.



Exposure in knee chest position



MRI of the lumbar spine. Herniated disc L5-S1.



Incision 5-8 cm



Vivosorb 3 x 2 cm placed bilaterally

The post-operative protocol involved supervised same day mobilization with hospital discharge the following day. Patients were restricted to light activities in the first six weeks. All patients were seen three weeks post operatively by the operating surgeon and were instructed by the onset of any adverse reaction to immediately contact the orthopedic department.

Results

One patient required re-operation due to the fact that the incorrect level had been operated. There were no cases involving progressive neurologic deficit, infection or spinal fluid leakage. No adverse reactions were observed or reported which can be attributed to the use of the Vivosorb material, such as inflammation or increased post-operative pain.

Conclusion

Vivosorb can be applied easily in the mini-open technique. Our experience demonstrates that Vivosorb can be safely used in herniated lumbar disc surgery. Further clinical study is needed to assess its effectiveness in the prevention of peridural fibrosis.

Dr. M.L. Ellis 24-01-2019