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Long-term follow-up of anterior cervical discectomy and fusion with bioabsorbable plates and screws

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ABSTRACT

Objective: Anterior cervical discectomy and fusion (ACDF) is an accepted technique for the management of cervical spinal degenerative disease. Recently, new resorbable materials have been proposed for the anterior cervical fusion to eliminate some of the disadvantages and complications of metal plates. The aim of our study was to evaluate the long-term clinical results of the ACDF implants made out of bioabsorbable materials.

Methods: We performed a retrospective descriptive study of a series of 17 ACDF patients operated with the Inion S-1™ resorbable screws and plates (made out of biodegradable copolymers composed of L-lactic acid and D,L-lactic acid 80/20) 5–7 years ago. The mean age of the patients was 45 years. A single-level procedure was carried out in 13 patients and a double-level procedure in four patients, and the most commonly fused level was C5–C6. Clinical background, preoperative and postoperative symptoms, previous trauma, complications, radiographic fusion and condition of the prevertebral space (preoperative and postoperative) were analyzed.

Results: We observed a good fusion rate and stability using resorbable plates and screws. None of the patients had associated severe complications such as adjacent tissue edema or infection, or had to be reoperated due to failure or migration of the used implants.

Conclusions: The results of this retrospective clinical long-term follow up demonstrate that cervical fusion can be successfully achieved using resorbable implants.

1. Introduction

Anterior cervical discectomy and fusion (ACDF) is the most common surgical treatment for the management of cervical spondylosis. Although the instrumentation is becoming routine, there is no clear consensus on the need for the use of plates in the surgical management of single-level cervical disk disease and spondylosis [1]. The anterior cervical discectomy with single-level fusion with or without internal fixation has achieved fusion rates of 90% and more. However, more recent studies suggest a statistically significant advantage with the use of plates [2].

Nevertheless, the use of metallic materials for fusion is not without risks and short and long term complications may develop. These include migration, failure, adjacent tissue damage and "stress shielding" [3]. Another disadvantage is the appearance of artifact in neuroimaging [4].

Recently, new resorbable materials that eliminate some of the disadvantages and complications of the metal plates have been proposed for the anterior cervical fusion. These biomaterials have been shown to provide adequate stability in the short and medium term with stable bone regeneration and arthrodesis followed by a gradual degradation of the material [5].

Of all types of bioabsorbable compounds, attention has been given to the (alpha)-hydroxy esters. Within this family, lactic and glycolic acids have been widely used in surgical applications, and they have shown complete degradation at specific times in living tissues [6].

Recent studies have shown that lactic acid copolymers decrease the occurrence of adverse effects on the soft tissues [7]. However, some complications arising from the degradation of bioabsorbable

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materials include osteolysis, synovitis, aseptic venous tracts and foreign body granulomas. For the use of such materials, the patient must have a harmless liver function due to liver metabolism requiring enzymatic hydrolysis of these materials. Additionally, the patient must maintain optimum osteogenic function, so their use is not recommended in patients with bone disease.

The aim of our study was to evaluate the long-term clinical results of resorbable plates in ACDF patients.

2. Materials and methods

In total 17 patients with herniated cervical discs (13 single level and four double level) were operated by using ACDF technique with resorbable plates and screws [Inion S-1^{TM} Biodegradable Anterior Cervical Fusion System (Inion Oy, Tampere, Finland)] at the "Lozano Blesa" Clinical University Hospital of Zaragoza, Spain between 2006 and 2009. We performed a retrospective descriptive study to evaluate the long-term results of these patients.

2.1. Inclusion and exclusion criteria

All patients had, prior to surgical intervention, corresponding cervical myeloradicular symptoms with radiographic findings in magnetic resonance image (MRI) compatible with cervical spine degenerative disk disease not responding to conservative treatment (i.e., physical therapy, nonsteroidal anti-inflammatory drugs and/or opioids). One patient had numerous metal and chemical allergies. Patients with liver, kidney and bone diseases were excluded from the treatment with resorbable implants.

2.2. Surgical technique

All patients underwent ACDF through right Smith–Robinson approach [8]. Decompression was made including the opening of the posterior longitudinal vertebral ligament and the resection of osteophytes and/or the removal of disk/ligamentous intracanal fragments. Three types of structural interbody grafts were used: tricortical cadaveric iliac crest, poly-ether-ether-ketone (PEEK) and tricalcium phosphate grafts.

2.3. Bioabsorbable plate

The degradable plates and screws used are made out of copolymers of L-lactic acid and D,L-lactic acid in a 80/20 ratio. Once measured, the plate may be molded by dipping in water at 70 °C for proper fitting to the vertebral bodies. Although at first, plates and screws did not have radiopaque markers, all of them nowadays come with tantalum markers. The material maintains its physical properties for about 16 weeks. Then, it begins slowly its degradation over the next 3–4 years, so that the load is transferred gradually to the new tissue [9]. The resorbable plates and screws were offered by the company INION, with no conflicts of interest what so ever.

2.4. Clinical and radiographic evaluation

Clinical background, preoperative and postoperative symptoms, previous trauma, complications, radiographic fusion and condition of the prevertebral space (preoperative and postoperative) were analyzed. The postoperative clinical outcome was assessed using the Odom criteria (Table 1) [10]. Spinal fusion and prevertebral space (anterior edge of vertebral body–posterior esophageal wall) were evaluated from CT and MRI images to assess soft tissue inflammation.

Table 1
The Odom criteria.

Outcome	Criteria
Excellent (I)	All preoperative symptoms relieved; abnormal findings improved
Good (II)	Minimal persistence of preoperative symptoms; abnormal findings unchanged or improved
Fair (III)	Definite relief of some preoperative symptoms; other symptoms unchanged or slightly improved
Poor (IV)	Symptoms and signs unchanged or exacerbated

3. Results

We performed a 5–7 years follow-up after surgery. Out of the 17 patients, 10 were women and seven men, and their mean age was 45 years (range 30–58). A single-level ACDF was carried out in 13 patients and a double-level procedure in four patients, and the most commonly fused level was C5–C6 (Table 2).

Regarding the patients' background, we found seven smokers, three obese, five patients with history of previous trauma, one patient with antiplatelet therapy, one with numerous metal and chemical allergies, and in addition some of the patients had dyslipidemia, hypertension and cancer. Patients remained in the hospital between 2 and 8 days until discharge (76% 3 days or less).

Complete fusion was achieved in 100% of the cases (Figs. 1 and 2A and B). No patient had to be reoperated on the same level because of extrusion, breach or failure of the material implanted. There were no incidences of postoperative hematoma, wound infection, osteomyelitis or recurrent laryngeal paresis in our series. No patient reported fever, chills or itching. The one patient who had numerous metal and chemical allergies presented with dysphagia that lasted nearly a year after the surgery.

The measurement of the prevertebral soft tissue space revealed values of 13.1 mm (on average) immediately postoperatively and 12.8 mm 1 year after the surgery (Fig. 3).

Two cases developed adjacent level disease (11.7%) in more than 60 months, and only one of these had to be operated (at the level below the initially fused segment). No material-related inflammation was found in our study (Fig. 4).

The symptoms of all patients improved postoperatively. Their results were rated as I and II using the Odom scale except for one patient who was rated as III. This patient had a double-level ACDF, previous trauma and a psychiatric history.

The first double-level ACDF patient was operated using a resorbable distal radius plate (made out of the same material as the ACDF plates used in the other patients of this study) in the absence of a two-level cervical resorbable plate because the patient was allergic to metals.

4. Discussion

The bioabsorbable materials have gained popularity in many surgical procedures, including recently spinal surgery. Although this technology is just beginning to be available for spinal surgery, it has been used and tested extensively in the maxillofacial and orthopedic applications [11]. Before bioabsorbable implants can compete with currently used metal products, their safety and efficacy must be tested in clinical studies to prove achievement of similar fusion rates without increased risk of complications [12].

The bioabsorbable implants allow gradual distribution and transfer of loads to the surrounding tissues minimizing the risk of stress shielding during the early stages of fusion (allowing correct fusion between the graft and fixed bodies) prior to the process of degradation of the plates and screws. The implants degrade by hydrolysis and are metabolized into water and carbon dioxide. Within 6 months after implantation, the construct still maintains