

Study of the Role of Nova Bone as a Filling Material in Cervical Cage in Anterior Fusion of Cervical Spine in Patients with Degenerative Cervical Disc Disease

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Abstract

Objectives: There are several reports about the therapeutic effects of cervical interbody cages for cervical degenerative disorders. Few have addressed the role of the filling material in fusion and improving the clinical symptoms. This study tries to study the effects of Novabone as a filling material in Solis cages in patients with cervical disc protrusions. The results have been compared with the results from studies that used autografts to fill the cage.

Material & Methods: This study includes patients treated surgically from 2003 to 2007 for cervical discopathy with anterior fusion technique. We used Solis cage filled with Novabone mixed with autologous bone fragments. The results for fusion and improvement in axial and radicular pain have been determined and compared with the results of other studies. Also the complications and radiologic findings have been reviewed.

Results: 33 patients were operated on from 2003-2007, anteriorly using Solis cages filled with Novabone. 19 were men (57.6%) and 14 women (42.4%). The average age was 47.1 y. 23 patients (69.7%) have been operated on one level and 10 patients (30.3%) were operated on more than one level. 44 cages were inserted. Mean follow up period was 14.3 months. After one year the fusion rate was 91.3% at one level and 80% in patients with more than one level and 87.8% overall.

Conclusion: According to our study, the fusion rate with Novabone and autologous bone filled cages were lower than that achieved in series using autologous bone but it reached the same rate later. It is highly recommended that the cervical cages be filled with autologous bone or Novabone mixed with patients bone chips.

Keywords: Cervical, Cage, Fusion, Novabone, Autologous, Bone

1. Introduction

The use of interbody cages has been popularized in cervical spondylosis (Schroder J, 2006). The cage consumes the pressure on the segment (Banwart JC, 1995) increases the stability of the motion segment (Kanayama, 2003), increases and maintains the height of the foramen (Xia L, 2006; Lu KW, 2006), restores the cervical lordosis (Lu KW, 2006), and also removes the necessity of iliac crest bone harvest and its complications (Xia L, 2006). Several studies have addressed the timing and amount of fusion in anterior cervical approach using interbody cages and comparing the results with fusion achieved with autografts without cage (Schroder J, 2006; Xia L, 2006; Chen JF, 2006). The effect of the filling material has not been studied extensively. The published articles either include cages filled purely with autograft (Schroder J, 2006; Slivka MA, 2006; Pascal-Moussellard H, 2006; Sekerci Z, 2006; Schmieder K, 2006; Ausman JI., 2006) or cages filled synthetic materials including hydroxyapatite (Hacker RJ, 2000; Mooney V, 1998; Kanayama, 2003), recombinant bone morphogenic protein (Gu YT, 2006; Wang W, 2006) and Triosite (biphasic calcium phosphate ceramic) (Cho DY, 2005).

Using several search engines such as Pubmed, Alta Vista, Google and Medline up to the January 2009, we did not find an article mentioning the fusion rate results in anterior cervical fusion with Solis cages filled with Novabone mixed with autologous bone.

Novabone or bioactive glass is a completely synthetic material which is able to induce new bone formation and consists of Na, Ca, P, and oxygen (Folletto Novabone Oonishi H, 1997). Inorganic combination of P and Ca has been included in a matrix of sodium silicate using heat. It is gradually absorbed in the body and is replaced with the new bone synthesized by the host tissue.

Our study benefits from the point that the patients had only disc protrusion without other abnormalities and the fact that all the cases were operated by a single surgical team. In all of them the Solis cage from Stryker made of PEEK (polyether ethyl ketone). In all cases the cage was filled with Novabone mixed with patients bone chips obtained during discectomy and removal of osteophytes and also the results are based on a relatively reasonable follow up period (at least one year).

2. Material and Methods

Patients were operated between Jan 2003 and Dec 2007. The patients aged 18-70 years. The patients had clinical evidence of degenerative disorder in cervical spine in one or more levels (radiculopathy or myelopathy) unresponsive to medical therapy including anti-inflammatory drugs, brace and physical therapy for at least three months. Indications for surgery included progressive cervical pain, radicular pain, decreasing motor force or sensory impairment. The imaging evidence concordant with the clinical findings such as pressure effect on the cord or nerve roots, signal change in cervical cord in T2 MRI and decreased disc height in x-ray studies.

Patients with underlying neuromuscular disorders, metabolic bone disease such as osteoporosis or osteomalacia or rheumatoid disorders, evidence of trauma or mechanical instability (more than 3 mm displacement in dynamic studies or more than 11 degrees kyphosis) or serious systemic problems rendering surgery a high risk procedure was excluded from our study. All the patients were operated under general anesthesia from the right side using microscope. With the use of micro drill the compressing disc material and osteophytes were removed (NBI Wheeler DL, 1998). Then the cage with proper size was selected and tried and after that was filled with Novabone mixed with the bone chips gathered from the operative site and placed in its final position. In all cases the Solis (Stryker Company) was used. After the operation our patients used a rigid collar for 3 months.

Demographic and clinical data were gathered both pre and postoperatively including: age sex, symptom duration, presenting symptom: (axial pain, radicular pain, sensory or motor deficit), clinical syndromes such as radiculopathy or myelopathy, number and the level of fusion and finally the fusion rate and improvement in signs and symptoms after surgery. In each monthly follow up patients underwent dynamic studies.

The fusion criteria were as follows: absence of lucency around the cage, less than 3mm mobility in dynamic studies, normal sagittal alignment and absence of migration or subsidence in radiographic studies (Kanayama, 2003). If the patients complaints remained or worsened MR studies were also included.

3. Results

From Jan 2003 to Dec 2007, 33 patients with cervical disc herniation underwent anterior cervical micro-discectomy and fusion (ACDF) using Solis cage filled with Novabone and autologous graft. 19 cases (57.6%) were male and 14 patients were female (42.4%). The mean age of our patients was $47.1 \text{ y} \pm 11.3 \text{ y}$. The youngest patient was 28 and the oldest case was 69 years old. The average duration of the symptoms was $49.9 \pm$

40.7 months. (range = 0.5 -120 mo) (table 1)

All of our patients complained of cervical pain and 31 patients (93.9 %) complained of radicular pain. On physical examination, 15 cases (45.5%) had radiculopathy, 3 patients (9.1%) had myelopathy and 14 cases (42.4%) had combined radiculomyelopathy. One of the patients presented with progressive cervical pain without evidence of radiculomyelopathy. In 23 patients (69.7 %) ACDF performed at one level, in 9 cases (27.3 %) at 2 levels, and in one patient (3.03%) at 3 levels. Total number of the cages was 44 in 33 patients.

The most common site of herniation was C5-C6 interspace, which occurred in 22 cases (50 %). C6-C7 discectomy performed in 16 cases (36.4%), C4-C5 discectomy in 4 cases (9.1%) and C3-C4 discectomy in 2 patients (4.5%).

The mean follow-up period was 14.3 ± 5.5 months. (range= 12-35 mo) The mean number of follow-up visits was 4 times. (range = 3-11)

In each follow-up visit, the outcome was assessed considering improvement of axial and radicular pain and radiographic fusion. The summary of the results in 6 months intervals are classified in table 2.

In 4 of our patients (12.1%) the radicular pain decreased but not eliminated. In all of the cases with retained radicular or axial pain, cervical MRI was performed and no one showed cord of nerve root compression. In all of these patients, the symptoms were relieved by medical treatment using Gabapentin, steroid and physiotherapy.

In each follow-up visit, cervical radiography performed and in all of the patients, the locations of the cages were unremarkable without any evidence of displacement, migration or subsidence.

Four patients (12.1%) had hoarseness after the surgery, but in all cases, this complication was transient and resolved completely.

Superficial wound infection occurred in 1 case (3.0 %) which responded successfully to oral antibiotics.

4. Discussion

The problems related to iliac crest bone harvest have been recognized for a long time. (Schmieder K, 2006; Hacker RJ, 2000; Nakase H, 2006) They had also been recognized in ACDF surgery. It is obvious that these problems are avoided when interbody cages are used for fusion. In our study, the PEEK cage filled with Novabone mixed with autologous graft acquired from removed osteophytes was used, therefore we did not encounter any problem associated with iliac crest bone harvest such as pelvic pain, pelvic fracture, incisural pain, hematoma, infection and clavicular nerve injury. We did not see cage subsidence or intervertebral collapse in any of our patients. Hacker has reported this complication in 4.2% of his ACDF patients (Hacker RJ, 2000). Other studies have reported the incidence of cage subsidence in up to 56% of cases. (Kao, 2005) In Bartel study, using cervical cage filled with autograft, the rate of subsidence was up to 29.2%. (Bartels, 2006) Kao encountered this problem in 19%. (Kao, 2005) Barsa and his colleagues also reported this complication in 19 % of their cases. (Barsa P, 2007) In a prospective study Hacker used two different cages filled with autologous bone graft and reported no case of subsidence in his patients. It seems that selection of an appropriate cage and choosing the proper size with applying the proper technique (such as avoiding over distraction during insertion of the cage) plays a key role to avoid this complication. It appears that the type of the cage and fusion material are not so important in this regard. (Bartels, 2006; Barsa P, 2007)

In our patients, the fusion rate was 91.3% in one level and 80% in two or more levels and in 87.8% overall. In Campbell and Wilson study using iliac bone the fusion rate was 85%. (Wilson DH, 1977) Martin and his colleagues used iliac bone graft in their ACDF patients and after 10 months follow-up, the rate of fusion was 92%. (Martins AN, 1976) Hacker reported that after ACDF in one level, the fusion rate 98.5% after 6 months and 97.9% after one year. In their study, the fusion rate in multiple levels was 76.2% after 6 months and 80.4% after one year. (Hacker RJ, 2000)

Kulkarni reported that with the use of Solis cage filled with autograft, the rate of fusion after 6 months was 93.3%. (30%)

Shroder used titanium cage filled with autograft and his reported fusion rate was 87%. (Schroder J, 2006)

Hacker after ACDF at one level with the use of cages filled with autograft reported that the fusion rate after 6 months was 99.1% and after 12 months was 97.1%. He also reported that, for multilevel fusion, this rate was 69.7 % and 72.7%, after 6 and 12 months respectively. (Hacker RJ, 2000) In comparison, our patients showed lower fusion rate after 6 months relative to Hacker's patients. (Hacker RJ, 2000) (table 2)

After 12 months, the rate of fusion in our patients was similar to Hacher's. (Hacker RJ, 2000)

Considering the similarity of our patients (table 1) to Hacher's (Hacker RJ, 2000), fusion was achieved slower in Novabone filled cages, but the success rate was nearly equal after 12 months. Despite the absence of factors such as osteoporosis, metabolic or infectious disorders in our patients, the slower fusion rate in our patients, might be due to the cage or filling material. (PEEK versus BAK/C or HA-BAK/C in Hacker's). The previous reports have not shown a difference in fusion rate related to cage type. (Yang P, 2006; Slivka MA, 2006; Gu YT, 2006)

Matge studied 250 patients in whom 5 different cage types were applied. In all of his cases, the cages were filled with autograft. He did not mention any significant difference in fusion rate. (Matge G., 2002) Hacker applied two different types of cages and the results were similar after one year. (Hacker RJ, 2000) It seems that the lower fusion rate in our patients relative to other series may be due to the filling material. Previous studies have shown that the ideal graft material should be osteogenic, osteoinductive and osteoconductive. (Stevenson S., 1999) The autologous spongy bone has these three characteristics and is considered an ideal graft. (Chase SW, 1995)

Novabone has both the osteoinductive and osteoconductive properties, but as it is a synthetic material, it lacks osteoblasts and osteogenic properties. So, it seems that with the use of Novabone, fusion occurs slower than autograft.

In our study, after 12 months, complete relief from axial cervical pain was achieved in 78.8% of the cases. In Young series, complete relief from axial pain with the use of iliac bone graft was 76.3% and 81.9% with Solis cage filled with autograft. (Yang P, 2006)

Matge reported that the rate of axial pain relief was 81.9%. (Matge G., 2002) It seems that in our study, the lower success in relief of axial pain is concordant with slower fusion rate. After ACDF in our patients, radicular pain was improved in 87.8% of the cases. In 4 of our cases, the radicular pain was not improved completely, so MRI of the cervical spine performed showed no neural compression. The improvement of radicular pain in Matge's series was 97 % (Matge G., 2002). It seems that persistence of radicular pain in these patients had a neuropathic origin due to long standing compression effects of disc protrusions and osteophytes. The good response of these patients to tricyclic antidepressants and Gabapentin is in favor of this hypothesis. (Hacker RJ, 2000; Matge G., 2002)

We advocate the use of the operative microscope in all of the cases and complete removal of the posterior longitudinal ligament and complete decompression neural foramina to achieve better results in patients with radicular pain. Our research is a case series study and to obtain more reliable results, multicentric randomized clinical trials are necessary.

5. Conclusions

Our study advocates the use of bone chips obtained from removal of osteophytes and end plates or foraminal structures to mix with Novabone to fill the cage in ACDF surgeries. We think that, the osteophytes in these fragments add the osteogenic properties to the filling material and help improve the fusion results.

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Table 1. The mean and standard deviation of age and duration of illness of the patients according to one level or multilevel ACDF surgery

| Variable | ONE LEVEL | | MULTI-LEVEL | |
|---------------|-----------|------|-------------|------|
| | SD | Mean | SD | Mean |
| Age(y) | 11.5 | 46.5 | 39.8 | 51.3 |
| Duration (mo) | 11.2 | 48.2 | 44.6 | 44.7 |

Table 2. Therapeutic results of in one level and multilevel cervical fusion using Novabone mixed with autologus graft in Mehrad Hospital according to the duration of follow-up

| Follow-Up duration | ≤ 1 mo | | 1-6 mo | | ≥ 6 mo | |
|--------------------|-------------|--------------|-----------|-------------|-------------|--------------|
| | One Level | Multi- Level | One Level | Multi-Level | One Level | Multi- Level |
| Pain improvement | 43.5% | 60% | 73.9% | 80% | 78.3% | 80% |
| Fusion | 47.5% | 40% | 78.3% | 70% | 91.3% | 80% |