The Fernstrom ball revisited

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Abstract

Introduction In 1959, Harmon was the first to implant a vitallium sphere into the intervertebral disc space in order to preserve mobility and maintain disc height in patients with back pain secondary to degenerative disc disease. Fernstrom reported good results after implantation of stainless steel spheres. However, a reduction in disc height frequently occurred secondary to sphere subsidence into the endplates. This often led to revision surgery, and the concept was abandoned.

Materials and methods We report on four patients who underwent cobalt–chrome sphere implantation, and later presented to us with symptoms that were a direct result of sphere subsidence. All four patients presented with low back pain and/or lower extremity pain, and some with weakness. Imaging demonstrated that all patients had a loss of disc space height with sphere subsidence. Three patients underwent sphere removal, anterior interbody fusion using femoral ring allograft and posterior pedicle or facet screw fixation. In the fourth patient, the sphere was subsided into both the L5 and S1 endplates prohibiting removal. The patient underwent a posterior L5–S1 posterolateral fusion and facet screw fixation. The length of time from sphere implantation to the revision surgery ranges from 8 to 41 months.

Results Ten months to 3 years after the revision surgery, all four patients reported an improvement in outcome.

Conclusion To the best of our knowledge, this is the first report describing the complications resulting from cobalt chrome sphere implantation and revision strategies for managing the recently resurrected cobalt chrome sphere.

Keywords Fernstrom ball · Degenerative disc disease · Complication · Revision surgery

Introduction

The intervertebral disc (IVD) is an integral part of the functional spinal unit (FSU). The IVD modulates motion, and determines the quality and quantity of motion. It allows for flexion and extension in the sagittal and coronal planes, rotation in the horizontal plane, and limits translation. The centre of the IVD is composed of a viscoelastic nucleus pulposus that acts as a dashpot which dampens, absorbs, and redistributes loads to the surrounding annulus fibrosus and the endplates.

The hallmark of IVD degeneration is proteoglycan depletion within the nucleus [1]. As the IVD degenerates, pathologic joint biomechanics ensue along with changes in IVD innervation [2, 3]. These events are thought to contribute to altered quality and quantity of motion, and subsequent discogenic low back pain.

Surgical solutions to persistent debilitating low back pain include fusion and more recently, disc replacement. Both of these options are associated with a success rate between 55 and 65%, as defined by improvement of or greater than 15 points on the Oswestry disability index [4]. These results have led clinicians to seek other technologies that would result in better outcomes and higher patient satisfaction. One device patterned after the historic “Fernstrom Ball”, which was recently resurrected, is a cobalt–chromium–molybdenum sphere, which was granted

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humanitarian use exemptions by the FDA in 2005 (Satellite Spinal System Medtronic Sofamor Danek, Memphis). This sphere was to be implanted between vertebral bodies from L3–S1 to help promote “intervertebral body fusion”. The device was intended for and designed to hold the vertebral bodies separated, and in proper alignment. According to the FDA label, the device was intended to be used with bone graft, bone substitute, or other osteobiologic. The device was to be used in the setting of discogenic back pain that has failed conservative treatment. The implant was considered to be used in an “off label” fashion if used for motion preservation (without bone graft). As a result of adverse outcomes in a number of treated patients, the cobalt–chromium–molybdenum sphere was removed from the US market in December 2007.

The purpose of this report is to present a single surgeon’s experience in treating patients who had undergone surgery using the cobalt–chromium–molybdenum sphere. The outcome of the index procedure and the revision strategy will likewise be discussed.

Methods

Between 2007 and 2009, four patients (three male and one female) who were treated by surgeons in the community with a cobalt–chromium–molybdenum sphere presented to the senior author (IHL), for evaluation of persistent debilitating mechanical or radicular symptoms. The time from cobalt–chromium–molybdenum sphere implantation to initial evaluation ranged from 6 months to 4 years. Information regarding duration and type of symptoms (back and/or radicular pain, neurogenic claudication), findings on neurological examination and evidence of fusion were recorded. All patients were evaluated with a combination of lumbar radiographs, CT scans, and MRI. All patients were determined to be candidates for revision and after review of the risks benefits, and alternatives to various treatment options they elected to undergo the prescribed revision. Follow-up was conducted via telephone interview and mail questionnaires.

Institutional Review Board approval was obtained prior to conducting this chart review.

Results

Median age at the time of surgery was 49 years (range 40–58 years). All patients were suffering from a combination of mechanical back pain and/or radicular leg pain resulting in limitations in daily function. The median duration of symptoms prior to revision surgery was 24 months (range 6–39 months). Follow-up ranged from

10 to 33 months. A summary of the four cases is shown in Table 1. Prior to revision all patients were unresponsive to, and had exhausted non-operative treatment modalities which included physical therapy, injection therapy, and administration of non-steroidal anti-inflammatory drugs.

Example case #1

A 46-year male presented with low back pain and bilateral lower extremity pain, and with X-ray evidence of a L4/L5 intervertebral metallic sphere partially subsided into the L4 vertebral body. In addition to the bilateral lower extremity pain, the patient was found to have generalized weakness in the left lower extremity. The patient reported that he underwent implantation of the sphere in February 2007 for chief complaint of low back pain. Since the sphere was partially subsided, and the patient had evidence of foraminal stenosis secondary to loss of disc height (Fig. 1), a decision was made to remove the sphere and perform an interbody fusion with femoral ring allograft. To avoid anterior approach related morbidity, and allow direct access to the sphere for removal, a straight lateral transpsoas approach was used. The use of a femoral ring allograft would allow for indirect foraminal decompression in addition to provide a large surface area for fusion. Intraoperatively, the sphere was found to be subsided into the L4 vertebral body. In order to remove the sphere, a partial osteotomy of the L4 vertebral body was required. The level was reconstructed with a femoral ring allograft and morcelized cancellous allograft, soaked in the patient’s bone marrow aspirate, followed by posterior spinal instrumentation (Fig. 2). Thirty months after the revision surgery, the patient reported that his symptoms improved.

Example case #2

A 38-year-old female presented with low back pain. There was no lower extremity pain. The patient had X-ray evidence of L5/S1 intervertebral metallic sphere, which was subsided into both the L5 and S1 vertebral bodies. The patient reported that she underwent implantation of the sphere in November 2006 for chief complaint of leg pain due to herniated disc. Since the sphere had subsided in both the L5 and S1 endplates, it would have been difficult to remove. This finding combined with the potential morbidity of the anterior-retroperitoneal approach, resulted in a decision to perform a less invasive instrumented facet and posterolateral fusion at L5/S1 using facet screw fixation (Fig. 3). The patient was informed that if this approach did not result in a desired outcome, then an anterior lumbar interbody fusion with sphere removal and femoral ring allograft reconstruction could be carried out at a future date. At her 10 months follow-up, the patient reported that her symptoms improved.

Table 1 Overview of the four cases

Case #	1	2	3	4
Age	46	38	56	51
Sex	M	F	M	M
Symptoms	LBP + LP	LBP	LBP + LP	LBP
Level	L4/L5	L5/S1	L4/L5	L4/L5
Imaging findings	L5/S1 endstage degeneration, L4/L5 sphere subsidence	Endplate sclerosis with progressive collapse around sphere	L4/L5 degeneration, disc herniation, lateral recess, foraminal stenosis, sphere subsidence	L4/L5 degeneration, L4/L5 sphere subsidence
Motor deficit	General weakness	No	General weakness	No
Sensory deficit	L5/S1	No	No	No
Reflex deficit	Yes	No	No	No
Fernstrom ball implantation date	Feb 2007	Nov 2006	Nov 2007	Nov 2005
Revision surgery date	Oct 2008	Aug 2008	Jul 2008	Apr 2009
Revision surgery type	Sphere removed. Anterior interbody discectomy, femoral ring allograft. Posterior L4/5 facet screw fixation	Sphere not removed. L5–S1 posterolateral fusion with cancellous allograft bone. L5/S1 facet screw fixation	Sphere removed. Anterior interbody L4/5 fusion using femoral ring allograft. Posterior L4/5 percutaneous pedicle screw fixation	Sphere removed. Anterior interbody fusion with femoral ring allograft. Posterior L4/5 facet screw fixation
Interval between two surgeries (months)	20	21	8	41
Follow-up time (months post revision)	30	10	33	24

LBP low back pain, *LP* lower extremity pain

Fig. 1 Lateral radiograph of a 46-year-old patient who underwent L4–L5 interbody implantation of a cobalt chrome metallic sphere. The metallic sphere can be seen subsiding into the endplate of L4

Discussion

This report outlines a single surgeon's experience with revision surgeries performed in four patients who originally had a cobalt–chromium–molybdenum sphere implanted to alleviate their low back pain and/or leg pain, and facilitate spine motion and biomechanics. This technology was

Fig. 3 **a** Pre-operative lateral X-ray of a 38-year-old female who underwent L5–S1 cobalt chrome sphere implantation at an outside hospital and presented to our institution 21 months later with significant low back pain. The sphere is subsided into both the L5 and S1 endplate prohibiting removal. **b** Post-operative lateral X-ray. The patient underwent a postero-lateral fusion with facet instrumentation

presented as a new alternative to fusion or contemporary total disc arthroplasty, despite the pre-existing history of implanting metallic spheres into the intervertebral space, which dates back to the 1950s.

In 1955, David Cleveland injected methyl-acrylic into the intervertebral disc space of a patient who underwent an open discectomy. In 1957, a similar procedure was performed by Hamby who reported his results at the meeting of the American Association of Neurosurgeons. In 1959, Harmon used a retroperitoneal approach to implant vitallium spheres

Fig. 2 **a** Lateral intra-operative X-ray demonstrating anterior interbody fusion with allograft at L4–L5 with posterior L4–L5 facet instrumentation. **b** The cobalt chrome metallic sphere after removal

into the intervertebral disc space [5]. Most of these attempts ended up in failure, regardless of the type of method of implantation or implant material used. The principal reason for these failures was the lack of understanding of spinal biomechanics by the early practitioners.

Historically, the concept of using an implant that maintains stable motion and preserves disc height proved difficult to resist. Fernstrom began implanting a spherical stainless steel prosthesis supplied by the Swedish Ball Bearing Factory. He implanted this metal prosthesis in 191 lumbar and 13 cervical discs in 125 patients, and in 1966 published his results [6]. He concluded that by using this metal prosthesis, he was able to match the clinical outcomes of a fusion procedure. However, a modulus mismatch between the vertebral body and Fernstrom's device led to significant subsidence. In addition, the implant was associated with loosening and extrusion, which eventually led to abandoning its use clinically. Reitz and Joubert also reported the use of the Fernstrom ball in the cervical spine for the treatment of cervical headache, with no long term follow-up reported [7].

Most recently, the cobalt–chromium–molybdenum sphere (Satellite Spinal System, Medtronic Sofamor Danek) was introduced to the US market. The device was approved by the FDA in 2005 for the surgical treatment of symptomatic discogenic back pain. It was subsequently taken off the market in 2007 due to poor clinical performance. According to company information, the sphere was intended to be inserted in the intervertebral space from L3–S1 to help provide stabilization (and to help promote intervertebral body fusion) in conjunction with the use of bone graft, bone substitute, or other osteobiologic. Its use without bone graft material was considered to be “off label”. In all the cases presented here, the device was used as a stand-alone device. We suspect that the cobalt–chromium–molybdenum sphere, implanted in a stand-alone fashion, was meant to function as a motion preserving implant. For this implant to function in a motion preserving manner, several biomechanical principles would have had to been met. The natural disc provides flexion and extension, lateral bending, rotation and compression. It is also viscoelastic, where the stiffness varies with the loading rate and magnitude [8]. For the Satellite spinal system to replicate this motion, the sphere would have to be perfectly located at instantaneous axis of rotation. Since the spheres are metal, they do not have the capability to deform, and therefore, they cannot replicate the function of the nucleus and spread the load evenly throughout the vertebral endplate. In addition to their rigidity, the spheres have a small footprint on the endplate. This coupled with their inability to distribute load evenly, resulted in point contact and subsidence into the endplate. Placing the sphere outside the instantaneous axis of rotation resulted in migration. Since

all spinal motion are coupled, these events happened simultaneously setting up the construct for biomechanical failure. This was confirmed during revision surgery, the small metal spheres were frequently subsided into the much softer endplates, making their removal challenging.

In this case series, all four patients reported subjective improvement in their initial symptoms after their revision surgery at the latest follow-up. Two patients also demonstrated improvement in their ODI at 2 and 3 years follow-up, respectively. Their ODI scores were still in the 40s, demonstrating moderate disability. Ideally, we would have preferred to compare the final outcome to that obtained during the initial presentation to the original treating surgeon, however, these data were not available for comparison.

As a result of this experience we advocate, whenever it is technically feasible, revision strategies for symptomatic patients should include sphere removal. We feel that sphere removal followed by an interbody fusion results in higher rates of union, restoration of lordosis, and indirect decompression of the foramina. This can be accomplished by either an anterior, lateral, or posterior approach, depending on the location of the subsided cobalt chrome sphere. In this series we did not encounter any issues removing the sphere and performing an anterior interbody fusion using the straight lateral transposas splitting approach. If it is not possible to remove the sphere, a posterior instrumented fusion is the treatment of choice.

Conclusion

Implanting metallic spheres into the intervertebral space in the surgical management discogenic back pain has been shown to result in high rates of failure. It is not possible to mimic the biomechanics of a nucleus and annulus with a rigid metallic device. Patients who were treated with intervertebral metallic spheres demonstrated sphere subsidence and clinical failure. Sphere removal followed by revision surgery consisting of instrumented interbody fusion results in pain reduction and patient satisfaction.

Conflict of interest None.

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