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CURVE/COUNTERCURVE

Cervical Disc Replacement vs ACDF

Case Presentation

A 26-year-old female graduate student working in a laboratory has developed a right-sided radicular pain in the C6 distribution with pain, numbness and paresthesia going down to her right thumb and first finger. She is otherwise healthy, very active, has no significant medical problems and has had no prior problems with her neck. She has failed six weeks of conservative care consisting of rest, physical therapy, oral steroids and anti-inflammatory medications. On physical exam, she has decreased sensation in the C6 distribution on the right side with weakness of her biceps and wrist extensors.

Magnetic resonance imaging (MRI) demonstrates a right-sided C5-6 herniated disc with compression of the lateral recess and nerve root. There is no compression on the spinal cord and no cord signal changes. The disc is midline and right-sided. The remaining discs look fine, except for some decreased signal and darkening of the C6-7 disc.

She had one epidural injection that gave her three days of complete relief of her arm symptoms, but the symptoms have now returned. She has no neck pain at all and has not been able to work or participate in recreational activities. She is interested in a surgical solution to alleviate her pain and allow her to resume her normal activities. She has heard a lot about disc arthroplasty and has performed extensive research on the internet and is wondering if she is a candidate.

What would you recommend?

Michael E. Janssen, DO, Responds

Cervical radiculopathy is one of the most frequently treated spinal conditions in the cervical spine. A decompression and cervical interbody arthrodesis has been the standard of treatment for the past 50 years. Only recently have clinicians begun to focus on the long-term mechanical effects of arthrodesis. This motion loss in the cervical spine does have some consequences, and patients often suffer from stiffness, functional limitations and degeneration of adjacent mobile discs. Currently, the demand from both the clinicians and society for a better solution in the treatment of symptomatic cervical radiculopathy beyond arthrodesis is universally increasing.

A 26-year old graduate student diagnosed with C6 radiculopathy has failed reasonable non-surgical options. A surgical decompression of the C6 nerve is the standard method of treatment for her condition. The surgical dilemma for this specific patient is the ideal reconstruction of the C5-6 interspace following decompression and total disc excision. The primary goal to treat this young woman's symptoms would be a surgical modality that offers precise decompression, preserved motion, retained disc space height, minimization of the incidence of adjacent level disease and rapid recovery.

Indeed this patient's symptomatic neural compression can be successfully addressed with a surgical decompression. One of the primary problems with offering this woman an arthrodesis is that it is a one-way, permanent procedure that results in loss of motion, prolonged recovery, and mechanical changes at the adjacent levels of her cervical spine. There is clear evidence that the

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historic treatment that Dr. Hilibrand is advocating (see next page) will increase the stress on the non-operated discs and therefore, adversely impact the rate of adjacent disc degeneration.[1-4] Cervical arthrodesis alters the normal disc structure, function and can result in long term complications related to the biomechanical changes. There is also the concern that cervical interbody fusion will result in accelerated degenerative changes occurring at the adjacent spinal levels, which may be a result of the disease as well as the mechanical effects of the fusion treatment.

In the past few years, spinal arthroplasty has become a logical alternative in the treatment of symptomatic disc disease in the cervical spine. The clear advantage of arthroplasty is its ability to restore and maintain the motion segmental anatomy and function, while successfully treating the patient's radicular symptoms. A cervical arthroplasty demonstrates reduced stresses in the adjacent annulus compared with motion segments stabilized with a fusion.[5] [AUTHOR: reference to annulus in previous sentence is to adjacent disc?} Cervical arthroplasty will further prevent or delay the degenerative changes (secondary to the mechanical effects of the fusion) that commonly occur at the adjacent level.

The basis for arthroplasty is dependent on the altered mechanical forces being the key factor promoting the accelerated degenerative changes. The anterior annulus of the adjacent levels has been demonstrated to show a reduction of stresses during dynamic flexion compared to arthrodesis.[5] Therefore, the majority of disc implant designs are constructed based on modern total joint replacement principles and materials that have demonstrated a successful history of clinical use (knee, shoulder and hip).

The current designs are expected to withstand maximum expected loads in torsion, tension, bending and compression for both single and repetitive events. The accepted wear rates in hip and knee arthroplasty range from 35 to 120 mg/mil cycles; this compares to the anticipated lumbar arthroplasty wear rates of 5 mg/mil and less than 1mg/mil in the cervical spine.

The rationale for consideration of cervical arthroplasty for this young patient with a single level radiculopathy includes: pain relief, decompression, avoidance of the mechanical adjacent segmental degeneration, retention of segmental range of motion, preservation of disc space height, decreased surgical morbidity and early return to function. Arthroplasty would allow normal motion in the adjacent segments and would provide solid axial load-bearing support in the cervical spine. Additionally, it has the potential benefit of restoring the joint mechanics, alignment and foraminal height, thus reducing pain and improving function with limited recovery. Therefore, the advantages of arthroplasty (preserved motion, improved clinical outcome, decreased load on adjacent segments) clearly outweigh the potential disadvantages (wear debris, revision, and failure).

Compared to the medical advances in knee and hip arthroplasty, the progress in the last 30 years has been slow for the development of spinal disc replacements. Although significant research has been conducted and knowledge has been accumulated, there has yet to be a specific cervical disc implant available in the United States for routine usage. Despite extensive research, engineering, and preclinical testing, the ultimate safety and efficacy in spine arthroplasty can only be determined by performing clinical studies. Strict regulations and the unfortunate litigious environment of the United States creating increased costs have retarded the development of this technology and its ability to treat many patients.

Currently three devices have completed Investigational Device Exemptions (IDE) for patient enrollment in the US: Prodisc-C (Synthes), Prestige and Bryan (Medtronic). The objective of these clinical trials is to clinically compare prospective, randomized preliminary results of patients with subaxial cervical radiculopathy who are treated with either anterior cervical decompression fusion (ACDF) or cervical disc replacements. These multicenter studies are in different phases of completion in North America, and longer follow-up will be available soon. However, early results of artificial cervical disc reconstruction following decompression for radiculopathy are encouraging. Low morbidity combined with improved outcomes favor this as a treatment compared to historic arthrodesis.

It can be assumed that the indications for usage of disc arthroplasty will be similar to current interbody arthrodesis techniques. If cervical spine arthroplasty produces clear benefits, similar clinical outcomes and acceptable risks, it will be an ideal adjunctive device to replace segmental arthrodesis following decompression in the management of symptomatic cervical radiculopathy. The acceptance of arthroplasty to replace techniques of cervical arthrodesis in disc disease will require a thorough analysis of the cost/benefit and risk/benefit assessment. Patient safety, efficacy and value compared to current fusion techniques will need to be similar with this new and exciting technology.

We are at the beginning of another period of technology explosion in the field of spine surgery. There are many obstacles to overcome, but the clinical need is compelling and the potential for cervical spine arthroplasty is great. Progress in implant development, the acceptance of cervical approaches, as well as the result of lumbar arthroplasty procedures have initiated willingness for scientific discussion and clinical acceptance of new ideas and technology in cervical disc replacements. It is, therefore reasonable to apply this advancing technology to the spine pathologies and create a new gold standard that allows our patients to preserve motion and function with symptomatic degenerative diseases.

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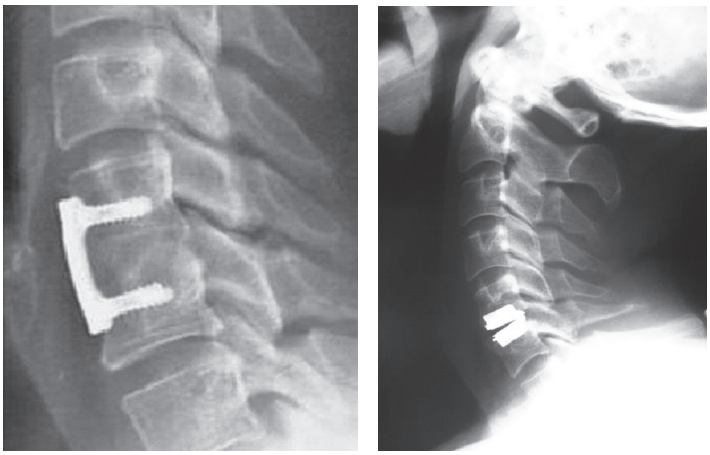

Left: anterior cervical discectomy with fusion (ACDF). Right: cervical disc arthroplasty.

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Additional Resources

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Alan Hilibrand, MD, Responds

This patient is a young woman who has a single level of pathology with a soft disc herniation at C5-6 compressing the right C6 nerve root. She has concordant symptoms and physical findings, and has failed appropriate nonsurgical intervention. Her pain is persistent to the point of limiting her ability to participate in normal daily activities. In summary, she is an appropriate candidate for surgical intervention, and perhaps she is in an optimal situation for cervical disc arthroplasty.

But wait a minute! Cervical disc arthroplasty remains an experimental procedure. Assuming that this patient would be an appropriate candidate for one of the current FDA trials, and assuming she went to one of the few spine surgeons in this country participating in those trials, we still must prove to ourselves and the patient that despite all of the excitement about total disc replacement, that this is in fact a better option for her than the current gold standard—anterior cervical discectomy with interbody grafting.

Few spine surgeons question the long history of successful treatment of cervical radiculopathy through anterior cervical discectomy and fusion (ACDF). Numerous authors have demonstrated that over 90% of such patients will see relief of their arm pain with this procedure.[1-3] More recent studies have demonstrated fusion rates approaching 100%, even with the use of allograft bone.[4] And, if the patient does develop a nonunion, isn't this another form of motion preservation? In fact, most such patients with nonunions do not need revision surgery.

On the other hand, there are the risks of adjacent segment disease to be considered. This has been observed in approximately 3% of patients in a retrospective long-term follow-up study, with a predicted prevalence at 10 years of approximately 25%.[6] It seems logical to assume that a total disc replacement would avoid this potential consequence of ACDF. However, there is little data in the literature at this time to support this theory. Biomechanical studies have demonstrated that after anterior cervical fusion, there are increased stresses and motion at adjacent levels that are not present following cervical disc replacement.[7] However, such studies do not incorporate the upper cervical region where most of the "lost" motion is probably accommodated. More importantly, there are no natural history studies yet available to demonstrate a difference between the likelihood of adjacent segment disease between ACDF, cervical disc arthroplasty and nonoperated yet symptomatic cervical spondylosis.

Some patients may be concerned with the concept of "losing motion" following a fusion of the cervical spine. However, our study looking at patients undergoing one- to four-level ACDF demonstrates that patients gained motion following ACDF.[8] This is most likely a function of both the elimination of the painful stimulus which limited motion prior to surgery, as well as the transfer of motion to the upper cervical spine, which is a much more flexible region, especially following four-level ACDF.

Further, there are certainly risks of cervical disc arthroplasty which must be considered in risk/benefit analysis that the surgeon discusses with the patient. There are obvious questions, as with total joint arthroplasty, as to whether these devices will wear out over time. This patient is only 26 years old and has an additional life expectancy of at least 60 years during which period of time this device is expected to function as a normal disc. This cannot be compared to total joint arthroplasty as no total joint prostheses have been observed for an equivalent period of time. In addition, we do not know whether over the longer term the persistence of motion at

the spondylotic level may result in recurrence of symptoms caused by regrowth of osteophytes. This phemonmenon has been shown in early follow-up in a small number of patients in at least one cervical disc arthroplasty trial.[9]

In summary, anterior cervical discectomy and fusion remains an excellent operation, even in the young patient with soft disc herniation. I personally am very enthusiastic about the role of cervical disc arthroplasty, especially in this particular patient. However, I believe that we must approach new technology with caution, especially in the current medical/legal environment. Consequently, with nothing more than the theory of decreased risk of adjacent segment disease to support its use, I would not advocate cervical disc arthroplasty in this patient at this time.

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Dr. Janssen Replies

Dr. Hilibrand states: "Wait a minute!" Does that imply another month, one year, two years, a decade or an entire a career? Should we simply wait or proceed to evaluate cervical disc replacement with caution?

The spine specialty is currently in a technology-rich era. We are regularly faced with the dilemma of evaluating new and "potentially" improved technology in lieu of the "historic gold standard." The question one must ask is how would any new technology be developed if clinicians adhered to the strict rule that "patients should not have access to rational, expanding technology until there is data to support its use." The logic that my esteemed colleague suggests, will lead clinicians to an endless philosophical loop: "I will not do it because I do not have the data," "if I do not do it, I will not have the data" or "if I do not have the data, I will not do it!" Historically, progress in medicine has only occurred by those that balance rational consensus for a new and "potentially" improved technique compared to the gold standard treatment of an illness or disease.

I agree this does not justify irrational enthusiasm or the aggressive application of a new technology in all circumstances. In medicine, certain criteria must be met in order to establish that a new technology warrants application, even in the most limited and controlled circumstances. In a classic risk/benefit analysis, we need to ask ourselves if the new treatment provides some theoretical benefit compared to the existing treatment and is this potential benefit commensurate with the "potential" risk of the new treatment. Many times in these analyses, the benefits are considered potential and the risks are guaranteed, when in fact, both are unknown.

So how does cervical disc replacement stand up to this rationale? Most spine specialists agree that the existing technology (ACDF) is the proverbial "gold standard" for the treatment of cervical radiculopathy and spondylosis. Dr. Hilibrand refers to the same shortcomings of ACDF, including adjacent segment disease, loss of motion at the fused segments, and stress increase at juxta levels. However, even the most skeptical clinician recognizes that the potential benefit of cervical disc replacement may potentially address these concerns!

How about risk? Compared to many recent advances in medical devices and pharmaceuticals, the risk profile of cervical disc replacements is relatively low. The specific techniques for cervical arthroplasties are virtually identical to the familiar procedure of decompression prior to fusion/instrumentation. Both arthrodesis and arthroplasty require an implant to be precisely placed in the intervertebral space and then secured to each vertebral body. Over the past decade, implant designs, materials and fixation techniques have been relatively standard for many orthopedic arthroplasty applications. This knowledge and experience mitigates the potential risk of implant-related complications (migration, extrusion, wear).

As spine specialists, we are faced with the challenge of treating the progressive disease of cervical spondylosis. However, any treatment may result in less than ideal outcomes and recurrence of symptoms in managing this disease. Following an arthrodesis, a nonunion may not result in functional or clinical adverse outcomes. Similar biological activities such as osteophyte formation and spontaneous fusion have been reported in early clinical series, but this is simply another method of achieving a fusion.

My early experience with cervical arthroplasty suggests that maintaining the previous gold standard creates an even greater risk than exploring new motion preserving technology for the treatment

of symptomatic cervical spondylosis. Because there are many unanswered questions, Dr. Hilibrand feels that we should simply wait and approach this new technology with caution. However, after we critically evaluate the risk/benefit analysis for this new technology, we should proceed with decompression followed by a cervical arthroplasty.

Dr. Hilibrand Replies

Cervical disc arthroplasty is an exciting option for this patient, but is it really the best option? All of our theories about the potential for avoidance of adjacent segment disease with arthroplasty are unproven. Nobody has ever systematically followed patients who declined operative treatment for cervical disc disease over a long-term basis. Consequently, we do not know the natural history of motion segments adjacent to a symptomatic cervical disc herniation. Such patients may be predisposed to new problems at adjacent levels because of a constellation of genetic and environmental factors. After all, isn't the patient who requires a right total hip arthroplasty for osteoarthritis much more likely than the average person to develop osteoarthritis requiring surgery in the opposite hip? Do we "blame" his left hip osteoarthritis on his right total hip arthroplasty? I would argue that it is premature to assume that the phenomenon of adjacent segment disease is predominantly the result of biomechanical factors, although they may play a minor role.

As a final consideration, I would ask the reader to answer the following question . . . in February of 2005, if this was your daughter whose problem was being discussed, what would you advise her? Most of us are very enthusiastic about the potential benefits of cervical disc arthroplasty, but I am uncertain how many of us would personally advocate this treatment at this time, even in this "ideal" situation.

Jeffrey Wang, MD, Comments

What you see presented is an issue we will be dealing with in the near future regarding this new and potentially beneficial technology. With the recent FDA approval of lumbar disc arthroplasty, the natural transition to cervical arthroplasty is at the forefront. At what point do we readily adopt this technology as one of the options that falls within the standard of care? Do we wait until we have definitive evidence with over 10- to 20-year follow-up or do we act on the short-term patient controlled prospective studies and utilize cervical arthroplasty at the current time? Both authors present a strong and rational argument for both sides and, perhaps, allow the reader insight into the advantages and disadvantages of each approach. Once cervical arthroplasty devices are approved for use, clinicians will need to make a decision. We hope that this Curve/Countercurve discussion helps to present the relevant issues and starts the process of critical thinking and evaluation of this technology.

Curve/Countercurve Survey

Tell us what you think . . .

What treatment would you recommend for this patient?

a. no surgery
b. anterior discectomy alone
c. posterior foraminotomy alone
d. anterior discectomy and fusion
e. cervical disc arthroplasty

Please vote at www.spine.org or fax your response to *SpineLine* at (708) 588-1080. Results will be reported in the next issue of *SpineLine* with the next installment of "Curve/Countercurve."

Results from November/December 2004, *How to Interpret Waddell Signs* . . .

1. As used in your practice, Waddell signs are most indicative of:

a. 10% repsonded "physiological impairment"
b. 66% responded "psychological distress"
c. 7% responded "personality disorder"
d. 17% responded "malingering"

2. If you were asked to consult on this patient, you would recommend:

a. 60% would recommend an interdisciplinary, comprehensive pain management program
b. 27% would recommend a four- to six-week work hardening program with a plan to return this patient to his original job
c. 3% would recommend referral to a psychiatrist
d. 10% would recommend no further treatment, immediate claim closure

3. In your opinion, treatment for psychological issues (as presented in this case), should be paid for by the industrial insurance carrier:

a. 67% yes
b. 33% no