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Quick Pulse

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MEDICARE COVERAGE ADVISORY COMMITTEE MEETING ON SPINAL FUSION FOR THE TREATMENT OF LOW BACK PAIN SECONDARY TO LUMBAR DEGENERATIVE DISC DISEASE

Baltimore, MD
November 30, 2006

The spine industry appears to have dodged a big federal bullet. The Centers for Medicaid and Medicare (CMS) convened a Medicare Coverage Advisory Committee (MCAC) to review the efficacy and safety of spinal fusion, raising the concern that the government might cut or eliminate payment for those procedures, but a CMS official opened the meeting with a strong statement that this was not the purpose of the session. At the end of the day, the panel members voted that the evidence on both safety and efficacy in elderly patients is sparse and called for further study, but there was no suggestion that the procedures should be restricted. The field will now have to wait to see what CMS decides the further study or studies need to be – a registry or a randomized clinical trial (RCT) – but there is little doubt further studies will be required.

CMS VIEW

No national coverage decision on spinal fusion in progress

Dr. Steve Phurrough, the CMS representative to the MCAC opened the meeting by declaring, "We are not doing a national coverage decision in spinal fusion…The purpose of this committee is to provide recommendations on the strength of evidence on a particular technology we asked them to review. The purpose is not to tell us if we should or should not cover something. That is not their role."

Dr. Phurrough said what CMS wants to know is: "Is the evidence sufficient for us to be comfortable as a healthcare community in the use of spinal fusion in degenerative disc disease (DDD), or are there gaps that need to be filled? And if there are gaps, we will be encouraging you to fill those gaps."

At the end of the meeting, Dr. Phurrough said, "We will have an extensive document based on this (meeting)…We will have a discussion on what an RCT should look like and what we, as an agency, can do to assist with that, including coding and claims issues that will help…We have taken the opportunity over the last couple of years to use different tools and techniques to stimulate data collection, and we would like to have continuing discussions on how to use those tools in this arena. I don't think we will mimic LVRS (lung volume reduction surgery) where we were concerned about 28% mortality when we stopped covering the surgery and required it be done only in a trial…I think we would have a difficult time saying we will no longer pay for fusion…But we are interested in continuing an interaction that will not stop here today but will assist the community – providers and patients – in understanding what are the best treatments for low back pain."

CMS Technology Assessment

Insufficient data of benefit of fusion, especially in older patients

Dr. Douglas McCory, Associate Professor of Medicine at Duke University, presented the technology assessment. He said the key question his team was charged with addressing was: *In patients ≥65-years-old with DDD and/or degenerative joint disease of the lumbar spine, what is the evidence regarding indications and outcomes, including adverse events, of lumbar spine fusion as compared to non-surgical conservative treatment/management or other surgical strategies?*

To answer this, they looked at randomized as well as non-randomized studies of >50 patients. They considered outcomes, quality of life, pain, disability, adverse events, and radiographic evidence of fusion. A clinically meaningful change was defined as a ~10-15 point change in the Oswestry Disability Index (ODI), a ~2.5-5 change in the Radiological Degenerative Index (RDI), and/or ~20 point change in the Visual Analog Scale (VAS).

The technology assessment found:

- **Axial back pain due to DDD.** The data here were described as generally not ***clinically*** meaningful, even when statistically significant.
- **Lumbar spinal fusion for spondylolisthesis.** In the one randomized clinical trial that compared fusion with conservative treatment, there was a statistically significant benefit to surgery over exercise in both pain and disability rating index at 1-2 years, but at 10 years the two groups were no longer statistically significantly different.
- **Instrumented (pedicle screws and cages) vs. non-instrumented fusion.** One review (by Gibson) of 7 studies found most studies had at least a trend favoring fusion, and clinical outcomes favored instrumented fusions. A Cochrane analysis found a non-significant trend in favor of instrumentation vs. non-instrumentation (p=0.089).
- **Studies of fusion in older patients,** with particular emphasis on perioperative complications. In a review of 15 studies in patients age ≥55, two studies compared older and younger patients, and in those perioperative complications were found to be increased in older patients (12.5% vs. 5% in younger patients, p>.05). They also found that younger patients more often underwent procedures involving instrumentation.
- **Biological fusion enhancement.** The conclusion was that there are "very few data" regarding the use of synthetic bone graft substitute or bone morphogenic protein (BMP), which may spread, if not contained, and cause tissue ossification.

Data Presentation

The MCAC Chair, Dr. Alex Krist, a family physician from Virginia, said the SPORT trial, which was recently published in the ***Journal of the American Medical Association***, would not be discussed or debated at the meeting because it was too new and the results on spinal stenosis and degenerative spondylolisthesis have not yet been presented. SPORT was a randomized, two-year trial which found that disc herniation patients who underwent surgical interventions had higher rates of satisfaction than those who didn't, though the difference between the two approaches declined over time. The trial had a high rate of crossover, with only ~50% of surgical patients actually getting surgery within three months of enrollment, and 30% of non-operative patients electing instead to have surgery. Patients in both groups – surgical and non-surgical – improved substantially during follow-up.

Two invited speakers offered different views of the value of lumbar spinal fusion for low back pain in Medicare patients.

Definite benefit

Dr. Steven Garfin, an orthopedic surgeon from the University of California, San Diego, offered some statistics on the extent of the back pain problem nationally:

- 70%-85% lifetime prevalence of back pain.
- Annual incidence is 15%-20%.
- Primary cause of disability in patients <age 50.
- Only 11% of back pain patients are chronic patients.
- 10%-25% of low back pain cases result in >75% of the cost.

Dr. Garfin speculated that there is confusion about the benefits of fusion because: (1) The pathophysiology of low back pain is unclear, and (2) The symptoms of low back pain are vague. Among the factors affecting the inability to determine the benefit of fusion has been:

- Lack of randomized clinical trials.
- Growing number of fusions being done.
- Lack of a clear diagnosis and indications. He commented, "The stricter the indications you put on, the better the surgical outcomes."
- Adverse events.
- FDA approval of more devices.
- Cost.
- Variety of techniques and options being used by surgeons. He commented, "The type of fusion matters."

Dr. Garfin told the committee that a "realistic" study of spinal fusion, not necessarily a randomized clinical trial, is needed. He said doing RCTs in the U.S. has been challenging because it is difficult to get Americans to randomize to an arm of therapy they've already had and failed – and most Americans, he and other surgeons claimed, do not get surgery until they

have failed conservative therapy. He said surgery can't be blinded, and shams don't work, so patients should be allowed to be their own control. He commented, "We don't fuse enough for low back pain as we are not sure exactly who will benefit. But we do know that in the right patients, fusion can drastically improve their quality of life…Fusion is not a perfect solution…It is ***not*** a good first-line treatment for discogenic low back pain, but fusion can be effective in select patients who have failed non-operative therapy…The overall reported clinical success rate is 60%-80%. Is this good enough? No."

Questionable benefit

Dr. Sohail Mirza, a spine surgeon from the University of Washington, pointed out that the U.S. lumbar spine fusion rate is much higher than in other countries, "I think all spine surgeons feel very confident about what they practice, but the reality is that we disagree tremendously among ourselves on when we offer fusion. It is not that we have more DDD in the U.S. than in other countries, but if you look at how often fusion is done for a DDD, the U.S. rate is 5-10 times the rate in some European countries." But he warned, "It is really important for patients to understand (the surgery) because this is not something you can undo and go back and start over."

There are also wide variations in lumbar spine fusion rates across the U.S. Dr. Mirza said the rate of spinal fusion for Medicare enrollees ranges from 0.21 to 4.48, just within various hospital regions of the U.S., "Depending on where you live and who you see, you can get a very different recommendation on what treatment you should have. There are tremendous variations across states and across individual cities within states. In contrast, if you have a hip fracture, it (the rate) is a pretty uniform recommendation. Fixation for hip fractures is not something orthopedic surgeons disagree about. For fusion for back pain, there are tremendous variations…The variations in the recommendation for a laminectomy varies 8-fold and fusion 20-fold, depending on where you live." He reported that lumbar fusion procedures doubled between 1993 and 2001, compared to a 10%-15% increase in hip and knee replacements.

Dr. Mirza cited several reasons for the variations in spine fusion surgery rates, including:

- Lack of scientific evidence.
- Financial incentives and disincentives.
- Clinical training and professional opinion.
- New technology.

Dr. Mirza also presented a 10-year, state-wide study of 2,000 workers compensation patients (primarily DDD patients) in Washington state who had inpatient spinal fusion in the 1990s. He reported:

- The disability rate at two years was the same whether patients had fusion with or without instrumentation.
- Post-operative complications were high.
- The re-operation rate at two years was 17.3% - 25.1%.
- Spondylolisthesis was the only diagnosis where fusion had a lower re-operation rate than non-fusion.

Lumbar Spine Fusion Outcomes in Workers Compensation Patients in Washington State

Procedure	Patients	Re-operations
Overall: 1990-1999		
Fusion	510	2,546
Non-fusion	4,142	22,767
Results by time period		
Fusions 1990-1993	2,752	25,313
Fusions 1997-1998	1,505	12,520

PUBLIC SPEAKERS

Seven spine surgeons and a Johnson & Johnson/DePuy official asked to be heard at the meeting during the public session.

➢ Dr. Hallett Matthews, an orthopedic surgeon from the Medical College of Virginia, spoke on behalf of Medtronic. He described an outcomes research initiative being planned with support from Medtronic, but controlled by the participating physicians: The Lumbar Spine Study Group (LSSG). This will involved 30 surgeons from 29 spine centers, tracking ~2,000 patients in a comprehensive longitudinal database. Dr. Matthews also recommended that a multidisciplpine workgroup be established, including CMS, the spine societies, and the spinal device industry, with these goals:

- Determine appropriate research methods for Medicare patients.
- Incorporate Medicare patients in future IDE spine studies.
- Utilize research findings to develop age-specific clinical guidelines.
- Further define patient outcome measures.

➢ Dr. Daniel Gelb, an orthopedic surgeon from the University of Maryland School of Medicine, who declared, "Patients clearly benefit from fusion surgery if they fail non-surgical therapy…To me the evidence is clear that this type of surgery is beneficial."

Officials of several spine societies, representing 25,000 practicing spine surgeons:

➢ Dr. Rick Guyer, a spine surgeon with Texas Back Institute and President of the North American Spine Society (NASS). He pointed out, "When non-operative treatment has failed, there is a clinically significant benefit to fusion…Non-operative care is always a first-line treatment, but there are variabilities in treatment regimens and outcomes."

➢ Dr. David Polly, a spine surgeon from the University of Minnesota and Secretary-Elect of the Scoliosis Research Society. He addressed directly several of the questions the panel was being asked to vote on later in the day:

- **Evidence of effectiveness of lumbar spinal fusion.** Dr. Polly pointed out that a review of >1,800 spine patients from FDA IDE clinical trials showed that the SF-36 score (a key measure of quality of life) was significantly increased in fusion patients, and the degree of benefit was comparable to that experienced by total hip and knee replacement patients, "The lumbar spinal fusion benefit is comparable to THR (total hip replacement) and TKR (total knee replacement)…Do we make them normal? No, but we make them significantly better in the activities of daily living."
- **Generalizability of the fusion data to the Medicare population.** He insisted there is an "exact parallel" in the SF-36 score in over 65 and under 65 patients. He also referred to a paper in press that found a comparable benefit in older and younger patients on ODI. He also pointed out that pain relief is a better outcome measure with the Medicare population than return to work.
- **Complications and adverse outcomes of spinal fusion for DDD.** He admitted there is not yet enough information on this.
- **Whether lumbar spinal fusion for DDD improves clinical outcomes vs. conservative treatment.** Dr. Polly argued that European patients getting conservative treatment are not directly comparable to U.S. patients who usually have exhausted conservative therapy before fusion surgery is considered, so randomizing American patients to a conservative treatment arm is not realistic. He also admitted that identifying predictors of satisfactory outcomes clearly needs further work.

➢ Dr. Charles Branch, an orthopedic surgeon at Wake Forest University, speaking on behalf of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS). He continued the societies' response to the MCAC questions.

- **Whether fusion procedures improve health outcomes.** He admitted this is a complex question but said, "There is really good evidence that internal fixation improves the fixation rate and improves outcomes when carefully applied in disabling conditions…The evidence does not clearly identify a specific technique or approach as superior…Instrumented surgical fusion treatment delivers improvements of 20-30 points on the ODI scale…And we believe this is strong evidence that instrumented fusions improve health outcomes in appropriate patients."
- **Whether radiographic interpretations are correlated with clinical outcomes.** He said, "Our review of 32 studies did not identify a correlation between clinical outcomes and fusion rates." However, he noted that new imaging technology should improve this.
- **Generalizability of fusion study results to the Medicare population.** He said, "We agree with the technology assessment that there are no studies pertinent to this…None of the studies focused specifically on the Medicare population…and none of the studies focused on the impact of comorbidities…(But) there are data that demonstrate the benefit of surgical treatment compared to non-operative treatment…All RCTs show the benefit of surgical treatment…In painful degenerative conditions of the lumbar spine, non-operative therapy is the first choice, but it is not always successful. The RCTs clearly demonstrate that, in patients with disabling back pain, there is a clear benefit of surgical treatment. The benefit from fusion is comparable to TJR (total joint replacement)… There are data that the Medicare beneficiary is as likely to benefit from fusion as the younger cohort."

Dr. Branch also suggested there are some practical studies – observational studies – that can be initiated to provide more information on the benefits and safety of lumbar spine fusion. He also recommended that CMS tighten and refine its coding nomenclature.

➢ A J&J/DePuy official. He emphasized that DDD is a complex disease with few treatment options. He said, "What we are trying to portray here is that this can be a pretty significant disease for a patient and can destroy a patient's quality of life…No present cure exists for these patients…This disease remains a public health concern…Clearly, more research is necessary, and we are committed to supporting these efforts. In the meantime, doctors and patients must carefully weigh the risks and benefits…We have reviewed the evidence and acknowledge that stronger data are needed. We are committed to working with CMS to design studies."

➢ Dr. Todd Albert, a spine surgeon at Thomas Jefferson University. His transportation was paid for by J&J, but he said he was speaking independently. His message: "The most important point to understand and for us all to realize is that DDD is a wastebasket of multiple diagnoses, including back and leg pain."

➢ Dr. Steven Glassman, a spine surgeon from Louisville KY, the author of the fusion study in press (***Spine Journal***) that offered data on fusion outcomes in older vs. younger patients. He said, "We looked at generic and disease-specific outcome measures, and an ODI improvement of 20 points wasn't surprising. Those are patients you know get better… But in the older patient population, the concern of all of us is if these patients are taking an overall health hit for this (fusion surgery). That is what we expected, and we didn't find that… We found a substantial improvement in SF-36, too…There was no difference in general health measures between the two groups…So, I think we can give the benefit of these operations without an increased risk." He said there also was no increase in complications at two years by age.

Panel Member Discussion and Questions for Presenters

Panel members asked presenters about a number of issues. The panel comments are followed by presenter responses.

Is there any value to lumbar spinal fusion? Panel member Barbara Boyan PhD from Georgia Tech said, "I don't think there is enough information about anything to compare the two things we were asked to compare (surgery vs. non-surgical therapy)." Another panel member, Dr. A. Mark Fendrick, a professor of internal medicine at the University of Michigan, said, "We heard nothing (to lead us to believe that if we) did a trial in the U.S. elderly that the findings would be substantially different from what we've seen in the four (European) RCTs (discussed by the presenters)…If the difference is not large in patients (in those trials) without comorbidities, why would we think there would be a larger difference in Medicare patients – except perhaps that surgery doesn't work well in them. What we don't know yet is the value and impact of non-surgical therapy in the U.S. elderly population…Surgeons say surgery works, but, surprisingly, so did non-surgery…And in two European trials, the natural history of the disease could have been the arm – people could have gotten better without doing anything." A guest panel member, Dr. Thomas Faciszewski, chairman of the Department of Orthopedic Surgery at Marshfield Clinic in Wisconsin, said, "I think (the European studies) are very flawed…There is no granularity in the studies…I feel strongly if nothing else happens from this panel, we need to define the terms and work on the coding, so when someone says DDD in the future, I'd know exactly what it is."

- Dr. Mirza said there is a value, "almost all the studies show (at least a trend in) the right direction."

Is there a long-term area-under-the-curve benefit to fusion? Even if the technology assessment finding that benefits of fusion are nearly lost at 8-10 years, moving closer to conservative (non-surgical) patients, panel members wanted to know if there is an area-under-the-curve benefit during those intervening years.

- Dr. McCory answered, "There is a clear short-term benefit, but what happens after two years is less well known…There isn't a lot of data in the intervening years (between 2 and 8 years)."

Is conservative therapy really being exhausted before lumbar spine fusions are done? Panel member Dr. Jeffrey Jarvik, a neuroradiologist from the University of Washington, commented, "There is a paucity of presenters on conservative therapy here…Have we really exhausted all conservative therapy?"

- Dr. Garfin said, "Cognitive behavioral therapy (CBT) is very time intensive…and we don't do it well in the U.S., probably because doctors don't get paid well for all the time they put in."

Are patients being appropriately selected for lumbar spine fusion? Are patients getting fusion for herniated discs? Medicare data indicate a substantial number of beneficiaries are getting fusion for herniated discs. CMS's Dr. Phurrough said, "The purpose of this meeting is to provide information ***not*** to the people who come to the meeting – generally those of you here are appropriately selecting patients who need the procedures you are doing. That is not necessarily the case for the broad Medicare population…The patients with lower back pain (herniated discs) who are getting spinal fusions are not necessarily a small percentage (of all spinal fusions)." Guest panel member Dr. Jon Lurie, an internist from Dartmouth Medical School, said, "We heard from Dr. Garfin that we (spine surgeons) don't do fusion for herniated discs, that that is not what we are about. But from the Medicare claims data it looks like someone does lots of fusion for herniated discs. If we are not doing them, who is doing them?

- Dr. Garfin responded that this may be due to coding differences, but he also indicated that there are some reasons for fusing in disc herniation cases, "In spine fusion, we have two (Medicare) codes: fuse with or without comorbidities. And fusion includes tumor, trauma, infection, scoliosis, etc. Every fusion is in one of these two codes."

- Dr. Mirza said, "Even though we don't typically do fusion for herniated discs routinely, there probably are instances …I've seen in our group and our community, patients getting fusion in conjunction with herniated discs."

Why aren't lumbar spine fusion procedures standardized? Panelist Dr. Boyan said, "What struck me about the studies is that surgeons don't just do the protocol that is defined, but they do the protocol plus their own little techniques. How much is attributable to the 'secret sauce' – the right BMP, the dose of BMP, etc.?"

- Dr. Mirza responded, "Each surgery is individualized, and that is one of the challenges of surgery vs. medical trials. There is no standardized surgical procedure…A patient can see two or three of us in a practice of seven surgeons and get three different opinions, and then go across the street and get a fourth opinion."

Is discography useful? A panel member who himself is a spine surgeon said, "We don't know the best way to find the painful disc…At least those who use discography are taking as much of a scientific approach as is available." Expert witnesses said:

- In his own practice, Dr. Garfin's criteria for fusion surgery are: Patients who have exhausted non-operative care, who are exhausted with pain, who have had an X-ray or MRI, and who have had a discogram. Even though discograms are only about 70% reliable, he said he believes they help identify appropriate patients. Asked about his level of confidence with discography, he said, "Intermediate, but zero in operating without it. For me, discography is important to the equation."

- Dr. Mirza said, "The highest re-operation rate (in his Washington state study) was in discography users…In real patients, very complicated patients, discography did not improve disability at two years and did not help reduce re-operation rates."

Are American patients different from European patients? Panel members wanted to know whether data from Europe on the benefits of conservative therapy could be applied to the U.S. Dr. Lurie asked, "A number of speakers…said we are more selective on who we operate on in this country, but how can you reconcile that with the higher rate of fusion surgery in this country? Where are all the fusion patients coming from?"

Speakers emphasized that American patients have already failed non-operative therapy when they come to surgery. They also responded that:

- There appears to be a lack of data on the types of conservative therapy given in Europe.
- American patients ***may*** get more non-operative treatment prior to surgery than European patients, but that is not entirely clear from the available data.
- Baseline ODI/disability scores tend to be lower in Europe.
- Entry criteria for the European patients in RCTs is not clear, nor is the type of conservative therapy they received.

What outcome measures should be used in clinical trials? There was considerable discussion on what endpoints would be appropriate – Oswestry score, SF-36, or a composite endpoint, etc. Panel member Dr. Kim Burchiel, a neurosurgeon from Oregon Health Sciences University, said, "Eventually, we need a primary outcome measure, and I don't know that it could be a blend of different scales…As a practicing neurosurgeon who does spine, having some years of better life has value." Another panel member, Dr. David Flum, a general surgeon from the University of Washington, said, "ODI is a validated measure, with good internal validity…ODI is a good outcome measure." Panel member Dr. Lurie said, "It is not outcome measures per se but how they are interpreted (that matters)…The percent of patients who get at least a minimally clinically important change in that (ODI) score is probably understandable to patients." A fourth panel member, Dr. John Kirkpatrick, a spine surgeon from the University of Florida College of Medicine in Jacksonville, said, "We have scales we can use. We can't focus on just one. We have to use a multifactorial approach – either a progressive measure or a combination of measures."

- Dr. Mirza said, "It is very hard for researchers and surgeons to interpret ODI and for patients to understand what an 8-10-15 point change means. One of the most important things that could come out of this panel is more clear definitions of what is success. It would have to be something of a composite measure, as in the artificial disc studies – some component of pain, function, pain medication use. We are recommending treatment (fusion) for something that is primarily pain."

Are randomized clinical trials feasible in lumbar spinal fusion? Several panel members appeared convinced that an RCT could be done in Medicare patients. Panel member Dr. Flum said, "The outcome metric shouldn't drive whether or not the RCT gets done. An RCT could get done. The practical barriers…all have to do with recruitment. Once payors become involved, it becomes possible...I think an RCT is a good thing to do…CMS could require that no patient gets fusion without being in a registry." The panel chair added, "There are big variations in non-operative care, but, in aggregate, we need to consider fusion vs. non-fusion…Most of the studies I saw compared operative to non-operative therapy. The idea study to assess this is with a non-operative control."

However, expert witnesses argued it would be very difficult to enroll American patients in randomized clinical trials of a surgical procedure like lumbar spinal fusion. The only somewhat positive comment was: "We've done a number of randomized clinical trials…and it is difficult to randomize people where things are the same…Where you could randomize is in the patients we see clinically who have had (physical) therapy but not injections. For older patients with stenosis that is a viable treatment we try before surgery. I think you could find a substantial cohort of patients – spondylolisthesis and stenosis patients – with fairly long therapy without blocks (injections), and you could randomize to blocks or surgery because those are both options, and then if they crossed over to surgery, that would be a failure of blocks."

CMS Questions for the Panel

The 13 voting panel members were asked to rank several issues on a scale of 1-5 (with 1 low, 3 intermediate, and 5 high). Overall, there was very little confidence in the data presented to the panel. None of the votes even reached 3.0 (intermediate).

Summary of Panel Votes

Question	Issue	Average level of confidence
1	Effectiveness of spinal fusion	2.89
2A	Safety of spinal fusion short-term (≤2 years)	2.33
2B	Safety of spinal fusion long-term (>2 years)	1.78
3A	Clinical outcomes are improved short-term (≤2 years)	2.22
3B	Clinical outcomes are improved long-term (>2 years)	1.50
5	Radiographic interpretations correlate with clinical outcomes	1.54
6A	Results generalize to the Medicare population on relief of pain	2.85
6B	Results generalize to the Medicare population on complications, adverse events, and other harms	2.46

Level of Confidence That Fusion Procedures Improve Health Outcomes

Time frame post surgery	Without instrumentation	With instrumentation
Short-term (≤2 years)		
Posterolateral (gutter fusion)	2.38	2.50
Posterior lumbar interbody/ transforaminal interbody	1.85	2.00
Anterior lumbar interbody	1.31	No vote
Anterior/posterior combined	1.92	2.42
Long-term (>2 years)		
Posterolateral (gutter fusion)	1.85	1.82
Posterior lumbar interbody/ transforaminal interbody	1.77	1.67
Anterior lumbar interbody	2.00	No vote
Anterior/posterior combined	1.69	1.92

Voting details

Following is a list of the questions, the vote, and the CMS post-vote question and any discussion of that question.

1. **What level of confidence does the evidence provide in addressing the outcomes needed to determine the effectiveness of lumbar spinal fusion for low back pain due to lumbar degenerative disc disease?**

   Intermediate

Level of Confidence in Effectiveness of Spinal Fusion

Rating	1 Low	2	3 Intermed	4	5 High	Average rating
Members voting	0	5	4	3	1	2.89

Discussion: *What does the variability in the surgical risk depend on? As this procedure is permanent, are there other potential long-term harms that have not been discussed?*

Panel members suggested several things that deserve further study including:

- Re-operation rates.
- The variability of surgical risk.
- The rate of change in ODI. Dr. Flum suggested, "Perhaps an ODI that doesn't move more than 10 points could be an adverse outcome."

2. **What level of confidence does the evidence provide for characterizing the complications, adverse events, and other harms from lumbar spinal fusion for degenerative disc disease?**

   Low-to-intermediate

Level of Confidence in Safety of Spinal Fusion

Time frame post surgery	1 Low	2	3 Intermed	4	5 High	Average rating
Short-term (≤2 years)	1	5	6	1	0	2.33
Long-term (>2 years)	6	5	0	2	0	1.78

Discussion:

- *What are the causes of low back pain?* Dr. Kirkpatrick said, "Ninety percent of the time, we don't know the cause."
- *Is patient selection important, and if so, what are the clinical and/or patient characteristics that are reliable predictors of satisfactory outcomes?* Dr. Kirkpatrick said, "Is patient selection important? Yes. Every speaker said 'in appropriately-selected patients.'" Dr. Lurie said, "I am in the unenviable position of defending the workers compensation population…You have to be clear about what predicts a 'not good' outcome or what predicts a difference in treatment effect."
- *If a clinical trial were to be done, what should it be?* Panel members were divided on whether an RCT could or should be done.

On the positive side:

- *Dr. Burchiel:* "An RCT has to have a well-selected population. One of the pitfalls in the field right now is it is still a maturing or dynamic field. We need to define stabilization at some point and go with it…We have to draw a line in the sand and not leave it up to the surgeons …Industry cooperation is critical…We need a trial where industry is donating equipment but has no other role…If industry is involved in the interpretation of data, it will be a worthless study."
- *Dr. Jarvik:* "I agree. Just because a randomized clinical trial is difficult, expensive, and time consuming doesn't mean it shouldn't be done, especially for a problem as critical and with such a high impact (as this)."

On the negative side:

- *Dr. Kirkpatrick:* "I agree with the spirit of an RCT…but the nature of selection bias, crossover, and outcomes issues make that very complicated…I think it will take five years to develop one…Meanwhile, I think we could do a good longitudinal follow-up."
- *Dr. Faciszewski:* "The RCTs from Europe were not designed to look at specific procedures…We have the best data here – consecutive case series. In the short-term, I think we need to look at prospective consecutive series…and we need to know potentially the effect of doing nothing."

In the middle:

- *Dr. Stephen Ondra, a spine surgeon from Northwestern:* "I would do both (an RCT and a longitudinal study)…I think sham surgery is a tough sell for spine surgery."
- *Dr. Jarvik:* "Case series uncontrolled data are good for complications and outcomes, comparing one group to another is not necessarily totally useful, but it has its limitations…On a sham arm, maybe there is a compromise. Perhaps sham open fusion – or bringing patients into the (surgical) suite, draping, prepping, giving them Versed (Roche, midazolam) – making the intervention as sexy as possible so they think they have had an intervention…I agree that the placebo effect is potentially very important and something we should try to get at."

3. Based on the evidence presented, how likely is it that lumbar spinal fusion for lumbar DDD improves clinical outcomes as compared to conservative treatment?

Low-to-intermediate in the short-term, and low for long-term

Level of Confidence That Clinical Outcomes are Improved

Time frame post surgery	1 Low	2	3 Intermed	4	5 High	Average rating
Short-term (≤2 years)	2	4	6	1	0	2.22
Long-term (>2 years) *	6	4	2	0	0	1.50

* One member did not vote.

4. Based on the evidence presented, how likely is it that the various fusion procedures improve health outcomes for lumbar DDD? Consider these procedures both with and without instrumentation.

Relatively low

Level of Confidence That Fusion Procedures Improve Health Outcomes

Time frame post surgery	Without instrumentation	With instrumentation
Short-term (≤2 years)		
Posterolateral (gutter fusion)	2.38	2.50
Posterior lumbar interbody/ transforaminal interbody	1.85	2.00
Anterior lumbar interbody	1.31	No vote
Anterior/posterior combined	1.92	2.42
Long-term (>2 years)		
Posterolateral (gutter fusion)	1.85	1.82
Posterior lumbar interbody/ transforaminal interbody	1.77	1.67
Anterior lumbar interbody	2.00	No vote
Anterior/posterior combined	1.69	1.92

5. What level of confidence does the evidence provide that radiographic interpretations are correlated with clinical outcomes for lumbar spinal fusion due to lumbar DDD?

Relatively low

Level of Confidence that Radiographic Interpretations Correlate with Clinical Outcomes

1 Low	2	3 Intermed	4	5 High	Average vote
7 members	5	1	0	0	1.54

6. Based on the evidence presented, how likely is it that the results generalize to the Medicare population?

Intermediate

Likelihood that the Results Generalize to the Medicare Population

Measurement	1 Low	2	3 Intermed	4	5 High	Average vote
Relief of pain	2	1	8	1	1	2.85
Complications, adverse events, and other harms	1	7	3	2	0	2.46

♦