An advisory panel listened to a day of mostly favorable testimony on vertebral augmentation.

BY JOYCE FRIEDEN
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WASHINGTON — Although some local carriers already cover vertebral augmentation through vertebroplasty or kyphoplasty, the Centers for Medicare and Medicaid Services does not intend to consider a national coverage policy for the procedure, especially given the lack of solid data available, Stephen Phurrough, M.D., said at a meeting of the Medicare Coverage Advisory Committee.

“We have no open national coverage determination, and we have no plans to open a national coverage determination,” said Dr. Phurrough, who is head of Medicare’s assessment group.

The group does plan to “produce some type of guidance document that may dis- till what we think about this particular field of spinal disease,” he said. That document will then be made available for comment.

Dr. Phurrough’s remarks came after a day of mostly favorable testimony on vertebral augmentation. “We are showing that these patients are better, and we’re making a difference in their pain,” said Isador H. Lieberman, M.D., a surgeon at the Cleveland Clinic Foundation.

Dr. Lieberman and colleagues performed a prospective controlled trial on 329 vertebral augmentation patients, 70% of whom had osteoporosis. Duration of symptoms prior to the procedure was 1 week to 5 years, mean follow-up was 55 weeks, and the average hospital stay was 1.1 days.

The researchers found that the vertebral augmentation patients showed a “statistically significant improvement in bodily pain, mental health, physical function, social function, and vitality,” compared with controls, said Dr. Lieberman, who serves as a consultant to several companies that make surgical equipment for vertebral augmentation. “Overall, these patients do well with this intervention,” he said. Dr. Lieberman gave several reasons why no randomized controlled trials had been done on the benefits of one procedure vs. the other. “I’ve been involved in five attempts. To sum it up, it’s lack of collaboration—we have not been able to get various factions to decide on how to do the study or whether to participate,” he said.

There are also study design and institutional review board (IRB) issues. “One study I was involved in demanded a sham procedure, my IRB would not let me do a sham procedure,” he said. Getting the funding for the study also is a problem. But probably the most important problem is recruitment. “We’re dealing with an elderly population who don’t have time or patience to come back for all these follow-ups or fill out all this paperwork,” Dr. Lieberman said.

Kevin McGraw, M.D., a Columbus, Ohio radiologist, testified that conserva- tion of vertebral tissue—such as metal tibial tray both move across a mobile polyethyl- ene insert. The insert creates a dual-surface articulation, absorbing force across a greater contact surface and en- suring congruent contact between the femoral and tibial components.

These implants, said panelist Douglas A. Dennis, M.D., “allow increased conformity in both planes without dra- matically increasing fixation stresses and the risk of com- ponent loosening.”

“This,” he said, reduces polyethylene wear—which should be the focus of “any total knee design.” Polyethyl- ene wear has been the major mode of total knee re- placement failure, said Dr. Dennis, of the Rocky Moun- tain Musculoskeletal Research Laboratory in Denver.

“We have seen in our laboratory better kinematics in gait with mobile bearings. They’re more tolerant of condylar lift-off, which should reduce the potential for polyethylene wear, and I think they’re more forgiving of component rotational mal-alignment—the bearing has the potential to self-correct,” he said.

In a 10-year study of total knee replacements, Dr. Den- nis and his colleagues found that mobile-bearing knees al- low for a wider range of axial rotation without creating excessive polyethylene stresses. “A fairly large number [of mobile-bearing knees] rotated greater than 20 degrees, which is beyond the rotational boundaries of most fixed- bearing designs,” he said.

Arlon D. Hanssen, M.D., argued that several studies have shown no difference in motion and no difference in polyethylene surface stresses between fixed and mobile bearing knees. Early dislocation and instability contin- ue to be a problem with the rotating-platform knee, and recently there have been reports of late dislocation.

Surgeons Wax Skeptical on Mobile-Bearing Knee Implants

BY CHRISTINE KILGORE
Contributing Writer

WASHINGTON — Mobile-bearing knee implants are hyped in advertisements and demanded by patients, but the jury is still out on whether the devices deliver what’s promised.

During a panel discussion on “controversial issues and hot topics” in primary total knee replacement at the annual meeting of the American Academy of Orthopaedic Surgeons, several panelists objected to the idea that ro- tating platform knee implants are superior in many ways to fixed-bearing designs.

“There’s certainly some skepticism here about whether mobile-bearing designs are really more forgiving,” (of rotation- al misalignment of the femoral and tibial compo- nents) and whether there truly is less wear,” said William J. Maloney, M.D., professor of orthopedic surgery at Stan- ford (Calif.) University, who moderated the discussion.

Rotating platform, or mobile-bearing, knee replace- ments are designed for potentially longer performance with less wear to parts of the prosthesis. The devices have been marketed and promoted by some companies, particularly for younger, active, or overweight patients.

The mobile-bearing knees use three components—just like fixed-bearing replacements—but have a different bearing surface. One surface is a metallic tibial tray both move across a mobile polyethyl- ene insert. The insert creates a dual-surface articulation, absorbing force across a greater contact surface and en-