Public Citizen

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President

TESTIMONY BY JOANNE MOTT, J.D., M.P.H.
PUBLIC CITIZEN HEALTH RESEARCH GROUP
HEARINGS BEFORE THE ORTHOPEDIC AND REHABILITATION DEVICES PANEL OF THE MEDICAL DEVICE ADVISORY COMMITTEE
CURRENT STATUS OF PEDICLE SCREW DEVICE SYSTEMS
July 22, 1994

Mr. Chairman, my name is Joanne Mott, and I am here today on behalf of Public Citizen Health Research Group. Because I represent an advocacy group, and am not here in an individual capacity, I would like to reserve the right to speak after all participants have been heard. The Health Research Group is a nonprofit research and advocacy organization, founded 23 years ago by Ralph Nader and Sidney Wolfe, M.D., and fights for consumer protection against unsafe foods, drugs, medical devices and workplaces, and educates the public about health care delivery issues.

1. PEDICLE SCREW FIXATION DEVICES SHOULD NOT BE CLASSIFIED INTO CLASS II

We are opposed to the reclassification of the pedicle fixation devices from class III (requiring manufacturers to provide evidence of their safety and effectiveness for use in the pedicle of the spine) to class II (no such requirement). Our position is that FDA should maintain bone screws for pedicle use in class III, and call for premarket approval (PMA) data as soon as possible, so that the devices may then be used only if data demonstrates their safety and effectiveness. Pedicle screws are implantable devices, placed into an area of the spine which is close to nerves, and depending upon the strength of the bone, often very fragile.

2. PEDICLE SCREW INSTRUMENTATION SYSTEMS ARE BEING GROSSLY OVERUSED

The retrospective studies now being conducted by the FDA and the manufacturers evaluate only two indications for pedicle screw fixation systems: spinal fracture and spondylolisthesis. A review of the literature indicates that an optimally placed fixation system, using optimal screw lengths and diameters, placed into healthy bone, may be beneficial in bringing about fusion (considered the successful endpoint

by surgeons) in patients with these conditions. These FDA-sponsored studies should continue, in order to provide some data about the fixation systems, patient selection, etc. It has also been stated that the pedicle systems have been found to be beneficial in treating scoliosis, again when placed optimally and when healthy bone is present.

The problem is that the devices are being grossly overused. It is our impression that the great majority of these screws are being used for indications other than the 3 mentioned above. Technical advances in diagnostic imaging techniques, such as MRI imaging, along with many other factors, have led to widespread use of pedicle screws for indications such as segmental instability and "diskogenic low back pain," a diagnosis often made by the orthopedic surgeon after complaints of chronic low back pain that is unresponsive to nonsurgical measures. An MRI from these patients may show disk abnormalities, and the patient then undergoes expensive, invasive, and complex spinal surgery with placement of pedicle screw systems. For many people with back pain, all the surgeon need do is show them their "abnormal" MRI films, tell them that the pedicle screw system is "state of the art," and the "greatest thing going," and they will agree to undergo the procedure.

Thus, despite the absence of diagnostic markers for this condition of diskogenic back pain, there is an ever increasing pool of surgeons and patients participating in surgical procedures utilizing pedicle screw systems, to treat it. Unfortunately, there is a dearth of evidence for the safety and efficacy of the procedures. Surgical outcome data are lacking. However, anecdotal evidence, which is all we have at this time, indicates that serious damage is being done to some patients who have the screws implanted. Many are left much worse off than before; bewildered after being deserted by their surgeons.

Lumbar surgery is most commonly performed after a patient has been diagnosed with a herniated intervertebral disk, which has been found upon MRI of the spine. However, a study published in the July 14, 1994 New England Journal of Medicine found that "[o]n MRI examination of the lumbar spine, many people without back pain have disk bulges or protrusions....Given the high prevalence of these findings and of back pain, the discovery by MRI of bulges or protrusions in people with low back pain may frequently be coincidental," meaning that there is often no relation between the pain and the herniation. An editorial in the same issue of the NEJM, entitled, "Magnetic Resonance Imaging [MRI] of the Lumbar Spine: Terrific Test or Tar Baby?" points out that up to 85% of patients with low back pain cannot be given a definitive diagnosis. The MRI imaging of more and smaller abnormalities is leading to an increase in the rates of spinal surgeries. The author points out that, a) most of these patients improve without an operation, b) exercise-based rehabilitation alone can be highly effective, and c) disk herniation tends to shrink all by itself over time! He concludes by saying, "We should generally regard bulging disks as normal findings, since two studies [referring to a 1990 study] now report that they are found in over half of asymptomatic adults..." If bulging or herniated disks can often be regarded as normal findings, then the risk of surgery and hardware cannot be justified in a large proportion of people who have bulging or herniated disks.

We are presently conducting a survey of recipients of pedicle screw fixation systems who have had problems associated with the use of these devices. We will thoroughly analyze the information we have obtained and continue our investigation into how the situation was ever allowed to get to where it is today - where thousands and thousands of people, sometimes with mere back pain, are being implanted with "hardware" and "screws"; and after these unfortunate patients complain about increased pain and disability, they are often dumped by their orthopedic surgeons, and called "psych cases." It is my belief, based upon what I have seen thus far, that this is a scandal comparable or even surpassing some of the other device debacles which we have followed over the years. The screws not uncommonly bend, break, migrate, and impinge on nerves. Patients may undergo numerous surgeries to have broken screws removed or replaced.

3. FDA HAS BEEN RELUCTANT TO REGULATE PEDICLE SCREWS, EVEN AFTER EVIDENCE OF ILLEGAL CONDUCT BY SOME MANUFACTURERS

It seems clear that the FDA has bowed to pressure by the manufacturers of pedicle screws and some surgeons. The devices have been illegally promoted for use in the spine by the manufacturers since 1984, and this illegal promotion continues today. Furthermore, bone screws were among the devices on the original list to be tracked by manufacturers in case of defects, which makes sense, because they are implantable devices. However, due to pressure from the industry, the devices were removed from the final list of trackable devices. We wonder why.

CONCLUSION

In conclusion, we urge the FDA to a) start the regulatory process leading to a call for PMA data from manufacturers of pedicle fixation systems, b) immediately call for restricted use of pedicle screw systems for uses other than spinal fracture, spondylolisthesis, and scoliosis. For these uses, the systems should only be used pursuant to investigational (IDE) study protocols, c) require manufacturers to label the devices as experimental for use in the pedicle, and thus restricted to the context of an IDE study protocol, and also contraindicated for indications other than spinal fracture, spondylolisthesis, and scoliosis.