Cheng, Joseph

From: Patrick Jacob [jacob@neurosurgery.ufl.edu] **Sent:** Thu 2/7/2008 6:30 PM
To: William Tobler
Cc: Jeff Cozzens; Greg Przybylski; Robert Harbaugh; Cheng, Joseph; Cathy Hill
Subject: Re: TranS1 Procedure
Attachments:

I appreciate your interest in the code. NASS is the author, so I would suggest that you get in touch w/ Bill Mitchell who will be presenting the code tomorrow. I know that Rick Simmons is meeting w/ him and may carry the message.

I am sensitive to your passion, successful work and great results with the Trans1 device. Unfortunately, the quality of the published data is not very strong at the moment. I agree that much of what is currently done in Spine surgery has very little Class I data for support, the Guideline for Lumbar Fusion published by the Spine Section a year or two ago demonstrated that clearly. Unfortunately, new devices are being held to a higher lever for approval of the Panel. I am not sure, but I assume the Trans1 device is approved for the current prevailing use (not as a 'bone screw').

The current Cat III proposal was reviewed with representatives from the Spine Section and they agreed. If you feel that this code is ready for Cat I, the best approach would be to go to the Spine Section and have them give the Coding and Reimbursement Committee a direction to pursue Cat I status. The likelihood of success would be enhanced by compelling Class 1 or 2 data published with 2 year follow-up in a peer review US journal. Obviously, NASS feels that Cat III is appropriate and they should be consulted as well, since they will have to be convinced about a change in status.

On 2/7/08 5:09 PM, "sbutler@mayfieldclinic.com" <sbutler@mayfieldclinic.com> wrote:

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> Dear Pat,
>
> I am writing to you to express my support for the validity of the TranS1
> procedure as an outstanding surgical technique for fusion of the L5-S1
> interspace. I am distressed to learn that the NASS CPT committee is
> recommending that the TranS1 procedure be assigned a Category III tracking
> code similar to total disc arthroplasty, interspinous spacers and believe
> that this is erroneous and may have very serious and regressive
> implications to our patients, and to the efforts of surgeons introducing
> valid, innovative technologies to our field.
>
> I am a neurosurgeon at the Mayfield Clinic in Cincinnatiand Associate
> Professor of Neurosurgery at the Universityof Cincinnatifor 22 years. I am
> a member of the AANS, CNS and NASS. I have devoted my career to the
> advancement of minimally invasive surgery in the brain and spine. When I
> learned of the TranS1 fusion technique a light switch was turned on: this

> was the intuitive technique for a minimally invasive lumbar fusion. The
> comparable approach that came to mind was the Henry Bohlman technique for
> fusing and stabilizing Grade III spondy¹s, but in a true axial plane. My
> personal challenge was can this be as good as it appears?
>
> I was one of the very first to do a TranS1 procedure in the United Statesin
> June of 2005. Since then me and my associates, Dr. Robert Bohinski and Dr.
> Lee Greiner have performed 180 TranS1 procedures at the ChristHospitalin
> Cincinnati. I have performed more TranS1 procedures than anyone worldwide.
> In this entire group of 180 patients there has been only one surgical
> approach/device complication (a rectal perforation resolved). Fusion rates
> at one year are in the 90-95% range. This success is equal to if not better
> than any other interbody fusion technique. We are tracking prospectively
> every patient treated at our institution.
>
> Enclosed is the abstract of a completed manuscript that is being submitted
> to the Journal of Neurosurgery Spine as soon as the art work is finished
> next week. This abstract has been submitted for podium presentation at the
> upcoming NASS and the CNS meetings in 2008. The data in this series of 50
> patients with one year follow-up evaluation treated with this technique is
> compelling. A strict definition of fusion is concisely defined, all 50
> patients underwent CT scanning at one year, and the results were evaluated
> by an independent radiologist. A detailed analysis of the fusion literature
> for ALIF, TLIF and PLIF is included in this paper. The results after one
> year in the TranS1 series equals the results published for other
> techniques. Some of these papers have poorly defined definitions of
> fusion. For the large number of interbody fusions performed in this country
> it is amazing how sparse the volume and how quality analysis is lacking. I
> could find no literature that assesses complications and fusion rates for
> the recently expanding XLIF or DLIF procedures which is a recently accepted
> anterior interbody fusion technique, not relegated to a Category III code.
> How can that be, and how can the Committee attempt to do this now, after
> 3000 TranS1 procedures have been performed? What interests are served to
> pursue a unique code for a more elegant, retroperitoneal version of the
> Bohlman fusion and stabilization technique for high grade
> spondylolisthesis?
>
> The TranS1 procedure is not a new operation, or a new concept like the
> x-stop, or arthroplasty. It is an interbody fusion technology utilizing an
> intuitive approach. For how many years have you looked at the lumbar spine
> model in your office forever sitting on a metal rod attached to a plastic
> base imitating the TranS1 approach? In my opinion from the outset, and now
> in my experience in 180 closely followed patients in almost three years it
> is my interbody fusion technique of choice at L5-S1. When more surgeons
> carefully evaluate this technique and the accumulating experience they will
> see the value of this approach to fuse the spine that avoids muscular
> disruption, vascular manipulation, dural sac and root exposure, and open
> anterior approach issues. With repetition this approach is as familiar and
> comfortable as the anterior approach to the cervical spine which contains
> many more serious and vital structures than in the pre-sacral space.
>
> I urge you to consider the compelling evidence that this procedure is a
> valid and now proven interbody fusion technique. It should therefore, not
> be assigned to a category III procedure. I would be happy to discuss this
> with you further, and would be pleased to have you visit for a procedure in

> Cincinnati anytime.
> Sincerely,
> (See attached file: AxiaLIF.1year.doc)
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>
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