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MEMORANDUM

To: John Pafford
David Brumfield

cc: Ted Bird
Ron Pickard
Alex Lukianov
Rick Duer
✓Brad Estes
Roger White

From: Larry Boyd

Date: January 11, 1994

Subject: **MEETING WITH DR. GARY KARLIN MICHELSON**

On Tuesday, January 11, Ron Pickard, Rick Duerr, Mark Merrill, and I met with Dr. Michelson and his attorneys. While the attorneys worked out the details of the various agreements, Ron Pickard and I were able to meet with Dr. Michelson to review his various ideas on interbody fusion and spinal surgery. Dr. Michelson reviewed with us the many assorted prototype implants and instruments covering a wide range of subjects.

Initially, Dr. Michelson pointed out that there are generally three steps performed in a spinal surgery. These would be a discectomy, an interbody fusion via either posterior or anterior approach, and some form of instrumentation for additional stability. Dr. Michelson pointed out that the ideal case would be to eliminate the need for additional instrumentation via improving the biomechanical performance of the implant used for interbody fusion. This would appear to be the ultimate goal of the various implant and instrumentation systems for interbody fusion that we were to discus with Dr. Michelson.

Next, Dr. Michelson reviewed step-by-step some of the details of the surgical procedure for posterior interbody fusion approach:

1.) The first step involved detailed pre-operative planning. This would be via templates of the various implant sizes that would be available in various magnification ranges. A lateral X-ray would be used to pre-operatively assess the anticipated implant depth and allow the surgeon to assess the anticipated implant height required in order to restore normal anatomy. An axial CT scan would be used to clarify the actual disc space available and the true anticipated implant depth to be used.

PLAINTIFF'S EXHIBIT
CASE NO. 08CV 01512
EXHIBIT NO. PX0114

Lukianov
EXHIBIT NO. 136
11/4/10
J. HOSTETLER

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2.) The second step would involve removing some small portion of disc after an exposure of the disc from a posterior approach. A simple curette or rongeur could be used to remove enough disc to allow for placement of the initial bullet-nosed long distractors.

3.) The third portion of the procedure involves placement incrementally of various bullet-nose long distractors. These will indicate to the surgeon when the normal disc height has been restored. The surgeon will be able to feel as the disc space becomes increasingly taut and stable. The long distractors also assure that a central axis parallel to the endplates is achieved prior to any drilling. Dr. Michelson pointed out that this predistraction phase is very critical. It is important that the patient be fused in the fully extended, distracted position, as opposed to some surgeons who have accidentally fused patients in a collapsed position resulting in eventual degeneration of adjacent disc levels. This predistraction is critical also to giving the necessary working space for insertion of the instrumentation and implant.

4.) The next phase involves impacting into the vertebral body an external tubular distractor (with engagement teeth) which will be the working channel for the rest of the procedure. This helps to maintain distraction throughout the procedure, along with the contralateral distractor. At this point, Dr. Michelson pointed out that it will be necessary to lock the surgeon into a given depth and diameter instrumentation set. Dr. Michelson suggested that the various depths used be color coded and that the surgeon be locked into using a given set for a predetermined diameter, also. At this point, the surgeon would then work with a specific set of reaming and tapping instrumentation, in order to avoid any potential for mixing of different sized instrumentation.

5.) The next phase is the insertion of the diameter-reducing inner sleeve and the protected drilling of the disc and bone in preparation for the implant. Having set the stage in terms of the surgical procedure, Dr. Michelson discussed some of the more specific details of the design. He mentioned that cutting an arc is a means of increasing the surface area contact and therefore reducing the likelihood of subsidence. He mentioned some data and analysis via computer modeling that was performed that clearly shows the advantage of both the domed shape as well as a tooth thread engagement into the vertebral bodies as opposed to simply placing a flat member in contact with the vertebral bodies. We will need to examine this information, now that the agreement is in place.

Dr. Michelson also mentioned that the device used to remove the disc and bone is not a typical sharp-pointed drill, but a side-cutting reamer that actually draws the disc and bony debris into the internal diameter-reducing sleeve. This captures the debris which would otherwise migrate about the body and perhaps cause further inflammation.

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6.) The next step is to remove a dowel of iliac crest autograft bone and load the implant with bone via the implant bone loading device, followed by insertion of the implant. This device holds the implant and bone dowel and drives the bone into the device. The bone is compacted into the device and extrudes from the pores in the device. Bone tapping is not normally required due to the fact that the implant is self tapping. Tapping could in fact result in potential cross threading and a less than ideal fit between the implant and bony interface. We will need to do some studies of our own to assess the need for tapping in the various cervical, thoracic, and lumbar applications of the implant and instrumentation.

We then discussed some of the specific implant features. The implant holes were contrasted with the two large holes on the Spine Tech BAK system. The width to depth ratio has a clear affect on bone ingrowth and incorporation through the implant. Dr. Michelson mentioned some studies that exist showing that the width across a hole must be at least as great as the depth, or thickness, of the material through which the bone must bridge. However, he pointed out that beyond some certain ratio if the bone width is too great incorporation will be less than ideal, as will load bearing capacity. This apparently has to do with the amount of support vs. thrugrowth of bony trabeculae provided by the implant. I asked Dr. Michelson about the reasons for the small holes along the side of the implant. This is contrasted with some other devices (BAK, Ray) which have left the sides of the implant closed in order to, supposedly, prevent fibrous tissue migration into the device. Dr. Michelson pointed out that this was a very clear misunderstanding on some investigators part. He stated that, in actuality, the way that he has judged success of a fusion has been by noting bony bridging along the outside of the implant. As such, he feels that the side holes and the bone that extrudes through them act as an aid in allowing the bone to grow not only through the implant but actually around and encasing the implant.

Dr. Michelson also mentioned that the HA coating is a preferred embodiment for the implant design, as this will further encourage active bone bonding and the migration of bone along the implant. He discussed the need to look into both short-term tricalcium phosphate and longer term hydroxyapatite coatings. The FDA's thoughts on a short-term vs. a long-term coating may weigh into this decision. Finally, he pointed out the good histology shown in animal studies that has demonstrated complete encasement of threaded implants in bone with bone bridging both through and around the implant.

Dr. Michelson reviewed all the implants and instruments already manufactured. I was most impressed with the manufacturing work done on all these components. Please see the attached copies of photographs given to me showing the complete instrumentation set for the posterior lumbar interbody fusion technique. Some additional instruments are required for the anterior lumber interbody fusion. We will be in touch with Dr. Michelson with the completion of the final agreement to secure several full sets of implants and instruments for review with other surgeons and for further design and development of this concept.

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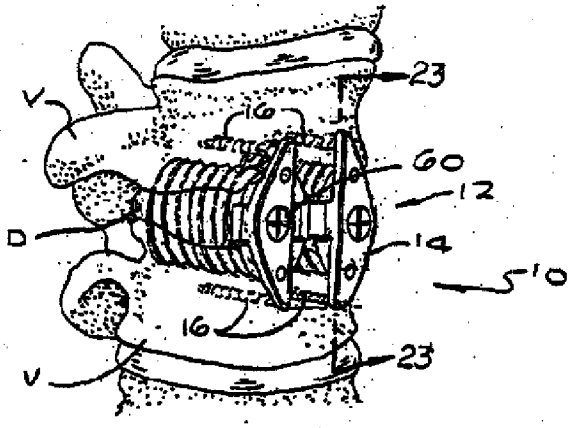
Next, Dr. Michelson discussed application of his device for an anterior lumbar interbody fusion. He pointed out that during an anterior lumbar interbody fusion it is necessary to clearly visualize the posterior wall in order to remove any extruded disc fragments and make sure that all extruded or herniated disc fragments have been retrieved. It was not extremely clear what method was preferred for disc evacuation. Dr. Michelson implied that the method used for the discectomy would be a typical rectangular incision in the annulus followed by a use of curette and rongeurs for evacuation of the disc and exposure of the vertebral endplates. However, I was somewhat concerned about the lack of any central restraining structures such as the anterior longitudinal ligament or medial portions of the nucleus to prevent contact between the two bilateral devices. This is a subject that I will hope to cover with Dr. Michelson and other surgeons using threaded dowel techniques via an anterior approach. It appears that contact between the devices is not a concern.

Dr. Michelson pointed out a very interesting concept for attaching a threaded dowel to the vertebral bodies via placement of an external staple. A figure of this is shown below.



This takes advantage of the fact that the threaded cage has a 1 degree of freedom method of extrusion, that is, via rotational unscrewing. The staple would have a 1 degree of freedom method of extruding via axial pull-out. When one combines these two fixation methods they act in concert to seemingly reduce the potential dislocation of the other. Additionally, the staples are placed such that they are driven into holes which over estimate their angulation and therefore compress down on the implant as they are driven into the vertebral bodies. A lock screw fixes the staple to the implant. The staples are low profile

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against the vertebral bodies. The round vertebral body is flattened via rongeurs or burrs to further encourage conformation of the staples to the vertebral body.

The methodology of distraction followed by compression is something most surgeons would be very familiar with. Testing would certainly be needed on the concept. However, this sort of technique of anchoring and attaching an interbody fusion device with some sort of an external member for purchase of the vertebral bodies has been contemplated as part of the IBFD project with Dr. Kozak, also. Staples are clearly clinically well-known devices and likely to be well accepted in this sort of spinal surgery. This technology is not covered by the current agreement but could be added later if there is such an interest. Dr. Michelson reinforced the fact that the current device alone is and has been found to be very safe without the use of the staples. Therefore, the staples may very well not be required in order to achieve a very good and successful result with the threaded dowel in an anterior lumbar interbody fusion. We will likely further review this concept later as we move forward with the development of this device.

Next, we discussed the difference between Dr. Michelson's concept and that of the BAK implant from Spine Tech. Overall, Dr. Michelson emphasized the fact that the primary design philosophy is to gently remove bone so as to not harm in any way the surrounding biological structures. Another goal is to maximize the available surface area for load bearing in order to reduce the likelihood of implant subsidence. Dr. Michelson discussed the Spine Tech device, emphasizing the limited area available for bone placement. The Spine Tech device provides for only a minimal amount of bone autograft placement. The polyethylene endcaps, increased sidewall thickness, Acme-type (square) threads, and the central strut all take up a great deal of room that is not available for bone. The Spine Tech device cannot be preloaded due to the central strut, which is used for strength and for driving the implant. The central internal strut has a slot used for engagement and insertion of the implant. However, this presents difficulty when one attempts to unthread or remove the implant due to lack of a positive locking onto the implant. This is contrasted with the very positive threaded and keyway attachment used with Dr. Michelson's technique, as documented in the patent drawings.

The Spine Tech BAK implant provides for a gradual tapered bullet-nosed lead in area to distract the disc space as inserted, where Dr. Michelson's technique achieves distraction via external means, presenting some very clear biomechanical and surgical advantages.

The Spine Tech device provides for no side holes due to their concerns over disc and fibrous tissue end growth. However, Dr. Michelson feels very strongly about the likelihood of bone bridging and incorporation not only through the implant, but along the outer margins.

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