DuraSeal: Increased Complication Rates in Chiari Malformation Surgery

Investigating cases of quadriplegia, paraplegia, and cauda equina syndrome that relate to the management of CSF leaks


Dr. Greg Vigna

SANTA BARBARA , CALIFORNIA , UNITED STATES , February 23, 2024 /EINPresswire.com/ -- “At the authors’ single center, use of sealants in posterior fossa decompression with duraplasty (PFDD) surgery for Chiari malformation type 1(CMI), especially DuraSeal, was correlated with a higher complication rate. Eliminating DuraSeal led to a significant decrease in the rate of symptomatic pseudomeningocele and aseptic meningitis” ... Dr. Ammar Shaikhouni, MD, Ph.D, Ohio State Wexner Medical Center.

What else did Dr. Ammar Shaikhouni, MD, Ph.D report in his article “Association between synthetic sealants and increased complication rates in posterior fossa decompression with duraplasty for Chiari malformations regardless of graft type”?

“RESULTS:
1). From 2011 to 2018, complications occurred in 24.5% of 110 patients. Sealant choice was correlated with complication rates: no sealant (0%), Tisseel (6%), and DuraSeal (15.3%)
2) No difference in complication rate was noted on the basis of choice of graft material
3) After eliminating DuraSeal, the authors followed 40 patients who underwent PFDD after 2018. The complication rate decreased to
12.5%. All complications after 2018 were associated with Tisseel”

Dr. Greg Vigna, MD, JD, national pharmaceutical injury attorney, national malpractice attorney states, “Clearly this study shows that DuraSeal and Tisseel should not be used in Chiari Malformation surgery as these products do not appear to provide a therapeutic benefit and lead to pseudomeningocele and aseptic meningitis that are both serious post-operative complications.”

The Federal Drug Administration (FDA) provided Pre-Market Approval in 2005 for DuraSeal, a

> We have evidence that DuraSeal should not be applied in the case of Chiari Malformation Type 1 surgery as these products lead to pseudomeningocele and aseptic meningitis."
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> *Greg Vigna, MD, JD*

synthetic nontoxic bioabsorbable hydrogel sealant, for use in brain surgeries that creates the risk of CSF leaks when cutting through the dura that covers the brain. A tear or cut in the dura, also called a durotomy, will create the risk of a CSF leak, and application of DuraSeal over a tear or cut with or without suture repair will seal the defect shut within seconds of application. In 2011, DuraSeal Exact received FDA approval and was advertised by the manufacturer as "New, improved formulation provides low-swell, watertight closure during spinal surgery".

https://www.fiercehealthcare.com/healthcare/covidien-announces-duraseal-tm-exact-spine-sealant-receives-fda-approval

Dr. Vigna continues, "There have been long-standing safety concerns regarding the use of DuraSeal in the management of incidental CSF leaks that may occur in spinal surgeries when there is a tear in the dura." The problem with DuraSeal is that it is 'known to swell' up to 50% between 3-14 days following surgery in any direction, and when it is applied into the tight and enclosed spaces along the spine, it can cause spinal cord compression by the 'DuraSeal Mass', potentially leading to quadriplegia in cervical spine surgeries, paraplegia in thoracic spine surgery, and cauda equina syndrome in lumbar spine surgeries."

Dr. Vigna concludes, "There is no reliable evidence that DuraSeal Exact which swells less than the original DuraSeal, eliminates the complications seen with DuraSeal when used in spine surgeries and there is no reliable evidence that DuraSeal Exact actually provides a therapeutic benefit when compared with other methods of surgical management of incidental dural tears and CSF leaks that occur in spinal surgery. Now, we have evidence that DuraSeal should not be applied in the case of Chiari Malformation Type 1 surgery."

To learn more about the complications of DuraSeal and spinal surgeries:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8571335/

To Read Dr. Shaikhouni article : Article in JNS, Vol. 30: Issue 5 (2022):
https://thejns.org/pediatrics/view/journals/j-neurosurg-pediatr/30/5/article-p507.xml

Greg Vigna, MD, JD, is a national malpractice attorney and has testified as an expert in spinal cord medicine, brain injury, catastrophic orthopedic injuries, and wound care. He is investigating cases of quadriplegia, paraplegia, and cauda equina syndrome that relate to the management of CSF leaks. The Vigna Law Group along with Ben C. Martin, Esq., of the Martin Law Group, a Dallas Texas national pharmaceutical injury law firm, jointly prosecute hospital, physician, and nursing home neglect cases nationwide.

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