To fuse or to replace? That is the question.

By Michael H. Weier ■ January 6, 2016

The November 5, 2015, issue of the *Journal of Bone and Joint Surgery* reported the results of a seven-year prospective, randomized cohort study[1] that compared the efficacy and safety of single-level anterior cervical discectomy and fusion with that of cervical total disc replacement.[2] The investigators declare that data indicate total cervical disc replacement with an artificial disc is a safe and effective surgical treatment for symptomatic cervical disc disease.

The study design limited subject participants to those with symptomatic degenerative disc disease.[3] Discectomies and fusions, and artificial disc replacements are also surgical procedures for treatment of symptomatic disc herniations and extrusions due to trauma. Thus, whether the cause of symptomatic cervical disc problems are due to a degenerative disease process, traumatic injury, or a combination of both degenerative disease and trauma, the two comparative, possibly competing, surgical procedures are similarly directed: removal of disc material and stabilization of the corresponding vertebral structures.

The recent study in which the investigators declare the data reveal artificial disc replacement is efficacious, efficient and safe for treatment of cervical disc problems is reminiscent of a study also reported in the *Journal of Bone and Joint Surgery* nearly a quarter century ago. However, rather than comparing fusion versus artificial disc replacement of the cervical spine over a seven year period, the 1991 study compared surgical discectomy versus chymopapain chemonucleolysis (chymopapain) by injection into the herniated disc of the lumbar spine.[4]

Chymopapain, an enzyme that metabolizes and breaks down certain molecules, is injected directly into a herniated disk. It is intended to dissolve the extruded portion of the disc and thereby relieve pressure upon a nerve, reduce or eliminate pain, and improve motor function.[5]

Quite simply, the chymopapain saga is a testament to the scientific idiom: one study does not a principle make.

The 1991 investigators reported the data revealed the surgical group had greater symptomatic relief and slightly less recurrence of pain, as compared to the chymopapain group. Nonetheless, they declared chymopapain injections efficacious and "safe with minimal serious complications."[6]

Chymopapain by injection to treat disc herniations did not fare as well as the 1991 study investigators or the pharmaceutical company that manufactured

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the drug[7] had anticipated. Chymopapain injections reportedly had serious side effects, including near-complete disc desiccation resulting in bone-on-bone-vertebral articulation, paralysis and death. Ultimately, the Food and Drug Administration discontinued authorization for sale and use of chymopapain in the United States on January 27, 2003.[8]

What does a quarter-century-old study subsequent history of chymopapain have to do with the most recent study on the efficacy of artificial disc replacement? Quite simply, the chymopapain saga is a testament to the scientific idiom: one study does not a principle make. Reproducible experiments or observational studies should be conducted with resultant similar findings before acceptance of a theory as fact or at least probable.

Artificial disc replacement may, in fact, be visible on the horizon. It may have actually arrived. It may be a safe, efficacious and effective procedure for relief of pain and functional limitations associated with disc degeneration or herniation. It may also be the next chymopapain. ■

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[1] A randomized study is an epidemiological experiment in which the subjects are randomly allocated into groups, in this case, one of two surgical groups: discectomy (partial excision) and fusion, or artificial total disc replacement. A prospective cohort study is an analytic observational study in which subjects in at least two groups are exposed to different agents, in this case different surgical procedures, and then monitored for an extended period to obtain and analyze data regarding exposure/surgical outcomes.

[2] Janssen, M. E.., et al. *ProDisc-C Total Disc Replacement Versus Anterior Cervical Discectomy and Fusion for Single-Level Symptomatic Cervical Disease*, Journal of Bone Joint Surgery America, 97:1738 (November 5, 2015).

[3] Cervical disc disease and cervical spondylosis are broad terms that describe the age-related chronic disc degeneration, which can also affect the cervical vertebrae, the facet and other joints and their associated soft tissue supports. Chronic disc degeneration results in increased mechanical stressors passing through the cervical spinal column, resulting in osteophyte formation and secondary degenerative changes in surrounding structures, such as the facet joints, the posterior longitudinal ligament and the ligamentum flavum. Kelly, J. C., Groarke, P. J., et al., *The Natural History and Clinical Syndromes of Degenerative Cervical Spondylosis*, Advances in Orthopedics, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3227226/ (November 28, 2011).

[4] Tregonning, G. D., Transfeldt, E. E., et al., *Chymopapain Versus Conventional Surgery for Lumbar Disc Herniation: 10-Year Results of Treatment,* Journal of Bone Joint Surgery America, Vol. 73-B, No. 3 (May 1991).

[5] *Drugs and Supplements: Chymopapain (Injection Route)*, The Mayo Clinic, http://www.mayoclinic.org/drugs-supplements/chymopapain-injection-route/description/DRG-20062811 (April 1, 2015); *Chymopapain (Injection Route)*, PubMed Health, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0009607/ (November 6, 2015).

[6] Tregonning, G. D., Id, Conclusion.

[7] Boots Pharmaceutical manufactured chymopapain chemonucleolysis, sold its rights to the German manufacturer Knoll Pharmaceutical, who then sold the product to Abbott, who decided to discontinue selling it worldwide in 2001. Young, A.T., *The Current Status of Chymopapain*, http://www.sciatica.com/physician--information/scientific-articles/file/24-the-current-status-of-chymopapain.html. (November 23, 2011).

[8] Whether the FDA removed chymopapain from the approved list of drugs for sale and use in the U.S. for reasons of safety remains in controversy.

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