Public Statement:

Manual percutaneous lumbar discectomy (PLD) uses cutting forceps to remove nuclear material from within the disk annulus. The automated percutaneous lumbar discectomy (APLD) uses a specially designed probe to excise small pieces of the nucleus, which is removed by aspiration. Results from PLD and APLD have varied widely, and there is not consistent scientific evidence that this technique improves health outcomes.

Medical Policy Statement:

Percutaneous discectomy, manual, automated or by laser, in the lumbar, thoracic or cervical spine is considered investigational and is not covered.

Background:

Manual PLD was developed in Japan in 1975, with a reported success rate of 70% immediately, and 72% at 14 years (reported 1989). Subsequently, a percutaneous PLD method which coupled the instrumentation from the manual approach with an endoscope, was developed.

Onik, et. al., reported in 1990 an uncontrolled study of 506 patients who had APLD. These patients had undergone conservative care for a mean of 11.6 months, and the subgroup considered to be ideal for APLD was 75%.

The AMA Diagnostic and Therapeutic Technology Assessment reviewed PLD in 1989.
and found that it was investigational. A re-review was done in 1991 because two large prospective (non-randomized) studies had been published, and the technique was diffusing rapidly into the community setting. The panel concluded that the technique was safe, but there remained a question as to the effectiveness.

Although some authors report a very high rate of success with APLD, others report poor results, with many patients requiring subsequent open discectomy. While the better outcome of some surgeons may be attributable to better surgical technique and more experience, there is considerable concern that use of subjective outcome measures and unblinded evaluation of patients, may inflate the success rates reported in these studies.

A 2000 Cochrane report (Gibson, 2003) concluded, “Three trials of percutaneous discectomy provided moderate evidence that it produces poorer clinical outcomes than standard discectomy or chymopapain.” For example, Chatterjee reported on the results of a study that randomized 71 patients with lumbar disc herniation to undergo either percutaneous discectomy or lumbar microdiscectomy (Chatterjee, 1995). A successful outcome was reported in only 29% of those undergoing percutaneous discectomy compared to 80% in the microdiscectomy group. The trial was halted early due to this inferior outcome. In a 1993 randomized study, Revel and colleagues compared the outcomes of percutaneous discectomy to chymopapain injection in 141 patients with disk herniation and sciatica (Revel, 1993). Treatment was considered successful in 61% of patients in the chymopapain group compared to 44% in the percutaneous discectomy group. Another trial cited in the Cochrane review, Mayer et. al., is not applicable since the technique used modified forceps in addition to a suction probe (Mayer, 1993). Finally, the last trial cited in the Cochrane review, Hermantin et. al., provided insufficient data to allow detailed analysis of results (Hermantin, 1999).

The only additional controlled study published since the 2000 Cochrane review was the results of the LAPDOG study, a randomized trial designed to compare percutaneous and open discectomy in patients with lumbar disc herniation (Haines, 2002). This trial was designed to recruit 330 patients, but only was able to recruit 36 patients, for reasons that were not readily apparent to the authors. Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful outcomes at 6 months. The authors concluded that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion. The authors state, “It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation.”

All of the trials reviewed above focused on lumbar disc herniation. There were no clinical trials of percutaneous discectomy of cervical or thoracic disc herniation.

Gibson and Waddel published an updated Cochrane review of surgical interventions for lumbar disc prolapse, concluding that there is insufficient evidence on percutaneous discectomy techniques to draw firm conclusions. A task force of the American Society

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of Interventional Pain Physicians reports that percutaneous disc decompression remains controversial; although all observational studies were positive, the evidence from 4 of 4 randomized published studies was negative (Boswell et al, 2007). Questions also remain about the appropriate patient selection criteria (particularly related to the size and migration of the disc herniation) for this procedure. (Gibson, 2007).

Freeman and Mehdian assessed the current evidence for three minimally invasive techniques used to treat discogenic low back pain and radicular pain: electrothermal therapy (IDET), percutaneous discectomy, and Nucleoplasty (Freeman, 2008). They report that trials of automated percutaneous discectomy suggest that clinical outcomes are at best fair and often worse when compared with microdiscectomy.

Two systematic reviews published in 2009 were identified, each analyzing the literature for a different device. Hirsch and colleagues reviewed 4 randomized controlled trials (RCTs) and 76 observational studies in their analysis of studies in which the Nucleotome was used (Hirsch, 2009). In two of the RCTs, the comparator was chemonucleolysis. The first, Revel et al, was reviewed in a previous update. The second of these RCTs did not meet Cochrane review criteria for randomized controlled trials. The other two RCTs compared automated percutaneous discectomy with microdiscectomy and also failed to meet study quality criteria. Singh et al. Performed a systematic analysis of studies in which the Dekompressor device was used (Singh, 2009). The authors identified no RCTs.

Goupille et al reviewed the literature on laser disc decompression and concluded that “although the concept of laser disc nucleotomy is appealing, this treatment cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment.” They cite the lack of consensus regarding technique, the questionable methodology and conclusions of published studies, and the absence of a controlled study in their discussion (Goupille, 2007). One recent study of laser disc decompression was identified. Ishiwata et al investigated the clinical results of their magnetic resonance-guided percutaneous laser disc decompression practice with reference to the site of the needle tip in the disc. They divided the disc on axial image into 4 quadrants and 3 concentric zones and evaluated clinical results by MacNab’s criteria in each subdivided area 6 months after the procedure. The authors report an overall success rate of 68.8% in their series of 32 patients, and conclude that targeting certain zones seems to result in better outcomes (Ishiwata, 2007).

References:


NHS - National Institute for Clinical Evidence. (2003) Laser lumbar discectomy -

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Application to Products

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