

## Treatment of Neck Pain

### Injections and Surgical Interventions: Results of the Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders

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**Study Design.** Best evidence synthesis.

**Objective.** To identify, critically appraise, and synthesize literature from 1980 through 2006 on surgical interventions for neck pain alone or with radicular pain in the absence of serious pathologic disease.

**Summary of Background Data.** There have been no comprehensive systematic literature or evidence-based reviews published on this topic.

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

Corporate/Industry, Foundation, and Professional Organizational funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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**Methods.** We systematically searched Medline for literature published from 1980 to 2006 on percutaneous and open surgical interventions for neck pain. Publications on the topic were also solicited from experts in the field. Consensus decisions were made about the scientific merit of each article; those judged to have adequate internal validity were included in our Best Evidence Synthesis.

**Results.** Of the 31,878 articles screened, 1203 studies were relevant to the Neck Pain Task Force mandate and of these, 31 regarding treatment by surgery or injections were accepted as scientifically admissible. Radiofrequency neurotomy, cervical facet injections, cervical fusion and cervical arthroplasty for neck pain without radiculopathy are not supported by current evidence. We found there is support for short-term symptomatic improvement of radicular symptoms with epidural corticosteroids. It is not clear from the evidence that long-term outcomes are improved with the surgical treatment of cervical radiculopathy compared to nonoperative measures. However, relatively rapid and substantial symptomatic relief after surgical treatment seems to be reliably achieved. It is not evident that one open surgical technique is clearly superior to others for radiculopathy. Cervical foraminal or epidural injections are associated with relatively frequent minor adverse events (5%–20%); however, serious adverse events are very uncommon (<1%). After open surgical procedures on the cervical spine, potentially serious acute complications are seen in approximately 4% of patients.

**Conclusion.** Surgical treatment and limited injection procedures for cervical radicular symptoms may be reasonably considered in patients with severe impairments. Percutaneous and open surgical treatment for neck pain alone, without radicular symptoms or clear serious pathology, seems to lack scientific support.

**Key words:** best evidence synthesis, surgery, injections, cervical spine, neck pain, whiplash-associated disorder, radiculopathy.

Surgical interventions are frequently recommended for persons with neck pain. When neck pain is associated with certain pathologic conditions, the decision to consider surgery is not controversial. After acute injuries such as penetrating trauma with hemorrhage, or blunt trauma with demonstrable instability causing neurologic deterioration, surgery may reasonably be considered as a means to arrest or reverse a catastrophic loss. In nontraumatic conditions such as spi-

nal infection or neoplasm with airway or neurologic compression, again, the consequences of delaying or neglecting surgical intervention may be serious or even fatal.

However, most people with neck pain, whether their symptoms follow minor trauma or develop insidiously, have neither clear aggressive pathology nor imminent risk to vital functions. As described elsewhere in this report,<sup>1</sup> the mandate of the Neck Pain Task Force was to look at neck pain in the absence of fractures or dislocations, and not involving primary structural conditions caused by serious disease such as metabolic, neoplastic, inflammatory, or infectious disease. This paper deals with evidence regarding surgical intervention for people with more common kinds of neck pain (with or without radicular problems). As opposed to the neck pain associated with serious structural disease, the role of surgery in alleviating more common kinds of neck pain is less well understood.

Surgical intervention involves a direct manipulation of specific anatomic structures. The decision to operate depends on knowing that a specific structure is diseased *and* that it is responsible for a certain clinical illness *and* that the condition is amenable to treatment.

- *For persons with combined neck and radicular pain*, the site of neurologic symptoms and signs, or electrophysiological changes may be confirmed by neurologic compression seen on imaging studies. In these cases, the pathoanatomic site of the problem may be clear, and a surgical approach to relieve specific nerve impingement, such as decompression or fusion, may be practically considered. Nonetheless, the efficacy and effectiveness of these measures have not been well defined in the literature to date.<sup>2-4</sup>

- *For persons with neck pain alone*, in the absence of serious destructive lesions, the specific anatomic cause(s) of pain and illness can rarely be known with certainty. Imaging studies may reveal no abnormality or show common degenerative changes that are most frequently observed among people without serious neck pain problems. Although most persons with neck pain do not have specific structural disease that is clearly causing specific symptoms, surgical interventions, such as fusion, radiofrequency neurotomy, *etc.*, are nonetheless sometimes recommended and performed.

The primary objective of this paper is to identify, critically appraise, and synthesize literature from 1980 through 2006 on surgical interventions for neck pain without serious underlying pathologic conditions.<sup>1</sup> Secondary objectives are to identify (1) gaps in and problems with the surgical literature and (2) areas where the resources associated with surgical interventions should be expended in an effort to reduce the individual and societal burden of neck pain and its associated disorders.

We will follow this outline in presenting our findings:

- Quantitative results of the literature screening
- Summary of evidence for surgical treatment of axial neck pain (alone)
  - Neck Pain associated with suspected facet joint pain
  - Neck pain associated with suspected discogenic pain or common degenerative changes.
  - Neck pain associated with suspected post-traumatic ligamentous injury
- Summary of surgical treatment for axial neck pain (with radicular symptoms)
  - Percutaneous surgical treatment of cervical radiculopathy
  - Surgical patients compared to persons without neck pain
  - Open surgical treatment of cervical radiculopathy: Decompression *versus* fusion methods
  - Open surgical treatment of cervical radiculopathy: Comparing different fusion techniques
  - Expected outcomes after surgical treatment of cervical radiculopathy
- Studies of complications
  - Percutaneous treatments
  - Open surgical techniques
- Systematic reviews of surgical interventions for neck pain

At the end of the paper we will present a series of evidence statements summarizing the findings in each area.

## ■ Materials and Methods

The strategy for our literature search and critical review is outlined in detail elsewhere.<sup>5</sup> Briefly, we systematically searched Medline for literature published from 1980 to 2005 on neck pain and its associated disorders; we also checked reference lists of relevant articles, and updated our literature search by including key articles published in 2006 and early 2007. We screened the citations for relevance to the Neck Pain Task Force mandate, using *a priori* inclusion and exclusion criteria, but made no attempt to assess the scientific quality of each study at this point in time. Studies were considered relevant if they pertained to the diagnosis, incidence, prevalence, determinants or risk factors, prevention, course, prognosis, treatment and rehabilitation, or economic costs of neck pain; if they contained data and findings specific to neck pain and/or disorders associated with neck pain; if they included at least 20 persons with neck pain or at risk for neck pain; or if they described a systematic review of the literature on neck pain.

We included articles on neck pain resulting from whiplash injuries and work-related injuries and strains, as well as neck pain of unknown etiology in the general population. We excluded studies on neck pain resulting from fractures or dislocations, inflammatory arthritis, infection, tumors, and other nonmusculoskeletal types of neck pain, except for diagnostic studies relating to ruling out fractures and dislocations in neck pain.

Rotating pairs of Scientific Secretariat members performed independent, in-depth critical reviews of each article, identify-

ing methodologic strengths and weaknesses. After discussing each article in Scientific Secretariat meetings, consensus decisions were made about its scientific merit. Those judged to have adequate internal validity were included in our best evidence synthesis. Because of large between-study heterogeneity with respect to study populations, intervention groups, outcome measures, follow-up times, and estimated effects, we did not pool studies for meta-analyses. Criteria used for appraising the methodologic quality of the studies can be viewed online through Article Plus. Briefly, we focused on sources of potential bias (selection bias, information bias, confounding) and compared these findings to the magnitude of any bias that would likely result in erroneous or misleading conclusions. Studies with such problems were not accepted in whole or in part into our best evidence synthesis.

Because of the small number of direct comparative trials in the surgical literature, we also considered articles that reported the results of 'extraordinary' clinical case series. Those case series were judged as being of special relevance to the Neck Pain Task Force if they were frequently cited in the literature, recommended by a member of the Scientific Advisory Committee or a professional society, if they might contribute evidence of safety of interventions, and/or if they were on a topic for which there was little or no other information available from reports involving greater methodologic rigor. In the case of surgical interventions for neck pain, these were identified *via* our literature screening process and specifically solicited from experts in the surgical field. Although many case series cannot be used to evaluate efficacy, and would be scientifically inadmissible for that purpose, we felt that reports of large and well-documented case series might contain useful data on prognosis and surgical complications. These are included in an analysis of surgical complications and safety.

Furthermore, to better understand and comment on the use of surgery in certain areas with few or no scientifically admissible studies, we carefully analyzed and directly commented on frequently cited studies purporting to establish definitive efficacy, even though the study may not have been accepted as scientifically valid.

## ■ Results

### **Literature Screening**

Of the 31,878 citations screened, 1203 studies were found to be relevant to the Neck Pain Task Force mandate, and 359 of these related to interventions (surgical and nonsurgical). After critical review, 170 intervention studies were judged to be scientifically admissible; of which 31 studies related to surgical interventions and comprise the following best evidence synthesis on surgical treatment of neck pain. Twenty-seven are primary studies and 4 are systematic review articles accepted as scientifically admissible in our best evidence synthesis. Of the primary studies accepted in the best evidence synthesis, 17 are randomized trials and 8 are nonrandomized (cohort) studies. We also accepted 2 'extraordinary' case series (definition above) as scientifically admissible for our best evidence synthesis. Experts in the surgical field, from whom we solicited key studies in this field, forwarded 53 references to us. Of these, 44 studies had been identified and screened by the Neck Pain Task

Force; none of the 9 remaining solicited studies were found scientifically admissible.

Among the scientifically admissible papers, the greatest number of primary studies involved the treatment of neck and radicular pain in degenerative conditions (26 studies).

The poorest quality evidence involved treating axial neck pain (alone) using open or percutaneous surgical procedures (1 study). Even though these procedures are sometimes recommended to patients, we found no scientifically admissible studies supporting these procedures. To better understand and comment on the use of surgery in certain areas (*e.g.*, for neck pain without radiculopathy), we carefully analyzed 5 frequently cited studies on the topic,<sup>6-10</sup> which the Neck Pain Task Force had found not scientifically admissible.

### **Summary of Evidence for Surgical and Percutaneous Treatment of Axial Neck Pain (Alone)**

We found just 1 study, a randomized clinical trial (RCT), with adequate numbers and controls to evaluate surgical intervention where the predominant complaint was axial neck pain. Neither this scientifically admissible study nor commonly cited studies on the surgical treatment of neck pain (alone) demonstrated clinical effectiveness.

**Neck Pain Associated With Suspected Facet Joint Pain.** We accepted 1 study on the topic of suspected facet joint pain.<sup>11</sup> Barnsley *et al* investigated the relative efficacy of intra-articular injection of corticosteroid and bupivacaine into cervical facet joints (*vs.* injection of bupivacaine only) in subjects reporting neck pain after motor vehicle accidents.

There were, however, some important weaknesses in this study, which should impact on the interpretation of the findings. Subjects were selected for this study based on their response to anesthetic facet joint blockade, using short- and long-acting anesthetic agents. The diagnostic protocol used for patient selection, however, has not been validated.<sup>5,12</sup> There was systematic 'work-up bias' in the subject evaluation, and all facet joints were not equally evaluated.<sup>13-15</sup> Furthermore, if pain relief was reported longer by any amount (even 5 minutes) with bupivacaine (expected duration of action 4-8 hours) compared to lignocaine (expected duration of action 1-2 hours), the subject was reported to be 'definitively diagnosed' with primary zygapophysial pain from that joint. This applied even if the duration of reported pain relief was well outside the expected pharmacologic range (*e.g.*, several days).

Using this method of selecting the site of injection, 42 subjects were randomized to receive facet injections of either steroid and anesthetic or anesthetic alone. No clear advantage was seen with the addition of the steroid: approximately 30%-40% of each group reported >50% of pain relief at 10 days after injection; 10%-15% reported continued relief after 90 days.



There were no scientifically admissible studies regarding radiofrequency neurotomy for suspected facet (zygophyseal) pain.

**Frequently Cited but Scientifically Inadmissible Study: Radiofrequency Neurotomy for Suspected Facet Joint Pain**

One study by Lord *et al*<sup>7</sup> is frequently cited as ‘definitively’ establishing high-grade efficacy of this treatment. In this study, the relative effectiveness of attempted radiofrequency (RF) neurotomy of the medial branches (MB) to the cervical facet joints was compared to a sham procedure.

All recruited subjects reported that their neck pain was related to a motor-vehicle collision. Subjects were selected on the basis of a nonvalidated response to facet blocks.<sup>5</sup> The test-blocks included a placebo and long- and short-acting anesthetics. However, the study did not require that the duration of reported pain relief with the longer-acting anesthetic actually be of longer duration; nor was it necessary that the reported duration of pain relief be in any reasonably expected pharmacologic range.

After selecting subjects using this selection criterion,<sup>12</sup> a small number of subjects ( $n = 24$ ) were randomized to either facet deinnervation by radiofrequency ablation, or to a sham probe placement without activation. There was an unequal distribution of potentially confounding baseline characteristics, for example, 10 of 12 (83%) subjects in the sham group were involved in litigation related to the perceived neck injury compared with only 4 of 12 (33%) subjects in the active intervention group. Furthermore, there were reported to be 18 symptomatic facet joints [13 (72%) treated] in the sham group and only 14 asymptomatic facet joints [12 (86%) treated] in the active treatment group; 4 subjects in the sham group (33%) (*vs.* 2 in the active group) had suspected *additional* cervical pain diagnosed by the authors, *which was not treated*. In addition, among other methodologic problems, blinding is in doubt. Five subjects (42%) in the actively treated group (*vs.* none in the control group) developed long-term anesthetic or dysaesthetic areas of skin. It seems likely this result revealed the treatment assignment in nearly half the active treatment group.

Nonetheless, despite apparent systematic biases in favor of the active treatment group confounding the study, there was no statistical between-group difference in the successful outcomes by the authors’ criteria during the first 3 months. At 3 weeks after surgery, 9 subjects in the RF group *versus* 6 subjects in the control group reported greater than 50% relief ( $P = 0.40$  Fisher exact test); at 3 months after surgery, 7 subjects in the RF group reported the same improvement in pain, *versus* 3 subjects in the control group ( $P = 0.21$  Fisher exact test). Notably, the reoperation rate was the same (5 in each group). The randomization code was broken at 3 months, and nonvalidated primary outcome measures were used thereafter.

**Neck Pain Associated With Suspected Discogenic Pain or Common Degenerative Changes**

We found no well-designed randomized clinical trials or cohort studies of open surgery for the treatment of neck pain alone, in the absence of suspected radiculopathy, in patients without destructive or inflammatory processes, demonstrable instability, serious deformity, or fracture/dislocation. At this time there is no acceptable clinical evidence supporting surgical procedures such as anterior cervical fusion, posterior cervical fusion, or cervical arthroplasty for neck pain alone, when only common degenerative pathology is found on evaluation. Although there are several widely quoted case-series of cervical fusion for common degenerative disease without radiculopathy or instability, none of these were judged as scientifically admissible by the Neck Pain Task Force reviewers or consensus group.

**Frequently Cited but Scientifically Inadmissible Studies: Cervical Fusion for Nonradicular Neck Pain With Only Common Degenerative Changes**

- In 1999 Palit *et al*<sup>8</sup> retrospectively reported on the outcomes of 38 patients out of a possible 175 subjects (22%) who underwent anterior discectomy and fusion (ACDF) for neck pain and degenerative disc disease (DDD). No concurrent, historical, or retrospective controls were identified. Fusion levels were determined by a painful and concordant response to disc injections. An unknown number of patients were excluded by the authors or declined surgery. Some potential patients (again, the number is unknown) were excluded because of psychological risk-factors. The number of subjects lost to follow-up or who refused follow-up is not reported. There was no apparent standard assessment interval, and the intervals between the surgery and the reported assessment varied widely, from 2 to 7 years. Other interventions that the subjects might have received during this period—which could have affected outcomes—are not reported. Of the reported cases, the mean numerical pain rating *after* surgery remained greater than 4 (of 10), and the Oswestry Disability Index score showed moderate-to-serious impairment in most of the select group of patients followed. No neck-specific functional outcomes were assessed. Only 18 patients out of an unknown number (between 38 and 175) who were operated on by the authors for neck pain and degenerative disc disease said that the surgery had ‘met their expectations’.

- In 2002, Garvey *et al*,<sup>6</sup> reported on 87 of 112 (78%) retrospectively identified patients who underwent ACDF for a diagnosis of ‘mechanical cervical spine pain.’ (This was defined by the authors as patients who had more neck pain than arm pain). Patients were evaluated 5 to 10 years after surgery. The number of patients evaluated or considered for surgery is unknown. The selection process and screening is not detailed. Other treatments received are not reported.

The group is heterogeneous for diagnosis: an unknown proportion of these patients had some radiculopathy, and/or radiographic instability and/or cervical deformity. The validity of the outcomes reported is uncertain. For example, it is not clear if pain and functional impairment measurements were recorded both before and after surgery; if validated functional assessments for neck pain were used; and whether subjects considered the occurrence of surgery to have been advantageous to their litigation claim (78%). Only 58 of these 112 patients (52%) reported feeling more than ‘somewhat better’ than they did before their surgery; only 25 patients (23%) reported feeling more than ‘somewhat satisfied’ with their neck condition on follow-up. The authors cited historical controls treated by *nonoperative care of neck pain alone*, 21% of whom reported complete pain relief and 49% who reported partial relief. These cited ‘control’ outcomes are similar to the authors’ reported surgical outcomes.

- Two additional studies—Whitecloud *et al*<sup>10</sup> and Simmons *et al*<sup>9</sup>—are frequently cited to support surgical treatment of neck pain. Both are case series, are retrospective, have poorly reported recruitment procedures and follow few acceptable study-design methods for outcome evaluation. For example, in these studies surgical outcomes are based solely on surgeons’ perceptions of patient improvement as opposed to validated outcome instruments. Yet Simmons *et al* report that the operating surgeon determined that 30 of 31 (97%) patients undergoing ACDF for neck pain were “*all found to have immediate lessening*” of symptoms after surgery; they further state that *in every case “all pain was gone in a week after surgery.”* This observation is unlike any recorded by validated outcomes measures or collected by independent examiners.

It is well documented that neck pain without serious underlying disease shows wide and spontaneous variations—both in severity and any accompanying impairment.<sup>16,17</sup> Thus, none of these frequently cited, uncontrolled studies can confidently estimate how much, if any, of the reported improvement was due to a surgical intervention, how much was due to natural history, and how much might be explained by various nonspecific and unidentified factors. Although these studies are frequently cited as demonstrating clear efficacy of cervical fusion for primary neck pain, none of these were found to be scientifically admissible by the Neck Pain Task Force. Instead, after critical review of the methods and data we found no clinical evidence, even in the best-known studies purporting definitive efficacy, to support the use of either cervical fusion or cervical disc arthroplasty in patients with neck pain without radiculopathy or serious underlying pathology.

**Neck Pain Associated With Suspected Post-Traumatic Ligamentous Instability.** Upper cervical or craniocervical fusion for possible specific ligamentous injury of the upper cer-

vical spine after trauma as suggested by MR imaging by Krakenes *et al*<sup>18–20</sup> and Kaale *et al*<sup>21</sup> or on CT by Dvorak *et al*,<sup>22</sup> has not been evaluated for efficacy. No clinical cohorts or case series have been reported (with adequate selection, description and postoperative monitoring) which can reliably estimate prognosis after an operative intervention for this supposed injury. Thus, no adequate clinical evidence exists to support upper cervical or craniocervical fusion on the basis of MR signal changes in the upper cervical ligaments.

### **Summary of Surgical and Percutaneous Treatment for Axial Neck Pain (With Radicular Symptoms)**

#### **Percutaneous Surgical Treatment of Cervical Radiculopathy.**

We accepted 2 studies (both RCTs) which evaluated the efficacy of percutaneous surgery for neck pain and radicular symptoms.

Stav *et al*<sup>23</sup> demonstrated possible benefits for short-term outcomes in subjects with cervicobrachialgia who received epidural lidocaine and steroid injections (compared to those who received injections into paraspinal muscles). In this small study, early pain, range-of-motion (ROM), and work status outcomes seemed to be more favorable in the epidural injection group. Although this study was found to be scientifically admissible, the Neck Pain Task Force noted some methodologic problems including relatively small numbers (one group contained fewer than 20 subjects); failure to blind both subjects and examiners; an unclear selection and randomization method; and the withdrawal of a large number of subjects (32%) from only one arm (the muscular injection arm). These weaknesses lead the Neck Pain Task Force to conclude that the study findings, especially beyond the short-term results, should be considered to be suggestive, but not conclusive.

In a double blind RCT, Slappendel *et al*<sup>24</sup> compared radiofrequency heating of the cervical spine dorsal root ganglion (to a temperature of 67°C, which would permanently damage the DRG) to physiologic temperatures alone (40°C, administered to the control group, which was expected to produce no change to nociception). The mean improvement in each group at 6 weeks after treatment was less than 2 points on a 0–10 scale. After 3 months, a slightly greater proportion of subjects in the control group (15 patients out of 29, 52%) reported being globally ‘better,’ *versus* 15 patients of 32 (47%) in the active treatment group. Of note is that this study did demonstrate that subjects (as selected for this trial) frequently report clinical improvement without having received the active treatment.

#### **Percutaneous Surgical Treatment of Cervical Radiculopathy**

We accepted 1 study that compared outcomes of open surgical interventions to nonsurgical treatment; we also accepted another 2 studies comparing possible functional impairments after fusion in surgical patients *versus* matched controls.

An RCT by Persson *et al*<sup>25</sup> compared a Cloward-type fusion (n = 27) to either physiotherapy (n = 27) or cervical collar (n = 27) in people with radicular pain and cervical spondylosis (*i.e.*, not acute disc herniation). At baseline, subjects had been off work for an average of 1 year. Those with serious psychological symptoms were excluded. Improvement in pain intensity was greater in the fusion group at 14–16 weeks, but functional scores were similar in both the physiotherapy and fusion groups. Pain reduction was slightly greater in the fusion group at 16 months (17 points compared to 12–14 for the nonsurgical groups), but no difference in functional outcomes was apparent. By the 16-month endpoint, crossover between groups was substantial. Reoperation rates were quite high (29%) in the fusion group, which might be related to the Cloward technique. Although this study was judged scientifically admissible, the Neck Pain Task Force cautioned that there were some baseline imbalances that may have biased outcomes.

#### **Surgical Patients Compared to Persons Without Neck Pain.**

Neck strength and mobility in patients who underwent cervical discectomy (with or without fusion) were compared to neck strength and mobility in healthy volunteers without neck problems.<sup>26</sup> As expected, mobility and strength seemed worse in the postsurgical group, especially when they were tested soon after surgery (as early as 3 months). It is not clear if the small observed differences in range-of-motion are clinically important.

Gore *et al*<sup>27</sup> noted degenerative changes occurring at levels adjacent to a cervical fusion as seen on radiographs; they compared these changes to changes seen in a group of age- and sex-matched controls without a history of neck pain. This study found no evidence of rapid acceleration of DDD at adjacent levels among the cervical fusion group *versus* the control cohort.

#### **Open Surgical Treatment of Cervical Radiculopathy: Decompression Versus Fusion Methods**

We accepted 4 RCTs and 1 comparative cohort study that compared cervical decompression alone to fusion methods.

Rosenorn *et al*<sup>28</sup> compared anterior cervical discectomy (ACD) alone to a modified Cloward-type fusion using a freeze-dried allograft in subjects (n = 63) with radicular pain and confirmed cervical disc herniation. Although baseline comparability was not demonstrated and only nonvalidated global assessments were followed after surgery, there seemed to be somewhat better subjective improvement in patients who underwent discectomy alone. (Subjects were followed for only 1 year after surgery.)

Similarly, van den Bent *et al*<sup>29</sup> randomized subjects (n = 81) to either ACD alone or ACD and bone cement stabilization. Overall, no clinical difference was found in outcomes up to 2 years after surgery. A *post hoc* subgroup analysis found that, based on early results, patients with the most severe baseline neck pain achieved somewhat greater relief after cement stabilization. Ra-

diographic follow-up showed loosening and displacement of the cement if spontaneous bony fusion did not occur.

An RCT by Abd-Alrahman<sup>30</sup> compared one- or two-level ACD alone (n = 40) to ACDF (n = 50) by the Smith-Robinson method without instrumentation (using ICBG). Subjects had radiculopathy, myelopathy, or both. At baseline, the ACDF group had longer duration of symptoms, greater kyphosis and more spinal cord involvement. The fusion procedure involved longer operative times, greater blood loss, and longer hospital stays. At 6 months after surgery no difference in neck or arm pain complaints between the groups was apparent. By Odom criteria for outcome success, 80%–90% of patients in each group were considered to have achieved ‘excellent’ or ‘good’ outcomes. Postoperative kyphosis was more common in the ACD group (55% *vs.* 26% in the ACDF group).

An RCT by Wirth *et al*<sup>31</sup> attempted a longer follow-up (to 5 years). The study compared ACD alone with either posterior laminoforaminotomy or cervical fusion using a modified Cloward technique. Findings should be interpreted in light of the fact that all outcomes were solicited by the operating surgeon, which may have led to overly positive findings. Nonetheless, at 2 months after surgery 70%–75% of subjects in either group had ‘complete pain relief,’ and about 90% had returned to work, with no clear advantage to any group. The Neck Pain Task Force did not accept the findings from the 5-year follow-up because of the high attrition rate (>40%).

In a clinical cohort of 33 patients with cervical radiculopathy and soft disc herniations, Herkowitz *et al*<sup>32</sup> performed either ACDF or a laminoforaminotomy on an alternating-case basis (nonrandomized). They found no difference in the proportion of subjects with ‘good’ and ‘excellent’ outcomes at a mean of 4 years after surgery. However, their data did show that a trend toward the best outcomes occurred in the ACDF group.

**Open Surgical Treatment of Cervical Radiculopathy Comparing Different Fusion Techniques.** In subjects with cervical radiculopathy, Hacker *et al*<sup>33</sup> studied a variety of ACDF procedures using autologous bone graft (n = 142) compared with a threaded cage (BAK), either with (n = 167) and without (n = 179) a hydroxyapatite coating. This RCT found no clear difference in outcomes up to 2 years after surgery. A nonvalidated assessment of fusion seemed to indicate better fusion rates in the threaded cage group, but this did not seem to have a clinical effect. The harvesting of bone graft did not seem to lower SF-36 scores.

In an RCT, Vavruch *et al*<sup>34</sup> compared outcomes after the Cloward procedure to those after ACD and fusion using a carbon fiber cage with cancellous autologous graft from the iliac crest in subjects with radiculopathy. Patients with myelopathy, psychological problems, drug abuse history or previous surgery were excluded. Imme-



diate 'severe' pain at the ICBG site was 31% in the Cloward group compared to 13% in the ACDF/cage group. There were no clear between-group differences in pain intensity, functional outcomes measures, or global assessment of outcome by the patient at either 1 or 2 years follow-up. The nonunion rate was higher in the ACDF/cage group—38% compared to 14% in the Cloward group; patients in whom a solid union was achieved showed a small improvement in outcome compared to patients with nonunions. Postoperative kyphosis seemed worse in the Cloward group. The effects remained the same during follow-up (to a mean of 6 years after surgery).<sup>35</sup> Male gender, nonsmoker status, greater segmental kyphosis at baseline, and less baseline pain and disability were predictive of better outcome at 1 year.<sup>36</sup> Nonetheless, these variables accounted for only 30% of the outcome variance.

An RCT conducted by Cho *et al*<sup>37</sup> compared ACDF with a PEEK cage supplemented with either autogenous iliac crest bone graft (ICBG) ( $n = 50$ ) or biphasic calcium phosphate ceramic ( $n = 50$ ). Although the fusion seemed to proceed more rapidly with autologous bone grafting, the fusion results were similar at 6 months, and clinical outcomes were similar as well.

Baskin *et al*<sup>38</sup> conducted an RCT that involved patients undergoing one- or two-level anterior cervical discectomy and allograft ring/plate reconstruction for either myelopathy or radiculopathy due to DDD. The trial focused on the effect of adding cancellous autograft from the iliac crest *versus* a bone morphogenetic protein (BMP) sponge to augment the fusion. There were significant methodologic problems, leading the Neck Pain Task Force to conclude that a comparison of differences between groups is difficult to interpret. These methodologic problems include important baseline differences; the ICBG subjects were more likely to be tobacco users; there were lower scores in pain intensity and Neck Disability Index (NDI) in the ICBG group; and the ICBG group was also younger. At 6- to 12-weeks follow-up after surgery, there was no between-group difference in pain intensity improvement, NDI (functional) scores or global health (SF-36) improvements. At 2 years after surgery, there were very small differences in pain intensity and NDI improvement favoring the BMP group; however, absolute outcome scores were similar, possibly due to baseline differences. This study did not seem to demonstrate clear outcome improvement with the use of BMP in cervical arthrodesis.

Zoega *et al* performed 2 small RCTs examining fusion with and without anterior cervical plate fixation for cervical radiculopathy.<sup>39,40</sup> Although these studies found that the addition of plate fixation improved construct stability (preventing kyphosis) in one- and two-level arthrodesis during healing, there was no clear effect on clinical outcome or progression to fusion. Whether this prevention of kyphosis will also prevent long-term problems from developing at adjacent segments is unclear.

**Open Surgical Treatment of Cervical Radiculopathy Comparing Fusion Versus Disc Arthroplasty Techniques.** Two RCTs compared anterior cervical discectomy and fusion with disc arthroplasty in subjects with cervical radiculopathy due to DDD. The studies, by Hacker *et al*<sup>41</sup> and Coric *et al*,<sup>42</sup> showed no clear advantage for either surgical treatment method during the year after surgery. SF-36 scores on pain intensity were similar, although there was a trend in favor of arthroplasty. The studies did not consider the comparative long-term risks associated with arthroplasty as opposed to fusion surgery—for example, implant failure, wear debris issues, adjacent segment degeneration, and the relative risks of surgical revision. The Neck Pain Task Force found no scientifically admissible studies with even medium-term safety data regarding cervical disc arthroplasty.

**Expected Outcomes After Surgical Treatment of Cervical Radiculopathy.** The existing data do not seem to strongly support one method of surgical treatment for cervical radiculopathy over another. However, the abundance of trials performed for this limited indication can help guide expectations among patients who decide to undergo surgery.

Recent RCTs using validated outcome measures have recorded detailed postoperative data on patients who have undergone cervical fusion (Table 1). These outcomes can be summarized as follows:

- In all studies documenting early outcomes, substantial improvements were reported to be seen rapidly after surgery (within 6 to 12 weeks).
- Most subjects achieved a 50% (or greater) reduction in pain.
- Most subjects achieved a 60%–70% improvement in functional scores.
- Few subjects were left with even moderate residual functional impairment as determined by validated metrics (*e.g.*, NDI >30).

However, none of these trials used a nonsurgical control group. For this reason, we cannot assess with certainty just what proportion of patients would have achieved these outcomes with continued nonsurgical care; nor can we say whether the positive results seen with surgery would have been seen as quickly with nonoperative care.

### Studies of Complications

**Percutaneous Treatments.** Many types of complications are reported with cervical injections. Some are generic (pain at the injection site, allergic reactions, infections, *etc.*); others are specific to the cervical spine and its particular anatomy (*i.e.*, catastrophic vascular and neurologic events).

Noteworthy among these specific complications is the risk of spinal cord or brain injury after attempted selective nerve root injections. We found no studies that could accurately assess this risk, as all the reports of cata-

**Table 1. Studies Reporting Short- and Medium-Term Validated Outcomes of Open Surgery for Cervical Radiculopathy in Subjects When Followed by Independent Observer at Fixed Follow-Up Points**

First Author (Yr)	Short-Term Outcomes	Medium-Term Outcomes
Hacker <i>et al</i> (2000) <sup>33</sup>	6 mo post-op Mean pain score improved 3/10 (approx. 40%)	2 yr Mean pain score improved 3/10 (approx. 40%)
Baskin <i>et al</i> (2003) <sup>38</sup>	6–12 wk post-op Mean pain score improved 3.5–4.5 (neck) (approx. 60%) 4.5–7 (arm) (approx. 80%)	2 yr Mean pain score improved 4.5–6.5 (neck pain) (approx. 75%) 4.5–7 (arm pain) (approx. 80%)
Hacker (2005) <sup>41</sup>	6–12 wk post-op Mean pain score improved 3.2–4.5 (neck) 3.5–4.8 (arm) PCS of SF-36 12–15 points	1 yr Mean pain score improved 3.4–4.6 (neck) 3.5–4.9 (arm) PCS of SF-36 14–16 points
Coric <i>et al</i> (2006) <sup>42</sup>	12 wk post-op Mean pain score improved 3.2–4.0 (neck) (approx. 55%) 3.6–4.5 (arm) (approx. 65%) NDI Mean NDI improvement 20–28 points (approx. 60%) PCS of SF-36 12–15 points	1 yr Mean pain score improved 3.2–5.0 (neck) (approx. 55%) 3.0–4.8 (arm) (approx. 65%) NDI Mean NDI improvement 22–32 points (75%) PCS of SF-36 15–18 points

NDI indicates neck disability index; PCS, physical component score.

strophic neurologic or vascular events were either very small series or cases reports. Some authors maintain the risk for neurologic injury during cervical injections is highly dependent on technique.<sup>43</sup>

The Neck Pain Task Force accepted 3 prospective or retrospective systematic surveys of complications after cervical injections.

Botwin *et al*<sup>44</sup> reported on retrospectively assessed complications after fluoroscopically guided epidural injections for radicular pain in a case series of 157 patients. Approximately 7% of the records remarked on increased pain, 5% reported a new headache, and only one injection was noted to puncture the dura mater.

Huston *et al*<sup>45</sup> reported on possible subjective complications (pain, headache, *etc.*) after selective nerve root blocks in a cohort of 37 subjects with radicular pain. These complications were compared to spontaneous events occurring in control cohort of 60 subjects with radicular pain who were eligible for but did not receive injections. The authors found that after 1 week, several outcomes—specifically pain at the injection site, non-spinal headache, and headache not associated with standing—were all more frequent after injection, even after controlling for spontaneous events in noninjection subjects. Immediately after injection many subjects reported minor problems: increased pain at injection site (23%), increased radicular pain (18%), lightheadedness

(14%), increased spine pain, headache or nausea (all 3%–10%).

Ma *et al*<sup>43</sup> prospectively documented complications after fluoroscopically guided extraforaminal root injections of the cervical spine for radicular pain in a consecutive case series of 844 patients (a total of 1036 injections). The authors described a protocol for injections and needle placement to avoid misdirected injections. Using this technique, they found no serious neurologic events among study subjects (95% CI, <0.35%). Transient pain or weakness occurred immediately after 6 of the 1036 injections (0.6%, 95% CI 0.2, 1.0%). Adverse events seemed to be associated with a relative anterior placement of the needle.

**Open Surgical Techniques.** We accepted 1 study on complications after open surgical treatment. Using the US National Inpatient Sample database (1992–2001), Wang *et al* assessed complications and mortality associated with cervical spine surgery for degenerative disease in the United States.<sup>46</sup> Apparently this database contains only complications reported at discharge, so it likely misses subtle or late-evolving complications. The majority of cervical spine surgery done in the U.S. during this time-frame was for herniated disc disease (56%) and spondylosis (19%). Complications were more common in older patients; after posterior or combined anterior/posterior surgery (9%); and in surgery performed after a primary diagnosis of spondylosis with myelopathy (6%). The odds ratio of inpatient mortality in patients over 75 years of age (compared with patients aged 20–34 years) was 18.5 (95% CI 10.9–31.5).

The following studies were reviewed specifically for descriptive information on complications, and in the absence of prospective control groups must be interpreted with caution. Nonetheless, they demonstrate that open techniques are associated with many types of complication at rates much higher than depicted in the U.S. National Inpatient Sample described above. Most systematically reported adverse events, such as dysphagia and recurrent laryngeal nerve injuries, were linked with the surgical approach to the cervical spine and its relevant anatomy. Other complications were associated with the use of implants and bone grafts.

Winslow *et al*<sup>47</sup> reported on the incidence of dysphagia by using a retrospective qualitative questionnaire which they sent to 497 patients who had undergone anterior cervical discectomy or fusion. Although only 46% of the study group responded, there was an overall 60% rate of dysphagia. Bazaz *et al*<sup>48</sup> prospectively analyzed 249 consecutive patients undergoing anterior cervical spine surgery and found incidences of dysphagia to be 50.2%, 32.2%, 17.8%, and 12.5% at 1, 2, 6, and 12 months, respectively. Surgery at multiple levels also increased the risk of postoperative dysphagia. Finally, Sagi *et al*<sup>49</sup> retrospectively reviewed 311 cases of anterior cervical surgery and found a 6.1% rate of postsurgical respiratory insufficiency; 1.9% of cases required reintuba-



tion. Lee *et al*,<sup>50</sup> in an observational cohort study, compared dysphagia rates after ACDF using anterior plate fixation. There seemed to be greater persistent dysphagia in subjects receiving a higher-profile and more irregular plate.

Neurologic complications of open cervical surgery can include injury to the recurrent laryngeal nerve, to the sympathetic chain, to cervical nerve roots, and to the spinal cord itself.

Recurrent laryngeal nerve injury may be the most common neurologic complication after anterior cervical spine surgery. A retrospective review of 85 patients who had undergone anterior cervical surgery by Heeneman<sup>51</sup> revealed a rate of 11% for vocal cord motion impairment with 3.5% of patients being left with a permanent impairment. Kriskovich *et al*<sup>52</sup> retrospectively reviewed 900 consecutive patients undergoing anterior cervical spine surgery and found a decrease in temporary vocal fold paralysis from 6.4% to 1.69% with the release of endotracheal tube cuff pressure after retractor positioning. A more recent prospective randomized study of 94 patients by Audu *et al*<sup>53</sup> found a 3.2% overall incidence of vocal fold paralysis; cuff manipulation did not reduce the incidence of vocal fold immobility. Flynn<sup>54</sup> reported on findings from a questionnaire sent to 1358 neurosurgeons about their experiences with anterior cervical discectomies and fusions. The surgeons reported a 0.17% rate of nerve root palsies and a 0.05% rate of postoperative spinal cord injury.

Injuring the vertebral artery during ventral approaches to the cervical spine is a rare occurrence, but such injuries can lead to stroke and even death. Burke *et al*<sup>55</sup> retrospectively analyzed 1976 patients who underwent anterior cervical surgery for herniated discs or cervical spondylosis at a single institution. They found a 0.3% incidence of iatrogenic vertebral artery injury. Two of the six patients with such an injury had serious clinical sequelae.

The surgeon's choice of bone grafting material for anterior cervical fusions can affect complication rates. Schnee *et al*<sup>56</sup> performed a retrospective review of 144 cases of anterior cervical fusion with autologous iliac crest bone graft; they found protracted pain in 2.8% of patients and poor cosmesis at the donor site in 3.5% of patients. They also found 1 case (0.7%) of meralgia paresthetica. Although the use of bone morphogenetic proteins (BMP) has increased significantly in treating diseases of the lumbar spine, the literature regarding BMP use in cervical spine interventions is limited. Shields *et al*<sup>57</sup> reported on a retrospective analysis of 151 patients who received high-dose rhBMP-2 during anterior cervical fusions. They found that 9.9% of patients developed a hematoma; 8 patients (5.3% of the total study group) required operative evacuation of the hematoma. Thirteen patients (8.6% of the total group) required either a prolonged hospital stay (>48 hours) or readmission to the hospital secondary to dysphagia, respiratory difficulties, and incisional swelling. Smucker *et al*<sup>58</sup> reported on a retrospec-

tive review of 69 patients who received rhBMP-2 for anterior cervical fusions *versus* a control group of 165 patients who did not. There was a significant difference in perioperative cervical swelling: 27.5% of the rhBMP-2 group experienced swelling compared to 3.6% of the control group.

Kaiser *et al*<sup>59</sup> reviewed the records of 251 patients who had undergone one- and two-level anterior cervical discectomies and fusions with plate fixation. The researchers compared them to a historical control group who did not receive plating. Whereas none of the patients who received a plate experienced graft- or instrumentation-related complications, 6% of the patients in the noninstrumented group demonstrated graft extrusion or subsidence. In longer fusion constructs, Vaccaro *et al*<sup>60</sup> retrospectively found graft/plate failure in 3 of 33 patients (9%) who had undergone two-level corpectomies, and in 6 out of 12 patients (50%) with three-level corpectomies.

### **Systematic Reviews of Surgical Interventions for Neck Pain**

We accepted 4 systematic reviews of surgical interventions for neck pain.<sup>2-4,61</sup> The authors of a 2001 review looking at radiofrequency interventions felt there was only 'limited evidence' for dorsal root ganglion heating as a treatment for cervical brachial pain. They found 'limited evidence' for radiofrequency neurotomy as a treatment for presumed zygapophysial pain caused by flexion/extension injury to the neck.<sup>3</sup> A 2002 review using the Cochrane methodology<sup>2</sup> stated there was inadequate evidence to conclusively determine risks *versus* benefits for surgery in patients with cervical radiculopathy. Two systematic reviews looked at alternative methods of anterior interbody surgery for single- or double-level cervical disease; the reviews found no clear advantage to any one method.<sup>4,61</sup>

The Cochrane group reported that only 'limited evidence' exists to support the following strategies: cervical plate instrumentation in two-level fusion; autograft over bovine xenograft; and BMP protein over autograft. Similarly, the Cochrane authors reported that 'moderate evidence' exists in the following areas: early pain relief is likelier after ACDF *versus* ACD; ACDF with autograft has improved global outcomes *versus* ACD with a cage; and ACD alone has less perioperative morbidity (blood loss, hospital stay, and work loss) compared to ACDF. This 2004 Cochrane review<sup>61</sup> concluded that simpler operations for cervical interbody fusion seem to confer the same clinical results as more complex procedures using allografts, plates or cages, but this evidence is weak.

## **Discussion**

### **Rationale for a Best-Evidence Synthesis in the Surgical Treatment of Neck Pain**

Surgical procedures are costly. They expose the patient to inherent serious risks and involve unavoidable perioperative pain and morbidity associated with the invasive

manipulation of vulnerable tissue. Such interventions are not usually considered in the absence of serious illness and without a reasonable expectation of clear and clinically important improvement. The definition of *minimal clinically important difference*<sup>62</sup> assumes the organic calculation of cost, risk and side effects before determining what degree of improvement may be reasonably considered clinically important. Consequently, surgical practice requires, on a *prima facie* basis, a higher level of clinical evidence and confidence than many nonsurgical measures.

Nonetheless, many surgical interventions for diseases associated with neck pain are well-established and strongly indicated. These include stabilization of certain cervical fractures or dislocation; control of tumor, hemorrhage or infection threatening airway or neurologic loss; and degenerative or inflammatory diseases causing progressive spinal cord compression and functional loss. In these clinical situations, neck surgery is often highly effective against imminent and catastrophic loss.

However, the current Neck Pain Task Force mandate was to look specifically at the best evidence regarding the surgical treatment of neck pain *in the absence* of these serious destructive, inflammatory, or neoplastic processes. The question under consideration was “What scientifically convincing evidence exists concerning surgical interventions in persons with neck pain and possibly radiculopathy, when only common aging and degenerative processes are found on evaluation?”

In some of the more dire clinical scenarios described above where serious morbidity, catastrophic loss or death are nearly certain, proof of surgical efficacy may *not* require a randomized controlled trial—for example, trials to prove that surgery can effectively control large vessel, massive hemorrhage. Even small case series demonstrating survival or minimal morbidity after a specific intervention may provide convincing and valuable evidence of surgical efficacy. These situations are comparable to the frequently-cited parachute analogy from the *British Medical Journal (BMJ)*: since survival from a high-altitude fall is so unlikely, the uncontrolled case series of ‘no’ or ‘minimal’ injury when using a parachute may represent all the evidence needed to assume efficacy, even strong efficacy, in principle.<sup>63–66</sup>

At the onset it was possible our review may have determined that certain subgroups of neck pain within our mandate may have fit this parachute paradigm: *both* uniformly poor outcome by natural history or alternative treatments, *and* consistent, well-documented case series of surgical cure. In that event, the level of evidence without any matched cohort study or RCT would allow for sufficient confidence in supporting efficacy.

However, as other work by the Neck Pain Task Force has clearly demonstrated,<sup>16,17,67–70</sup> neck pain in the context of this review does not fit the ‘parachute’ paradigm of clinical research. The neck pain syndromes this task force has considered are very common: the associated pain intensity and impairment range across the spectrum

of severity; the clinical course is not highly predictable; episodes of exacerbations are frequent; spontaneous diminution or resolution of pain are also common; and the chance of progression to grave and permanent disability is neither frequent nor uniform, even among the most high-risk subgroups.

In this context, higher levels of evidence—beyond what is normally produced by case series and uncontrolled cohort designs—are needed to determine whether clinical changes seen after surgical interventions are simply a spontaneous variation of the illness, the nonspecific effects of applying any intervention, the result of changes in patients’ social support or expectations, or *possibly* an effect of the surgery itself.

#### **Evidence for the Surgical Treatment of Neck Pain Syndromes in the Absence of Serious Pathology**

The studies looking at surgical interventions for neck pain alone in 3 common clinical situations do not show clear or convincing evidence that these interventions are effective (Table 2).

1. Commonly used percutaneous interventions (*e.g.*, facet joint injection and radiofrequency neurotomy) for neck pain showed no clear advantage compared to sham or placebo procedures, when subjects and procedure sites were selected by the person’s responses to anesthetic injections.
2. Cervical fusion for chronic neck pain alone has not been evaluated in any scientifically admissible studies. The many case series commonly cited have serious methodologic problems, particularly in terms of their retrospective design, poorly validated measures and a high proportion of missing subjects at follow-up. Even so, despite some surgeons’ perceptions of extremely high efficacy,<sup>9</sup> most of these studies still report only modest improvements in symptoms years after the surgery: Many patients remained moderately or severely impaired,<sup>10</sup> only half reported being more than ‘somewhat better’, and only a minority felt they were more than ‘somewhat satisfied’ with their current neck condition.<sup>7</sup> None of these surgical intervention studies for neck pain alone convincingly identifies the cause of the subjects’ serious neck pain and/or disability.<sup>5</sup> The failure of surgical interventions to prove highly effective when performed for common degenerative changes alone (*i.e.*, changes not usually associated with serious symptoms) is perhaps not unexpected.
3. Neck pain associated with upper cervical trauma may represent a more concrete pathologic entity. Specific structural injury to the upper cervical ligamentous stabilizers after whiplash exposure has been suggested on special sequence MRI evaluation Krakenes *et al*<sup>18–20</sup> and Kaale *et al*.<sup>21,71</sup> The purported lesions may be similar to those suggested by Dvorak *et al* on functional computed tomography (CT) imaging.<sup>22</sup> To date, no con-

**Table 2. Best Evidence Synthesis Summary for the Surgical Treatment of Neck Pain and Associated Disorders**

Population	Likely Helpful (Worth Considering)	Possibly Helpful (Might Consider)	Likely Not Helpful (Not Worth Considering)	Not Enough Evidence to Make Determination
Grade IV neck Pain with serious structural pathology (unstable fracture, infection, tumor, vascular injury, etc.)	Beyond the NPTF mandate Aggressive surgical treatment of many of these conditions is generally accepted as effective and often strongly advised. Readers are referred to literature of specific pathological conditions.			
Grade III neck pain (with cervical radiculopathy)	ACD (short-term*)  ACDF (short-term*)	Limited (<4 injections) root or epidural corticosteroid injections (short-term*)  ACDF + instrumentation/ cages (short-term*)  Single-level cervical disc replacement† (short-term*)	Thermal heating of the dorsal root ganglion	Multilevel cervical disc replacement (long-term efficacy and safety)  Spinal cord stimulator implantation or implantable intrathecal narcotic pump Disc nucleoplasty or anuloplasty
Grade I or II. Axial neck pain without radiculopathy (without serious underlying structural pathology)	None	None	Corticosteroid injections to cervical facets  RF Neurotomy to cervical facets nerves without confirmed zygapophyseal pain‡ Cervical decompression  Cervical fusion or disc replacement (comorbidities present§)	RF Neurotomy to cervical facets nerves with confirmed zygapophyseal pain³  Cervical fusion (comorbidities absent)  Cervical disc replacement² Spinal cord stimulator implantation or implantable intrathecal narcotic pump Disc nucleoplasty or anuloplasty
WAD-related axial neck pain without fracture, dislocation, or instability	None	None	Corticosteroid injections to cervical facets  RF Neurotomy to cervical facets nerves without confirmed zygapophyseal pain³ Cervical decompression  Cervical fusion or disc replacement (comorbidities present⁴)	RF Neurotomy to cervical facets nerves with confirmed zygapophyseal pain³  Craniocervical or upper cervical fusion¶  Cervical fusion comorbidities absent Cervical disc replacement²  Spinal cord stimulator implantation or implantable intrathecal narcotic pump Disc nucleoplasty or anuloplasty
Cervicogenic headache without serious underlying structural pathology	None	None	Corticosteroid injections to cervical facets	RF Neurotomy to cervical facets nerves with confirmed zygapophyseal pain³

(Continued)



**Table 2. (Continued)**

Population	Likely Helpful (Worth Considering)	Possibly Helpful (Might Consider)	Likely Not Helpful (Not Worth Considering)	Not Enough Evidence to Make Determination
			RF Neurotomy to cervical facets nerves without confirmed zygapophyseal pain <sup>3</sup> Cervical decompression	Craniocervical or upper cervical fusion <sup>5</sup>
			Cervical fusion or disc replacement (comorbidities present <sup>4</sup> )	Cervical fusion comorbidities absent Cervical disc replacement <sup>2</sup>
				Spinal cord stimulator implantation or implantable intrathecal narcotic pump Disc nucleoplasty or anuloplasty

\*Benefit over nonsurgical care is most clearly seen in the first year after surgery.

†Safety data for disc replacement not available beyond short-term trials (2 yr). Not enough evidence to determine safety over intended life of disc replacement prosthesis (40 yr). Caution recommended in younger patients and those comorbidities excluded from clinical trials.

‡See "Diagnosis and Assessment" Chapter for validity of zygapophyseal pain diagnostic strategies.

§Comorbidities Cervical pain as part of generalized pain syndrome (e.g., fibromyalgia, somatization disorder, etc.), serious psychological distress or impairment, or metabolic diseases complicating cervical procedures.

¶Upper cervical or craniocervical fusion for asymmetric alar, transverse or other upper cervical ligaments as seen on MRI or functional CT scan (absent radiographic instability).

trolled surgical trials corroborating the existence of such lesions have been conducted. The performance of highly morbid surgical procedures such as craniocervical fusion, in the absence of any scientifically valid evidence, is clearly not supported.

Of 4 previous systematic reviews accepted by the Neck Pain Task Force as scientifically valid in methodology, only one suggested even 'limited evidence' regarding any of these procedures in the clinical situation of neck pain without radiculopathy. Some recent systematic reviews of percutaneous interventions in neck pain<sup>72-74</sup> were found by the Neck Pain Task Force to be scientifically invalid in their method of review and analysis. These scientifically inadmissible reviews purporting efficacy of these procedures were all authored by the same group.

#### **Evidence for the Surgical Treatment of Neck and Radicular Pain Syndromes Due to Degenerative Condition**

The surgical treatment of cervical radiculopathy due to disc herniation or spondylosis is fairly well documented in the literature by well-designed trials (Table 2). One small study seemed to show some relative short-term effectiveness of cervical epidural injections for cervicobrachial pain; however, heating of the dorsal root ganglions (DRG) seemed to have no beneficial effect. Although steroid injections around the lumbar nerve roots has been shown to decrease the rate of surgery for lumbar stenosis, similar injections around the cervical root has not been shown to perform better than anesthetic injection alone.<sup>75</sup>

We accepted only 1 study comparing nonoperative outcomes to open operative surgery for cervical radicu-

lopathy due to chronic cervical spondylosis; this study showed an early advantage from surgery *versus* physiotherapy that diminished over time.<sup>25</sup> No similar trial has been reported for cervical disc herniation alone, despite the fact that surgery for disc herniation represents the overwhelming majority of cervical operations performed in persons under age 65 years.<sup>46</sup>

The data from several well-conducted RCTs regarding treatment for *lumbar* disc herniation show a similar pattern—significantly earlier resolution of pain and return of function in the surgically decompressed group.<sup>76</sup> Although this effect may hold true for the cervical spine as well, the data do not currently exist. Observational data from well-designed trials (Table 1) show very substantial and consistent decreases in pain and improvement in function over the first 6 to 12 weeks after open surgery for cervical radiculopathy. These effects seem preserved at 1- and 2-year follow-up. These data cannot compare outcomes after open surgery to outcomes from nonsurgical treatments or from natural history (*i.e.*, if cervical radiculopathy followed its natural course without intervention). However, data from existing research can serve as a guide to patients and clinicians who are considering neck surgery for radiculopathy. The findings may describe the outcomes that can reasonably be expected and how quickly they might be achieved.

In this context, carefully selected patients who are considering surgery for cervical radiculopathy (with root compression on imaging studies) may reasonably expect pain and functional impairments to improve substantially in the early postoperative period. However, these patients should be aware that, contrary to the oft-cited statistic that 90% of patients who undergo neck surgery for cervical radiculopathy enjoy excellent re-

sults,<sup>67</sup> the best scientific evidence suggests a significant proportion (20%–30%) will experience only modest or no real improvement.

There have been a number of well-conducted RCTs comparing different surgical treatments for cervical radiculopathy. These trials do show some between-treatment differences. However, our synthesis of these data suggests that large advantages in outcome are not apparent with fusion *versus* decompression, with decompression and fusion *versus* disc arthroplasty, or in the use of various fusion-adjuvant measures among carefully selected patients. Minor differences in surgical treatments do seem to be supported by the evidence in favor of decompression alone *versus* fusion (for decreasing early operative morbidity)<sup>30</sup>; in favor of cervical plating in multilevel fusions,<sup>39,40,77</sup> in favor of some technologies that may be associated with higher union rates<sup>34</sup>; and in favor of certain technologies, which avoid ICBG harvesting, decrease some postoperative donor site pain.

Benefit from surgical intervention for radiculopathy does not seem to be generalizable to all patients in whom preoperative imaging studies have confirmed neurologic compression. Some authors have suggested the best predictor of functional outcome after ACDF may be preoperative psychometric testing (*i.e.*, there are poorer outcomes in patients with higher levels of psychological distress).<sup>78</sup> Other factors independently associated with better outcomes are: male gender; greater kyphotic deformity (before fusion surgery); and less reported preoperative functional impairment.<sup>78</sup>

#### **Limitations of the Literature**

- Evidence from relatively small, although well-designed and carefully monitored clinical trials may not be generalizable and thus does not necessarily support wider application of the procedure in clinical practice.
- Many device trials for administrative approval (*e.g.*, trial results submitted to the U.S. Food and Drug Administration) may have strict enrollment criteria; they are more likely to exclude subjects with significant psychological troubles, those involved in litigation issues, and subjects with associated metabolic or constitutional illnesses (*e.g.*, osteoporosis), thus the findings may have limited generalizability to many surgeons' practices.
- Furthermore, subjects hoping to enter trials of a new treatment are often required to have liberal insurance coverage and/or private means of paying for an expensive operation. On a systematic basis, these clinical trials may be biased towards more optimistic outcomes if the enrolled subjects are better off economically, better insured, have fewer medical and psychological comorbidities, and have access to first-tier medical systems which are willing to undergo the scrutiny of randomized clinical trials.
- In addition, surgeons may find it less desirable to enroll medically, socially or emotionally 'at risk' sub-

jects when a careful review of outcomes is assured by independent observers. Compared to the most well-designed and well-monitored clinical trial, reviews of spinal surgery outcomes which use administrative, geographic or occupational databases often demonstrate less positive outcomes, as well as higher complication rates and more frequent reoperation.<sup>79,80</sup>

#### **Research Recommendations**

Although every aspect of surgical care may benefit from further research, we have made the following observations and recommendations:

- Further effort, expense, and time spent in preparing, editing and publishing case series of common procedures or minor variants are very unlikely to add to our clinical knowledge.
- In the absence of an extraordinary observed effect size, the spontaneous variability of most neck pain syndromes suggest that very small, randomized trials ( $n < 20-30$  in individual arms) are also unlikely to be helpful, and may in fact be misleading.
- The CONSORT proposals for the design of future trials should help with study design standardization.

**Outcome Metrics.** Based on many clinical studies reviewed by the Neck Pain Task Force, we believe that, without concomitant standard metrics, it is extremely difficult to interpret and compare outcome measures provided by operating surgeons themselves using subjective, physician-rated global grading scales (*e.g.*, Odom or Prolo scales).

We agree with the recommendations of Deyo *et al* and others that multiple validated outcome measures be assessed at regular intervals. At a minimum, these should include measures to determine: pain intensity; functional ability; medication usage; work status; and subjects' global satisfaction.

There is evidence that speed of recovery and resuming benchmark activities are important to patients, and they consider these factors when deciding whether or not to undergo surgical intervention. For this reason, researchers should be strongly encouraged to adopt earlier interval outcomes measures (1.5 months, 3 months, and 6 months) along with the standard medium-term (2 to 5 years) measurements. Results from the best-designed lumbar radiculopathy spine studies demonstrate that early differences between surgical and nonsurgical interventions may be of greatest importance in decision-making for certain patient subgroups. Evaluation of similar early stage changes may be important in the treatment of cervical radiculopathy.

**Minimum Acceptable Outcomes.** Investigators might consider conducting systematic preoperative assessments of each patient's minimal acceptable outcome (using parameters similar to those previously described for preoperative assessment in lumbar surgery). Before surgery, enrolled subjects can be asked to describe what, for them, would be minimally acceptable out-

comes in terms of pain intensity, medication intake, and recovery after surgery (e.g., a average daily neck pain intensity of 2/10; taking only occasional NSAIDs and no narcotics; returning to part-time work). We suggest that achieving patients' reasonable goals can be more confidently considered a 'success' than arbitrary improvements of 2 points on a VAS scale or findings from *post hoc* satisfaction assessments. This method has been applied in defining minimum acceptable outcome in lumbar spine surgery.<sup>81,82</sup>

**Safety and Estimates of Complication Rates.** Studies designed to test safety or compare complication risk of low frequency events (e.g., device failure, infection) must have large number of subjects followed. Small cohort studies (<100 subjects) of new techniques or devices are often purported to demonstrate 'safety', but these studies are usually grossly underpowered. For example, if the acceptable *increased* deep infection rate when using BMP supplement in cervical fusion (associated with increased swelling and drainage after surgery) is 0.5%, a study involving 50 subjects with one deep infection can only estimate a deep infection rate of <10% with 95% confidence (approximately 3/n). Even if no infections are found, the results from such small studies still cannot reassure the clinician that the new technique has an acceptable risk profile. However, these studies rarely indicate the *a priori* minimally acceptable serious failure rate (e.g., 0.5% device failure) or the precision around the estimates of these rates (confidence levels).

**Independent Evaluator and Custodian of Data.** The use of an independent outcome assessment and independent custodian of data for important clinical trials has been recommended as a means to allow transparency in data analysis and presentation. It is likely that in the future, major scientific publishers may require some type of prospective and independent data security and the ability to audit the findings of clinical trials. Given the enormous personal and economic burden of neck pain disorders, commercial and governmental interests in this field and the importance in confirming findings and disseminating both positive and negative research results, the Neck Pain Task Force believes that the use of independent outcome assessments and custodians of research data should be strongly considered.

#### **Recommendations for Research Focus in Specific Clinical Topics**

- The efficacy of percutaneous neurotomy for suspected facet joint pain is not supported by the current evidence. As the only trial published to date was very small and the effect estimate likely confounded, these procedures should be evaluated with a much larger RCT before being more broadly applied in clinical use. A multicenter design with an independent examiner/observer and data custodian would be extremely desirable in this case to minimize the influence of operator variability and bias.

- Randomized trials are needed to evaluate the effectiveness of open surgery for neck pain associated with common degenerative changes only. This should be combined with a concurrent assessment of diagnostic tools thus far poorly validated in neck pain<sup>75</sup> such as MR imaging, functional radiography (e.g., flexion and extension radiographs) and provocative discography. Although it may be that extensive cervical arthrosis proves amenable to surgery, intervention may have serious negative effects on patients with more limited degenerative changes and those in more complex circumstances (e.g., minimal DDD, concomitant fibromyalgia symptoms and severe psychological distress). Given the relatively modest improvements we have seen in the literature reviewed,<sup>6,8</sup> we believe a large, multicenter design is needed to avoid performing further underpowered and potentially misleading studies.

- No clinical studies have been done to evaluate surgical treatment for suspected ligamentous injury to the upper cervical spine as reportedly demonstrated on special sequence MR. If strictly audited feasibility studies are promising, these should be followed by larger RCTs which are urgently needed to confirm the clinical utility of interventions for this theoretical diagnosis.

- Clinical trials regarding the relative effectiveness of new technologies for cervical radiculopathies have not shown large differences in therapeutic effect. Such technologies are often very expensive adjuvants to a basically sound procedure (e.g., ACDF supplemented with cervical plating or bone morphogenic protein fusion enhancements). When new technologies demonstrate only marginal gains in effectiveness, understanding the cost-benefit analysis is vital. This is especially relevant as patients assume greater primary responsibility for certain costs, and as third party payers seek justification for new technology expenses. Yet our review of the literature found that basic economic analyses of these interventions are notably lacking.

#### ■ **Conclusion**

Surgical treatment for cervical radicular symptoms may be reasonably considered in patients with severe impairments. It is not evident that one surgical technique is clearly superior to others for radiculopathy. Invasive interventions such as fusion, injections and radiofrequency neurotomy as treatment for neck pain alone, without radicular symptoms and without clear serious pathology, seems to lack scientific support with current diagnostic and therapeutic methods.

#### ■ **Evidence Statements**

##### **Cervical Injections for Neck Pain and Radiculopathy**

- There is evidence supporting short-term symptomatic improvement of radicular symptoms in patients not involved in litigation when treatment involves a



short course of epidural or selective root injections with corticosteroids. There is no evidence that multiple injections (>3) or repeated courses are beneficial.

- There is no evidence that the use of cervical root or epidural injections in seriously symptomatic radiculopathy patients can decrease the rate of open surgery.

#### **Cervical Injections or Radiofrequency Neurotomy for Neck Pain Without Radiculopathy**

- There is evidence that intra-articular steroid injection is not an effective intervention for suspected zygapophysial pain that is otherwise temporarily diminished by various anesthetic blockade protocols.
- There is no clinical evidence to support the use of radiofrequency neurotomy for suspected zygapophysial pain.

#### **Open Surgical Treatment of Cervical Radiculopathy**

- It is not clear that long-term outcomes are improved with the open surgical treatment of cervical radiculopathy compared to nonoperative measures; however, relatively rapid and substantial pain and impairment relief in the short-term (6 to 12 weeks after surgery) following surgical treatment of cervical radiculopathy seems to be reliably achieved.
- Anterior cervical plating in one- and two-level fusions seems to reduce kyphosis progression after surgery.
- It is not clear that complex open surgical procedures for cervical radiculopathy (including fusion, cage or plate instrumentation, or fusion augmentation with bone morphogenetic protein) provide clinically important superior outcomes *versus* simple cervical decompression alone.
- Early results from trials of cervical disc arthroplasty for radicular symptoms seem to show similar 1- to 2-year outcomes after anterior fusion surgery. The long-term safety of cervical disc arthroplasty is unknown.

#### **Open Surgical Treatment for Neck Pain Without Radiculopathy**

- Anterior cervical fusion or cervical disc arthroplasty for neck pain without radiculopathy or serious underlying pathology is not supported by current evidence.
- There is no evidence to support surgical intervention for suspected upper cervical ligamentous injury after whiplash exposure as determined by signal changes within these ligaments on MR imaging.

#### **Complications Associated With Surgical Interventions for Neck Pain**

- Cervical foraminal or epidural injections are associated with relatively frequent minor adverse events (5%–20%); however, serious adverse events are very uncommon (<1%).

- After open surgical procedures on the cervical spine, potentially serious acute complications are seen in approximately 4% of patients; these are more common in older patients; after combined anterior and posterior surgery; and after surgery for myelopathy (as opposed to radiculopathy or neck pain alone).
- Minor complications after open surgical procedures on the cervical spine (*e.g.*, dysphagia, hoarseness, donor site pain) are frequently reported and usually resolve with time.

#### **Key Points**

- Evidence does not support intra-articular steroid injections or radiofrequency neurotomy for neck pain.
- Anterior cervical fusion or cervical disc arthroplasty for neck pain without radiculopathy or serious underlying pathology is not supported by current evidence.
- There is support for short-term symptomatic improvement of cervical radicular symptoms with epidural or selective root injections with corticosteroids; however, it has not been shown that using root injections in seriously symptomatic radiculopathy patients can decrease the rate of open surgery.
- It is not clear that long-term outcomes are improved with the surgical treatment of cervical radiculopathy compared to nonoperative measures; however, relatively rapid and substantial pain and impairment relief after surgical treatment seems to be reliably achieved.
- Early results from trials of cervical disc arthroplasty for radicular symptoms seem to show similar early outcomes compared with anterior discectomy and fusion surgery; long-term viability of cervical disc replacement prosthesis has not been demonstrated.
- There has not been adequate testing to support surgical intervention for possible upper cervical ligamentous injury after whiplash exposure.

#### **Acknowledgments**

The authors thank Ms. Oksana Colson and Ms. Leah Phillips (M.A.) for their administrative assistance and to Mr. Stephen Greenhalgh (M.A., MLIS), Ms. C. Sam Cheng (MLIS) and Ms. Lori Giles-Smith (MLIS), research librarians, for their assistance in the work of the Neck Pain Task Force. The authors also thank Ms. Evelyn Michaels for her assistance in editing the manuscript. The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders was supported by grants from the following: National Chiropractic Mutual Insurance Company (USA); Canadian Chiropractic Protective Association (Canada); State Farm Insurance Company (USA); Insurance Bureau of Canada; Länsförsäkringar (Sweden); The Swedish Whiplash Commission; Jalan Pacific Inc. (Brazil); Amgen

(USA). All funds received were unrestricted grants. Funders had no control in planning, research activities, analysis or results. The report was not released to grantors prior to publication and no approval was required from funders regarding the final report. Dr. Côté is supported by the Canadian Institutes of Health Research through a New Investigator Award and by the Institute for Work & Health through the Workplace Safety and Insurance Board of Ontario. Dr. van der Velde is supported by the Canadian Institutes of Health Research through a Fellowship Award. Dr. Carroll is supported by a Health Scholar Award from the Alberta Heritage Foundation for Medical Research. Dr. Cassidy is supported by an endowed research chair from the University Health Network.

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