Update to the Treatment of Degenerative Cervical Disc Disease

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DISCLOSURE

• I have no direct or indirect financial interest in any pharmaceutical, medical device, or other health-care related company
Overview

- Cervical/neck pain is common reason for visiting doctor
  - **Over 6 million patient visits** in the US for neck pain
  - Represents 1.5% of all health care visits to hospitals and physician offices (*The Burden of Musculoskeletal Diseases in the United States*)

- Main causes
  - Soft tissue strain
  - Degenerative arthritis
  - Trauma
  - Cervical disc disorders

- Pain can be accompanied by paraesthesias and weakness
It’s a Natural Process

- Natural process that all people undergo as they age
  - Nucleus dehydrates, compromising its cushioning ability
  - Annulus may also begin to degenerate under the repeated stress of daily activities or trauma => disc herniation and loss of disc height
Treatment Options

- Non-surgical treatment
  - physical therapy
  - chiropractic care
  - spinal injections
  - bed rest
  - bracing
  - analgesics / NSAIDs

- Most patients improve without surgery

- If the disability/pain is non-responsive to conservative care, surgery may be considered
Surgical Treatment

- Decompression of neural structures to alleviate pressure
  - Disc, bone, ligaments may be removed

- Removal of disc and bone creates instability between the two vertebrae

- Surgeon must stabilize, or reconstruct, the spine after decompression
  - Option 1: anterior discectomy with fusion (ACDF)
  - Option 2: total disc replacement (TDR)
Treatment Options: Fusion (ACDF)

- ACDF goal is to join two vertebrae together in a position that will stabilize the spine by preventing motion

- Traditionally, ACDF is procedure of choice
  - 50 years of clinical experience
  - Widely accepted technique

- Fusion rates very high with ACDF (90-97%)
Sequelae of ACDF

- Adjacent-level degeneration
  - 25.9% of cervical fusion patients predicted to have second surgery within 10 years (Hilibrand, 1999)

- Why?
  - Adjacent level has to compensate loss of motion of fused level
    - Extra motion fatigues adjacent disc and accelerates its degeneration (Schwab, 2006)
  - Hardware (plate and screws) may impact adjacent levels
    - 23.7% of ACDF patients developed moderate to severe ossification at adjacent level (Park, 2005)

- Natural History & Genetics
Treatment Options: Arthroplasty

- Arthroplasty - total disc replacement with artificial disc

Rationale
- By allowing motion, adjacent level will not be “overworked” to compensate
- Early neck motion without bracing requirement
- Implant contained within disc space (limit damage to adjacent levels)
- Eliminate bone graft donor site complications and possible disease transmission from donor bone graft
Treatment Options: Arthroplasty

- Newer procedure
- 20 years of clinical experience with total disc replacement in the cervical spine
Indications

- Patient should
  - be skeletally mature
  - have only one or two **symptomatic** disc levels (C3-C7)
  - have radiculopathy or neurologic deficit that has failed 6 weeks of conservative therapy
Contraindications

- Patient should not
  - have any type of infection, especially infection in the spine and/or surrounding area
  - osteoporosis or osteopenia (BMD T-score < -1.5)
  - Trauma or other anatomic deformity (AS, RA)
  - Biomechanical instability
  - allergies or sensitivity to implant material
Old vs. New

- Fusion and arthroplasty both require same surgical approach
  - Anterior
  - Same approach-related risks
  - Similar OR time
  - The devices vary in placement technique and biomechanical components

New is not always better ... Let’s look at the evidence ...
2007

Prospective, multi-center, randomized with two-year follow-up

541 patients randomized to disc or fusion

78% follow-up

Re-ops: 5 discs, 23 fusion

Results as good as or better compared to fusion

Return to work rate statistically significantly higher in arthroplasty group than fusion group

Clinical Evidence

- 2010
- Prospective, multi-site, randomized clinical trial with 24-month follow-up and additional data at 36 and 60 months
- 144 patients with 60 month follow-up and 127 with fusion
- At both 36- and 60-month periods, differences in NDI scores statistically significant in favor of patients who received TDA
- Statistically higher rate of neurologic success compared to fusion at 24, 36 and 60 months
- Statistically significant lower revision and supplemental fixation rates for TDA versus fusion patients

2009

Prospective, multi-center, randomized with two-year follow-up

209 patients randomized to disc or fusion

8.5% of fusion patients needed a re-operation within the post-op period compared to 1.8% of TDA patients (p = 0.033)

“The results of this clinical trial demonstrate that [total disc arthroplasty] is a safe and effective surgical treatment for patients with disabling cervical radiculopathy…”

“By all primary and secondary measures evaluated, clinical outcomes after [total disc arthroplasty] implantation were either equivalent or superior to those same clinical outcomes after fusion.”

Adjacent Segment Disease

- February 2015
- Meta-analysis of 8 prospective studies (1726 patients)
- ACDF patients 1.3x more likely to develop adjacent segment disease @ 2 years
- TDA patients 50% less likely to require adjacent segment operations @ 2 years

One vs. Two Levels

- March 2015
- Multicenter Prospective RCT
- 164 one level; 225 two level
- Evaluation at four year follow-up

- No difference between one vs. two level TDA in NDI, VAS, adverse events, reoperations

Recent Meta-analysis

- January 2015
- Analysis of 18 RCTs (4061 patients)
- TDA superior ($P < 0.00001$)
  - Neurological improvement
  - Motion preservation
  - Need for repeat surgery at index level
  - Fewer adverse events

Recent Meta-analysis

- No significant difference:
  - Operative blood loss (low overall)
  - Length of stay (short overall)
  - VAS Neck pain (low overall)
  - VAS Arm pain (low overall)

Case Study

• 40 yo right-handed male presents with left arm pain and weakness in his biceps and grip.
• Onset was 3 weeks prior to presentation, upon waking in the morning.
• He is gainfully employed, and although he works in management, occasionally will help out in the factory and lift heavy objects (> 50 lbs).
• He briefly tried chiropractic therapy. His symptoms do not respond to NSAIDs.
Case Study
Case Study

• Given his young age, unremarkable medical history, and healthy-appearing adjacent disc levels, a two-level total disc arthropasty or two-level ACDF was offered.

• He elected to pursue total disc arthroplasty.
Case Study
Case Study

• In the recovery room, his arm pain was completely relieved.
• Length of stay: 1 night.
• Return to work: Post-op day 11.
• On 2 week follow-up, he had residual numbness in his left thumb.
• On 6 week follow-up, he had no symptoms.
Thank you

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