

Artificial cervical (and lumbar) disc implants

Noertjojo K, Martin CW, Dunn CT

Workers' Compensation Board of BC

Clinical Services

Evidence Based Practice Group

Outline:

- **Background.**
 - WorkSafeBC mandate
 - Degenerative disc disease
 - The premise behind artificial disc
 - Alternative surgical treatment for DDD
 - Why did we review artificial disc?
 - WorkSafeBC Visiting Specialist Clinic
- Objectives.
- Methods.
- Results.
- Search update.
- WorkSafeBC conclusions.

Background:

- The mandate of the Workers' Compensation Compensation Board of BC is to:
 -
 - Rehabilitate those who are injured and provide timely return to work
 - Ensure sound financial management for a viable workers' compensation system
 -

- **Degenerative disc disease (DDD):**
 - One of the most common spinal 'disorder'
 - > 50% of middle age population has radiological or pathological evidence of cervical DDD
 - > 80% asymptomatic
 - 10-15% has associated nerve root compression
 - Doesn't mean that untreated patients would progress into disability
 - The disease does not remain static over period of time
 - Pathogenesis is still unknown
 - Natural aging maybe the only significant factor
 - Source of pain is unknown
 - Conservative and surgical treatments are 'available' incl. exercise, anti-inflammatory, weight loss, physical therapies, therapies, discectomy, IDET, disc arthroplasty, prosthetic disc disc nucleus device, bioengineered nucleus pulposus replacement

- Past 50 years, spinal fusion becomes 'standard surgical care' for numerous spine conditions incl. DDD
DDD
- Hypothesis behind spinal fusion: spinal pain is associated with continued motion at the affected disc disc level
 - stabilization at motion segment would remove the pain
- Problems:
 - Diagnosing cause of spinal pain is problematic
 - Possibility of stress & increase to the adjacent segment which which may initiate or accelerate the DD process in the adjacent segment → hence the emergence of artificial disc disc

- The premise behind artificial disc:
 - Abnormal motion correction
 - Restoration of intervertebral space height
 - Normalization of physiological curvature and instantaneous axis of rotation
 - Relief of pain & return to normal function
- One major argument against spinal fusion is the acceleration of the adjacent segment degeneration:
 - It seems the data used for this argument were misinterpreted.
 - In fact, the contrary is true

- Alternative surgical treatment:

Bagby & Kuslich cage

- September 2004:
 - Proposal received
 - Funding for trial on the evaluation of the role the role and potential benefits of artificial artificial cervical discs (Bryan's disc) in WorkSafeBC patients

The Visiting Specialist Clinic.

- Developed in May 1997
- Based on the concept of expedited services
- Includes:
 - Surgical services
 - Consultations
 - Surgical procedures
 - Surgical facilities
 - Diagnostic medical imaging
 - MRI
 - CT Scans

Objectives:

- To investigate:
 - the safety and effectiveness of intervertebral intervertebral cervical disc implants in treating DDD
 - the relative advantages compared to cervical fusion in treating DDD
- Secondary objective:
 - summarize available literature (systematic (systematic reviews) on artificial disc implantation

Outline:

- Background.
- Objectives.
- **Methods.**
 - Search date
 - Inclusion criteria
 - Search strategy
 - Keywords
 - Sources
- Results.
- Search update.
- WorkSafeBC conclusions.

Methods:

- Date:
 - Inception date up to week 4 October 2004
- Inclusion:
 - Human, English language (at least the abstract)
- 2 steps search:
 - Identifying primary research on cervical disc implant
 - Identifying review (systematic or non systematic) on any any spinal disc implants

- **Keywords:**

1. **Identifying primary research on cervical implant:
implant:**

- bryan cervical disc prosthesis OR cervical disc prosthesis OR intervertebral cervical disc prosthesis OR artificial cervical disc OR OR artificial cervical implants OR artificial cervical disc implants OR OR prestige cervical disc OR cummins disc* OR bristol disc* OR cummins cervical disc OR bristol cervical disc OR prestige cervical OR cervical OR prestige artificial cervical OR prestige cervical disc OR OR cummins artificial cervical disc OR cummins cervical disc OR prodisc-c implant OR prodisc-c artificial cervical disc OR prodisc-c cervical disc OR prodisc c implant OR prodisc c artificial cervical disc cervical disc OR prodisc c cervical disc OR prodisc c OR prodisc-c OR OR cervicore device OR cervicore artificial cervical disc OR cervicore cervicore cervical disc OR cervicore artificial disc OR cervicore disc* disc* OR pmc prosthesis OR pmc cervical disc OR pmc implant OR OR pmc disc OR pmc artificial cervical disc OR prestige implant

- 22 published primary research identified, 15/22 were relevant

2. Identifying review (systematic or non systematic) systematic) on any spinal disc implants :

- (artificial discs OR artificial disc implant OR artificial disc artificial disc prosthesis) AND (review OR systematic systematic review)

- Sources:
 - OVID® Gateway Databases :
 - ACP® Journal Club, BIOSIS®, CINAHL®, EMBASE®, OVID® Medline
 - Cochrane Library:
 - Cochrane Database of Systematic Review, Cochrane Central Trial registry, DARE
 - INAHTA and its member countries:
 - CCOHTA, AHFMR, Aetmis, VATAP, NCCHTA, MSAC, NZHTA, NZHTA, SBU, HAS-ANAES, DACEHTA and GR
 - Other non commercial organizations incl. the Ontario Ministry of Health & Long-Term Care, the the US ICSI, the Minnesota Department of Health Health

- Other workers' compensation boards:
 - Canada: Yukon and Northwest Territories, Alberta, Saskatchewan, Manitoba, Nova Scotia, Newfoundland, Newfoundland, PEI, Quebec and Ontario
 - US: Washington State Department of Labor and Industries, Colorado Department of Labor and Employment, California State Compensation Insurance Insurance Fund and Oregon Workers' Compensation Insurance
- Health insurances:
 - AETNA, Medicare-Medicaid, Regence group, Blue Cross Cross Blue Shields, Humana, Permanente Medical group, group, Cigna, Tuft and Western Health Advantage

- Websites of orthopaedics and spine surgeon associations:
 - in the US, the UK, Canada and Australia
- Federal agencies websites:
 - Health Canada, the US FDA and the US NIH

Outline:

- Background.
- Objectives.
- Methods.
- **Results.**
 - Some facts about spine and artificial disc
 - Published primary research
 - Published reviews/systematic reviews
 - The US FDA device exemption study on Charité III® artificial artificial lumbar disc
 - Reimbursement status of artificial disc
- Search update.
- WorkSafeBC conclusions.

Results:

- Some facts:
 - it is estimated that the spine undergoes ± 100 million flexion flexion cycles during a lifetime and ± 6 million per year of of slight motion during breathing.
 - It is estimated that 30 million cycles appear to be the optimal optimal life length of a disc implant and 10 million cycles cycles should be the minimum number that any implant should withstand
 - Intervertebral disc replacement has been investigated since since 1950s
 - 1st disc implanted, in late 50s, was SKF ball bearing

- Summary published primary research on cervical disc implant:
 - Is available in the handout
 - Consists of 9 case series (majority small case series) on Bryan's cervical disc, 1 small case series on Pointillart cervical disc and 5 (3 case series, 2 RCTs, one of this in abstract only) on Cummins cervical disc.
 - It is heterogeneous in patient selection and outcome measurement
 - These studies, including the RCTs, are of low quality

- **Published reviews on artificial discs.**
 1. **Disc prostheses and arthrodesis in degenerative degenerative disease of the lumbar spine:**
 - Published by the French HAS-ANAES in May 2000
 - Only English summary available online
 - **Conclusions:**
 - The use of disc prosthesis could not be regarded as routine routine practice
 - Follow up > 10 years to assess complications
 - Development of a central registry for prostheses for evaluation purposes.

2. Prosthetic intervertebral disc replacement:

- Guidance issued by the UK-NICE in November 2004 2004
- Based on 2002 ASERNIP-S review
- 10 case series on SB Charité III lumbar disc
- Surgical complication rates 13% - 45%
- Re-operation rate varied from 3% - 24%
- Rates of implant related problems 1% - 4%
- Majority reported (statistical) significant pain relief
- Conclusions: not enough evidence on the safety and efficacy of prosthetic intervertebral disc

3. Procedure brief: Artificial cervical disc replacement

- Developed by ASERNIP-S in 2001
- Reported 3 studies (case control and case series)
- Not discuss further due to discrepancy in the references references

4. Rapid review: Artificial intervertebral (lumbar) disc (lumbar) disc replacement

- Published by ASERNIP-S in May 2003
- Comprehensive review up to October 2002
- 10 case series and 1 case control
- Results:
 - Good or excellent outcomes in 24 – 79%
 - Poor outcomes in 7 – 14%
 - Complication rates 13 – 17%
 - Implant migration noted in 3 of 4 studies
 - Implant failure rates 1% & 17%
 - Re-operation rates 3 – 24%
 - Only 25% benefited from 2nd procedure
- Conclusions → might be effective in reducing pain but but high levels of complications could occur

5. Total disc replacement for chronic low back pain: pain: background and a systematic review of the the literature

- Reviewing adverse events associated with intervertebral intervertebral disc arthroplasty and arthrodesis
- Comprehensive search up to January 2002
- Conclusions:
 - Studies were of low quality
 - Short term results (1-68 months) similar
 - None address potential long term problems (SB Charité III Charité III lumbar disc has been available > 10 years)
 - None on radiologic loosening, foreign body reaction
 - Not consistent regarding mobility of the operative and adjacent segment
 - High variability in complication rates

6. Artificial discs: Applications to cervical and lumbar lumbar spinal surgery for degenerative disc disease

- Produced by the Ontario Ministry of Health and Long Long Term Care
- Comprehensive search up to November 2003
- Parts of methodology unclear (despite personal contact contact)
 - 438 citations, 130 selected full review, 9 used for final final review
- Authors conclusions:
 - Intervertebral prostheses have been widely used in Asia Asia and Europe
 - Comparative efficacy data against fusion were sparse

- The US FDA device exemption study on Charité III® artificial lumbar disc.
 - Was a non inferiority study
 - Approval granted based on 16 center RCTs
 - Important points on indication of the implant, exclusion criteria, requirement for surgeons to complete company training, manufacturer to conduct post market surveillance on the original original study patients
 - Problems with this study:
 - Issues on DDD as the cause of chronic LBP
 - Choice of BAK as comparative treatment
 - Discrepancy in the study methodology

Reimbursement status:

- Workers' compensation board in Canada and and the US → no information
- The US private health insurances:
 - Cigna, Blue Cross of California and the Regence Regence Group → not covered (experimental)
 - Aetna[®] → March 2005, covers for 1 level DDD from from L4-S1.
 - Skeletally mature
 - Failed ≥ 6 months conservative management
 - Cervical disc still experimental

Search update:

- Up to November 10, 2005
- Same strategy, same sources
- Found 68 hits → 30 relevant.
 - 23 case series (majority small and short follow up)
 - 9 non English
 - 3 reporting adverse events
 - 5 RCTs:
 - 3 reported using same data on Charité III®
 - 1 'interim' analysis on ProDisc II®
 - 1 systematic review (non English)
 - 1 guidelines update (NHS NICE on cervical spine)

- **NICE guidance:**

- Studies relied on patients' self reported outcomes to determine efficacy
- At present no major safety concern
- Patients need to understand long term uncertainty of this this procedure and the available alternatives
- Develop audit and review outcomes
- Indications:
 - Patients with acute disc herniation or cervical spondylosis spondylosis
 - Reserved for patients:
 - with neurological threat, or
 - patients whose symptoms fail to settle with conservative care care
 - (standard surgical treatment is decompression by discectomy discectomy with or without fusion)

- These additional data do not change WorkSafeBC conclusions
- Fact → 6 months after FDA approval on the the device:
 - 2500 surgeons already trained
 - Up to 120 are being trained every week
- Interesting recent Cochrane review conclusion conclusion on surgery for DDD:
 - ...fusion does not appear to be more effective than than a modern rehabilitation programme...

WorkSafeBC conclusions:

- Concept of DDD as the cause of spinal pain still unclear
- Insertion of artificial discs has many technical issues and is not risk free
- Lack of comparative data against 'established' treatment
- At present, artificial intervertebral disc, esp. esp. artificial cervical discs, still at an experimental stage

- Complete review document is available at:

http://www.worksafebc.com/for_health_care_providers/Assets/PDF/artificial_cervical_lumbar_bar_disc.pdf

THANK YOU.

Questions ?

http://www.worksafebc.com/for_health_care_providers/related_information/evidence_based_medicine/default.asp

E-mail: kukuh.noertjojo@worksafebc.com