Cervical Artificial Disc: From Past to Present!

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Macro- and Microscopic Anatomy of the Intervertebral Disc (IVD)

The telescope had also been recently invented. It and the microscope both need lenses to operate.
Functions of the Cervical Spine!

**Movement**
- Flexion
- Extension
- Rotation
- Lateral Flexion

**Protection**
- Lamina
- Spinal Cord
- Vertebral Body
- Invertebral Disc
- Nerve Root

**Support**
• **Annulus Fibrosus (AF):**
  - Made of water, proteoglycans and type 1 collagen fibers produced by fibroblast-like cells.
  - 15-20 concentric layers or lamellae.
  - Each lamella is oriented at 30 degrees from horizontal axis.
  - Pattern alternates in successive layers.
  - Provides rotational stability and resists compressive stress.
  - Outer layers attach to ring apophysis (Sharpey's fibers).
  - Inner layers attach to the end plate.
  - High collagen/low proteoglycans ratio:
    - 70% of dry weight is collagen, mainly type 1.
  - Outer to inner layers:
    - Fibroblast to chondrocytes.
    - Type 1 to type 2 collagen fibers.

• **Nucleus Pulposus (NP):**
  - Made of water, proteoglycans and type 2 collagen fibers produced by chondrocyte-like cells.
  - Low collagen/high proteoglycans ratio:
    - 20% of dry weight is collagen, mainly type 2.
  - Proteoglycans: *aggrecan*, *versican*, *decorin*, *biglycan*, and *fibromodulin*.
  - Glycosaminoglycans (GAGs): *chondroitin* and *keratan sulfates*.

• **Cartilaginous End Plate (CEP):**
  - Anchors the NP and inner AF superiorly and inferiorly to the vertebral bodies.
  - Made of thin layers of hyaline cartilage.
  - Passive diffusion of nutrient, oxygen and metabolic byproducts.
Aggrecan is the largest proteoglycan found in the NP.

An aggrecan aggregate:
- Aggrecan monomers attached to hyaluronic acid (HA) filament via a link protein (LP), that is a glycoprotein.
- Aggrecan has a protein core and globular regions (G1, G2 and G3)
- GAGs: Keratan sulfate (KS) and chondroitin sulfate (CS) attach to the protein core.
- GAGs confer a net negative charge to the aggrecan molecule attracting water molecules
- Influx of water to NP is created by osmotic gradient and water molecules are retained in the NP by type 2 collagen fibers meshwork.

Higher proteoglycan concentration -> higher swelling pressure.
Higher proteoglycan concentration -> slower rate of disc creep.
Degenerated discs lose height more quickly than normal ones!

The role of aggrecan in normal and osteoarthritic cartilage by Peter J Roughley, John S Mort
Relaxed State:
Hydrophilic proteoglycan aggregates draw water molecules in causing the aggregate to swell until an equilibrium is reached where swelling is balanced by the tensile forces exerted on the collagen fibrils. This provides the stiffness required to maintain disc height and turgor against compression.

Compressed State:
Water molecules are displaced out of the disc into the paravertebral muscles with sustained loading. The proteoglycan aggregates are brought into close proximity increasing their tendency to swell and expand again. Sustained loading during human daily activities result in 20 - 25% of water slowly diffusing out of the disc.

*The role of aggrecan in normal and osteoarthritic cartilage* by Peter J Roughley, John S Mort
• Cells of the avascular disc nucleus pulposus and inner annulus fibrosus are supplied by vertebral blood vessels:

  Nutrients (e.g. oxygen and glucose) diffuse from the capillary bed through the cartilaginous endplate under gradients arising from metabolic demands of disc cells, while metabolic wastes (e.g. lactic acid) diffuse in the reverse direction.

• Cells of the outer annulus fibrosus are supplied by capillaries from blood vessels in the surrounding soft tissues that penetrate a few millimetres into the disc.

• In dynamic states, the cyclical movement of water in and out of the disc is thought to help movement of nutrient and by-products.
Initiation of the degenerative process thought to start in the NP!

- Notochord cells (NC) are thought to play a major role in IVD homeostasis:
  - After birth in humans, progressive loss of large vacuolated-NC via terminal differentiation into cartilage-like NP cells
  - The loss of NC in NP results in loss of inhibition of angiogenesis and axonal growth.

Hallmark of degenerative IVD:
- Increased inflammation
- Blood vessel ingrowth
- Neuronal ingrowth
- Loss of boundary between NP and AF
- Widening of the interlamellar space in the AF resulting in disc bulging
- Calcification of endplates and osteophyte formation in advanced cases.
• Synthesis: Increase in CS and decrease in KS.
  • Higher CS content -> axonal growth inhibition!
Changes in a degenerate disc limiting nutrient transport leading to decreased cell viability:

- Ca of cartilaginous endplate
- Occlusion of marrow spaces.
- Atherosclerosis of supplying blood vessels.
- Reduced capillary density.
The structural, functional and pathogenic factors related to the cervical disc create a complex challenge for the development of an efficient cervical artificial disc!
“You can’t connect the dots looking forward; you can only connect them looking backwards. So, you have to trust that the dots will somehow connect in your future. You have to trust in something - your gut, destiny, life, karma, whatever. This approach has never let me down, and it has made all the difference in my life.”

- Steve Jobs
Currently available artificial cervical disc in USA. (A) Prodisc-C, Synthes® (B) Prestige LP, Medtronic® (C) MobiC, LDR Medica® (D) Discover, DePuy® (E) M6, Spinal Kinetics® (F) ActivC, Aesculap® (G) Discovery, Scient’X® (H) Bryan, Medtronic®.

“Fernström Ball”

Injected methylmethacrylate into the disc space of 14 patients and had “acceptable” results.

He developed his concept after visiting James Gardner who replaced hundreds of lumbar discs with Lucite pegs.
In 1957 at the AANS, Wallace Hamby presented his reproduction of Cleveland’s work in 14 patients:

He compared discectomy alone vs discectomy with methylmethacrylate and after 1 year follow up he found no difference in term of:

• hospital stay
• return to work
• back pain
• maintenance of disc height

Hamby WB, Glaser HT. Replacement of spinal intervertebral discs with locally polymerizing methyl methacrylate. J Neurosurg 1959;16311–3

- To evaluate the long-term outcome after ventral disectomy and PMMA interbody fusion.
- Mean follow-up of 12 years.
- 77.5% “good and excellent” outcome.

**RESULTS:** Complications related to surgery occurred in 13 (5.2%) patients, but only three (1.2%) had persistent problems. Of the 249 patients, 101 (40.6%) were without any symptoms (Odom I), 92 (36.9%) had a good outcome (Odom II), and 47 (18.9%) a fair outcome (Odom III). Only nine patients (3.6%) reported an unchanged or worse status than before surgery (Odom IV). Additional lumbar symptoms, high occupational physical stress, and discrepancy of preoperative findings were significantly correlated with a worse outcome. Short duration of symptoms and soft disc disease were favorable prognostic factors.
The concept of disc prosthesis was first established in 1956 in a French patent:


In 1959, Paul Harmon devised Vitallium spheres and implanted them between 1959 and 1961 in the lumbar spine of 13 patients through an anterior retroperitoneal approach.

Harmon PH. Anterior excision and vertebral body fusion operation for intervertebral disk syndromes of the lower lumbar spine. Clin Or-thop 1963;26:107
The Swedish Academic Brawl!

VS.

Ulf Fernström
Uddevalla

Rigid metal prosthesis to restore:
Disc articulation
Disc height

Carl Hirsch

Alf Nachemson
Uppsala

Believed in an elastic prosthesis to resemble the anatomic disc!
The Fernström Ball:

- Stainless steel spherical endoprosthesis
- Between 1962-1964, Fernström implanted the device into:
  - 191 lumbar discs in 125 cases
  - 13 cervical discs in 8 patients


- Results were better than discectomy alone and similar to discectomy and fusion.

The procedure was eventually abandoned as a result of subsidence of implant.
In 1962, Nachemson reported on a study involving the injection of silicone rubber implants into the disc space.

Nachemson A. *Some mechanical properties of the lumbar intervertebral disc*. Bull Hosp Joint Dis (NY) 1962;23:130–2

The study was carried out in vitro in autopsy specimens and couldn’t be proven in vivo.
In 1964, Reitz and Joubert from South Africa, implanted the Fernström ball prosthesis:

- 75 in 32 patients with intractable headaches and cervicobrachialgia
  - No neurological complications of subluxations of the Balls.
  - Long-term follow up necessary to conform viability of the technique.
  - Follow up of <1 year -> Need for a longer follow up interval.
Frenchay 1

- In 1989, the Department of Medical Engineering at Frenchay Hospital, Bristol, United Kingdom, began the initial design process for an artificial cervical joint and clinical trials were initiated in 1991 for the Cummins-Bristol Disc.


  - A two-piece, stainless steel, metal-on-metal, ball-in-socket configuration with anchoring screws placed anteriorly.
  - Between 1991 and 1996, 22 Cummins joints were placed in 20 patients, with follow-up durations ranging from 3 to 65 months (mean 2.4 years).
  - 2 of this group of patients received 2 artificial discs at C3/4+C6/7, C2/3+C6/7
  - Results for 18 patients were available for review in 1996, and 16 of these individuals demonstrated continued joint motion of 5° in flexion and extension.
  - With regard to pain relief, 16 of 20 patients reported improvement.
  - No subsidence and no wear debris noted.

- Complications:
  - Dysphagia (100%) and persistent in 4 patients due to device profile.
  - Anchoring screw(s) failure in 7 patients.
## Frenchay 2 - Pilot

- The Bristol cervical disc was modified and a second generation was designed:
  - From ball-in-socket to ball-in-trough design.
  - Increased freedom of translation and rotation.
  - Redesigning of screw locking mechanism.
  - Lower profile.
- Eventually this becomes the Prestige cervical disc.

  - 15 patients who were particularly prone to adjacent-segment degeneration were enrolled in the study.
    - Adjacent level disease to a previously fused segment or
    - Asymptomatic disc degeneration adjacent to a symptomatic targeted disc.

### RESULTS

In all cases, the artificial joint maintained motion at the operative levels while reestablishing intervertebral height. The procedure was considered safe for experienced spine surgeons to perform, and the device was stable, with no dislocation of components or backing out of screws. Two screws broke, but without any consequence. Improvements in assessment scores were noted.

### CONCLUSIONS

Cervical intervertebral motion can be maintained with the new device, which is clinically stable. Meticulous attention must be paid to the surgical technique to maximize the chances of a good result. The pilot study was successful, although it has yet to be determined what conditions will benefit most from this technology.
Frenchay 2 vs Fusion

  - The fusion group experienced increases of their adjacent segment motion by 5% at 6 months and 15% at 12 months (p < 0.001).
  - The increase in movement occurred predominantly at intervertebral discs that were preoperatively regarded as normal (p < 0.02)
  - Overall adjacent-level movement for the group that received the Frenchay device was minimally affected.

- CONCLUSIONS:
  - Fusion results in increased motion at adjacent levels. The increase in adjacent-level motion derives from those discs that appear radiologically normal prior to surgery. It remains unknown whether ACJs have a protective influence on adjacent intervertebral discs.
The Prestige Cervical Disc Lineage

- PRESTIGE® II (1998)
- PRESTIGE® ST (1999)
- PRESTIGE® STLP (2002)
- PRESTIGE® LP (2003)
- Ti/Ceramic Alloy Ball-and-Trough Keel (2004-2014)
Table 14.5 Summary of Contemporary UHMWPE/Metal Cervical Artificial Disc Designs*

<table>
<thead>
<tr>
<th>Design</th>
<th>ProDisc-C</th>
<th>PCM</th>
<th>Mobi-C</th>
<th>Activ-C</th>
<th>Discover</th>
<th>SECURE-C</th>
<th>Baguera C</th>
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<tbody>
<tr>
<td>Number of components for surgeon assembly</td>
<td>Two</td>
<td>Two</td>
<td>Three</td>
<td>Three</td>
<td>Two</td>
<td>Three</td>
<td>Three</td>
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<tr>
<td>Number of articulating surfaces</td>
<td>One</td>
<td>One</td>
<td>Two</td>
<td>Two</td>
<td>One</td>
<td>Two</td>
<td>Two</td>
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<tr>
<td>Bearing design</td>
<td>Ball-and-socket</td>
<td>Surface replacement</td>
<td>Mobile bearing</td>
<td>Mobile bearing</td>
<td>Ball-and-socket</td>
<td>Sliding core (spherical superior; cylindrical inferior)</td>
<td>Mobile bearing</td>
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<tr>
<td>Constraint</td>
<td>Semiconstrained</td>
<td>“Minimally” constrained</td>
<td>Semiconstrained in core translation</td>
<td>Semiconstrained in core translation</td>
<td>Semiconstrained</td>
<td>Selectively constrained</td>
<td>Guided mobile nucleus</td>
</tr>
<tr>
<td>Bone/implant fixation</td>
<td>Keel and Ti textured coating</td>
<td>CaP/Ti coating</td>
<td>Lateral self-retaining teeth and Ti textured coating</td>
<td>Lateral self retaining teeth and Ti textured coating</td>
<td>Teeth and Ti textured coating</td>
<td>Serrated keels and Ti plasma spray</td>
<td>Fins and Diamolith-coated Ti</td>
</tr>
<tr>
<td>Keel</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Published clinical studies</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
<td>Longest published average follow-up</td>
<td>5 Years prospective [60] 7.7 years retrospective [89]</td>
<td>None</td>
<td>7.5 Months</td>
<td>2 Years</td>
<td>26.4 Months</td>
<td>24 Months</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

*Information extracted from Veruva et al. [7].

From UHMWPE Biomaterials Handbook by Steven Kurtz
<table>
<thead>
<tr>
<th>Name/Company</th>
<th>Bryan Medical</th>
<th>Prestige ST Medtronic</th>
<th>Prestige LP Medtronic</th>
<th>Mobi-C LDR</th>
<th>ProDisc-C DePuy Synthes</th>
<th>PCM NuVasive</th>
<th>Secure C Globus</th>
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<tbody>
<tr>
<td>Material</td>
<td>Ti/PolyUretane</td>
<td>Stainless Steel</td>
<td>Ti/Ceramic Alloy</td>
<td>CoCr/UHM WPE</td>
<td>CoCr/UHM WPE</td>
<td>CoCr/UHM WPE</td>
<td>CoCr/UHM WPE</td>
</tr>
<tr>
<td># of levels</td>
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<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
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</table>
Prospective, Randomized Comparison of One-level Mobi-C Cervical Total Disc Replacement vs. Anterior Cervical Discectomy and Fusion: Results at 5-year Follow-up.

Hisey MS\(^1\), Zigler JE\(^2\), Jackson R\(^3\), Nunley PD\(^4\), Bae HW\(^5\), Kim KD\(^6\), Ohnmeiss DD\(^7\).

CONCLUSIONS: Five-year results demonstrate the safety and efficacy of TDR with the Mobi-C as a viable alternative to ACDF with the potential advantage of lower rates of reoperation and adjacent segment degeneration, in the treatment of one-level symptomatic cervical degenerative disc disease.

Cost Utility Analysis of the Cervical Artificial Disc vs Fusion for the Treatment of 2-Level Symptomatic Degenerative Disc Disease: 5-Year Follow-up.

Ament JD\(^1\), Yang Z, Nunley P, Stone MB, Lee D, Kim KD.

RESULTS: The cTDR costs $1687 more than anterior cervical discectomy and fusion (ACDF) over 5 years. In contrast, cTDR had $34,377 less productivity loss compared with ACDF. There was a significant difference in the return-to-work rate (81.6% compared with 65.4% for cTDR and ACDF, respectively; \(P = .029\)). From a societal perspective, the incremental cost-effective ratio (ICER) for cTDR was -$165,103 per QALY. From a health system perspective, the ICER for cTDR was $85,188 per QALY. In the sensitivity analysis, the ICER for cTDR remained below the US willingness-to-pay threshold of $50,000 per QALY in all scenarios (-$225,816 per QALY to $22,071 per QALY).

CONCLUSION: This study is the first to report the comparative cost-effectiveness of cTDR vs ACDF for 2-level degenerative disc disease at 5 years. The authors conclude that, because of the negative ICER, cTDR is the dominant modality.

ICER: Incremental Cost-Effective Ratio.
QALY: Quality Adjusted Life Year.
Costs of cervical disc replacement versus anterior cervical discectomy and fusion for treatment of single-level cervical disc disease: an analysis of the Blue Health Intelligence database for acute and long-term costs and complications.

Radcliff K\textsuperscript{1}, Zigler J, Zigler J.

RESULTS: There were 6635 ACDF patients and 327 CDA patients. There were no significant differences in the incidence of comorbidities or mean follow-up time (ACDF 25.7 mo vs. CDA 26.1 mo) between groups. By 36 months postoperatively, the reoperation rate was significantly increased in the ACDF group (10.5\%) versus the CDA group (5.7\%) (hazard ratio, \textit{P} = 0.0214). The index surgery and 90-day global window costs were significantly lower in the CDA groups. At final follow-up, there was a statistically significant reduction in total costs paid by insurer in CDA patients (CDA $34,979 vs. ACDF $39,820).

CONCLUSION: Patients who underwent CDA for single-level degenerative disease had lower readmission rates, lower reoperation rates, and reduced index and total costs than those treated with ACDF. CDA was effective in reducing the monthly cost of care compared with ACDF.

Prospective, Randomized Comparison of Cervical Total Disk Replacement Versus Anterior Cervical Fusion: Results at 48 Months Follow-up.

Hisey MS\textsuperscript{1}, Bae HW, Davis RJ, Gaede S, Hoffman G, Kim KD, Nunley PD, Peterson D, Rashbaum RF, Stokes J, Ohnmeiss DD.

RESULTS: The composite success rate was similar in the 2 groups at 48-month follow-up. Mean Neck Disability Index, visual analog scale, and SF-12 scores were significantly improved in early follow-up in both groups with improvements maintained throughout 48 months. On some measures, TDR had significantly greater improvement during early follow-up. At no follow-up were TDR scores significantly worse than ACDF scores. Subsequent surgery rate was significantly higher for ACDF compared with TDR (9.9\% vs. 3.0\%, \textit{P}<0.05). Range of motion was maintained with TDR having a mean baseline value of 8 degrees compared with 10 degrees at 48 months. The incidence of adjacent-segment degeneration was significantly higher with ACDF at inferior and superior segments compared with TDR (inferior: 50\% vs. 30\%, \textit{P}<0.025; superior: 53\% vs. 34\%, \textit{P}<0.025).

CONCLUSIONS: Significant improvements were observed in pain and function. TDR patients maintained motion and had significantly lower rates of reoperation and adjacent-segment degeneration compared with ACDF. This study supports the safety and efficacy of TDR in appropriately selected patients.
Comparison of dysphagia between cervical artificial disc replacement and fusion: data from a randomized controlled study with two years of follow-up.

Skepholm M, Olerud C.

RESULTS: Demographics and dysphagia short questionnaire levels were similar in both groups preoperatively. At 4 weeks of follow-up postoperatively, dysphagia was significantly higher in both groups than baseline levels, P < 0.01. No significant differences were seen between the groups until follow-up at 2 years, which showed significantly higher dysphagia short questionnaire levels in the ACDF group, P = 0.04. The difference was statistically significant in both patients treated with 1- and 2-level surgery, P = 0.029 and P = 0.032, respectively. A logistic regression model showed a stronger association to type of implant than to number of surgical levels. Duration of surgery was highly associated to number of surgical levels but did not differ significantly between types of implant.

CONCLUSION: Long-term postoperative dysphagia could be explained by bulk of implant or decreased motion in the cervical spine. However, it is doubtful if differences between the groups in this study can be interpreted as a clinically important difference.

Persistent axial neck pain after cervical disc arthroplasty: a radiographic analysis.


RESULTS: The average radiographic follow-up was 13.5 months and the rate of persistent axial neck pain was 17.2%. For patients with persistent neck pain, the rate of HO formation per level studied was 22.6%, whereas the rate was significantly lower for patients without neck pain (11.7%, p=.03). There was no significant association between the severity of HO and the presence of neck pain. Patients with a preoperative diagnosis of cervicalgia, compared to those without cervicalgia, were significantly more likely to experience continued neck pain postoperatively (28.6% vs. 13.1%, p=.01). There were no differences in preoperative facet arthrosis, pre- or postoperative disc height, segmental range of motion, or placement of the device relative to the posterior edge of the vertebral body. However, patients with implants more centered between the uncovertebral joints were more likely to experience posterior neck pain (p=.03).

CONCLUSIONS: We found that posterior axial neck pain is relatively frequent after CDA, and patients with persistent neck pain were significantly more likely to have preoperative cervicalgia and develop HO postoperatively. We also found that patients with implants that were placed off-centered were less likely to also complain of neck pain, although the reasons for this finding remain unclear.
Cervical spine alignment in disc arthroplasty: should we change our perspective?

Di Martino A¹, Papalia R¹, Albo E¹, Cortesi L¹, Denaro L², Denaro V³.

RESULTS: In most of the retrieved studies, a tendency towards a more postoperative kyphotic alignment in TDR was reported. The reported mean complication rate was of 12.5 % (0-66.2 %). Complications associated with cervical prosthesis included heterotopic ossification, device migration, mechanical instability, failure, implant removal, reoperations and revision.

CONCLUSIONS: Even though cervical disc arthroplasty leads to similar outcomes compared to arthrodesis in the middle term follow-up, no evidence of superiority of cervical TDR is available up to date. We understand that the overall cervical alignment after TDR tends towards the loss of lordosis, but only longer follow-up can determine its influence on the clinical results.

Safety and cost-effectiveness of outpatient cervical disc arthroplasty.

Wohns R¹.

RESULTS: There was no mortality and no major complications. Pain was present in 100% and motor deficit in 33% of the patients. There were no co-morbidities reported in the group. There were no cases that required hospital transfer and there were no post-op Emergency Room visits or subsequent hospitalization. At the time of the first post-operative visit, 100% of the patients believed that they were improved and no patient had any post-operative complications. The cost of outpatient single-level cervical disc arthroplasty was 62% less than the outpatient single-level cervical anterior discectomy with fusion using allograft and plate and 84% less than the inpatient single-level cervical disc arthroplasty.

CONCLUSIONS: Outpatient cervical disc arthroplasty is safe and clinically efficacious in selected patients and is cost-effective compared with both inpatient cervical disc arthroplasty and outpatient anterior discectomy with fusion.
Long-term outcome for cervical arthroplasty:
- Durability/Life span —> Need for revision/replacement.
- Patients long term clinical functional outcome
- Recognition and approval by insurance companies
- Reimbursement for the procedure.
- Evolution of material/constituents of implants
- Development/evolution of disease-modifying treatments to delay or prevent the IVD degeneration:
  - Replenishing the NP with stem cells, chondrocyte cells, disc cells, etc.
Thank You!