# Meta-analysis of Clinical & Radiological Outcome of Cervical Disk Replacement

**Essay**

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**Presented By**


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# Abstract

The Bryan Cervical Disc is a metal-on-polymer implant with some elastic properties and a relatively mobile center of rotation.
The Prestige Disc was designed with a ball-socket stainless steel articulation.
The Pro Disc-C is a semi constrained metal-polyethylene design allowing pure rotary motion that may stress the facet joints.

Although there are no long-term data available yet, these three cervical prostheses appear promising in the non fusion treatment of cervical degenerative disc disease.



## Key words:

Clinical & Radiological Outcome of Cervical Disk Replacement

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# Abbreviations

- **ACDF : Anterior cervical diskectomy and fusion.**
- **ALL : Anterior longitudinal ligament.**
- **C – R : Clinical and Radiological.**
- **CDA: Cervical disk arthroplasty.**
- **CDR : Cervical disk replacement.**
- **CI : Confidence Interval.**
- **FSU : Functional spinal unit .**
- **HO : Heterotopic ossification.**
- **NDI : Neck disability index.**
- **OR : Odds Ratio.**
- **OVR : Overall Success rate.**
- **OVSR: Overall success rate .**
- **Post-op. : post- operative.**
- **Pre-op. : pre-operative.**
- **ROM : Range of motion.**
- **RSA : Radio sterometric analysis.**
- **SF-36 : Short form -36.**
- **ttt: Treatment.**
- **VAS : Visual analogue scale.**

# CONTENT

# Chapter 1

## Introduction

### Literature Search

Technological advances made in large joint reconstructive devices and biomaterials have revolutionized the treatment of all types of degenerative joint disease. (1,4)

Following the success of total joint arthroplasties for the hip and knee joints, attention has more recently focused on the successful development of intervertebral disc prostheses. (2,4)

The **goals** of anterior cervical diskectomy and fusion are to decompress the neural elements, provide permanent segmental stabilization and lordosis, and preserve anatomical disk space height. Numerous grafting techniques have been used to meet these objectives .(6,8,10,14)

A comprehensive literature search of Pub Med ( October 2002– January 2013), was conducted to identify studies that met the inclusion criteria:

1. **Prospective**: A prospective study, loosely defined, is a study that starts in the present and continues forward in time. It is differentiated from a retrospective study, which looks at a known outcome backwards, determining the factors that influence the outcome.

2. **Randomized** study , to order or select in a random manner, as in a sample or experiment, especially in order to reduce bias and interference caused by irrelevant variables; make random.

3. **Controlled** means comparative between Cervical disk replacement (CDR) and Anterior cervical diskectomy fusion (ACDF).
4. Published only by **English** language .
5. Follow up **2** years .

Search procedure: consisted of a combination of keywords concerning the technical procedure (*total disk replacement*, *prosthesis*, *implantation*, *diskectomy*, and *arthroplasty* ) and keywords regarding the anatomical features and pathology (*cervical vertebrae*).

All relevant randomized controlled trials, searched reference lists of review articles, and included studies to identify other potentially eligible studies.

From the selected databases, 143 references were obtained. By screening the titles and abstracts, 112 references were excluded due to the irrelevance to this topic. The remaining 31 reports underwent a detailed and comprehensive evaluation. Finally, 7 prospective , randomized and controlled trials were included in this systematic review and meta-analysis .

A systematic review and meta-analysis to evaluate whether there is a beneficial clinical effect of total disk replacement compared with anterior cervical diskectomy and fusion for the treatment of symptomatic cervical disk disease.

## Data Extraction

Relevant data extracted from the included studies regarding design, age, gender, type of disk prosthesis, type of control intervention, and follow-up period.

# QUALITY OF THE LITERATURE

The quality of evidence is an important and critical step in the systematic review process. In studies we evaluate the quality according to methods used .

There are 4 levels of evidence based medicine (EBM) as

**Level 1** : Randomized controlled trials – includes quasi – randomized processes such as alternate allocation .

**Level 2** : Non – randomized controlled trial – A prospective (pre-planed) study .

**Level 3** : Observational studies with controls includes retrospective , case control studies, and health services .

**Level 4** : Observational studies without controls .

**source** : the United States Department Of Health And Human Services http://www.icabestpractices.org

**this table shows papers including the level of evidence for every research , name , type and methods used.**

| No. | Name | No of centers | Level Base of evidence | Disc-Level | Investigation |
|---|---|---|---|---|---|
| 1 | Segmental kinematics of adjacent level degeneration | Single | Level 1 | Single | ROM-VAS-RSA |
| 2 | Fusion versus Arthroplasty with Bryan disc | Multi center | Level 1 | Two level | NDI-VAS-ROM-SF36 |
| 3 | CDA compared + arthrodesis for ttt of myelopathy | Multi center | Level 1 | single | VAS-NDI-SF36 |
| 4 | Clinical outcome of Bryan 24 month follow up | Multi center | Level 1 | Single | VAS-NDI-Sf36 |
| 5 | Clinical outcome of Bryan 48 months follow up | Multi center | Level 1 | Single | NDI-VAS-SF36 |

| | | | | | |
|---|---|---|---|---|---|
| **6** | **Comparison of radiograph changes after ACDF versus Bryan** | **Single** | **Level 1** | **Single and 2 level** | **Flexion + extension x-ray – MRI- ROM- NDI-VAS neck** |
| **7** | **Long term C-R outcome of CDR +prestige disc** | **Single** | **Level 1** | **single** | **NDI- SF36 - flexion extension x-ray,MRI, VAS** |

# Chapter 2

## Meta-analysis of cervical disk replacement

1. Meta-analysis is a statistical technique for combining the findings from independent studies.

2. Meta-analysis is most often used to assess the clinical effectiveness of healthcare interventions; it does this by combining data from two or more randomized control trials.

3. Meta-analysis of trials provides a precise estimate of treatment effect, giving due weight to the size of the different studies included. (27)

4. The validity of the meta-analysis depends on the quality of the systematic review on which it is based. (13)

5. Good meta-analyses aim for complete coverage of all relevant studies, look for the presence of heterogeneity.(12)

**Heterogeneity:**
A major concern about meta-analyses is the extent to which they mix studies that are different in kind (heterogeneity). One widely quoted definition of meta-analysis is: statistical analysis which combines or integrates the results of several independent clinical trials considered by the analyst to be combinable .

In many medical specialties it is common to find that several trials have attempted to answer similar questions about clinical effectiveness; for example:

Does the new treatment confer significant benefits compared with the conventional treatment?

Often many of the individual trials will fail to show a statistically significant difference between the two treatments. However, when the results from the individual studies are combined using appropriate techniques (meta-analysis), significant benefits of treatment may be shown **.** **(11,13,21)**

## Requirements for meta-analysis:

The main requirement for meta-analysis is a good systematic review with a complete, unbiased collection of all the original studies of acceptable quality that examine the same therapeutic question **.(18)**

## Conducting meta-analyses Location of studies:

Meta-analysis requires a comprehensive search strategy which interrogates several electronic databases (for example, http//:www.Pub-Med.com, http//:www.medline.com , http//:www.embase.com, http//:www.Cochrane.com). Hand searching of key journals and checking of the reference lists of papers obtained is also recommended.
The search strategy – the key terms used to search the database – needs to be developed with care.
The strategy is written as a sequence of requirements: include papers with specified terms, exclude papers that do not meet certain criteria (for example, age or diagnostic group), only include studies that follow certain research designs (for example, randomized controlled trials).

**Calculating effect sizes** :

Clinical trials commonly present their results as the frequency of some outcome in the intervention groups and the control group. For meta-analysis these are usually summarized as a ratio of the frequency of the events in the intervention to that in the control group. Most common summary measure of the effect size is the **Odds Ratio** .

The Odds Ratio : a ratio of 2 implies that the defined outcome happens about twice as often in the intervention group as in the control group; an odds ratio of 0.5 implies around a 50% reduction in the defined event in the treated group.
The findings from individual studies can be combined using an appropriate statistical method.
The methods use a similar approach in which the estimate from each study is weighted by the precision of the estimate group compared with the controls.[7,11]

The outcomes pooled in this analysis include overall success rate, reoperation rate for secondary surgery, reoperation rate for revision surgery, improvement of movement and function measured by a disability scale (Neck Disability Index [NDI]), improvement in pain measured by a validated pain scale (Visual Analog Scale [VAS] for the arm, and VAS score for the neck), and SF-36 Mental and Physical Health Surveys.

**overall success rate :**

Defined as the percentage of individual patients achieving success in all 4-component endpoints.

To be considered an overall success, patients had to achieve all of the following:

1- A ≥15-point improvement in their NDI scores .

2-Maintenance or improvement in their neurologic status .

3-No serious adverse events related to the implant or implant/surgical procedure .

4- No subsequent surgery or intervention.

**Neck Disability Index (NDI) *;***

it is parameter used to monitor the progression of a patient throughout the treatment period. Specifically, this questionnaire evaluates changes in a patient's function and measures a self-evaluated disability as a result of neck pain.

Each of the 10 items of the index receives a score from 1 to 5; therefore the maximum score that can be attained is 50.

It is recommended the questionnaire be administered at the initial point of contact.

At least a five-point change is needed to determine a development or progression in therapy that is clinically meaningful.(5)

**Visual Analog Scale** :

The Visual Analog Scale (VAS) is designed to present to the respondent a rating scale with minimum constraints. Respondents mark the location on the 10-centimeter line corresponding to the amount of pain they experienced. This gives them the greatest freedom to choose their pain's exact intensity. It also gives the maximum opportunity for each respondent to express a personal response style.

VAS data of this type is recorded as the number of millimeters from the left of the line with the range 0-100.**(10)**

| | | |
|---|---|---|
| **No pain** | <-- 10 cm. --> | **Pain as bad as possible** |

**SF-36 :**

The SF-36 is a multi-purpose, short-form health survey with 36 questions.

It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index.

It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group.

Accordingly, the SF-36 has proven useful in surveys of general and specific populations, comparing the relative burden of diseases, and in differentiating the health benefits produced by a wide range of different treatments.

**Radiostereometric analysis (RSA) :**

**http://www.hss.edu/conditions_radiostereometric-analysis-at-hss.asp**

RSA is a powerful research technique that is currently being studied at Hospital for Special Surgery (HSS) for joint replacement patients .

It describes a special way of taking two x-rays from different directions at the same time, creating a “stereo” image.