


Results of Total Cervical Disc Replacement with a Minimum Follow-up of 10 Years*

Resultados da artroplastia total de disco cervical com acompanhamento mínimo de 10 anos

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Abstract

Objective In the present study, we present the results with at least 10 years of follow-up of the cervical disc prosthesis implanted in a single level.

Methods Retrospective study of patients undergoing single-level total cervical disc replacement (TCDR). Clinical results included the neck disability index (NDI) and the visual analogue scale (VAS) in the preoperative period, one year postoperatively, and a minimum of 10 years of follow-up. The radiographic parameters included cervical mobility, segmental lordosis, C2-C7 angle, heterotopic ossification (HO), facet and joint degeneration (FJD) and adjacent segment disease (ASD).

Results We identified 22 patients, 16 women and 6 men with mean age of 39.7 years old (26-51 years old), of which fifteen completed a minimum follow-up of 10 years. There was a statistically significant improvement of NDI and VAS ($p < 0.001$) between the preoperative and the postoperative periods (1 year or > 10 years). At the end of 10 years, HO was observed in 59% of the cases. The mobility of the implant was preserved in 80% of the patients. Radiological evidence of ASD was recorded in 6 patients (40%). There was no correlation between the clinical parameters evaluated and the presence of ASD or the different classes of HO.

Conclusion Clinical improvement in all evaluated parameters, which persists over time. Most implants maintained mobility, as has already been demonstrated in other studies with shorter follow-ups. In a significant percentage of cases, ASD was observed, questioning the concept of motion preserving technology. However, we did not have any surgical intervention for this reason, since there was no correlation with worse clinical results.

Keywords

- ▶ total disc replacement
- ▶ arthroplasty
- ▶ cervical vertebrae

Resumo

Objetivo No presente estudo, apresentamos os resultados com um acompanhamento mínimo de 10 anos da artroplastia total do disco cervical (ATDC) em um nível.

* Study conducted at the Department of Orthopedics, Hospital São João, Porto, Portugal.



Palavras-chave

- ▶ substituição total de disco
- ▶ artroplastia
- ▶ vértebra cervical

Métodos Estudo retrospectivo de pacientes submetidos a ATDC em um nível. Os resultados clínicos incluíram o índice de incapacidade relacionada ao pescoço (IIRP) e a escala visual analógica (EVA) no período pré-operatório, um ano pós-operatório e um mínimo de 10 anos de acompanhamento. Os parâmetros radiográficos incluíram a mobilidade cervical, lordose segmentar, ângulo C2-C7, ossificação heterotópica (OH), degeneração facetária e articular (DFA) e doença do segmento adjacente (DSA).

Resultados Identificados 22 pacientes, 16 mulheres e 6 homens com média de idade de 39,7 anos (26–51 anos), dos quais 15 tiveram um acompanhamento mínimo de 10 anos. Foi verificada melhoria estatisticamente significativa do IIRP e EVA ($p < 0,001$) entre pré-operatório e pós-operatório. (1 ano ou > 10 anos). Ao final de 10 anos, OH foi observada em 59% dos casos. A mobilidade do implante foi preservada em 80% dos pacientes. Houve evidência radiológica de DSA em 6 pacientes (40%). Não houve correlação entre os parâmetros clínicos avaliados e a presença de DSA ou as diferentes classes de OH.

Conclusão Melhoria clínica em todos os parâmetros avaliados, que persiste ao longo do tempo. A maioria dos implantes manteve a mobilidade, como já demonstrado em estudos anteriores com acompanhamentos mais curtos. Numa percentagem significativa, a DSA estava presente, questionando o conceito da tecnologia de preservação de movimento. No entanto, sem nenhuma intervenção cirúrgica por esse motivo, uma vez que não houve correlação com piores resultados clínicos.

Introduction

Total cervical disc replacement (TCDR) is an alternative surgical procedure to arthrodesis. In theory, by maintaining movement at the operated level, arthroplasty may decrease the demand for adjacent levels and subsequent degeneration and adjacent segment disease (ASD). Several randomized studies have demonstrated the equivalence or even the superiority of TCDR in terms of resolution of pain and/or neurological success compared with anterior cervical discectomy and intersomatic fusion.^{1–4} However, its indication, clinical benefit, costs, safety, and long-term complications remains unclear.

In the present study, we present the results with at least 10 years of follow-up of the cervical disc prosthesis implanted in a single level.

Materials and Methods

Retrospective study of patients undergoing single-level TCDR (Prestige or Bryan, Medtronic, Dublin, Ireland) according to the inclusion criteria (► **Table 1**) between January 2003 and December 2006.

Table 1 Inclusion criteria for the study

| Inclusion Criteria |
|--|
| Symptomatic degenerative cervical disc disease at one level with cervicalgia and/or brachialgia and/or neurological deficits confirmed by magnetic resonance imaging |
| Surgery at one cervical level and between C5-C7 |
| Age between 18–65 years old during the period of surgery |
| Bad results with conservative treatment |
| Informed consent of the patient |

Clinical results included the neck disability index (NDI) and the visual analogue scale (VAS) in relation to the severity and frequency of cervical pain and brachialgia assessed in the preoperative period, 1 year postoperatively, and a minimum of 10 years of follow-up. The perspective of the patients regarding the success of the surgery, complications and subsequent surgical interventions was also analyzed.

All of the radiographic evaluations were performed by an independent observer. The antero-posterior (AP), lateral and dynamic (flexion/extension) X-rays were obtained. The radiographic parameters included cervical mobility ($\geq 2^\circ$ variation in dynamic views), segmental lordosis, C2-C7 angle, heterotopic ossification (HO) according to McAfee et al.,⁵ osteolysis, facet and joint degeneration (FJD), migration and translation. The presence and severity of ASD was also evaluated.

The criteria for the presence of ASD were:

- 1 - Disc degeneration and/or FJD (both grade 0 to 4 according to Côté et al⁶) \geq grade 2 and minimum 1 degree higher than the preoperative;
- 2 - New instability (≥ 3.5 mm translation and/or $\geq 11^\circ$ rotational variation in relation to adjacent segments);
- 3 - Instrumentation added.

The surgeries were performed by different surgeons in 2 hospitals. Follow-up examinations were performed by investigators or other surgeons in their respective hospitals. The present study was approved by the ethics committee for health.

Results

We identified 22 patients, 16 women and 6 men with mean age of 39.7 years old (26–51 years old). Eight patients had nonrestrictive prostheses (Bryan) and 14 had semirestrictive prostheses (Prestige). A total of 15 patients completed a

minimum follow-up of 10 years. All of the patients had cervicobrachialgia (68.75% on the left side and 31.25% on the right side). In 68.75% of the patients, the level operated was C5/C6, and in 31.25% the level was C6/C7. There was a statistically significant improvement of NDI and EVA ($p < 0.001$) between the preoperative and postoperative (1 year) periods. A statistically significant improvement in the VAS was observed after at least 10 years of follow-up compared with 1-year postoperatively ($p < 0.001$). The NDI remained stable at the end of 10 years ($p = 0.63$) (► **Table 2**).

A total of 75% of the patients were very satisfied/satisfied, and 94% would repeat and recommend the procedure. At the end of 10 years, HO was observed in 59% of the cases, being 41% of grade 0, 26% of grade 1, 13% of grade 3, and 20% of grade 4. The mobility of the implant was preserved in 80% of the patients. Preoperative cervical lordosis ($\sim 6.3^\circ$) increased significantly in the early postoperative period ($\sim 13.5^\circ$), but significantly reduced between this evaluation and the minimum 10-year postoperative follow-up ($\sim 9.8^\circ$). The segmental lordosis increased significantly between the preoperative ($\sim 4.1^\circ$) and the early postoperative ($\sim 5.8^\circ$) periods, but decreased in the late follow-up ($\sim 4.9^\circ$). Radiological evidence of ASD was recorded in 6 patients (40%) (► **Table 3**). There was no correlation between the clinical parameters evaluated and the presence of ASD or the different classes of HO throughout the follow-up. One patient required conversion to anterior cervical arthrodesis in the immediate postoperative period by medullar compression, with progressive neurological deficits.

Discussion

In the present study, we observed that TCDR has excellent clinical results that remain stable for at least 10 years. When considering a significant improvement in NDI as a minimum difference of 15 points, it was reached at $\sim 87\%$ at the end of 1 year of follow-up, and then remained stable at the end of at least 10 years of follow-up. These results are in agreement with previous studies. Sasso et al⁷ demonstrated an improvement in NDI by 90.6% following a 4-year follow-up with the Bryan disc implant. Burkus et al⁸ observed an improvement in NDI by 83.4% after a 7-year follow-up with the Prestige disc implant.

Total cervical disc replacement is performed to maintain mobility at the operated level and to prevent hypermobility from the adjacent levels and a consequent increase in regional stress. The long-term functionality of TCDR is of particular importance. According to Heller et al,⁹ 2-year follow-up results indicated that TCDR could preserve local mobility and was a viable alternative to anterior cervical discectomy with fusion in patients with persistent symptomatic cervical disc disease at one level. The same result was verified by Du et al.¹⁰ The results of our study indicates that the implant remains functional in the long term, with $> 80\%$ of prostheses with mobility above the 2° threshold after 10 years of follow-up.

Anterior cervical discectomy with fusion is considered the standard in the therapeutic approach in degenerative cervical disc disease with cervical radiculopathy and/or myelopa-

thy for patients who did not respond to conservative treatment.¹¹ Although adjacent-level degeneration is observed after fusion in the cervical spine in between 7 to 17% of the cases, the discussion remains whether this phenomenon is induced or accelerated by fusion or is simply the natural progression of the disease.¹²⁻¹⁴ Some studies have shown that between 5.7 and 37% of patients submitted to cervical fusion require new surgical intervention to relieve clinical symptoms of ASD with a follow-up of 3.5 years.¹⁵ Although there is no consistent data that preservation of disc movement prevents or reduces the occurrence of adjacent segment degeneration, there is at least a theoretical benefit, especially in multilevel disease. On the other hand, the presence of radiographic changes is not directly associated with symptomatic disease. Cases of surgical intervention due to symptomatic degeneration of the adjacent segment after TCDR are scarce to date, as demonstrated in the present study, despite the 40% rate of radiological signs of ASD.

The HO after TCDR is a subject of controversy, in a way that counteracts the preservation of movement. The mechanism of the development of HO in the cervical spine has not yet been clearly defined, but the possible causes appear to be multiple, including preoperative degenerative disease, surgical technique, implant design, limited movement or genetic factors.¹⁶ Yi et al¹⁷ performed a study on 170 patients undergoing TCDR and found significant differences in HO occurrence rates based on the gender of the patients and on the type of prosthesis. Leung et al¹⁸ described the incidence and outcome of HO in patients treated with the Bryan cervical disc. A total of 18% of the 90 treated patients had HO, and 6.7% had advanced degrees (3rd and 4th) HO after 1 year of follow-up. The detailed mechanism of pathophysiology and HO prevention require more precise studies. Following the TCDR procedure, the loss of mobility due to HO is one of the possible consequences. However, the results of the present study indicate that the occurrence of HO may not be a major complication with respect to its clinical consequence. After 10 years of follow-up, 3 patients presented grade 4 HO without any movement of the intervened disc. None of the patients required an intervention due to HO.

In terms of complications, we reported a rare major complication in which immediate neurological compression occurred and there was the need of early conversion to anterior arthrodesis. The early identification and appropriate and immediate treatment of these potential complications are essential to obtain a good end result in these patients.

The present study has some limitations. We emphasize the retrospective nature of the study. Second, it is composed of a relatively small sample. Third, the study lacks a control group. For more valid results and conclusions, further rigorously planned prospective trials will have to be performed.

Conclusion

The present study demonstrates good results of cervical disc arthroplasty at one level with a minimum follow-up of 10 years. Clinically, we observed an improvement in all

Table 2 Patients with > 10 years follow-up - Clinical results

| Patient | Prosthesis | Gender | Age | Level | NDI (%) | | VAS (Cervical) | | | VAS (Upper Arm) | | |
|---------|------------|--------|-----|-------|--------------|------------------------|----------------|------------------------|------------|-----------------|------------------------|------------|
| | | | | | Preoperative | Postoperative (1 year) | Preoperative | Postoperative (1 year) | > 10 years | Preoperative | Postoperative (1 year) | > 10 years |
| 1 | Bryan | ♂ | 44 | C5C6 | 68 | 32 | 9 | 4 | 4 | 5 | 0 | 2 |
| 2 | Bryan | ♀ | 45 | C5C6 | 62 | 40 | 7 | 4 | 1 | 6 | 2 | 0 |
| 3 | Bryan | ♀ | 46 | C5C6 | 38 | 42 | 9 | 6 | 2 | 6 | 1 | 2 |
| 4 | Bryan | ♂ | 44 | C5C6 | 48 | 2 | 8 | 0 | 0 | 6 | 0 | 0 |
| 5 | Bryan | ♂ | 48 | C5C6 | 60 | 6 | 10 | 3 | 2 | 10 | 0 | 0 |
| 6 | Prestige | ♂ | 40 | C6C7 | 80 | 14 | 9 | 2 | 0 | 8 | 4 | 2 |
| 7 | Prestige | ♀ | 33 | C5C6 | 98 | 14 | 8 | 1 | 1 | 8 | 2 | 0 |
| 8 | Prestige | ♀ | 35 | C6C7 | 82 | 10 | 10 | 4 | 3 | 10 | 1 | 2 |
| 9 | Prestige | ♀ | 26 | C5C6 | 98 | 8 | 8 | 1 | 0 | 8 | 1 | 1 |
| 10 | Prestige | ♀ | 42 | C6C7 | 92 | 8 | 8 | 3 | 0 | 8 | 3 | 0 |
| 11 | Prestige | ♀ | 51 | C5C6 | 68 | 60 | 8 | 8 | 6 | 10 | 5 | 0 |
| 12 | Prestige | ♂ | 35 | C6C7 | 68 | 2 | 8 | 0 | 0 | 10 | 1 | 0 |
| 13 | Prestige | ♀ | 36 | C6C7 | 82 | 8 | 8 | 0 | 0 | 10 | 4 | 0 |
| 14 | Prestige | ♀ | 30 | C5C6 | 72 | 14 | 7 | 4 | 0 | 9 | 1 | 0 |
| 15 | Prestige | ♂ | 41 | C5C6 | 60 | 14 | 7 | 5 | 1 | 7 | 0 | 0 |
| 16 | Prestige* | ♀ | 47 | C5C6 | 70 | - | 7 | - | - | 8 | - | - |

Abbreviations: NDI, neck disability index; VAS, visual analogue scale.

*Complication with conversion to anterior arthrodesis in the 24–48h post op period .

Table 3 Patients with > 10 years follow-up - Radiographic results

| Patient | McAfee | | | | | Cervical Lordosis | | | Segmental Lordosis | | | ASD |
|---------|--------|---|----|-----|----|-------------------|------------------------|------------|--------------------|------------------------|------------|-----|
| | 0 | I | II | III | IV | Preoperative | Postoperative (1 year) | ≥ 10 years | Preoperative | Postoperative (1 year) | ≥ 10 years | |
| 1 | X | | | | | 15 | 23 | 15 | 3 | 12 | 3.7 | X |
| 2 | X | | | | | 10 | 11.0 | 10.0 | 4 | 3 | 6.0 | X |
| 3 | X | | | | | 8 | 13.0 | 12 | 3 | 3.2 | 3.2 | X |
| 4 | | | | | X | 14 | 13.0 | 11 | 12 | 13 | 10 | √ |
| 5 | | X | | | | 5 | 10.0 | 7 | 4 | 9 | 5 | X |
| 6 | | | | | X | 9 | 22.0 | 10 | 3 | 3 | 3 | X |
| 7 | X | | | | | 2 | 20.0 | 12 | 2.1 | 2 | 2 | X |
| 8 | X | | | | | 20 | 15.0 | 13.1 | 11 | 10 | 10 | √ |
| 9 | | X | | | | 12 | 25.0 | 18 | 3 | 5 | 5 | X |
| 10 | | X | | | | 10 | 18.0 | 12 | 5 | 3 | 3 | X |
| 11 | X | | | | | 10 | 19.0 | 15 | 0 | 5 | 5 | √ |
| 12 | | | | X | | 9 | 17.0 | 17 | 4 | 7.7 | 6 | X |
| 13 | | | | X | | -17 | -5.0 | -5 | 6 | 9 | 9 | √ |
| 14 | | X | | | | -20 | -9.0 | -9 | 2 | 2 | 2 | √ |
| 15 | | | | | X | 8 | 10.0 | 9.3 | 0 | 0 | 0 | √ |
| 16* | | | | | | - | - | - | - | - | - | - |

Abbreviation: ASD, adjacent segment disease.

*Complication with conversion to anterior arthrodesis in the 24–48h post op period.

evaluated parameters, which persists over time. Radiologically, most implants maintained mobility. In a significant percentage of cases, ASD was observed, questioning the concept and benefits of motion preserving technology. However, we did not register any surgical intervention for this reason, since there was no correlation with worse clinical results.

This technique is not free from complications and a rigorous selection of patients is essential to obtain the best results.

Conflict of Interests

The authors have no conflict of interests to declare.

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