

The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis

46 CONSECUTIVE CASES

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We present data relating to the Bryan disc arthroplasty for the treatment of cervical spondylosis in 46 patients.

Patients with either radiculopathy or myelopathy had a cervical discectomy followed by implantation of a cervical disc prosthesis. Patients were reviewed at six weeks, six months and one year and assessment included three outcome measures, a visual analogue scale (VAS), the short form 36 (SF-36) and the neck disability index (NDI). The results were categorised according to a modification of Odom's criteria. Radiological evaluation, by an independent radiologist, sought evidence of movement, stability and subsidence of the prosthesis.

A highly significant difference was found for all three outcome measurements, comparing the pre-operative with the post-operative values: VAS (Z = 6.42, p < 0.0001), SF-36 (mental component) (Z = -5.02, p < 0.0001), SF-36 (physical component) (Z = -5.00, p < 0.0001) and NDI (Z = 7.03, p < 0.0001). The Bryan cervical disc prosthesis seems reliable and safe in the treatment of patients with cervical spondylosis.

Cervical spondylosis is a common cause of neck pain, radiculopathy and myelopathy. Degenerative changes in a disc can cause it to prolapse or osteophytes to be formed. Each of these can cause pressure on the spinal cord leading to myelopathy or radiculopathy. The traditional treatment for this condition consists of an anterior cervical discectomy with a bridging bone graft, originally described by Cloward¹ and Smith and Robinson.² Recent alternatives to bone grafting have been described including interbody cages,³ bone substitutes or spacers,⁴ in order to avoid the complications of grafting.⁵

Cervical discectomy and fusion has provided good clinical results for radiculopathy and acceptable ones for cervical spondylotic myelopathy. The short-term clinical results (12 months) published by several authors report a good outcome in 70% to 90% of cases.⁶⁻¹⁰ However, some patients return after a few years with similar symptoms associated with degenerative changes affecting an adjacent segment. The concept that arthrodesis causes an increased biomechanical stress in adjacent segments has been widely postulated.¹¹⁻¹⁴ A recent publication by Hilibrand et al¹⁵ reported that up to one third of their patients suffered from degenerative changes in an adjacent segment at ten years and further surgery

was required in two thirds of this group (58 procedures in 374 fused patients). Many suggest that the adjacent segments are degenerative at the time of the first procedure and that the requirement of further surgery reflects the chronic nature of the disease process.

The disc arthroplasty, in preserving the motion segment, might prevent degenerative changes in adjacent segments and therefore avoid the need for further surgery. The design of the Bryan disc prosthesis is based on a proprietary, low-friction, wear-resistant, elastic nucleus (Fig. 1). The prosthesis has been through a number of biomechanical modifications and was tested in animals before being implanted in humans.¹⁶ We wish to present our initial experience.

Patients and Methods

In March 2001, we started an observational clinical study with the aim of evaluating the safety and efficacy of the Bryan disc arthroplasty for the treatment of cervical spondylosis. Inclusion criteria included single level disease between C3/4 and C6/7 and patients with either radiculopathy or myelopathy, not responding to conservative management. Exclusion criteria included active infection, metabolic bone disease, subluxation of more than 3 mm and malignant disease. The senior

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Fig. 1a

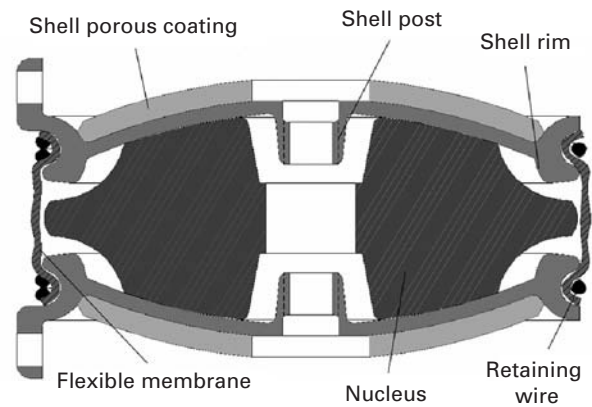


Fig. 1b

Figure 1a – Photograph of the Bryan disc replacement held by its introducer. Figure 1b – Diagram of its internal structure.

author (ATHC) was involved in the original Bryan Disc study (European consortium).^{17,18} The current study specifically excluded those patients involved in the European study.^{17,18}

There were 46 patients in our study, 28 male and 18 female. The mean age was 47.6 years (33 to 70; SD = 10.5); 30% were smokers; no patient was engaged in a legal claim for compensation.

Radiculopathy was present in 80% and myelopathy in 20%. The duration of symptoms ranged between one month and six years (mean 13.8 months; SD = 11.9). One patient who presented after six years, had a large disc which caused a progressive quadraparesis (Ranawat grade IIIb);¹⁹ he was wheelchair-bound on admission. Myelopathy was present in nine patients of whom five had a normal gait and four were ataxic; two patients had a sensory disturbance at C4/5; five patients had had previous spinal surgery; two had had lumbar discectomies and three a previous cervical fusion at one level. Radicular symptoms were present in 37 patients.

All the patients had lateral cervical radiographs (neutral and dynamic), CT scans to size the disc pre-operatively and MRI to identify compression. Twelve patients underwent standard nerve conduction and/or electromyography studies in order to exclude a peripheral neurological cause for the symptoms.

Operative technique. All patients underwent an anterior cervical discectomy followed by the implantation of a Bryan prosthesis, following the standard surgical technique with parallel drilling of endplates and circular milling to a predetermined size (14 mm to 18 mm). The mean operating time was 80 minutes (50 to 180) and the mean blood loss was 90 ml (50 to 130). Five patients had a soft collar on discharge; 34 patients were discharged within 24 hours following surgery, nine after 48 hours, two remained 72 hours and one was admitted to rehabilitation due to his condition at presentation.

Complications. One patient, who was admitted with severe incapacity, experienced worsening of his muscle spasms but the symptoms improved by the time he was discharged. Three patients (7%) suffered mild post-operative dysphonia which resolved completely by the time of the first clinic appointment. One patient required further surgery to have the prosthesis removed following a fall seven months after the operation. The patient complained only of neck pain and suffered no neurological deficit but the inferior disc plate was dislodged. The prosthesis was removed and replaced with an interbody cage, followed by a smooth recovery. There were no cases of post-operative haematoma or infection.

The patients were reviewed at six weeks, six months and one year. All patients completed follow-up, which consisted of a neurological examination performed by a neurosurgeon (JL) not directly involved with the surgery. Radiological evaluation assessed movement, stability and subsidence of the prosthesis and was performed by an independent radiologist (SB) using the Cobb angle²⁰ with a sensitivity of 2°, through dynamic cervical radiographs. Patients were asked to make their own assessment of pain using a visual analogue scale (VAS)²¹ and of general health and functionality with the Short Form 36 (SF-36)²² and the Neck Disability Index (NDI).²³ The results were categorised as excellent, good, fair or poor according to the modified Odom's criteria.²⁴

The SF-36 has been accepted for measuring the outcome in several conditions, including cervical spondylotic myelopathy.^{3,25} There are eight scales, namely physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health which measure physical and mental components of health.²³ The neck disability index described by Vernon and Mior²³ is derived from the Oswestry score. There are 10 questions; the maximum score is 50 and represents maximum disability.

Table I. Movement in flexion/extension at the implanted segment (obtained by analysing lateral dynamic x-rays in 46 patients; two patients did not move)

Duration of follow-up	Number of patients with movement (%)	Mean range of movement ($^{\circ}$) \pm (SD)
6 weeks	44 (95)	7.8 (4.0)
6 months	44 (95)	7.4 (4.3)
1 year	42 (97)	7.77 (4.7)

Statistical analysis. All statistical analyses were performed using SAS (V8.2) software (SAS Institute Inc, Cary, North Carolina). Because of non-gaussian distribution, median values and the range are shown. Groups were compared using the non-parametric, two-sample, exact Wilcoxon rank-sum test for two and an unbalanced two-way ANOVA (general linear model) for more than two variables. Categorical data analysis was done using chi-squared tests. Maentel-Haenzel chi-squared tests were applied to analyse trends. The linear relationship between continuous variables was evaluated using the Spearman correlation coefficient. Multiple correlations were corrected using the Bonferroni method. Linear regression analysis was performed using the least-squares method. Two-tailed tests were used throughout and p values of < 0.05 were accepted as significant.

Results

Radiological. There was no subsidence or migration of any prosthesis apart from the one mentioned above. The range of movement in the prosthesis is shown in Table I. It varied between 0° and 17° with a mean of 7.72° (SD 4.5).

Outcome measures. All patients were followed up for a minimum of 12 months with a mean of 14 months. Table II shows the clinical results after one year. There was improvement in all outcome scales.

Statistical analysis. There was a significant difference ($p < 0.05$) between the age at presentation of patients with radiculopathy (mean 46 years; SD = 9.4) and those with myelopathy (mean 54 years; SD = 13.7). Similarly there was a significant relationship between the age of the patients and their hospital stay ($F(3, 43) = 11.09$; $p < 0.0001$). The *post-hoc* analysis showed that patients under 50 years of age had a shorter hospital stay. There was also a highly significant difference between duration of symptoms in patients with radiculopathy (10.7 months; SD = 5.8) and those with myelopathy (24 months; SD = 19.5); $F(1, 44) = 12.94$, $p < 0.008$). Patients with myelopathy had suffered symptoms for a longer period.

A highly significant difference was found for all three measurements of outcome, comparing the pre-operative baseline with the post-operative 12-month follow-up values. VAS ($Z = 6.42$, $p < 0.0001$), SF-36 mental component ($Z = -5.02$, $p < 0.0001$), SF-36 physical component ($Z = -5.00$, $p < 0.0001$) and NDI ($Z = 7.03$, $p < 0.0001$). Two patients (4.3%) had radiological evidence of bony ankylosis at the level of the implanted disc. Their clinical

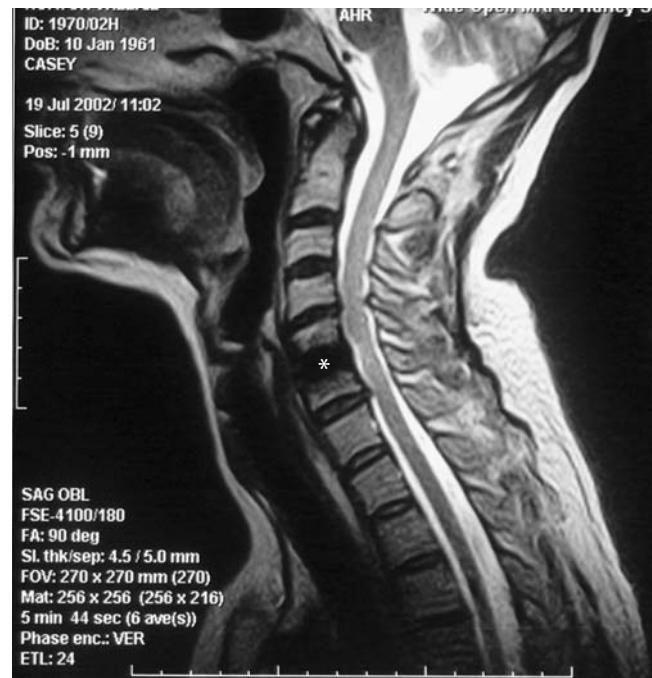


Fig. 2

The Bryan disc replacement is compatible with MRI. The vertebral canal can be seen clearly behind the disc replacement at C5/6 (*).

outcome was not statistically different from those with a successfully functioning arthroplasty.

Discussion

The first cervical disc prosthesis, implanted by Fernstrom²⁶ consisted of a metal ball which had to be 1 mm larger than the disc space. Sadly, effective follow-up data was not provided by the author. Subsequently Cummins, Robertson and Gill²⁷ from Bristol presented a small series of 20 patients with articulated prostheses in place of cervical discs. After two years follow-up, 88% (16 of 18) of the patients had functional movement, and the clinical results were acceptable. However these were end-stage patients, potentially biasing the study. This stainless steel device cannot be imaged by MR and cannot be implanted into two adjacent segments. The design of the Bryan disc not only allows the opportunity of operating on two adjacent pathological segments, but also its compatibility with MRI facilitates follow-up with the advantage of demonstrating the nerve root exits as well as the canal (Fig. 2).

Goffin et al^{17,18} presented the preliminary results of a European multi-centre study of the Bryan disc replacement, of which our institute was a participant centre. The major outcome tools were modified Odom's criteria and the SF-36 scores. Neither a VAS nor the NDI were used. The results showed that 86% patients after one year and 90% patients after two years had excellent, good or fair results according to modified Odom's criteria. Our study showed similar results. Of the 46 patients with a one year follow-up there

Table II. Outcome results in 46 patients

Case	VAS*			SF-36MCS†			SF-36PCS‡			NDI§			Odom¶	
	Pre-op	6 mths	12 mths	Pre-op	6 mths	12 mths	Pre-op	6 mths	12 mths	Pre-op	6 mths	12 mths	6 mths	12 mths
1	3	0	4	19.7	43.3	40.5	23.6	42.4	32.2	38	6	15	E	G
2	6	2	2	44	58.8	55.6	28.9	49.9	46.7	25	14	11	F	F
3	8	2	2	43.6	57.5	53.4	42	52.3	53	18	4	2	E	E
4	9	2	2	44	54.5	52.9	41.6	53.3	51.9	18	2	0	E	E
5	2	0	0	34.4	55.4	54.4	33	44	43.5	19	11	7	F	F
6	6	0	1	51.4	57.5	56.8	39	59.3	55	22	0	0	E	E
7	8	2	2	47.8	59.8	58.8	37.9	53.5	54.8	19	1	0	E	E
8	9	1	1	47.6	53.4	54.7	34	51.1	50	23	4	2	E	E
9	5	1	7	23.3	39	34.5	19.5	42.4	30.3	39	12	29	G	P
10	10	4	0	34.4	52.5	55.6	41	47.8	55.8	24	7	3	F	G
11	9	0	1	39	57.7	57.7	41.3	57.7	54.5	22	2	1	E	E
12	9	5	6	23.4	45.6	44.4	22.4	25.4	28.9	35	24	26	P	P
13	0	0	0	21.4	58.5	54.4	23.7	33.2	28.8	22	15	14	P	P
14	0	0	0	36.7	40.3	38.7	32	34	36.9	28	11	7	F	F
15	10	5	0	41.2	54.5	55.6	33.7	39.9	56.6	22	16	3	P	E
16	8	4	5	44.6	57.5	56	35.8	47.8	49	21	3	3	E	E
17	9	2	2	38	48.4	49.8	39.8	54.3	51.7	16	1	0	E	E
18	10	1	1	36.8	55.5	52.2	29.9	53.3	49.4	21	2	2	E	E
19	8	3	3	46.8	58.5	57.5	31.8	42.6	37.8	13	8	7	F	F
20	7	2	2	42	54.5	54.5	38.9	46	45.9	17	4	2	E	E
21	6	2	2	39.3	43.3	44.4	21.1	30	31.1	24	22	21	P	P
22	6	7	7	27.9	45.4	45.6	33.6	34.3	27.6	23	21	22	P	P
23	6	0	4	34.6	43.5	40.3	34.3	51.5	32.9	18	2	17	E	P
24	10	4	1	45.6	54.5	50.3	42.8	49.4	55.6	16	11	4	P	F
25	7	2	7	30.4	49.9	43.3	38.9	43.9	34.4	18	4	11	E	F
26	7	3	3	38.5	48.4	44	36.8	39.9	34.3	17	6	5	E	E
27	6	2	2	45.6	56.6	54.5	32.8	49.7	52.3	19	4	1	E	E
28	8	2	2	24.2	45.4	27.4	31	39.4	37.4	24	5	2	E	E
29	6	1	1	42	56.6	51	38.9	53.3	51.1	16	1	1	E	E
30	1	1	1	47.8	55.6	54.5	41.8	45.5	42.1	18	3	5	G	G
31	6	0	0	46.7	58.5	56.4	37.8	55.6	54.5	22	0	0	E	E
32	7	1	1	52.3	55	53.3	23.5	58.5	58.5	24	0	0	E	E
33	7	0	0	55	59.5	59	28.7	53.3	54.4	26	1	0	E	E
34	9	4	0	43.8	49.4	44.3	26.8	47.6	57.5	21	8	0	G	E
35	9	3	3	37	49.5	44.9	34	46.6	48.4	19	4	5	E	E
36	8	4	4	45	54.4	55	26.7	48.5	44.5	28	3	3	E	E
37	7	1	1	45.6	57.5	51.1	33.7	53.4	55.5	20	0	0	E	E
38	7	3	3	52.4	58.4	52	35.8	39.4	37.5	22	4	2	E	E
39	9	4	4	43.4	54.3	47.3	44.8	49.9	51.1	8	2	2	E	E
40	7	5	5	34	50.4	30.3	32.5	43.3	44.8	11	3	3	E	E
41	10	4	0	33	44	41.5	27.8	36.5	44.5	22	14	8	P	F
42	10	2	2	45.6	54.5	49.9	34.7	53.4	54.4	9	0	0	E	E
43	2	2	2	42.7	55.4	49.9	31.8	47.4	45.5	18	8	5	G	G
44	3	0	6	47	56.6	47.4	33	38.8	28.8	23	7	15	E	F
45	7	2	2	40.9	49.9	44.4	36.8	49.4	47.4	18	7	5	G	G
46	6	2	2	46	58.5	56.6	33.8	43.4	44.8	19	5	5	E	E

* VAS, visual analogue scale

† SF-36MCS, short form mental component of health

‡ SF-36PCS, short form physical component of health

§ NDI, neck disability index

¶ Odom²⁴, E, excellent; G, good; F, fair; P, poor

were satisfactory results in 84% (29 patients, 4 good and 6 fair). In the 22 patients with a two-year follow-up, there were satisfactory results in 15 (89%), excellent in 13, good in one and fair in one.

One of the potential criticisms about artificial discs is that in the absence of fusion there may be further pain. This is certainly the case with pseudoarthroses. Our analysis of VAS and NDI show that this has not been a problem in our patients. The radiological results showed that 91% of the 42 patients retained movement at the operated segment at

one year. Our results compare favourably with the initial Bristol experience, in which 16 of 18 patients (88%) had evidence of movement in the prosthesis at two years.²⁷ Our clinical results also compare favourably with series of anterior cervical discectomy which have used Odom's criteria to assess outcome.⁶⁻¹⁰

One of the main difficulties when comparing surgical results in other series in the literature, is the wide variation of patients' clinical and radiological characteristics. The new generation of methods of assessment, such as the NDI,

SF-36 and myelopathy disability index,²⁸ will eventually solve most of these problems as outcomes may be compared objectively with age-matched populations. In our study, there were statistically significant differences in age, duration of symptoms and post-operative outcomes between patients with radiculopathy and those with myelopathy. Future clinical trials should analyse these two clinical groups separately. Patients with radiculopathy patients generally do well and return to normal. This is not true of patients with myelopathy.

In our observational study, the Bryan cervical disc replacement was shown to be reliable and safe for the treatment of patients with cervical spondylosis, producing minimal complications and good surgical results.

Supplementary material



A further opinion by Alistair Ross is available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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