CERVICAL ARTHROPLASTY: BEYOND THE EUROPEAN AND UNITED STATES FDA STUDY

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PURPOSE OF STUDY

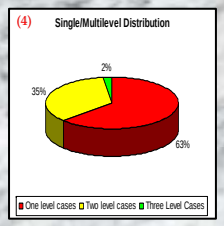
The current FDA Bryan® (Medtronic-Sofamor Danek, Memphis, TN) cervical arthroplasty trial and published multicentered European data to date,[1,2] both focus on examining single level arthroplasties used in the management of soft disc protrusion or spondylosis causing radiculopathy or myelopathy in previously unoperated patients. The latter have recently described bi-level results.[2] We describe the indications, results and outcomes of interventions beyond this initial indication, encompassing two and three level arthroplasties for neural decompression, arthroplasty for axial neck pain and arthroplasties performed after previous surgery.

METHODS

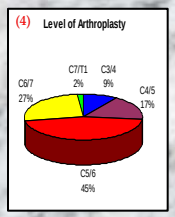
A total of 46 patients are reported who underwent placement of a total of 64 Bryan® cervical disc prostheses over a 33 month period by the two authors. The surgical technique has been described before.[3] The demographics of the patients are summarized in the table along with the clinical presentation.

Indications for surgery comprised neural compression or axial neck pain. Previous surgery was not an exclusion factor. One patient had a previous pseudoarthrosis that was converted to an arthroplasty. Follow-up was for a minimum of 6 weeks with assessments comprising initial static and dynamic x-rays and CT scanning and subsequent serial imaging at 6 weeks, 3 months, 6 months and yearly thereafter. All myelopathic patients underwent postoperative MR scanning and clinical assessment was performed after each interval study. A CT scan was performed on a yearly basis.

(4) Single/Multilevel Distribution



(4) Level of Arthroplasty



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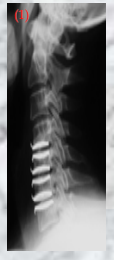

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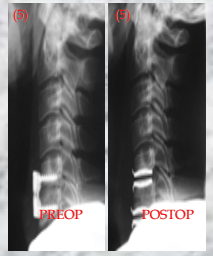

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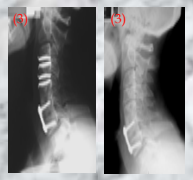

PATIENT DEMOGRAPHICS (n=46)		%
Males	19	41
Females	27	59
Age	45.2±9.6	
Smoking	2	4
Preop duration of symptoms (mths)	13.2±12.2	
Time since surgery (mths)	16.6±9.8	
No previous surgery	33	72
Previous fusion surgery	6	13
Previous posterior surgery	7	15

PREOPERATIVE SYMPTOMS (n=46)		%
Radiculopathy	30	65
Myelopathy	21	46
Myeloradiculopathy	15	33
Neck pain	28	61
Neck pain alone	7	15
Arm pain (unilateral)	21	46
Arm pain (bilateral)	15	33

COMPLICATIONS (n=46)		%
Death	0	0.0
Neurological Deterioration	1	2.2
Vascular Injury	0	0.0
Worsening neck/arm pain	2	4.3
Fusion	1	2.2
Blood Transfusion	2	4.3
Infection	0	0.0
Subluxation/loosening	1	2.2
Reoperation	1	2.2
Subsidence	0	0.0
Persistent dysphagia	2	4.3
Clicking	2	4.3
Persistent interscapular pain	6	13.0
Any residual symptoms	16	34.8
Any residual neurological symptoms	11	23.9

OUTCOMES	
Preop Nurick Grade (of 12 cases)	2.00±1.00
Postop Nurick Grade (of 12 cases)	1.09±0.30
Preop VAS (of 24 patients)	6.9±2.7
Preop VAS (of 24 patients)	1.8±2.2
Preop Oswestry NDI (of 24 patients)	34.9±8.9
Postop Oswestry NDI (of 24 patients)	17.5±9.8

SUMMARY OF FINDINGS

No patients were lost to at least 3 month follow up and only 2 patients were lost to follow up beyond twelve months. Complications are summarized in the table. Movement was noted in over 80% of implants at latest follow up. Two patients, both slim short females, required blood transfusions for excessive epidural bleeding after undergoing multilevel procedures. One patient who underwent a two level decompression and arthroplasty for severe myelopathic compression suffered a clinical deterioration two weeks after surgery. She was managed expectantly with corticosteroids and at follow-up 12 months after surgery had lost most of her preoperative myelopathic symptoms with an postoperative MR scanning confirming neural decompression. One patient developed immediate worsening of preoperative arm and leg pain and suffered a continuous regional pain syndrome with essentially normal postoperative investigations. The etiology for this was not clear. One patient, lost to follow-up, had removal of a prosthesis by surgeons elsewhere with conversion of this level to a fusion and decompression and fusion at an adjacent level. The reasons for this are not clear and the patient was lost to follow-up. Finally, one patient had worsening of preoperative neck pain which continued despite antiinflammatory therapy. Seventeen months after surgery radiographic osseous fusion was noted across the posterior surface of her implant with improvement of her pain. The reason for the fusion was thought to be due to a combination of loss of motion and a proliferative form of osteoarthritis. No heterotopic anterolateral calcification was seen in any case and all patients after the initial 10 cases underwent one month of oral antiinflammatory therapy.

Of note was that in a subset of patients preoperative deformity was worsened and 13% of patients had persisting interscapular pain, presumably of a facet joint origin. Shell tilting was noted in several patients and the significance of this is currently being investigated.

In terms of patient outcome assessments, 82%, 76% and 83% of patients had excellent or good outcomes in terms of neck pain, arm pain or other symptoms, respectively. Nurick grades overall improved in subset of myelopathic patients and VAS and Oswestry Neck Disability Scores also improved in patients that were assessed. As a group, over 90% of the patients felt the surgery was worthwhile and would have the surgery again.

All patients who underwent prior posterior decompressions had resolution of arm pain with no evidence of instability.

Patients who had undergone previous fusion surgery also had good outcomes, although relative hypermobility was often noted at the level that was arthroplastied. No prosthesis to date had to be revised because of premature wear.

The frequency of multilevel arthroplasties increased from the initial 20 cases as more cases with spondylotic disease were addressed. Again the results in terms of clinical outcome were indistinguishable from the overall pool.

The results in patients with primarily neck pain as a presenting symptoms showed general improvement overall.

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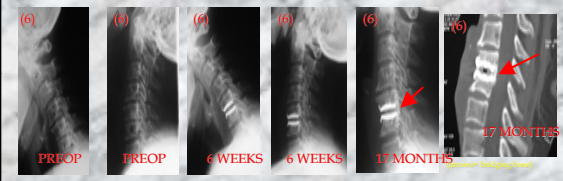

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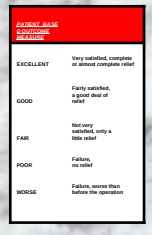

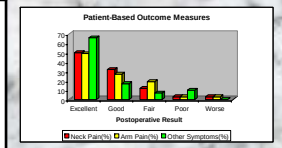

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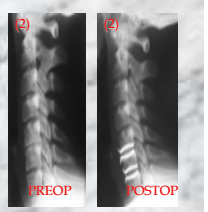

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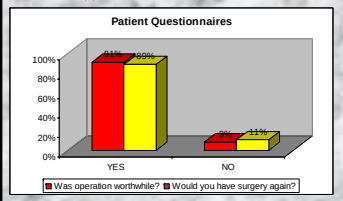

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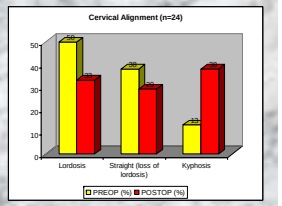

CONCLUSIONS

The scope for arthroplasty in the cervical spine extends beyond the indications described in the European studies or in the current U.S. FDA trial. This early study suggests that cervical arthroplasty may play a role in the management of adjacent segment cervical degeneration, multilevel neural compression, primary axial neck pain and cervical pseudoarthrosis. Unlike lumbar arthroplasty, our early results suggest that after limited posterior cervical decompression, cervical arthroplasty can still be used as a potential treatment option. The implications of cervical arthroplasty in terms of deformity and its potential correction and potential accelerated wear adjacent to cervical fusions will need further investigation. Clearly longer term follow-up and more detailed analysis is required in each of these settings.

REFERENCES

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3. Sekhon LH: Cervical arthroplasty in the management of spondylotic myelopathy. J.Spinal Disord.Tech. 16:307-313, 2003