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RANDOMIZED TRIAL

Very Late Complications of Cervical Arthroplasty

Results of 2 Controlled Randomized Prospective Studies From a Single Investigator Site

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Study Design. Prospective, single-site, randomized, Food and Drug Administration–approved investigational device exemption clinical trials of 2 cervical arthroplasty (CA) devices.

Objective. To evaluate complications with CA occurring more than 4 years after the surgical procedure in Food and Drug Administration clinical trials of the Bryan and Prestige LP arthroplasty devices.

Summary of Background Data. Reports of several randomized clinical studies have shown CA to be a safe and effective alternative to anterior cervical fusion in the treatment of degenerative cervical disc disorders. A majority include follow-up intervals of 4 years or less.

Methods. Between 2002 and 2006, 94 patients were enrolled in Food and Drug Administration studies of the Bryan and Prestige LP cervical disc devices. Charts, imaging studies, and hospital records were reviewed for those who underwent arthroplasty and returned more than 4 years after their surgical procedure with neck-related pain or dysfunction.

Results. Excluding adjacent segment disease that occurred with a similar rate for patients who underwent fusion and arthroplasty, 5 patients, all treated with arthroplasty, returned for evaluation of neck and arm symptoms between 48 and 72 months after surgery. Four patients had peridevice vertebral body bone loss. One patient had posterior device migration and presented with myelopathy. Three required revision surgery and 2 were observed. Four patients maintained follow-up and reported stabilization or improvement in symptoms.

Conclusion. Despite their similarities, CA and fusion are not equivalent procedures in this study in regard to very late complications. Similar to large joint arthroplasty, delayed device-related complications may occur with CA. These complications commenced well beyond the time frame for complications associated with more traditional cervical spine procedures. Both patients and surgeons should be aware of the potential for very late device-related complications occurring with CA and the need for revision surgery.

Key words: cervical spine, cervical arthroplasty, degenerative cervical disc disease, cervical fusion, artificial cervical disc.

Level of Evidence: 1

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Cervical arthroplasty has been shown in clinical studies to provide satisfying results in the treatment of degenerative cervical disc disease. Outcome measures have shown improvement in neck and arm pain that has equaled or surpassed results obtained with cervical fusion.[1,2] Compared with a more than 50-year experience with cervical fusion, experience with arthroplasty is limited.[3] Hence, the long-term outcome and complications remain unknown.[4] Results from large clinical trials of artificial cervical disc trials have been published.[5,6] Most clinical studies of spine fixation for fusion include follow-up intervals of 2 to 4 years. Published reports of arthroplasty have included similar lengths of follow-up. However, devices that promote spine fusion may have different failure characteristics and occurrence intervals than arthroplasty. Extrapolating this follow-up interval to spinal arthroplasty may not capture complications occurring with a motion-preserving device. Very late complications such as implant failure, and wear debris–induced osteolysis, are well known in large joint arthroplasty.[7,8] Thus, an appropriate follow-up interval for spinal arthroplasty may extend beyond that typically applied to patients who undergo cervical fusion. This study examines delayed device-related complications that call into consideration the appropriate follow-up interval for patients who undergo cervical arthroplasty (CA).

MATERIALS AND METHODS

The corresponding author agreed to take part in a single-site Food and Drug Administration device study of the Bryan cervical disc prosthesis. The device is a metal-on-polymer design with titanium endplates and a core of polyurethane surrounded by a polyurethane shell. After obtaining investigational review board approval and undergoing procedure training on cadavers, we began enrolling patients in our

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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randomized controlled study of the Bryan cervical disc prosthesis. Eligibility was limited to patients who failed conservative therapy with 1-level degenerative cervical disc disease causing radiculopathy and/or myelopathy with or without neck pain. Diagnostic studies included magnetic resonance imaging, and computed tomographic scanning, obtaining plain radiographs with dynamic anteropostero and lateral motion views. Loss of motion at the symptomatic level was a contraindication to the procedure.

All patients underwent anterior microdiscectomy with one-to-one randomization to Bryan CA or anterior cervical fusion (ACF). A total of 28 patients enrolled in the clinical trial received the Bryan disc. An additional 3 patients were included in continued access status without randomization, and 1 patient was granted compassionate use who did not meet study requirements because of a previous 2-level cervical fusion. None of these 4 patients returned with very late complications. Patient radiographs and clinical data were recorded preoperatively and scheduled postoperatively at 1, 6, 12, and 24 weeks and at 12, 24, 48, and 60 months.

The authors also participated in a Food and Drug Administration device study of the Prestige LP CA device. The Prestige LP device is a metal-on-metal design constructed of titanium-aluminum alloy (Ti-6Al-4V) with carbide dispersion. The study design and enrollment criteria were similar to the Bryan study. Nineteen patients received Prestige LP arthroplasty devices.

All study patients were told to return any time for complaints of neck or extremity symptoms. The authors defined very late complications as those occurring beyond 48 months from a surgical procedure in distinction to the designation of late complications applied to those occurring 24 months after a procedure.

RESULTS

Similar numbers of patients in the ACF and CA study groups presented with symptoms attributed to adjacent segment disease and were not studied further. Five patients in the arthroplasty groups presented with symptoms thought to be due to their device. Four of these patients had undergone Bryan CA, and 1 patient has a Prestige LP device. Of the 4 Bryan patients, 2 were beyond 4 and 2 others had past 5 years of follow-up. The Prestige LP patient was beyond 4 years of follow-up. Clinical data for these patients were similar to the entire clinical series in regard to preoperative symptoms, age, and cigarette smoking. Females accounted for 53 percent of our study population, whereas all 5 patients with late complications were females. Two Bryan patients underwent surgical revision. One patient had device subluxation with ventral cord effacement and subtle findings of cervical myelopathy. Device removal was followed by cervical fusion. At the last follow-up, she rated her outcome as fair. The other Bryan revision involved marked loss of vertebral body bone with deformity (Figure 1). The patient noted recurrent neck and arm pain. Device explantation was followed by 2-level ACF (Figure 2). She reported a good outcome at the last follow-up. Despite extensive tissue review by independent laboratories in all explantation cases, hers was the only 1 to show abnormal findings. Evaluation of the tissue and bone samples adjacent to the device suggested the potential for a low virulence bacterial infection based on microscopic slides of macrophages. However, no pathological agent was identified, and all cultures were negative.

The 2 other Bryan patients had symptoms of neck pain only. Haloing about their arthroplasty devices consistent with bone loss was identified. They were observed only. One patient reported improvement, and follow-up films 1 year later showed resolution of the haloing. The other patient was

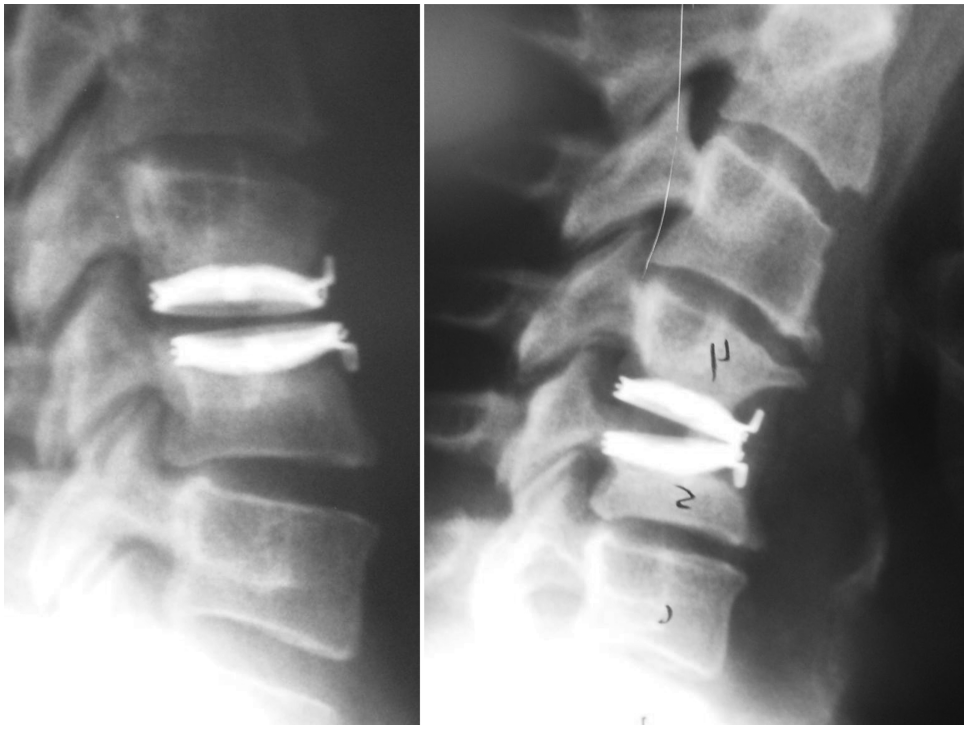

Figure 1. Bryan case with extensive bone loss presenting with neck and arm pain. On the left is a lateral view six weeks following the procedure. On the right is a lateral view 52 months postop.

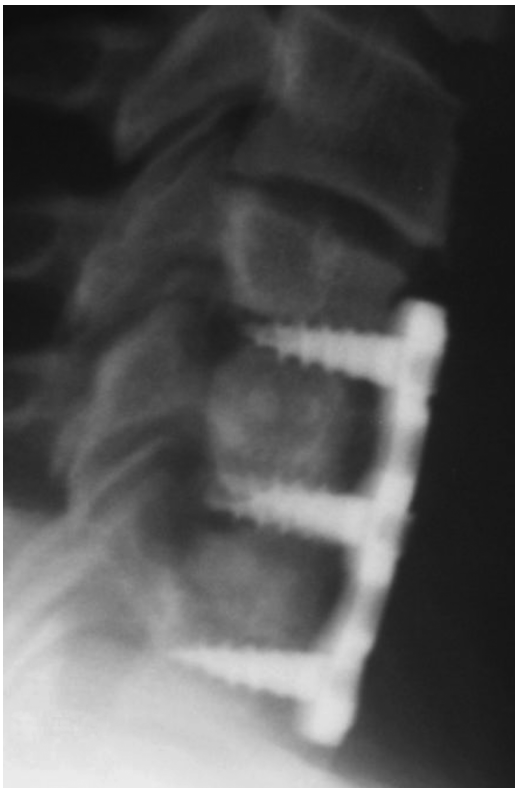

Figure 2. Bryan case after device removal and 2-level ACF. ACF indicates anterior cervical fusion.

lost to follow-up. Upon review of their earlier films, subtle haloing could be seen as early as 6 months postoperatively in the patient who noted later improvement.

The Prestige LP patient noted neck and arm pain, and studies showed loss of vertebral body height, deformity, and heterotopic ossification *versus* regrowth of an osteophyte compressing her right C6 nerve root in the neural foramen (Figure 3). Device removal was followed by 2-level fusion. Improvement was minimal. Her fusion grafts subsided, causing marked kyphosis necessitating corpectomy and posterior fusion fixation. She reported a fair outcome.

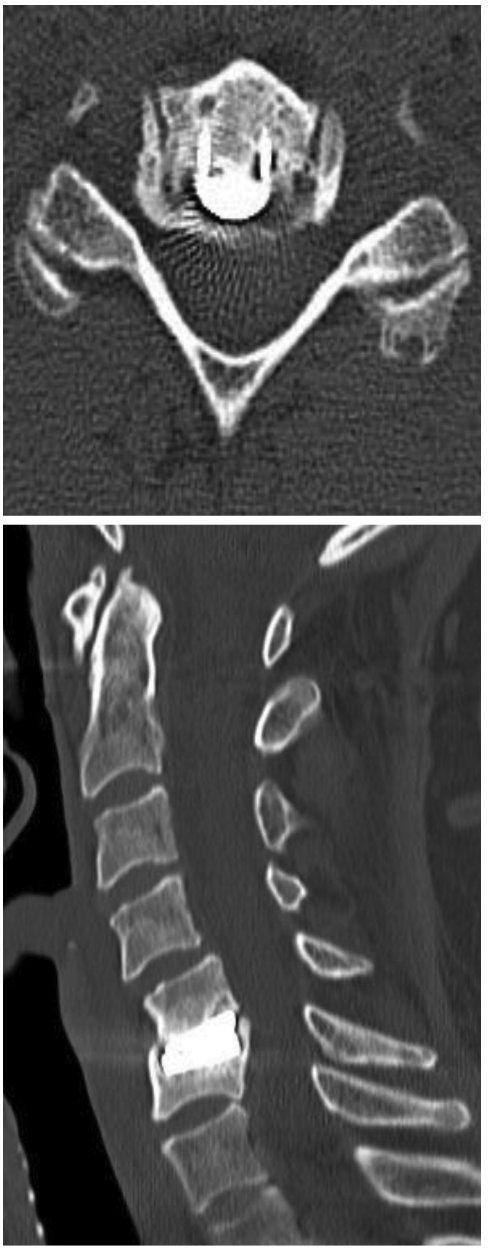

Figure 3. Prestige case with extensive bone loss and device subsidence. The top CT image is an axial view that confirms foraminal narrowing due to heterotopic ossification or recurrent osteophyte. The lower image is a lateral CT image showing extensive bone loss and device subsidence. CT indicates computed tomography.

DISCUSSION

The purpose of this publication is to make surgeons aware that device-related complications may occur in a delayed fashion with CA. Surgeons who routinely perform and follow patients after cervical fusion must be cognizant that arthroplasty and cervical fusion are distinctly different procedures in regard to the occurrence of very late complications.

Preservation of the spinal motion segment is an attractive alternative to spine fusion. Benefits have been described such as a more rapid return to work and avoidance of bracing.[9] Yet, the trade-off for preserving motion is exposing patients to potential complications largely unknown in the cervical fusion population. Infection or device malfunction with loss of motion are obvious potential device-related complications. Less obvious may be a failure of "fusion" or osteointegration of the arthroplasty device into the adjacent verterbral bodies. This failure of a solid attachment may result in neck pain or device migration. A device with moving parts creates wear debris. This has been well documented in large joint arthroplasty and was confirmed in the initial Bryan Disc bench top testing.[10,11] Device failure resulting from osteolysis with spine arthroplasty has been reported. van Ooij *et al*[12] described osteolysis of the sacrum occurring in 1 patient who had disruption of a CHARITÉ lumbar arthroplasty polyethelene core. Histological study demonstrated an inflammatory response. Three other patients who underwent lumbar arthroplasty had device wear-related biomechanical problems that included migration. Kurtz *et al*[13] reported 18 patients who underwent additional surgery after CHARITÉ lumbar arthroplasty because of pain.

The implants had been placed between 1.8 and 16 years earlier. They noted fracture and wear patterns in the polyethelene core that increased over time with surface damage similar to that described with hip and knee implants.

The cause of bone loss as it relates to the complications described in this article is unknown. No convincing evidence of osteolysis was seen. However, given the experience with lumbar devices, the potential for CA-related osteolysis must exist.

No treatment currently exists that restores the degenerative cervical spine to its normal state. Our surgical treatments all carry trade-offs of 1 sort or another. ACF sacrifices a motion segment but achieves satisfying results leaving behind only the patient's biology with, depending on the surgeon's preference, a fixation plate. CA also achieves satisfying results and has the benefit of preserving the motion segment. However, the patient who underwent arthroplasty from that point forward has a mechanical device residing in their neck. We know from implanted "moving parts" elsewhere in the body that they are generally safe but do not come with lifetime guarantees.

CONCLUSION

CA is a unique cervical spine surgical procedure. Longer follow-up intervals should be considered for these patients in comparison with those treated with cervical fusion. We recommend that patients treated with arthroplasty undergo lateral cervical spine radiography every 2 years. They should also be well informed about the potential for very late complications.

➢ Key Points

- ❑ CA and cervical fusion are different procedures in terms of very late complications.
- ❑ Spine arthroplasty exposes patients to complications similar to those seen in large joint arthroplasty.
- ❑ The most appropriate follow-up interval for CA has not been defined by recent clinical trials. Our study suggests that it extend significantly longer than that typically applied to patients who underwent cervical fusion.

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