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The Prestige Cervical Disc

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Anterior cervical decompression and fusion (ACF), first described over 50 years ago, has become the most common surgical procedure for patients with symptomatic cervical spondylosis who have failed to respond to nonoperative therapy [1–3]. Treatment with an ACF provides immediate decompression and long-term stability. Global cervical spinal mobility is not significantly altered by a single segment fusion; however, it is decreased in multilevel arthrodeses. Although fusion is beneficial at the diseased level of the spine, data show that cervical arthrodesis increases the stresses on discs that have not been operated on, and these stresses probably adversely impact the rate of disc degeneration [4–10].

Indications

A comprehensive discussion of the indications and contraindications of total cervical arthroplasty is not the focus of this article, but some discussion of this topic is relevant. In general, any patient with anterior pathology and who has normal or near-normal segmental motion and sagittal alignment, may be a candidate for reconstruction with the Prestige LP (Medtronic Sofamor Danek, Memphis, Tennessee) artificial cervical disc.

Individuals without evidence of segmental motion cannot be expected to regain mobility by implanting a total disc replacement. Patients with instability will not be well-served by reconstruction with an artificial disc replacement. At this time, there are no solid scientific data supporting the correction of significant kyphosis with an arthroplasty device. Patients presenting with these problems are better served with an arthrodesis.

History of the Prestige cervical disc

The Prestige artificial cervical disc originated with Mr. Brian Cummins, who attempted to address the shortcomings of cervical arthrodesis some 16 years ago, when, in 1989, he began to develop an artificial cervical disc in collaboration with the Department of Medical Engineering at Frenchay Hospital, Bristol, United Kingdom [11]. His pioneering efforts in the development of a metal-on-metal artificial cervical disc laid the foundation upon which the Prestige artificial cervical disc system was built. After 2 years of multiple modifications, the original ball-and-socket Cummins design had been modified and finally approved for human implantation. Between 1991 and 1996, 22 joints were implanted in 20 patients. Eighteen of these patients were re-examined in 1996, and all but two were mobile at the implanted level. Although there were some minor setbacks (one device was removed because of a manufacturing error; there was some screw breakage and minor back-out) no implant failed. Patients with radiculopathy improved, and those with myelopathy either improved or stabilized.

Outcomes for Prestige I cervical disc

The Prestige I device retained most of the design of the original Bristol disc. It was precisely manufactured and secured to the adjacent vertebral bodies with screws covered with a cap to prevent the screws from backing out of the bone. The Prestige I was evaluated prospectively in a cohort of 17 patients, each of whom required a surgical intervention in a segment adjacent to a previous fusion. The objective of the study was to assess the safety and stability of the device once implanted, as well as the preservation of motion in

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the cervical spine after decompression and arthroplasty [12]. The patients were assessed for 4 years following placement of the device [12]. Throughout the study, the Prestige I effectively maintained motion with a mean sagittal rotation (flexion and extension) of 7.5°. At 24 months, all joints were mobile and there was an average of 6.5° of flexion and extension motion. Normal anteroposterior (AP) translation was also preserved. There was no back-out of the screws, and none of the joints failed. Radiographic analysis at 48 months revealed that 12 patients had an average sagittal plane rotation of 5.7° and a mean AP translation of 0.83 mm. These results are consistent with data from the biomechanical study by DiAngelo and colleagues [13], which emphasized the maintenance of normal motion at all segments of the spine with the placement of the Prestige cervical disc, compared with the decreased motion of adjacent segments following surgical arthrodesis.

The Neck Disability Index (NDI) is a 10-question assessment instrument that measures cervical pain and disability associated with the activities of daily living [12]. Higher scores on the NDI reflect increased neck pain and greater disability. NDI assessments were performed preoperatively and at regular intervals (6, 12, 24, 36, and 48 months) postoperatively. Fourteen patients were evaluated at the end of 48 months, and they demonstrated a 30% improvement in their NDI scores.

The SF-36 questionnaire is an instrument that measures a patient's general health status, with breakdown into mental and physical component scores. Similarly, it was administered preoperatively and at regular intervals postoperatively. The SF-36 demonstrated positive results for the duration of arthroplasty implantation.

Two screws broke without clinical consequence, and no screws backed out. Two of the implants were removed. In one case, the amount of bone removal was excessive, producing overloading of the facets, which led to a chronic pain syndrome. No significant tissue reaction was noted, and the implant showed minimal wear of the articular surfaces. The second removal was required to treat an adjacent level pre-existing condition. This implant, removed more than 3 years after the original surgery, had minimal wear, and there was no evidence of a host inflammatory response.

This Prestige I study demonstrated that all devices maintained motion at the treated levels along with the re-establishment of disc height throughout the duration of the study. The procedure was safe and the implant proved stable, with no dislocation of the components. The success of this pilot study permitted further device evolution and paved the way for application of the Prestige device on a more widespread scale.

Wigfield and colleagues [14] assessed the motion of the segments adjacent to levels reconstructed with either the Prestige I or an autologous bone graft. The adjacent segments were assessed with an MRI scan preoperatively and scored in terms of the degree of degenerative change present. Preoperative sagittal angular motion was also measured in these segments. The two treatment groups were identical in terms of these pretreatment parameters. Sagittal angular motion was assessed again at 6 and 12 months following surgery. A slight reduction in the motion at the adjacent segments was noted in the patients who received the Prestige I device. Overall cervical motion was maintained in these individuals, almost certainly the result of preserved mobility at the operative level. In contrast, arthrodesis resulted in a significant increase in sagittal plane rotation at the adjacent levels 1 year following the fusion surgery.

Prestige II cervical disc

The Prestige II was designed in 1999. A key improvement over the Prestige I device was the replacement of the hemispherical cup with an ellipsoidal saucer (trough), which facilitated normal physiological motion. The design of the two components of the joint allows the upper vertebral component to passively find its own axis of rotation as determined by the facet joints and coupled motions of the adjacent vertebrae. The endplate surface was also roughened to promote bony in-growth for long-term stability.

Outcomes for the Prestige II cervical disc

The Prestige II was the first cervical artificial disc to be compared with fusion in a prospective randomized trial composed of patients with primary disease [15]. This study randomized patients in a 1:1 fashion to compare decompression and placement of the Prestige II device to decompression and uninstrumented arthrodesis with autograft. Patients with symptomatic single-level disease who had no prior cervical surgery were enrolled in the study. Twenty-seven patients were randomized to the Prestige II group and 28 to the

arthrodesis (control) group. Cohort demographics were comparable. The 2-year data demonstrate that most outcome measurements favor arthroplasty over arthrodesis with regard to the NDI, Visual Analog Scale (VAS) for neck and arm pain, and the mental and physical component scores of the SF-36, although these differences did not reach statistical significance [15]. Importantly, motion analysis demonstrated maintenance of motion in the arthroplasty patients; whereas, the fusion patients displayed no significant motion. If the Prestige II disc alleviates pain and symptoms comparable to a fusion, while simultaneously maintaining radiographic motion across the segments operated in every patient, then its utility is validated. Additional long-term follow-up is certainly warranted, because the observation period in the previously mentioned study is to too short to draw any conclusions about the presumed benefits of the preserved motion segment. Moreover, further trials are necessary with larger sample sizes and greater statistical power to confirm these preliminary results.

Prestige ST cervical disc

The Prestige ST became available in 2002. The significant change between the Prestige II and the Prestige ST was a 2-mm reduction in the height of each anterior flange. The Prestige ST is the device currently being evaluated in a US Food and Drug Administration Investigational Device Evaluation study. It is constructed of stainless steel and consists of two articulating components attached to the cervical vertebrae with screws (Fig. 1). The ball-and-trough design of the Prestige ST provides relatively unconstrained motion comparable to that of a normal cervical spinal segment (Fig. 2). The angulation between the base of the components and the anterior portion matches the normal anatomy of the cervical vertebrae. The anterior face is 2.5 mm thick, which is comparable to the thickness of most anterior cervical plates. The surfaces of the device contacting the endplates are grit-blasted to promote bone osteointegration. The Prestige ST comes in a variety of sizes. There are implants of 12 mm depth that will allow for interspace heights of 6, 7, and 8 mm. Larger patients may require the 14 mm depth, and these implants have interspace heights of 7, 8, and 9 mm. The width of all devices is comparable to clinically successful anterior cervical plate systems at a consistent 17.8 mm. The specific instrumentation required to implant the Prestige ST includes interspace sizing trials, an anterior reamer, and an implant holder, which also serves as drill, tap, and screw guide.

Fig. 1. The Prestige ST total joint replacement device consists of two articulating components that are attached to the adjacent vertebral bodies by four bone screws. A locking cap screw prevents back-out of the bone screws.

Implantation of the Prestige ST cervical disc

The patient is positioned supine on the operating table, and all pressure points are padded. The surgical site is sterilized, and the anterior cervical spine is exposed through a standard fascial dissection. The disc is removed and all osteophytes are resected. It is important to be certain that a meticulous bilateral decompression is performed. Particular attention should be directed toward completely removing osteophytes arising from the uncinate processes.

The anterior inferior lip of the rostral vertebral body is resected with a 45° rongeur if necessary. Any remaining anterior vertebral column osteophytes should be removed with a rongeur or bur. The vertebral endplates are denuded of cartilage and burred until there are two parallel surfaces of subchondral bone. This may be accomplished with any of a variety of high-speed burs. Partially or completely preparing the endplates for placement of the Prestige device before the decompression, increases the corridor through which the spinal canal is accessed.

Fig. 2. Ball-and-trough articulation of the Prestige ST.

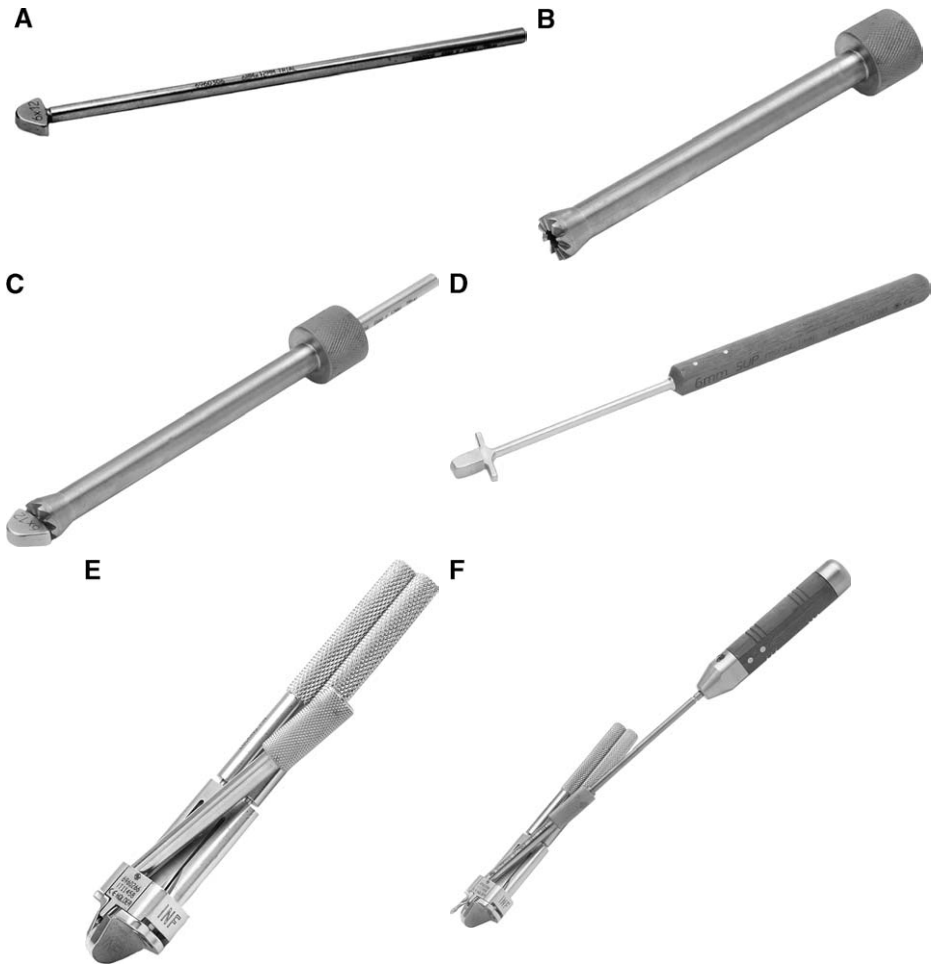

Fig. 3. (*A*) Trial sizing device for a 6 mm × 12 mm implant. (*B*) Anterior vertebral reamer. (*C*) Anterior reamer over size trial device. (*D*) Interspace anterior face device for a 6 mm × 12 mm implant. (*E*) Prestige ST mounted in the implant holder. (*F*) Prestige ST mounted in the implant holder with drill engaged.

Prestige ST sizing trials are placed into the interspace to determine the appropriate size of the prosthesis. The trial device (Fig. 3A) should fit snugly. If it is too tight, the ligaments that surround the segment may become overly taut, thereby restricting motion. If it is too loose, the interspace height will not be proper and the implant may not function optimally. The trial device is inserted in the correct orientation. If it does not fit precisely, more endplate preparation may be necessary. Once the interspace preparation is completed, the sizing trial is inserted and the anterior vertebral reamer is placed over the handle of the trial device (Fig. 3B, C). This reamer is rotated back and forth to plane the anterior surface of the vertebral bodies, so that the anterior face of each of the components of the Prestige total disc replacement lies flush against the spine. A final check of the interspace and anterior vertebral surfaces is performed by sweeping the anterior face profile trial medially and laterally (Fig. 3D). Any bony irregularities detected during this maneuver should be addressed.

A Prestige device matching the interspace trial device is attached to the implant holder and inserted into the interspace (Fig. 3E). A sleeve is placed into one of the implant holder drill ports, and a hole is drilled into the vertebral body (Fig. 3F). The sleeve is removed, the hole is tapped, and a screw is placed. This is repeated

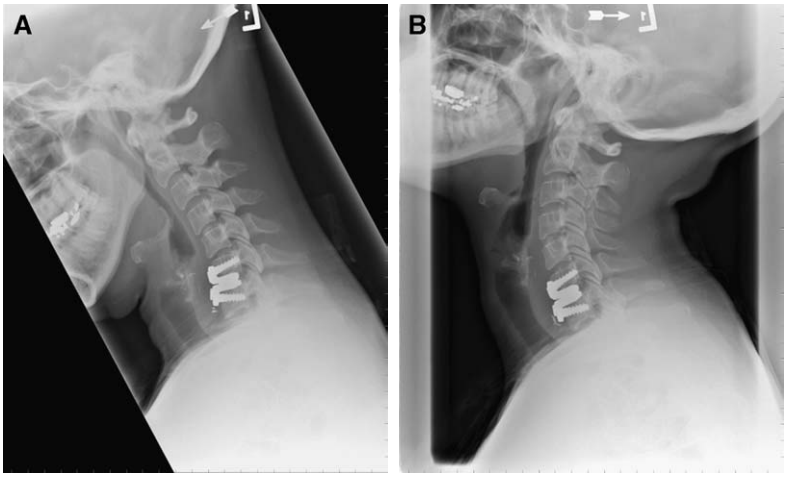

Fig. 4. Flexion (*A*) and extension (*B*) lateral cervical radiographs of a patient with a Prestige implant.

until all screws are engaged. The implant holder is then detached from the Prestige implant. Two locking cap screws are engaged and tightened to prevent back-out of the bone screws.

It is optimal to place the device using fluoroscopy. If the surgeon chooses not to use intraoperative imaging, a lateral cervical radiograph should be obtained at this point to assure that the device is properly implanted (Fig. 4). The wound is irrigated thoroughly and closed in the usual fashion. Postoperative immobilization is not necessary, and patients may resume all activities as soon as they feel able to do so.

Prestige LP cervical disc

The Prestige LP (Fig. 5) is the latest generation in the Prestige family of cervical discs. Several features differentiate this device from its predecessors. The Prestige LP is manufactured from a unique titanium ceramic composite material, which is highly durable and image-friendly on CT and MRI scans. A porous titanium plasma spray coating on the endplate surface facilitates bone in-growth and long-term fixation.

Fig. 5. Prestige LP.

Implantation of the Prestige LP cervical disc

The surgical technique to implant the Prestige LP device is similar to an anterior cervical discectomy and fusion (ACDF). Instead of screw fixation, as with earlier versions of the Prestige disc, initial fixation is achieved through a series of four rails, two on each component, which engage the vertebral bodies (Fig. 6A). After decompression, the endplates are burred to make them parallel. A rasp may be used to help with this step (Fig. 6B). A trialing device is inserted to verify the correct size of the implant (Fig. 6C). A rail cutting guide is inserted into the interspace, and two small holes are drilled into each vertebral body. A rail punch is used to connect these holes with the interspace (Fig. 6D, G). The Prestige LP is then gently tamped into place (Fig. 6H).

Discussion

All of the standard complications associated with anterior cervical spinal surgery could occur with arthroplasty. Osteoporosis is a contraindication to screw fixation, and this should be taken into consideration when planning any spinal reconstructive procedure. Paraspinous calcifications have developed in a few patients

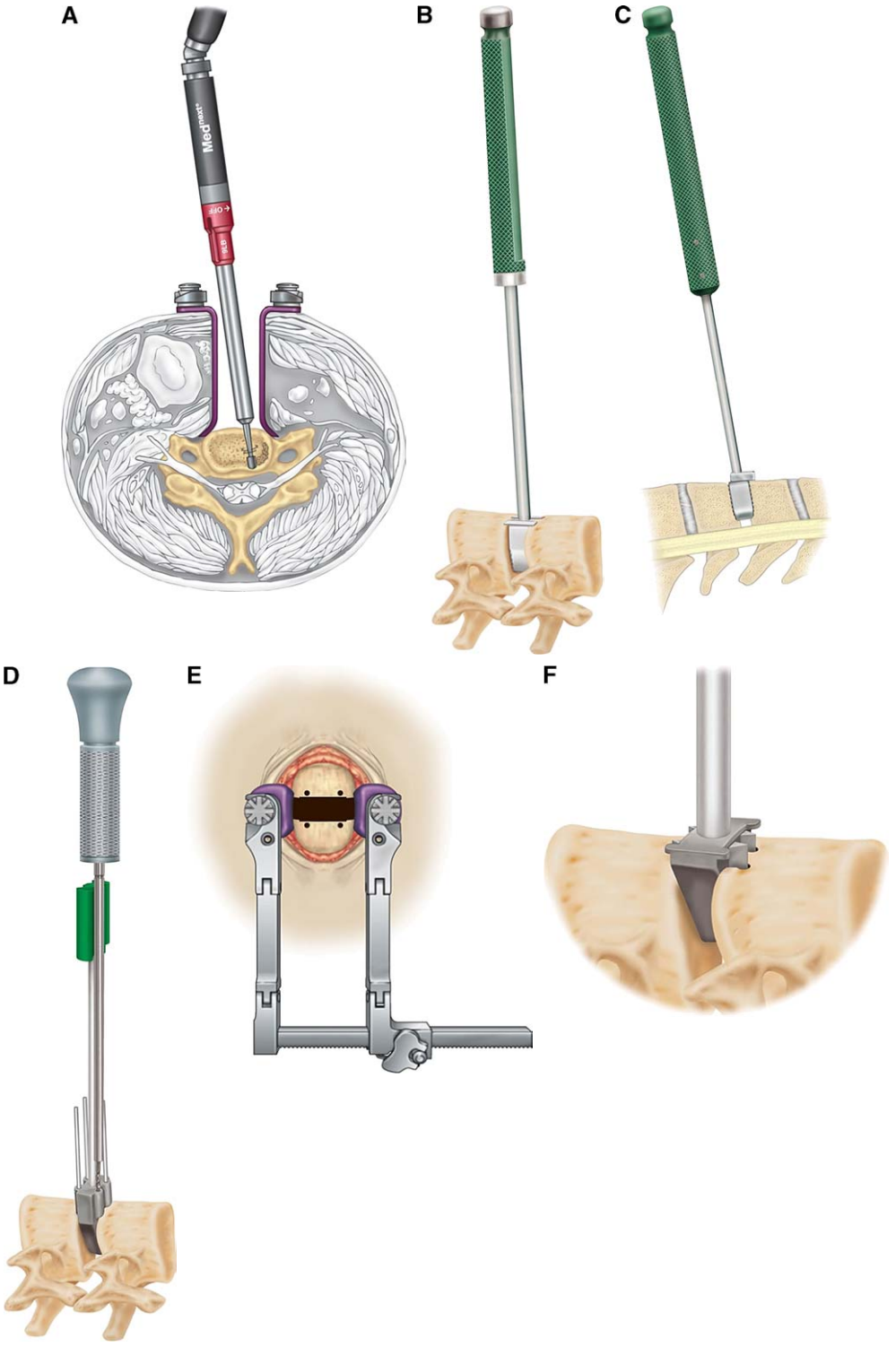

Fig. 6. (*A*) Burring endplates. (*B*) Rasp in interspace. (*C*) Sizing trial in interspace. (*D*) Prestige LP railcutter. (*E*) Initial rail holes in vertebral bodies. (*F*) Prestige LP rail punch. (*G*) Completed rail holes in vertebral bodies. (*H*) Implant in place.

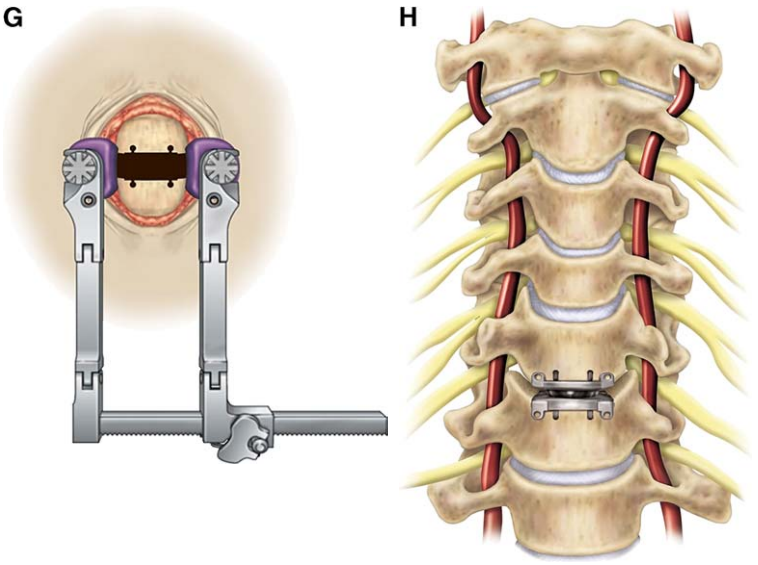

Fig. 6 (*continued*)

following cervical arthroplasty with a different device. This is not inconsistent with hip and knee arthroplasty. The administration of nonsteroidal anti-inflammatory medication for the first several weeks following surgery has significantly decreased this problem with lower extremity arthroplasty and is recommended following cervical spinal arthroplasty.

Cervical arthroplasty preserves motion in almost all patients who have preoperative mobility and does not alter the kinematics of adjacent motion segments [11,14,16]. It has been recognized for years that cessation of segmental motion may reduce or eliminate neurological symptoms regardless of whether a complete decompression is performed. Because arthroplasty preserves motion, strict attention to neural decompression is necessary. Even osteophytes on the asymptomatic side should be completely resected to minimize the chance of developing radiculopathy.

Total cervical disc replacements preserve normal motion at adjacent segments and in doing so will hopefully decrease the incidence of adjacent segment degeneration. The metal-on-metal cervical disc replacement was born more than 15 years ago in the form of the Cummins–Bristol cervical disc prosthesis. Today the design incorporates multiple advances and enhancements developed over the years. It physiologically reconstructs the cervical spine by providing solid axial load-bearing support, while at the same time allowing for normal physiological cervical spinal motion.

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