Recent artificial disc technology has rapidly advanced and provided great potential for changing treatment strategies for several spinal disorders.\(^2\),\(^3\),\(^5\),\(^6\),\(^8\),\(^12\),\(^13\),\(^16\),\(^17\),\(^19\)–\(^26\),\(^39\),\(^40\),\(^44\) Specifically, in the cervical spine, great attention has been focused on adjacent-segment disease after anterior and posterior arthrodesis.\(^18\),\(^30\) Although patients who present with neural compressive lesions causing radiculopathy or myelopathy often require anterior decompressive surgeries, anterior arthrodesis has generally been an unavoidable procedure following a neural decompression. Hiliibrand, et al.,\(^18\) reported on 374 patients undergoing 409 anterior cervical arthrodeses with Smith–Robinson anterior cervical fusion who were followed for up to 21 years. They found symptomatic adjacent-segment disease occurring at a relatively constant incidence of 2.9%/year (range 0–4.8%/year). Although this adjacent-segment disease could not be differentiated exactly from progressive spondylotic changes because of natural history, survivorship analysis projected that 25.6% of the patients (95% confidence interval 20–32%) in whom an anterior cervical arthrodesis had been performed would have new disease at an adjacent level within 10 years after surgery. New disease was defined as new onset of myelopathy or radiculopathy significant enough to require surgery. As an alternative to arthrodesis, an artificial disc serves to replace the symptomatic disc, restores the functional mobility and disc height of the motion segment, and protects neurovascular structures.

Our artificial intervertebral disc is based on the concept of a durable and biomimetic design with surface modification that enables a biological bonding to the VB. The 3D FD consists of a triaxial 3D polymer fabric woven from a UHMWPE fiber, that is spray-coated with bioactive ceramics on the disc surface.\(^20\),\(^23\),\(^33\),\(^34\),\(^37\) Previous studies have demonstrated that its biocompatibility, endurance, and biomechanical properties were similar to those of a normal disc.\(^20\),\(^23\),\(^33\),\(^34\),\(^37\) An in vivo study in which a sheep model was used demonstrated excellent interface bonding.
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and preservation of segmental spinal mobility for up to a 2-year period.\textsuperscript{23,24,37}

Although there are some reports and investigations of cervical artificial discs in clinical trials, only a few in vitro studies have been conducted on the biomechanical properties of spinal segments that have been replaced with cervical artificial discs.\textsuperscript{35,43} There is still a paucity of information regarding multidirectional flexibility changes in artificial intervertebral disc replacement when compared with intact spine and other conventional spinal reconstruction procedures. Specifically, how do the device design of a constrained, unconstrained, or biomimetic prostheses and surgical technique influence the local and global biomechanics of replaced cervical spines?

To investigate the initial biomechanical effect of artificial intervertebral disc replacement in the cervical spine, the multidirectional flexibility of replaced discs and adjacent spinal segment were analyzed using a cadaveric cervical spine model.

Materials and Methods

Design and Biomechanical Properties of the 3D FD

The triaxial 3D FD was semielliptically shaped and near-net woven with a UHMWPE fiber bundle, which was coated by linear low-density polyethylene (Fig. 1).\textsuperscript{20,23,24,33,34,37} The 3D FD consisted of a number of fibers in the x, y, and z axes and their respective multilayers with some alignment ratios in three dimensions. To enhance the initial stability to the vertebral endplate, two ultrastrong biodegradable pins made of hydroxyapatite/poly(L-lactide) composite (HA/PLLA) were placed near the center of the prosthesis.\textsuperscript{35,56} The bioactive ceramic granules were spray-coated to the designed depth with particulate unsintered hydroxyapatite.

Several human 3D FD prototypes were woven with orthogonal or off-angle fiber alignment and underwent cyclic tensile-compressive and torsional tests. Finally, the off-angle 45˚ model was selected based on its superior torsional property to the orthogonal and off-angle 30˚ models.\textsuperscript{20,23,24,33,34,37} The arrangement of layer numbers and alignment ratio among three weaving axes resulted in balanced mechanical properties.

Specimen Preparation

A total of seven fresh-frozen human cadaveric occipitocervical spines (occiput–T2) were harvested en bloc and used in this investigation. The specimens were immediately packaged in double-thickness plastic bags and stored at \(-20\text{°C}\). Prior to biomechanical analysis, standard anteroposterior and lateral plain x-ray films were obtained to exclude specimens demonstrating intervertebral disc or osseous disease. In preparation for biomechanical testing, the specimens were thawed to room temperature and cleaned of all residual musculature, with care taken to preserve all ligamentous attachments and facet joint capsules. The proximal (C1–2) and distal (T1–2) ends of the specimen were secured in rectangular metal containers by using eight compression screws and cross-fixed Steinmann pins, respectively, for fixation. Four Plexiglas motion detection flags were then placed on the posterior aspects of C4–7 VBs. Each flag was equipped with three noncollinear light-emitting diodes designed for detection by an optoelectronic motion measurement system (3020 Optotrak System; Northern Digital, Inc., Waterloo, ON, Canada).

Three-Dimensional Flexibility Testing

Testing was performed using a custom-designed 6 df spine simulator configured with the motion analysis system. The spine simulator apparatus is configured with three independent stepper motors, harmonic drives, and electromagnetic clutches, which are capable of applying pure, unconstrained rotational moments (\(\pm\)) around the x, y, and z axes. Unconstrained translations (\(\pm\)) were permitted using linear bearing guide rails for the x and z axes and an MTS Actuator (Eden Prairie, MN) for the y axis (Fig. 2). To determine multidirectional flexibility, nondestructive unconstrained loading parameters including six pure moments—flexion–extension (\(\pm x\) axis), lateral bending (\(\pm z\) axis), and axial rotation (\(\pm y\) axis)—were applied to the superior end of the vertically oriented specimen while the caudal portion of the specimen remained fixed to a testing platform. A maximum applied moment of \(\pm 2\text{Nm}\) was used for each loading mode and applied at a stepper motor rate of 3°/second. A total of three load/unload cycles was performed for each motion with data analysis based on the final cycle. For the six main motions, corresponding to the moments applied, the operative and adjacent-level vertebral rotations (°) were quantified in terms of peak ROM and NZ. The ROM is defined as the peak displacement from the initial neutral position to maximum load, and NZ represents the motion from the initial neutral position to the unloaded position at the beginning of the third cycle.\textsuperscript{59} To prevent desiccation during assessment, specimens are moistened with 0.9% NaCl sterile irrigation solution.

Surgical Reconstruction Groups

Following analysis of the intact spine, a complete discectomy was
performed at the C5–6 level to permit implantation of the 3D FD device (Fig. 3 upper left). The complete removal of the cartilaginous endplates as well as exposure of posterior longitudinal ligament allowed the appropriate placement of the 3D FD. The cervical 3D FD was 18 × 15 × 7 mm in width, anteroposterior length, and height, respectively. Using a specially designed distracter and disc inserter, the 3D FD was inserted into the disc space under adequate distraction force while protecting the two bioresorbable pins. After tapping the device into the final placement position, the distraction force was released and bioresorbable pins strongly held both endplates (Fig. 3 upper center and upper right). Following testing of the 3D FD, the C5–6 level was reconstructed using a tricortical autologous graft from iliac crest (Fig. 3 lower left). The graft height was strictly sized to fit the discectomy gap under sufficient distraction force. Following the anterior iliac bone graft testing, an anterior plate system (Atlantis Anterior Plate System; Medtronic Sofamor Danek, Memphis, TN) was placed according to the manufacturer’s surgical standard (Fig. 3 lower right). Biomechanical testing of the destabilization defect was not performed, because this might have disrupted the remaining anulus and facet capsule integrity.

Statistical Analysis

The intervertebral ROM at the operative C5–6 level was calculated as the sum of the NZ and elastic zone (NZ + EZ = ROM) and represented the peak total ROM (Euler angles rotation) at the third loading cycle. The expressed degrees of rotation (axial rotation ± y axis, flexion–extension ± x axis, and lateral bending ± z axis) for multidirectional flexibility analyses are done according to the 3D conceptual framework of Panjabi.27 The nondestructive ROM data were normalized to the intact spine condition for each loading mode. The NZ was also expressed by normalized percentage to the intact spine value. Statistical analysis included descriptive statistics and a one-way analysis of variance with the Student-Newman-Keuls test for group-to-group comparisons. Comparisons with probability values less than 0.05 were considered statistically significant.

Results

Operative Level ROM Analysis

In axial rotation, the intact spine and the three surgical reconstruction groups formed statistically different subsets (F = 6.16, p = 0.003). The reconstruction with the 3D FD demonstrated statistically equivalent rotational motion of 123% compared with the intact condition (Fig. 4 upper); however, the addition of autograft (71.4 ± 56%)
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and anterior plate (59.5 ± 33%) significantly reduced motion compared with the 3D FD construct (p < 0.05). In flexion–extension, the 3D FD increased overall motion to 145.2 ± 41.6% compared with the intact condition (p < 0.05). The addition of autograft (46.6 ± 32.4%) and anterior plate (16.8 ± 10.9%) significantly reduced flexion–extension ROM compared with the 3D FD construct (p < 0.05). Reconstruction with the 3D FD demonstrated statistically equivalent lateral bending ROM to 111.5 ± 15% compared with the intact condition. The addition of autograft (48.2 ± 26.9%) and anterior plate (56.55 ± 31.8%) markedly reduced the motion compared with the 3D FD (p < 0.05).

Operative Level NZ Analysis

The NZ at the operative level demonstrated a similar trend to the operative ROM data (Fig. 4 lower). In all three loading modes, the NZ of the 3D FD group was statistically equivalent to that of the intact spine. The NZ of the autograft and anterior plate groups demonstrated significantly lower values than those of the intact spine and the 3D FD in flexion–extension (p < 0.05). In lateral bending, the autograft significantly reduced the NZ when compared with the intact spine (p < 0.05).

Adjacent-Level ROM Analysis

The upper adjacent segment ROMs at the C4–5 level were statistically equivalent among the intact spine and the three surgical groups in axial rotation and flexion–extension (Fig. 5 upper). In lateral bending, reconstruction with the 3D DF, anterior autograft, and anterior plate demonstrated significantly larger ROM values than that of the intact spine (p < 0.05).

The lower adjacent segment ROMs at the C6–7 level were statistically equivalent among the intact and three surgical reconstructions in all loading modes (Fig. 5 lower). Following all biomechanical testing, the 3D FD device did not show any device loosening or dislodgment. The initial stability afforded by an effective disc height and two bioresorbable pins was maintained after several cycles of testing.

Discussion

To date, several cervical artificial discs have been reported with different device designs and concepts; however, basic biomechanical studies have been scarcely reported. Recent artificial disc designs were classified into a metal-on-polymer composite, metal-on-metal design, and exclusive polymer fabric. Goffin, et al., reported 1-year preliminary clinical data obtained in 60 patients in whom Bryan Cervical Disc prostheses had been placed. The device consists of a polyurethane nucleus designed to fit between two titanium plates with a sterile saline lubricant. This disc was designed as a constrained type in contrast to an unconstrained type such as the lumbar SB Charité disc. The mean ROM at 1 year was ± 6° with acceptable patient pain reduction and neurological recovery. Cummins, et al., reported an artificial metal joint allowing screw fixation to two consecutive VBs and the segmental spinal motion at the joint placed in the original disc space. The authors did not describe the quantitative segmental motion preserved but did document the metal-related complications of screw pullouts, broken screws, and subluxation of the device. Transient hemiparesis and dysphagia were among reported clinical symptoms. In hip joints, the metal-on-metal joint mechanism was reported to cause an early loosening of the device and was then modified to a polyethylene back mechanism allowing shock absorption and stress relaxation. This concern was also reported by van Ooij, et al., in lumbar metal-on-metal prostheses when they described complications of the SB Charité disc in 27 cases.

There are several advantages of the 3D FD in cervical disc replacement. The 3D FD consists of a monofilament involving multi-UHMWPE fibers, which allow the arrangement of textile density and fiber alignment. Its dynamic mechanical mobility is biomimetically controlled to values nearly equivalent to the natural disc. Construction with soft organic materials will prevent sur-
indicates a statistically significant difference compared with the intact segment. This initial hypermobility of the unconstrained artificial disc has been demonstrated in the lumbar SB Charité disc in a cadaveric spine model reported on by Cunningham, et al.\(^5\) The cervical 3D FD demonstrated a 45% increase in flexion-extension ROM; however, its long-term effect on operative level degeneration and adjacent disc level was unknown. When we calculated the absolute rotational angle, the angle was 14°, which was considered within the normal range reported by White, et al.,\(^41\) and Dvorak, et al.\(^10,11\)

Previous in vivo animal and clinical studies have demonstrated that the spinal segment replaced with an artificial disc tended to be stiffer in living tissue over time.\(^15,23–25,29\) The multicenter clinical trials of the Bryan Cervical Disc prosthesis also demonstrated a tendency toward immobilization; flexion-extension was retained at a mean of 9° (1–21°).\(^15\) The appropriate initial mobility of cervical artificial discs is still unknown; however, it differs among constrained, unconstrained, and biomimetic device designs. When considering a basic device design of the biomimetic structure of the 3D FD disc, the initial mobility can be set at a relatively hypermobile setting, and it may approach the normal mobility over the long term. The control of in vivo motion preservation is the future problem to be solved in this field.

Adjacent-segment biomechanics is another matter of concern in artificial intervertebral disc reconstruction. The lower adjacent segment ROM of the 3D FD was statistically equivalent to that of the intact segment in all loading modes. The upper adjacent segment ROM of the 3D FD was statistically equivalent to the intact segment in both axial rotation and flexion-extension loadings; however, in lateral bending, statistically higher ROM values were detected in the 3D FD, autograft, and autograft combined with anterior plate reconstruction when compared with the intact segment. This adjacent-segment response in autograft and anterior plate groups was explained by the operative level increase of lateral bending stiffness in these groups; however, the change in the 3D FD segment was inexplicable. There has been only one report by Wiggsfield, et al.,\(^41\) demonstrating adjacent-segment biomechanics after replacement with the Bristol artificial metal joint. In this study, the internal stress distribution at the adjacent segment was investigated between spinal fusion and artificial joint replacement in the cadaveric spine model. These investigators clearly demonstrated the decrease of anteriorly situated stress peak at the upper adjacent level in artificial joint replacement when compared with spinal fusion. The present study showed that the physiological adjacent-segment mobility was preserved in most of the spinal loading modes except lateral bending.

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The cervical artificial intervertebral disc has great potential for extending the frontiers of cervical spine surgery. Although patients with single- or two-level cervical lesions and myelopathy or radiculopathy have been often treated via the anterior approach, this has necessitated anterior spinal fusion with bone graft. Anterior artificial disc replacement will preserve segmental spinal mobility and disc height even following neural decompression. There are still unsolved problems in the use of multiple and contiguous artificial discs, the physical endurance of the device at adjacent disc disease to the multilevel arthrosis, and revision strategies. Artificial disc replacement surgery has great possibilities to change the biomechanical property of functional spinal units and instantaneous axis of rotation at the operative segment; therefore, its inherent biomechanics as well as segmental properties in cadaveric spine models should be carefully examined in vitro. Multilevel disc replacements have the potential to change cervical spine mechanics extensively as well as to decrease the chance of interface bone ingrowth. Using artificial discs to treat adjacent-segment disease and obtain multiple-segment arthrosis will dramatically increase the mechanical stress on the artificial disc; therefore, they must have sufficient durability with physical dynamic mobility. The 3D FD did not cause wear debris after 63 million alternating stresses for antifatigue testing, which were equivalent to natural biological movements for a period of more than 30 years. There has been no experimental study reported in terms of high cycle stress testing except that by Shikinami and Okuno. In an in vivo goat study, Anderson, et al. demonstrated that there was polarizable foreign material and partially polarizable intracellular granular material exterior to the dura mater and in macrophages in periprosthetic tissues after Bryan Cervical Disc replacement. The significance of this wear debris cannot be determined unless cytokines are specifically sought out; however, the metal-on-polyethylene prosthesis has a tendency to cause wear complications, as shown in general joint arthropasty. Van Ooij, et al. reported complications of lumbar artificial disc replacement in 27 patients with the SB Charité disc prosthesis, highlighting recent problems with the metal-on-polyethylene prosthesis. The most frequent types of failure reported were a subsidence of the device, migration, progression of facet arthrosis, and polyethylene wear, requiring salvage spinal reconstruction surgeries. One case in this series also required the removal of the device due to anterior dislocation with compression of great vessels. There have been a few clinical reports regarding cervical artificial disc replacement, demonstrating two major issues of device failures and spontaneous segmental fusion. Pointillart, et al. described a hemiarticular type disc prosthesis and encountered circumferential spontaneous fusion in eight of 10 patients. Cummins, et al., reported on artificial metal joint prostheses and described a significant number of complications such as screw pullouts, broken screws, transient hemiparesis due to drill injury, and persistent dysphagia. Considering these complications, the cervical artificial disc should have a low-profile design, superior initial stability that holds both endplates, and be composed of materials that are less vulnerable to surrounding important structures. Revision surgery of the metal-on-metal or metal-on-polyethylene prosthesis requires a significant amount of bone resection as well as being technically demanding to perform and posing neurological risk. The present prosthesis provides three benefits and facilitates revision surgery with simple evacuation of the material. To ensure in vivo biological and long-term effectiveness of the 3D FD, we are conducting a baboon study before beginning clinical implantation.

Conclusions

To investigate the initial biomechanical effect of artificial intervertebral disc replacement in the cervical spine, the multidirectional flexibility of the replaced and adjacent spinal segments were analyzed in a cadaveric cervical spine model. The stand-alone cervical 3D FD demonstrated nearly physiological biomechanical characteristics at both operative and adjacent spinal segments in vitro, indicative an excellent clinical potential for cervical artificial disc replacement.

References


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