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Technical Report

A biomimetic artificial intervertebral disc system composed of a cubic three-dimensional fabric

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Abstract

BACKGROUND CONTEXT: In the quest for clinically functional artificial intervertebral discs (AIDs), multidisciplinary technologies have been employed. Existing solid mobile AIDs essentially consist of the superposition of solid plates and core materials; however, it is thought that an ideal surgical AID technology has not yet been developed. To overcome the limitation of these existing AIDs, we developed a unique flexible AID disc system on the basis of our original biomimetic concept. The AID is composed of a cubic three-dimensional fabric (3DF) with a triaxial fiber alignment, which offers biomimetic long-term dynamic mechanical behavior along with durability.

PURPOSE: This article substantiates the potential clinical use of the 3DF disc system that quite differs from existing ones.

STUDY DESIGN: We designed the lumbar and cervical 3DF discs that improved the structural weaknesses caused by the collagenous fiber alignment of biological intervertebral disc. Bioresorbable hydroxyapatite particles were deposited on the surface layer of the 3DF disc to promote new bony ingrowth and to ensure secure binding at the interface of the contacting vertebral bodies. A stand-alone system was devised for surgical reliability in terms of both positioning and fixation, allowing tight press fitting with the vertebral bodies. Bioactive and bioresorbable pins were penetrated through the 3DF disc body and projected from the surface to allow ideal insertion and fixation to the disc space, preserving the precise position during dynamical movement. In vitro endurance of the 3DF disc was examined under long-term alternating stresses, and the in vivo animal tests were conducted in the intervertebral lumbar discs at L5–L6 excised from baboons and replaced with the lumbar 3DF disc.

METHODS: The static mechanical endurance was assessed through a creep test. In vitro endurance of the 3DF disc under repetitive stresses including axial compressing, flexion-extension, torsional twisting, and lateral bending were applied to the 3DF disc for a long-term for up to 105 million stresses, which is roughly equivalent to exposure of natural biological movement for more than 50 years. In the animal test, eight baboons were euthanized 6 months postoperatively. To their extracted spines, six pure moments (flexion and extension, left and right lateral bending, and left and right torsion) were applied vertically to the superior end of the specimen and then values of range of motions (ROMs) were calculated. Histological analyses were conducted on 12 reticuloendothelial and systemic tissues.

RESULTS: The 3DF disc retained its biomimetic "J-shaped" stress-strain behavior without generating wear debris for up to 105 million stresses. A 130-N loading for the creep test decreased the height of 0.3 mm during 80 to 1,000 hours. In the biomechanical test, ROM values of axial rotation and flexion-extension showed no significant difference from the intact excluding that of lateral bending because the location of each pin to stand alone certainly controlled the bending behavior only. The histological analysis indicated no significant pathologic changes induced by the 3DF disc.

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CONCLUSIONS: The 3DF disc system is clinically suitable for human disc replacement arthroplasty based on the findings of long-term durability with dynamic motion in vitro and effective animal tests in vivo. This system surely overcomes the limitations of existing solid AIDs, and the clinical potential of the biomimetic 3DF discs has been verified. This new biomaterial technology delivers most of the functions and characteristics required by a clinically available AID if applied correctly by surgeons.

Keywords: Artificial intervertebral disc; Cubic three-dimensional fabrics; Biomimetic; Long-term dynamic durability; Animal study

Introduction

This article describes the characteristics as a whole including the long-term endurance of a biomimetic artificial intervertebral disc (AID) system that improved a cubic three-dimensional fabric (3DF) previously published as an article [1], which has the potential to be used in reliable surgical AID products and technologies. We also describe the clinical potential of a cubic 3DF disc, in terms of its stand-alone construction, long-term biocompatibility with biomechanical dynamic motion, and surgical application, as well as addressing a few possible concerns.

The use of mobile AIDs for disc replacement arthroplasty is being studied, it restores dynamic physiological motion at a similar level to that of an undamaged disc. Multidisciplinary technologies have therefore been employed in the quest for clinically functional AIDs. However, an ideal surgical AID technology has not yet been developed.

The structure of existing AIDs essentially consists of the superposition of solid plates and core materials, for example, metallic end plate (shell and socket)/metal, plastic, or ceramic core (ball)/metallic end plate (shell and socket) [2]. The surfaces of the metal end plates have the potential to allow bony ingrowths to form tight bonds with the vertebral bodies [3] because inharmonious movements of each component can weaken the bonding at this interface.

These solid artificial intervertebral discs (SAIDs) can have a pseudobiological mobility effect that potentially leads to deterioration, immobilization, sinking into the vertebral bodies, or dislodgement, and they can generate wear debris and minor defects through friction at the interfaces between the solid plates and the cores or the contacting vertebral bodies, such that dangerous complications might arise over prolonged periods [4].

Lumbar and cervical AIDs must meet the following minimum design criteria. First, they must be composed of safe materials with good biocompatibility, which cause no serious, organotoxic, or carcinogenic tissue reactions due to the base components or secondary debris generated during the life span. Second, a biomimetic structure, including shape and materials, should be applied to replicate the biomechanical behavior of normal biological intervertebral discs (BIDs) and to allow translation and rotation in all three planes of motion along the x, y, and z axes. This will achieve a three-dimensional flexible deformation without specific fixed pivots, as in a natural disc. Third, the AID must display sufficient mechanical properties, biomimetic motion, and superb endurance with little reducing fatigue resistance; mechanical testing more than 100 million biomimetic repetitive motions to equate with a 40- or 50-year life span [5–7] would be a typical design criterion. Fourth, to allow accurate placement, several designs with size and shape variation need to be produced to determine the ‘‘sweet spot’’ where the implant is positioned at the correct height within the disc space. Fifth, a simple method of insertion into the correct position and a reliable stand-alone system in the disc space with tight press fitting to the vertebral bodies with possible bone bonding is required; this will allow the AID to be applied in cases with disc heights, spaces, and geometries that vary according to differences in patients and indications.

The flexible AID is not currently in Food and Drug Administration (FDA) trials, although some soft spinal implants, with the exception of the so-called AID, have been studied. This is because of a lack of practical approaches for applying knowledge about biomaterials and biomechanics to AID technology. Our original concept could create an AID system with a biomimetic monolithic structure that has the potential to tolerate dynamic motion in a way similar to a BID over a long period. In other words, the present AID is a biomimetic product with similar characteristics to a BID.

Biomimetic approaches provide great potential for the creation of new biomaterials with structures and properties that mimic those of biological materials [8]. Accordingly, the employment of the biomimetic concept could achieve great results in terms of AIDs.

As is well known, BIDs have a laminate structure (Fig. 1, middle), in which biaxial three-dimensional reinforcing plane materials with winding collagenous fibers are piled on top of one another (as schematically represented in Fig. 1, top) [9]. In contrast, our biomimetic 3DF disc (Fig. 1, bottom) is one of the next generation of AIDs that have fiber alignments and motional stress-strain (S-S) behaviors with hysteresis loss that differs significantly from those of existing SAIDs. The 3DF discs remain in the middle of the vertebral bodies and confer biomimetic

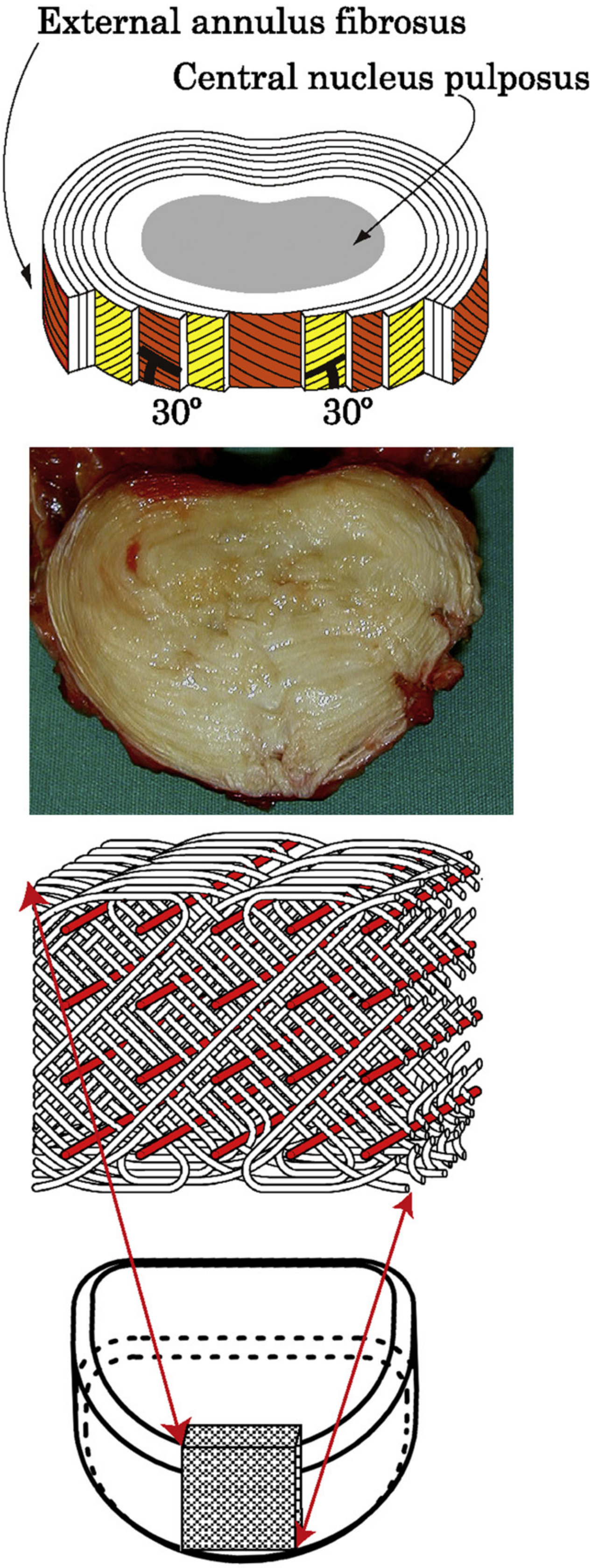


Fig. 1. (Top) Fiber alignment of a BID. (Middle) A human lumbar intervertebral disc. (Bottom) Fiber alignment of a 3DF disc in a lateral view. BID, biological invertebral disc; 3DF, three-dimensional fabric.

S-S behaviors that yield flexibility in three dimensions in response to spinal motion [1,10].

This system may overcome the limitations of existing SAIDs, and the clinical potential of the biomimetic 3DF discs will be verified.

Materials and methods

Size and texture variation

The size of an AID required for a surgical operation varies depending on the spinal location and the size of the fenestral space for the implant. Accordingly, a 3DF disc should be produced with variation in size, height, and texture to meet these requirements. In this article, we describe the physical and clinical applications of several 3DF discs that were suitable for different types of animal and location (cervical and lumbar). We selected the appropriate 3DF disc in terms of size and texture in each of the experiments described.

Mechanical characteristics

Fixation method and endurance under long-term alternating stresses

The standard test method for the static and dynamic characterization of spinal AIDs (as described in American Society for Testing and Materials (ASTM) F2346-05 [11], recommended by the FDA) and the standard wear test (as described in International Organization for Standardization 18192-1 [12]) are appropriate for SAIDs but not for 3DF discs; this approach is effective only for examining the wear produced by friction at the interface between each hard layer in existing superposition SAIDs and cannot be applied to biomimetic, monolithic, soft, and flexible 3DF discs. We therefore conducted original testing as described below.

We assessed the dynamic mechanical endurance over the average human life span, which is an essential factor for clinically available AIDs. The biological disc movement of the functional spine units (FSU) over 10 years is generally recognized to equate to roughly 20 million movements [7], including axial compressing, flexion-extension, torsional twisting, and lateral bending, which corresponds to approximately 5,500 motions per day, without taking into account the slight movement and insignificant load that accompanies breathing, which is estimated to equate to 6 million movements a year [13].

The optimal life span of existing SAIDs is generally set at 30 million motions [14]. However, as an average human lifetime is around 70 years, an AID might be required to show durability for up to 50 years, assuming that it is implanted into a patient at around the age of 20 years. This target could be achieved if the 3DF disc could withstand about 100 million biological repetitive motions.

The total lumbar 3DF disc was fixed on the simulated vertebral body, and one cycle of long-term alternating stresses as reported previously was repeated for up to 105 million stresses, thereby simulating the natural motions of a human spinal disc for approximately 50 years, using a spine fixture with Model 858 Mini Bionix II (MTS Systems Corporation, Eden Prairie, MN, USA) [1]. A 0.3-second period was allowed between each motion, during which time the material could recover from the strain and return to the original state of physical relaxation. The strain change in each hysteresis loss curve in response to a given stress was calculated as a component of the total cyclical motion that accompanied each distortion of the 3DF disc. The dry condition was chosen as a worst-case scenario rather than the greasy wet condition because linear low-density polyethylene is a highly hydrophobic material and displays less friction in water than in dry air.

Detection of debris arising from mutual wear among textural filaments

The debris around the 3DF disc was carefully observed during the repetitive loadings. After 15 million cycles of repetitive loading (105 million motions), the 3DF disc was immersed in LR white resin (London Resin Co., Ltd., UK) and cured at 40°C for 1 day. We also searched carefully for traces of debris dispersed in the uncured resin solution. A cured resin block embedded with the 3DF disc was then cut along the x-y plane using a BS-3000CP EXAKT cutting system (EXAKT Technologies, Inc., Oklahoma City, OK, USA) and ground by abrasive paper (#2000; Sankyo Rikagaku Co., Ltd., Saitama, Japan). Each section was examined for wear debris using polarized microscopy (BX51; Olympus Co., Ltd., Tokyo, Japan).

Creep and recovery tests to evaluate height change

These tests were conducted in distilled water at 37±2°C. A compressive force of 130 N was loaded onto the same 3DF disc used in the previous test [15] for 1,000 hours (ASTM D2990-01 [16]) and was then unloaded for 1,000 and 4,000 hours to examine the recovery. The compressive rate was 20 N/s.

Animal tests (stand-alone 3DF disc tests in baboons)

The range of motion value in baboons

The intervertebral lumbar discs at L5–L6 were excised from baboons and replaced with 3DF disc test samples using an anterior approach instrument (Orthopedic Research Laboratory, Union Memorial Hospital, Baltimore, MD, USA). Eight baboons were euthanized 6 months postoperatively, and their spines extracted. The FSU from T2 to the sacrum was axially rotated right and left, flexed and extended, and laterally bent right and left at ±4 N·m and applied at a stepper rate of 3°per second using a Model 858 testing machine (MTS Systems Corporation) device attached to a six-degrees-of-freedom spine simulator (6DOF-SS). The range of motions (ROMs) were measured by an OptoTrak 3020 motion analysis system (Northern Digital, Inc., Ontario, Canada). Each extracted FSU was sagittally dissected near the midpoint at 5-mm intervals. The specimens were fixed in alcohol and embedded in resin. They were then stained with Villanueva osteochrome bone stain, polished up to 100 μm, and observed using a light microscope.

Histological analyses

Histological analyses were conducted on the following 12 reticuloendothelial and systemic tissues: axillary lymph nodes, inguinal lymph nodes, periaortic lymph nodes, mesenteric lymph nodes, liver, lungs (right and left), kidneys (right and left), spleen, pancreas, heart, spinal cord (operative level), and local tissues surrounding the operative disc levels.

Other experiments eliminated in this article

We conducted other significant experiments, for example, surface modification for bone bonding and pins for stand-alone system [1,10,17], compressive-tensile and torsional S-S curves of 3DF disc initially and after 100,000 repetitive loading compared with biological disc [10], static axial shear test (ASTM F2077-03), insertion and fixation techniques (and X-ray detection by Y-TZP spheres), and animal test in sheep [15,18,19] and human cadaveric tests [20,21]. This report is based on these results.

Results

Size and texture variation

We fabricated representative, stand-alone, press-fit-type 3DF cervical discs with two bioresorbable composite pins for temporary fixation between intervertebral bodies as shown in Fig. 2. These discs have three large sizes and three small sizes (width/depth: 17.7/14.0 mm in large size and 15.8/12.0 mm in small size and every size has three different heights, 9.0, 11.0, and 13.0 mm) that took into consideration the human cervical disc height. Respective heights decrease to 5.0, 7.0, and 9.0 mm under an 80 N compressive force while inserting of which loading is ordinarily stressed on the cervical disc by the superior vertebral body including the head weight.

Mechanical characteristics

Long-term endurance under alternating stresses with no debris occurrence

The stress change in each hysteresis loss curve in response to a given strain is shown as a component of the total motion that accompanies each distortion of the 3DF disc (Fig. 3).

Figure 3 (top) demonstrates the hysteresis-loss change and the maintenance of four types of dynamic motion during a simulated 50-year period in vivo under harsh dry conditions as a worst-case scenario. The 3DF disc maintained similar profile patterns over periods of 0, 10, 20, 30, 40, and 50 years, despite the fact that reduced resistance was observed in the axial compression over time and in the flexion-extension after 40 and 50 years, with the exception of the axial rotation and lateral bending (Fig. 3, bottom right). As shown in

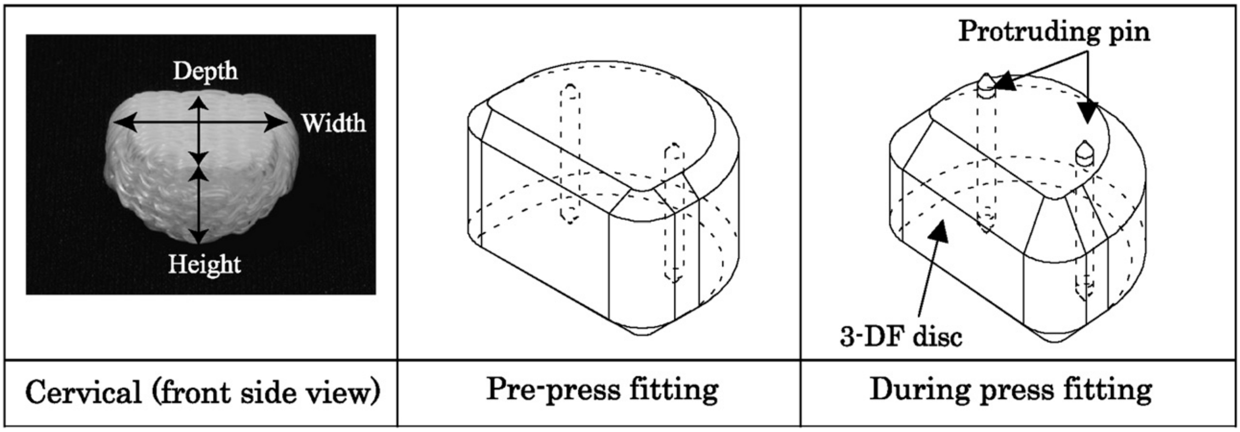


Fig. 2. A stand-alone press-fit-type cervical 3DF disc. 3DF, three-dimensional fabric.(Left) Real 3DF cervical disc. (Middle) 3DF cervical disc diagram in the pre-press fitting condition (left backside view). (Right) 3DF cervical disc diagram during press fitting condition (left backside view).

Fig. 3 (bottom left), the peak of the strain value in each S-S profile in response to a given strain decreased over time while preserving the initial J-shaped S-S pattern as shown in Fig. 3 (top). Each peak of the strain-value declined in an irregular but approximately rectilinear manner and reached about 60% of the respective initial value. We regard these retentions as evidence of sufficient physical endurance of the 3DF disc over a period of 50 years in comparison to the aging degeneration of a biological disc.

We confirmed throughout the test that the 3DF disc underwent changes only in the structure of the textile (see the polarized micrograph in Fig. 4 [left, middle]) after 105 million repetitive motions. Nonstructural textural collapse without wear debris derived from mutual friction of the filaments was observed in the 3DF disc. The predicted changes shown in the polarized micrograph in Fig. 4 (right) for a case in which wear debris was deposited on the 3DF disc were not observed, in contrast to the collision and friction that have been frequently reported in artificial hips and knee joints, as well as SAIDs [22]. This was because of the alleviating effects of the flexible 3DF disc with J-shaped yielding behavior. The unique cubic three-dimensional textile allowed the 3DF disc to improve on the physical limitations of BIDs, to mimic the moving behavior of biological discs, and to endure repetitive loading over a human lifetime, thereby allowing superior performance compared with existing solid prostheses. Significant shrinkage of the 3DF disc along with reduced fatigue resistance derived from the collapse of the architecture was not naturally observed during the measuring period.

Creep test to evaluate height loss

The change in strain height was measured for 4,500 hours as shown in the strain-time profile in Fig. 5 (top). The press-fit 3DF disc had an original height of 9 mm at point A and was compressed to 5 mm at point B; thereafter, a 130 N loading caused a decrease in the height of 0.3 mm during 80 to 1,000 hours and the height then spontaneously recovered to 6.1 mm at 4,500 hours (point C). The height of a normal human intervertebral disc is known to decrease by 0.5 mm, under a compressive load of 150 N [23]. Hence, the 3DF disc would be able to maintain the same height as that of a normal BID.

The cross angle of the x, y axes of 45°in the intact state (Fig. 5, bottom [i]) changed to 34°in the crept state (Fig. 5, bottom [ii]) and thereafter recovered autonomously to an angle of 40°after 4,500 hours (Fig. 5, bottom-[iii]). The cross angle shown in Fig. 5 (bottom [iii]) could increase to 51°if the disc bonded firmly to the end plates or the vertebral bodies and the height was enlarged by the extending force (Fig. 5, bottom [iv]). Thus, the height of the 3DF disc changed freely in response to the various external loadings without showing decisive creep strain.

Animal tests (in vivo test using a stand-alone 3DF disc in baboons)

The ROM value in baboons

To determine the multidirectional flexibility, six pure moments (flexion and extension, left and right lateral bending, and left and right torsion) were applied to the superior end of the vertically oriented specimen, while the caudal portion of the specimen remained fixed to a testing platform. In total, three load/unload cycles were performed for each motion, and the data analysis was based on the final cycle.

The lateral bending ROM value was remarkably low, because of the large distance between each pin, which was one-half of the width of the 3DF disc. Thereafter, the distance was reduced to one-third of the width of the 3DF disc, so that the ROM value increased to some extent as the bending ability increased. Nevertheless, the restricted motion could continue for up to 6 months until the pin was degraded and lost mechanical strength. Thereafter, the 3DF disc was released from these restrictions and achieved a high ROM value with no restriction by pins (Fig. 6).

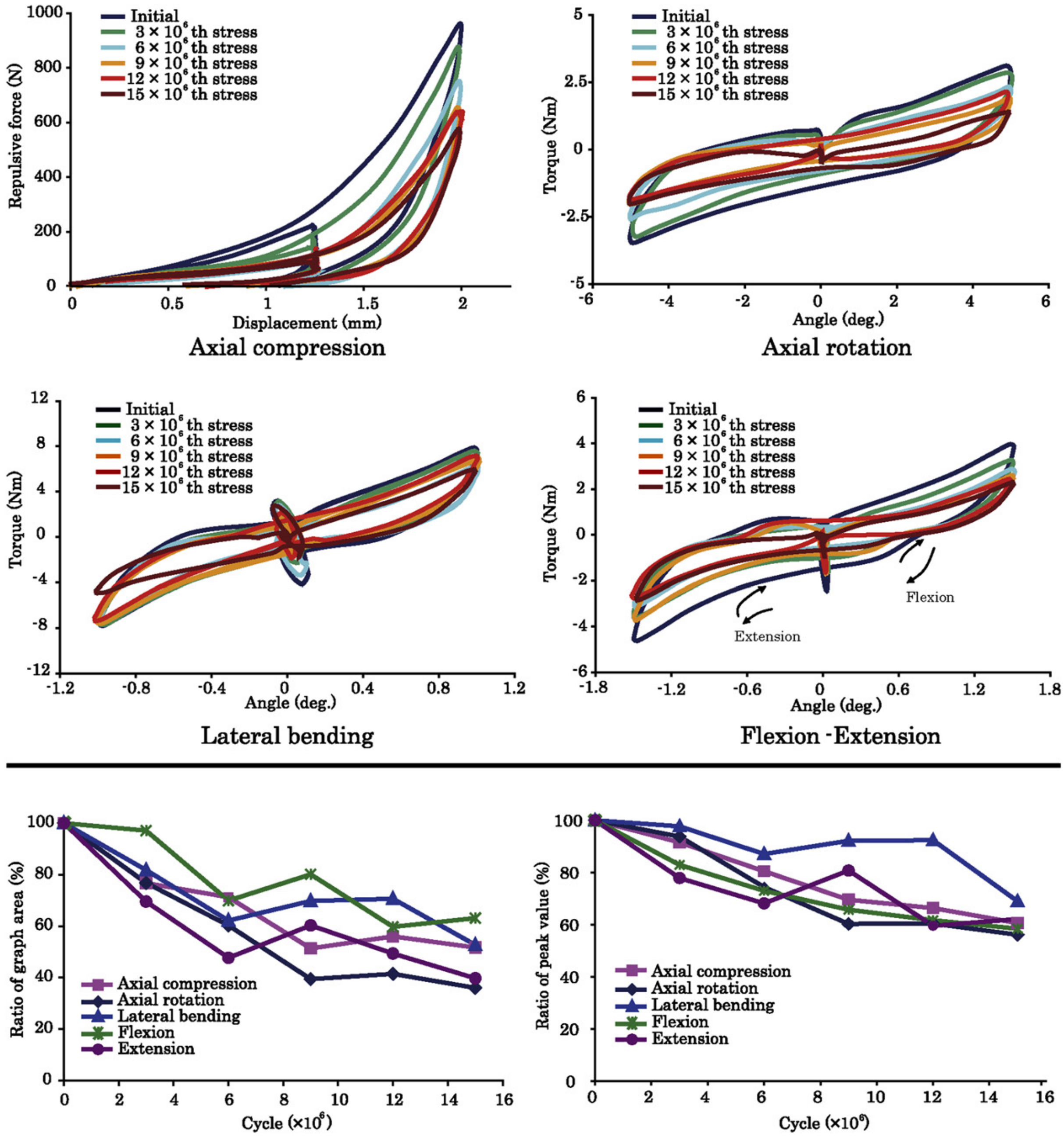


Fig. 3. (Top) Profiles for hysteresis loss change under up to 105 million alternating stresses. (Bottom) Changes in peak values (left) and hysteresis loss areas (right) with time.

Histological analyses

As an overall statement, histological analysis of the local and systemic tissues at the 6-month time interval indicated no significant pathologic changes induced by the 3DF disc. Light microscopic histological and gross morphological views of a typical baboon lumbar test are shown in Fig. 7 (top). After 6 months of testing in non-human primates, the 3DF disc showed good biocompatibility, with few inflammatory responses and histological changes. Bridging ossification to the adjacent living vertebral bodies was not observed, although cancellous bones were observed close to the surface of each textile filament in the 3DF disc surface textile layer, no invasion of fibrous tissues was observed, as shown in Fig. 7 (bottom).

Static axial shear behavior

When the load reached 1,600 N, there was a 14 mm extension and the disc showed a J-shaped profile with sufficient load-bearing strength as shown in Fig. 8.

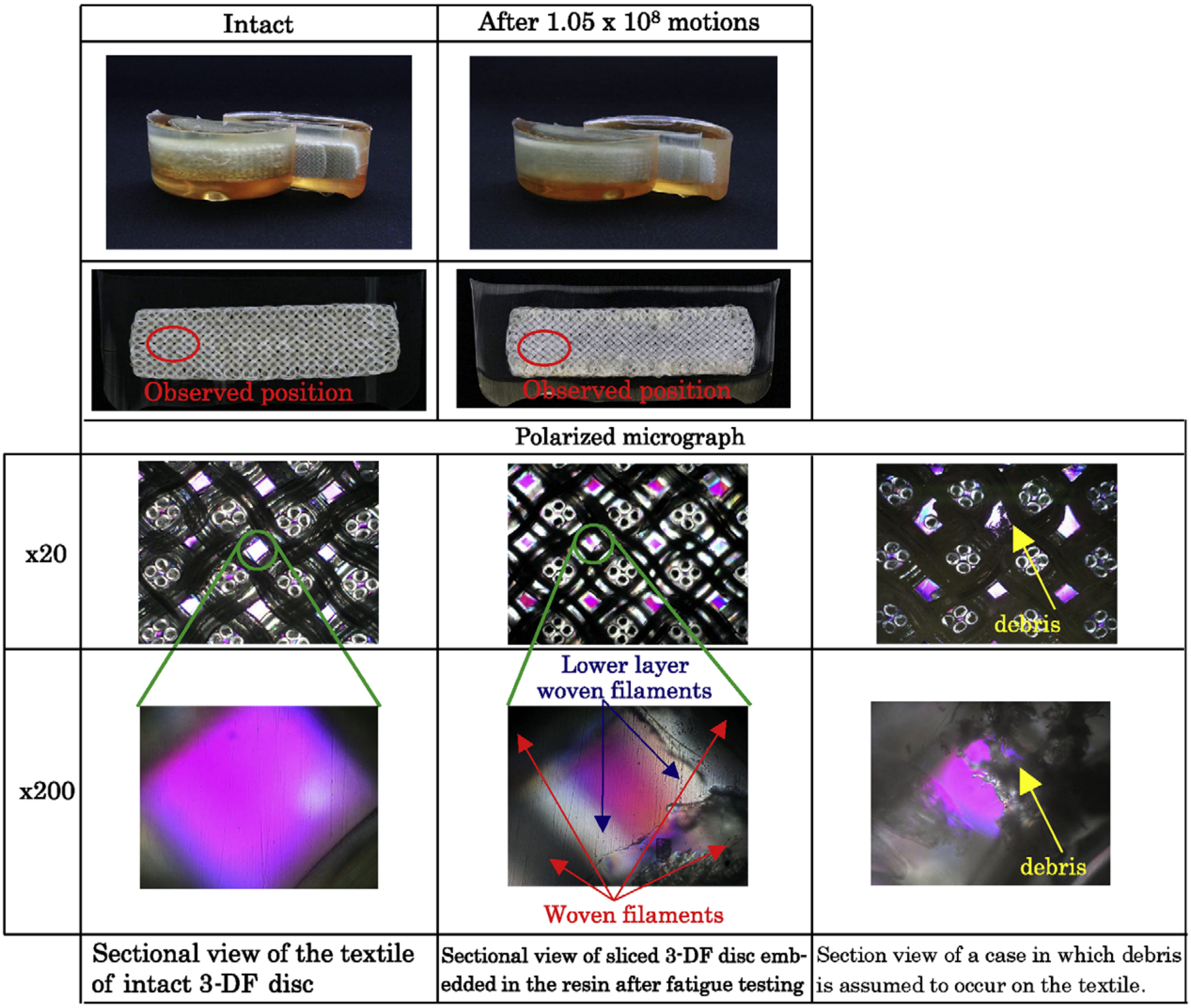


Fig. 4. 1.05×10^8 alternate motions changed only the structure of the networks and produced overlapping filaments without destroying the original 3DF structure. 3DF, three-dimensional fabric.

Discussion

Differences between SAIDs and BIDs including 3DF disc

Several points at issue of existing SAIDs are compared as follows. First, as shown in the Fig. 9, (3) and (4), various types of AID have different superposition structures by various material combinations and include the following categories: metal (Ti or stainless steel) on polymer (polyethylene, polyurethane, or elastomer)/(large radius) ball and socket; metal on polymer/(semi) mobile bearing (core); metal on metal/ball and trough; ceramic on ceramic/ball and trough; and polyetheretherketone on polyetheretherketone/semiconstrained ball and trough hybrid [2].

Second, the SAIDs shown in Fig. 9 column (4) (A), typified by the CharitÈ Disc (DePuy Spine, Inc., Raynham, MA, USA), form the three separate layers of the superposition structure and slide (red lines in Fig. 9) elliptically along the contacting interface between the oval ball as a core and the concave surface of the superior and inferior sleeve end plates. This system is essentially based on two-dimensional (2D) mobility on the spherical surface.

The SAIDs shown in the Fig. 9 column (3), form two separate layers of the superposition structure. This system is similarly based on 2D mobility. The system (A) typified by the ProDisc (Synthes, Inc., West Chester, PA, USA) moves (red lines in the Fig. 9) while fully contacting at the interface of core ball and the spherical surface of an end plate. The system (B), typified by Prestige (Medtronic Sofamor Danek, Minneapolis, MN, USA), moves longitudinally along a trough, and the contact way in the coronal view is different from that in the sagittal view. However, these superposition constructions are markedly dissimilar to BIDs.

Third, these SAIDs do not deform compressively because of the hardness of solid components, which is preferable if no creep change is required to maintain the original

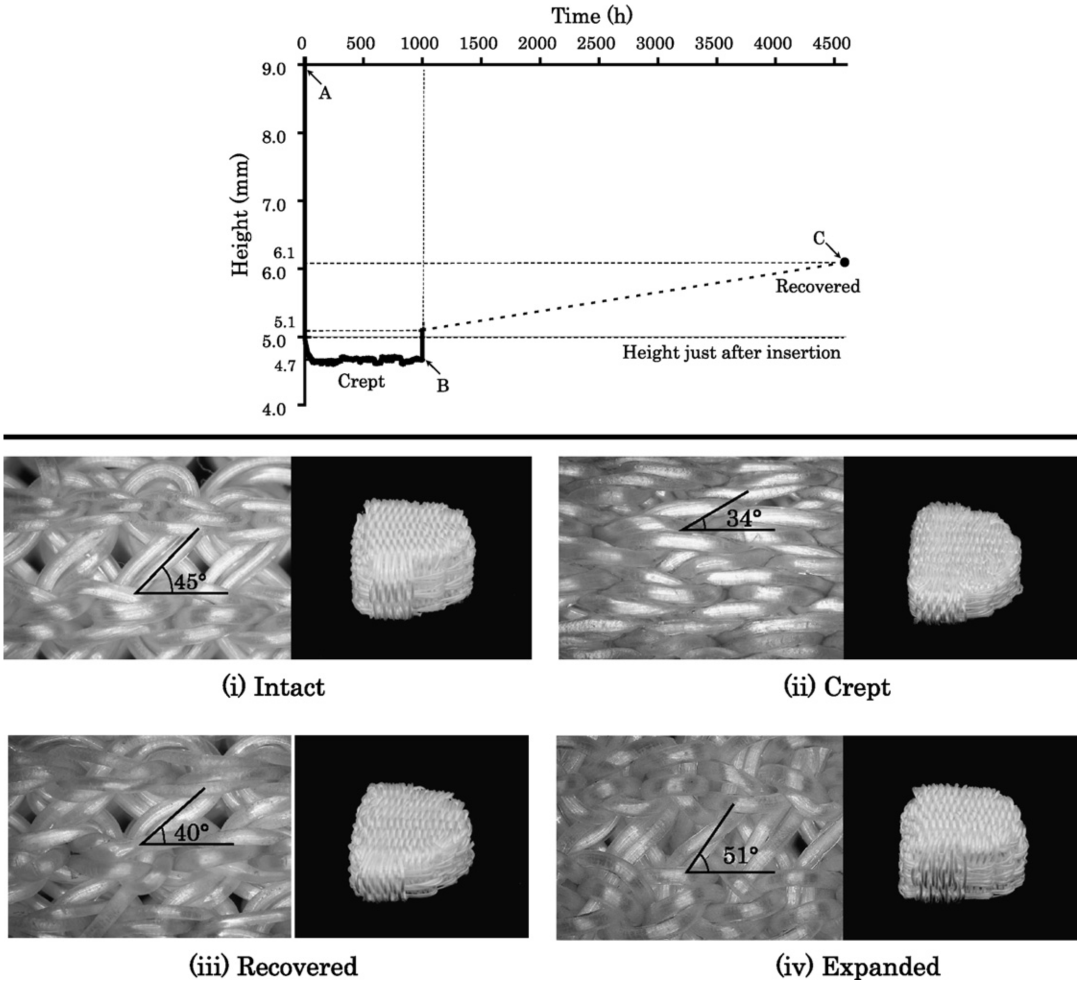
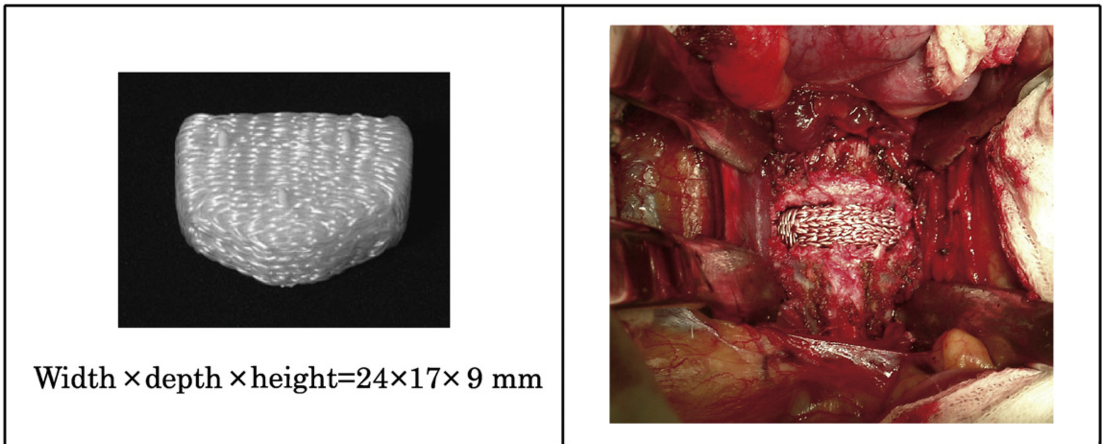


Fig. 5. (Top) Creep and recovery trace with time. (Bottom) Change in the height of press-fit 3DF disc and the cross angle of filaments. 3DF, three-dimensional fabric.

disc height. However, if SAIDs showed height reduction with a certain residual creep strain, they would be irrecoverable to the original height. This is a disadvantage because the biological disc is recoverable to the original height from a standstill weighing condition.

Fourth, BIDs have a monolithic textile structure that mainly comprises a collagenous gel component (Fig. 1) with less physical strength than SAIDs. This component passively deforms three dimensionally in response to the behavior of simultaneous or independent external loadings, along with a limitless number of central axes for distortion of the annulus including the nucleus. The center of the nucleus moves dorsally in flexion and ventrally in extension, and the center of the intervertebral disc moves dorsally [24]. The biological vertebral segment has limitless numbers of central axes in normal physiological motion. However, the center of the BID never translates simply along the 2D plane, such as the two-layer system ball and trough movement, but deforms three dimensionally along with the multi-axes for distortion while receiving several kinds of loadings. The physical endurance of soft and weak BIDs is achieved through support from the surrounding ligaments and musculoskeletal regions as well as the shared loading by each consecutive BID. Therefore, it might be undesirable for AIDs to have excessively high strengths like those of existing SAIDs, and it could be preferable to provide the same mobility as BIDs. When a BID is compressed, the height naturally reduces in proportion to the compressive loading and is restored to normal after unloading due to expansion by the end plates that firmly bind to the vertebral bodies, as shown by the respective blue lines in Fig. 9 (1) and Fig. 5 (bottom). Another effect is because of the damping behavior for adsorbing the external stress energy that is displayed by the J-shaped S-S hysteresis-loss loop [1,10].

Fifth, as shown in Fig. 9 (2), 3DF discs also deform passively while corresponding to the various external physical loadings. The mobility of 3DFs differs from that of existing SAIDs, but the biomimetic motion is similar to that of BIDs. However, the 3DF discs have no relation to the delamination often provoked in biological annulus layers holding nucleus jelly. The S-S characteristics under all



ROM (°) Mean value (standard deviation)	3DF disc(n=6)	Intact disc
Axial rotation	2.7 (0.9)	2.4 (1.3)
Flexion– extension	4.9 (1.9)	6.9 (2.9)
Lateral bending	3.3 (0.9)*	14.1 (4.8)

Fig. 6. (Left) A lumbar 3DF disc. (Right) Insert condition. (Bottom) Angular displacement (ROM). *Significant difference between intact disc versus 3DF disc at p=.05. The date were analyzed by Welsh test. 3DF, three-dimensional fabric; ROM, range of motion.

types of external loading show J-shaped curve behaviors retaining biomimetic hysteresis loss with a damping effect and biological mobility. The flexible distortion of textile 3DF discs with long-term stabilization also differs from the three layers of SAIDs, as shown in Fig. 9 (4) and (B), which have an elastic core as a sort of ‘‘water tank’’ with no sufficient flexibility in 3D directions and long-term instability.

Lumbar and cervical AIDs

Theoretically, an AID in the lumbar area should preserve the natural motion and correct the abnormal motion present in the degenerative disc and restore the disc height, lordosis, and normal axial rotation.

Lumbar AIDs generally dominate the pure axial disc pain, and the requirements for lumbar AIDs [25] differ significantly from those for cervical AIDs in terms of the design, biomechanical characteristics, disease treated, and expected outcomes. In contrast, cervical AIDs have much lower load-bearing and dynamic stabilization than lumbar AIDs and are applied in response to indications such as bony pathology and osteophytes causing radiculopathy or myelopathy.

The posterior lumbar interbody fusion (PLIF) type is intended to replace only the degenerative disc component of the entire lumbar joint in cases where good facet posterior ligaments and muscular structures still remain. We are also currently developing a comma-shaped 3DF disc as a PLIF AID, as shown in Fig. 10, which can be inserted using a posterior approach with similar instruments to those used for PLIF cages.

Several issues

Several issues should be recognized correctly and improved successfully, on matters such as reliable stand-alone system with capable surface bone bonding, no serious subsidence or creep causing loss of height, and FDA examinational standards for existing SAIDs. Here, we describe about only two issues as limited below.

Debris occurrence at the interface

The pseudobiological mobility of SAIDs causes potential immobility or dislocation from the normal spinal condition and so eventually generates wear debris through the friction at each interface of the superposition solid end plates and the core, which may lead to the occurrence of osteolysis over prolonged periods [4].

In the case of the monolithic 3DF disc, fraying wear debris could be produced through in vitro harsh rubbing friction at the contacting interface between the disc and the vertebral body; however, no wear debris was observed in vivo due to no mutual friction among textural filaments because the versatile space among the fabric networks would have prevented rubbing contact of each monofilament, probably due to the ameliorative effect on the external loading and the binding effect on the vertebral body, as verified in Figs. 4 and 7 (bottom); nevertheless, better stand-alone and fixation systems for the disc space should be devised

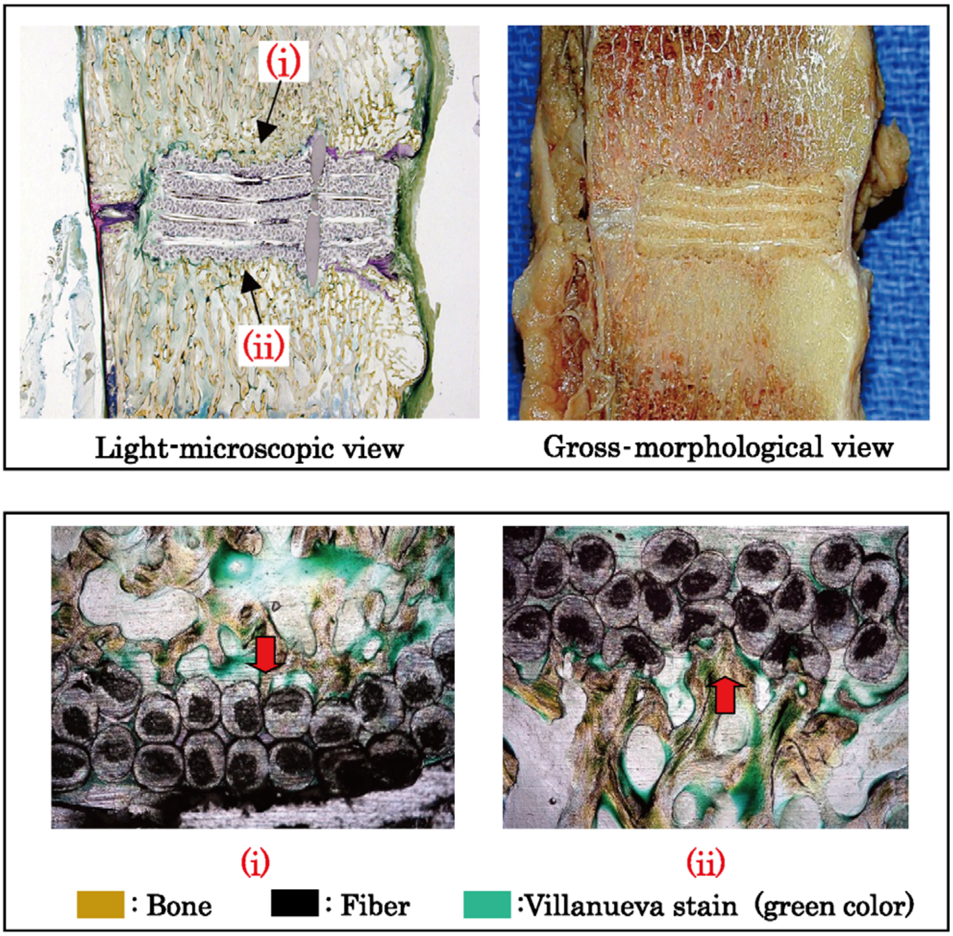


Fig. 7. (Top) Sagittal planes of a stand-alone 3DF disc implanted between L5 and L6. (Bottom) Magnified light microscopic view close to the upper (i) and lower (ii) surface of the stand-alone 3DF disc implanted between L5 and L6. 3DF, three-dimensional fabric.

in case of either direct bone bonding to the vertebral bodies or the invasion of fibrous connective tissues, to avoid fraying wear debris caused by rubbing friction at the interface of the 3DF disc and the vertebral body.

The ROM significance

As the instability caused by denaturing or traumatic disordering naturally affects the ROM value in the neutral

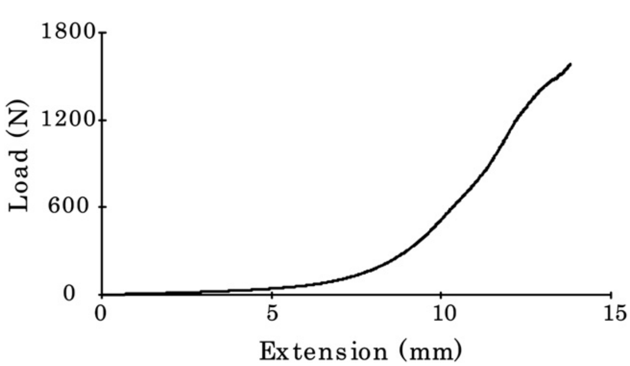


Fig. 8. Static axial shear behavior.

zone, it is necessary to examine the reduction in the degree of angular displacement to judge the mobility of AIDs over the long-term. Solid artificial intervertebral discs as unloaded devices before implantation have limitless rotational mobility around the center of axis due to the rolling movement by the ball and socket system, the so-called ball bearing construction. Biological invertebral discs and 3DF discs have limited initial ROM values showing some resistance to displacement with compressive deformation, as shown in the Fig. 9.

A simple evaluation of the ROM values of the 3DF disc compared with those of existing SAIDs is inconclusive because the driving behavior is quite different from each other, although the ROM values provide some information about mobility.

Conclusions

The original concept of an ideal AID [13] has been realized by adopting the concepts and technologies of biomimetic biomaterial sciences. The 3DF disc represents

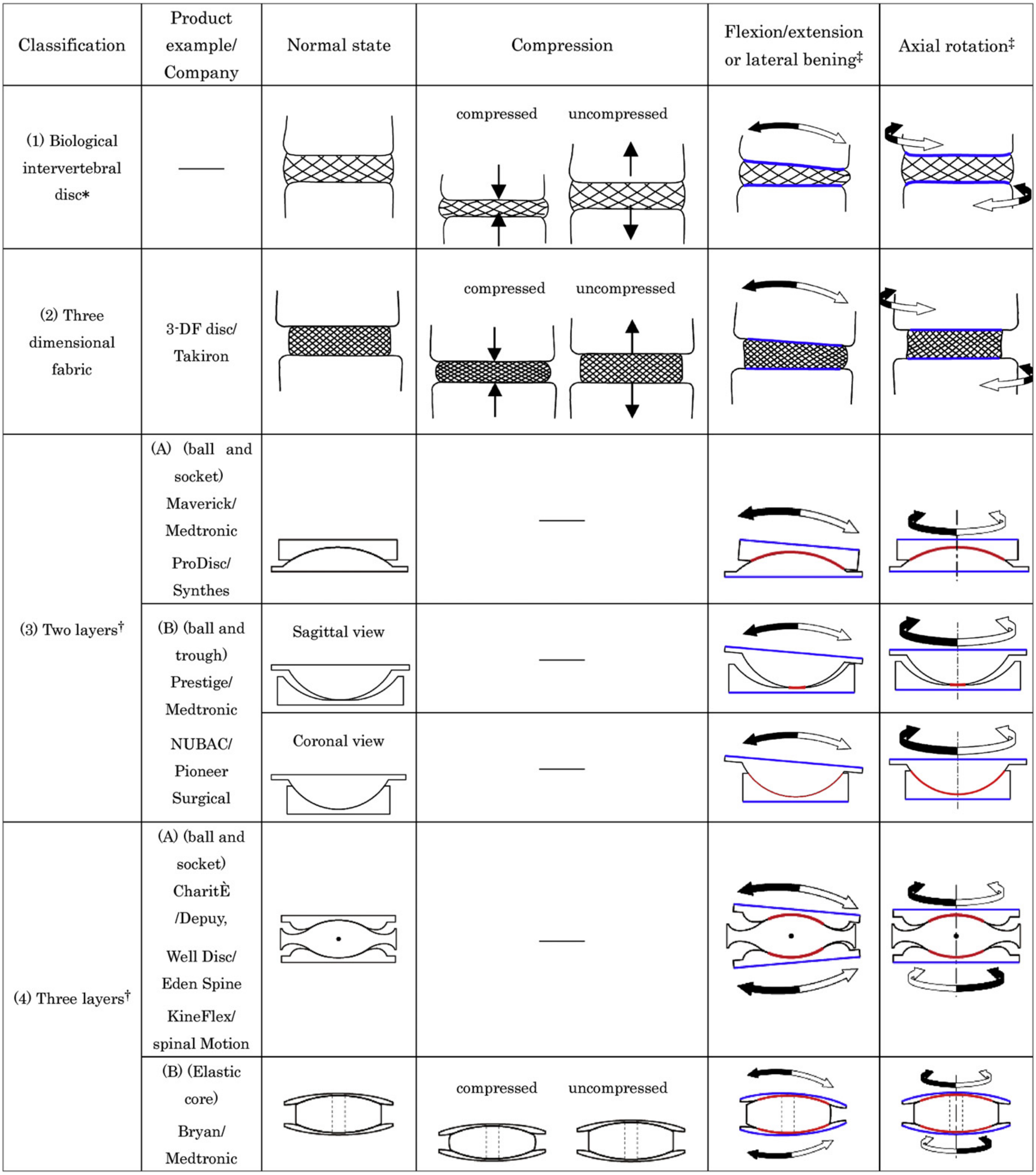


Fig. 9. Comparative movability of 3-DF disc, SAIDs, and BIDs. *Biological intervertebral disc: Biomechanics of Spine Stabilization (partially modified) [24]. †Maverick, CharitÈ: Spine 2003;28:S139 -52 (partially modified) [7]. ‡The red lines exhibit the sliding interface between the core (ball) and the socket (end plate), and the blue lines exhibit the fixing interface between the endplate and the disc body.

a flexible textile AID that can mimic the natural motion of BIDs and withstand external physical dynamic loadings over the long-term. The stand-alone 3DF disc system has the ability to be firmly fixed in the correct position (the ‘‘sweet spot’’) within the disc space and can be simply inserted and adjusted. We earnestly hope that surgeons who are disaffected with the existing SAIDs will clinically apply this practical and AID system.

web 4C/FPO

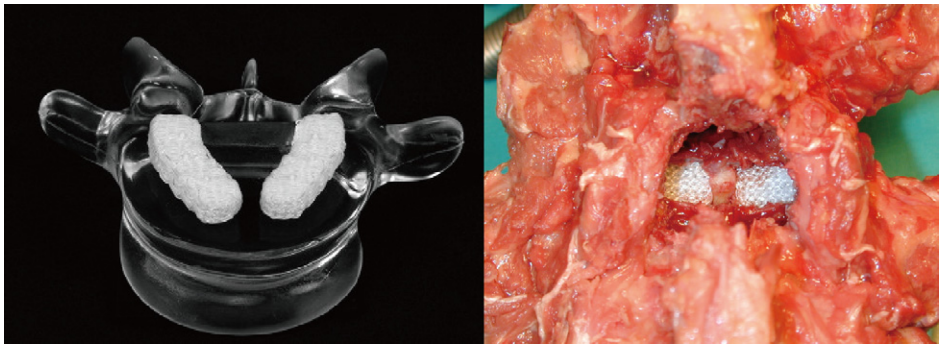


Fig. 10. An example of a comma-shaped 3DF disc as a PLIF AID set on a (Left) vertebral body model and (Right) implanted into L2–L3 of a baboon. Laminectomy was performed at the L2–L3 intervertebral level of the baboon, followed by discectomy. Two 3DF discs were then implanted posteriorly using the implantation instruments and technique described. AID, artificial intervertebral disc; PLIF, posterior lumbar interbody fusion.

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