FRISBEE – THE FIRST ARTIFICIAL CERVICAL DISC OF 3RD GENERATION

FRISBEE - O PRIMEIRO DISCO CERVICAL ARTIFICIAL DE 3ª GERAÇÃO

FRISBEE - EL PRIMER DISCO CERVICAL ARTIFICIAL DE 3RA GENERACIÓN

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ABSTRACT

Objective: The current cervical disc arthroplasty is limited by postoperative facet joint arthritis, heterotopic ossification and segmental kyphosis. The total Frisbee disc, which has an upper convex/concave non-spherical surface and a lower flat sliding surface, is a new approach for improved outcomes. Prior to clinical application, safety and suitability tests are required. Methods: The Frisbee is the first 3rd generation disc according to a new classification of total disc because it can precisely mimic the segmental ROM, including the soft limitation of axial rotation. The ISO 18192-1 test was carried out to determine the rate of wear debris. A FE model was used to assess the safety of prosthetic components. In the sagittal plane several variables to determine the most favorable lordotic angle were evaluated. Results: Two angled prosthetic plates are safer than one sliding angled core to prevent the displacement. The lordosis of 7° of the Frisbee leads to kyphosis of no more than 2° without reduction of the ROM. The wear rate of the Frisbee is five times smaller compared to an FDA-approved disc with a spherical sliding surface. Conclusions: Based on the test results, the clinical application of Frisbee can now be studied. The postoperative kyphosis observed with other devices is not an issue with the Frisbee design. Physiological ROM is combined with the significant reduction of wear debris. For these reasons the Frisbee has the potential to provide a better balanced segmental loading reducing the degeneration of the joint surface and heterotopic ossification.

Keywords: Arthroplasty, replacement; Cervical vertebrae; Intervertebral disc; Joint prosthesis.

RESUMO

Objetivo: A atual artroplastia de disco cervical é limitada pela artrite facetária pós-operatória, pela ossificação heterotópica e pela cifose segmentar. O disco Frisbee total, que tem face superior não-esférica convexo-côncava e face inferior plana e deslizante, é uma nova modalidade para melhores resultados. Antes da aplicação clínica, são necessários testes de segurança e adequação. Métodos: O Frisbee é o primeiro disco de 3ª geração, de acordo com uma nova classificação de disco total, pois pode imitar precisamente a AM segmentar, incluindo a limitação suave da rotação axial. O teste ISO 18192-1 foi realizado para determinar a taxa de resíduos de desgaste. Um modelo de FE foi utilizado para avaliar a segurança dos componentes protéticos. No plano sagital, foram avaliadas diversas variáveis para determinar o ângulo de lordose mais favorável. Resultados: Duas placas protéticas anguladas são mais seguras para evitar o deslocamento do que um núcleo angulado deslizante. A lordose de 7° do Frisbee leva a uma cifose de não mais de 2°, sem redução da AM. A taxa de desgaste do Frisbee é cinco vezes menor em comparação com um disco aprovado pela FDA, com superfície de deslizamento esférica. Conclusões: Com base nos resultados dos testes, a aplicação clínica do Frisbee pode, agora, ser estudada. A cifose pós-operatória, observada com outras próteses não constitui problema com o desenho do Frisbee. A AM fisiológica é combinada com a redução significativa dos detritos de desgaste. Por essas razões o Frisbee tem o potencial de fornecer uma carga segmentar mais equilibrada, reduzindo a degeneração da face articular e a ossificação heterotópica.

Descritores: Artroplastia; Vértebras cervicais; Disco intervertebral; Prótese articular.

RESUMEN

Objetivo: La actual artroplastia de disco cervical es limitada por la artritis facetaria posoperatoria, por la osificación heterotópica y por la cifosis segmentaria. El disco Frisbee total, que tiene faz superior no esférica, convexo-cóncava e faz interior plana y deslizante, es una nueva modalidad para mejores resultados. Antes de la aplicación clínica, se necesita de pruebas de seguridad y adecuación. Métodos: El Frisbee es el primer disco de la tercera generación, de acuerdo con una nueva clasificación de disco total, pues puede imitar, con precisión, la AM segmentaria, incluyendo la limitación suave de la rotación axial. La prueba ISO 18192-1 fue realizada para determinar la tasa de residuos de desgaste. Un modelo de FE fue utilizado para evaluar la seguridad de los componentes protéticos. En el plano sagital, se evaluaron diversas variables para determinar el ángulo más favorable de lordosis. Resultados: Dos placas protéticas anguladas son más seguras, para evitar el desplazamiento, que un núcleo angulado deslizante. La lordosis de 7mo del Frisbee lleva a una cifosis de no más de 2do, sin reducción de la AM. La tasa de desgaste del Frisbee es cinco veces menor en comparación con un disco aprobado por la FDA, con superficie esférica de deslizamiento. Conclusiones: Con base en los resultados de las pruebas, la aplicación clínica del Frisbee puede ser estudiada en la actualidad. La cifosis posoperatoria, observada con otras prótesis, no es un problema con el diseño del Frisbee. La AM fisiológica se combina con la reducción significativa de los detritos de desgaste. Por esas razones, el Frisbee tiene el potencial para suministrar una carga segmentaria más equilibrada, reduciendo la degeneración de la fase articular y la osificación heterotópica.

Descriptores: Artroplastia; Vértebras cervicales; Disco intervertebral; Prótesis articular.

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INTRODUCTION

Artificial cervical discs have been in clinical use since the late 1990s.[1] Following approval of the Charité Artificial Disc by the American Food and Drug Administration in 2004, artificial cervical discs have become increasingly widespread. At the same time, the variety of designs has increased. Today, the implantation of artificial cervical discs is a standard procedure for neurosurgeons, orthopedic surgeons and spinal surgeons in Europe, North America and other continents.

Artificial cervical discs with simple implantation techniques are preferred by surgeons. However, there is increasing interest in the biomechanical functionality of the implants. The long-term stability and physiological functionality of the implants should ensure treatment success over the long term. This publication will present the first 3rd generation artificial cervical disc.

Advantages and Disadvantages of Artificial Cervical Discs

Despite striking design differences and thus different biomechanical and clinical functionalities of the various artificial cervical discs, the following problems have in general not yet been solved:

- The postoperative development and progression of facet joint osteoarthritis[2]
- The formation of heterotopic ossification with and without loss of segmental motion[3-5] and
- Postoperative kyphosis of the surgical level[6] with the risk of a pathological sagittal profile of the cervical spine.

On the other hand, one positive aspect is that there is less degeneration and frequency of disease in the adjacent segments to artificial cervical discs as compared to fusions.[7-9] In a prospective radiological investigation over 8 years postoperatively, Walraevens *et al*.[10] come to the conclusion that the insertion of the prosthesis did not lead to an increased mobility of the adjacent levels and seems to protect against acceleration of adjacent-level degeneration. However, Burkus *et al*.[11] did not find any significant difference in later surgeries in the adjacent levels following artificial cervical discs as compared to fusions. Harrod *et al*.[12] called for independently funded, blinded long-term follow-up prospective comparative studies between motion-preserving implants and fusions to definitively identify the radiographic or clinical adjacent segment pathology. At the index level, repeat surgical procedures are less frequent after artificial cervical discs than following fusion surgeries.[11,13] Additionally, the rate of postoperative ossifications is lower after total discs.[9]

Since the implantation of artificial cervical discs is considered to be a reliable treatment method due to the long-term reduction in pain or elimination of pain[14] and provides clinical treatment results that are identical to or better than those following fusion surgery,[15,16-18] further developments of artificial cervical discs are worthwhile. The objective of new developments is to eliminate or at least to reduce the disadvantages of known artificial cervical discs and thus the associated negative clinical results. It is a matter of the improved adaptation of the segmental physiological ranges of motion. Even with genetic disposition to degeneration, new artificial cervical discs should provide greater protection for the surgical level and protect adjacent segments from premature degeneration and disease. Age-related physiological adaptations of the cervical spine, including the development of degenerative changes[19] will, however, also affect future results of comparative investigations between artificial cervical discs and fusion surgeries.

Generations of Total Disc Replacement

Classifications of artificial discs have already been published in the past.[20,21] Since that time, the lead author of this publication has developed a new classification (*Büttner-Janz Total Disc Classification*) which is intended to make the quality of artificial discs discernible. The division of artificial cervical discs into three generations is based on the degree of simulation of a healthy mobile segment; it is not based on a chronological sequence of prosthesis developments. The modified three-dimensional coordinate system of White and Panjabi[22] is intended to show the differences between the generations of artificial discs. (Figure 1)

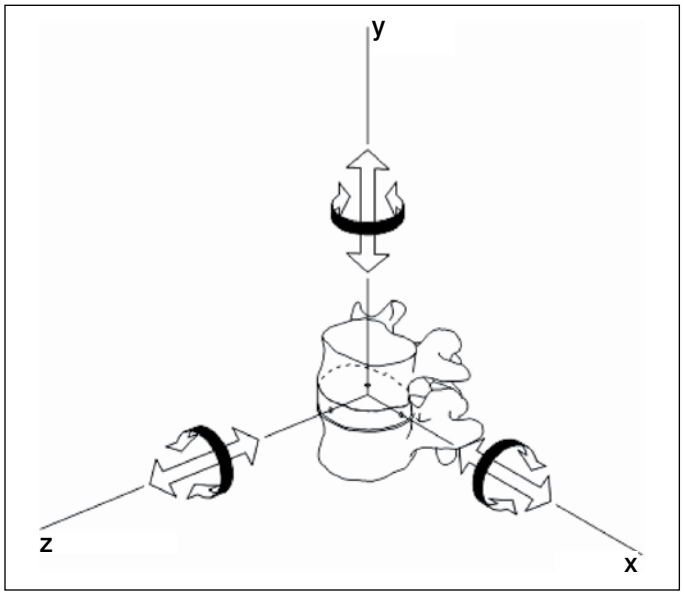

Figure 1. Three-dimensional coordinate system of the mobile segment, modified according to White and Panjabi[22].

Based on healthy intervertebral discs, the objective of the quantitatively and qualitatively best possible disc replacement is the simultaneous protection of segmental facet joints and equilibrated spinal balance. Then the best clinical results can be expected over the long term.

1st Generation Artificial Cervical Discs: The 1st generation artificial cervical discs consist of at least two prosthetic components that are in motion together. Motion takes place in at least one sliding area of adjacent sliding partners or between at least two individual, possibly connected prosthetic components without a sliding area. The non-physiological pattern of motion is typical of a 1st generation artificial cervical disc. The movement of these artificial cervical discs corresponds in the various directions to a mobile segment, not to the physiological range of motion (ROM). The 1st generation artificial cervical discs include in particular all prostheses with the pattern of motion of a spherical "ball-and-socket construction," that is, for example, Prodisc-C, Mobi-C, Granvia, Discover, Secure-C, Kineflex-C, Baguera C, PCM and Discocerv. These artificial discs permit hypermobile motions of the prosthetic components in relation to one another in all directions of rotation around the x-, y- and z-axis of the three-dimensional coordinate system. In the sagittal and frontal plane, there is mismatched motion between adjacent vertebrae via the function of these prostheses, depending on the radius of the convexity and concavity. Additional structural prosthetic elements can influence the range of motion. A translational motion along the y-axis exists for structural or material reasons of some 1st generational artificial cervical discs, for example for the Baguera C. In addition, prosthetic components made from the material ultra-high-molecular-weight polyethylene have minimal elasticity for craniocaudal motion along the y-axis. 1st generation artificial cervical discs with its free axial rotation in the y-axis can cause symptomatic degeneration for both facet joints of the surgical level over the medium to long term. The radii that vary in size of the convex-concave sliding areas of the prostheses exert extra influence on the facet joints.[23] With 1st generation artificial cervical discs, depending on the surgical technique, segmental kyphotic or scoliotic segment positioning can result postoperatively caused by hypermobility of the prosthetic components, with a negative effect on the sagittal balance of the section of the spine and, if applicable, subluxation of the facet joints of the surgical level. The term "instability", which is difficult to define for the mobile segment even without an implant, should in principle be re-evaluated for 1st generation artificial cervical discs.

2nd Generation Artificial Cervical Discs: 2nd generation artificial cervical discs are prostheses which mostly consist of a viscoelastic

spacer adhered to two metal plates. The motion is not associated with sliding areas or other constructs with motion between individual prosthetic components. Segmental motion is enabled due to the material properties of the implant. Above all, as a result of the translation property along the y-axis, the deformable material assumes the intervertebral motion. In 2nd generation artificial cervical discs with continuously uniform material properties and circular footprint, the ROM in extension, flexion and lateral bending is equally large on any side. Therefore, these prostheses are not adapted to the physiological segmental motion. In the natural human mobile segment, by contrast, clear differences can be seen between the ranges of motion along the rotating arrows of the coordinate axes x, z and y. The motions of viscoelastic compact prostheses are rigid, with a potential protective effect on the facet joints, due to the limited ROM. Because the material properties are mostly associated with polycarbonate polyurethane, this material must be proven over the long term to be not too soft and not too stiff with regard to plastic deformability and elasticity. Viscoelastic material that is too soft means hypertranslation with hypermobility and reduction in height of the intervertebral space, including of the intervertebral foramina. This could result in an overload of the facet joints and postoperative segmental kyphosis as a permanent condition. Otherwise, an overly stiff material does not permit sufficient mobility in all directions of motion along the 3 axes of the modified White/Panjabi coordinate system. Prostheses of this type, with the limited ROM, represent a streamlined transition to similar properties of a fusion, for example with a cage. As result, there is the potential failure of the implant to protect from adjacent segment degeneration and disease. Furthermore, these prostheses involve the risk, at least in the initial postoperative weeks, of wobbling movements between the rigid implant and the adjacent vertebral body end plates when the patient is active, with good spinal movement, because postoperative motion in the cervical region should be possible without significant limitation.

3rd Generation Artificial Cervical Discs: 3rd generation artificial discs are intended to simulate the physiological segmental ROM of a healthy intervertebral disc. Thus different ranges of motion along the three axes of the modified White/Panjabi coordinate system (1990) are intended. In 3rd generation prostheses, the significant disadvantage of 1st generation artificial discs is remedied; there is no unconstrained hypermobility for all rotating movements along the x-, y-, and z-axis. The translation along the x- and z-axis should also be physiologic in 3rd generation artificial cervical discs. A translation along the y-axis is possible depending on design variants and material characteristics. Through physiological motion in the intervertebral disc space, the facet joints will move in a kinematically normal fashion. With the 3rd generation prosthetic design, the disadvantages of previous artificial cervical discs with regard to the facet joint degeneration and postoperative kyphotic positioning should be eliminated. With hyperflexion that is no longer possible and the absence of segmental kyphotic positioning, there cannot be any subluxation of the facet joints in the surgical level. 3rd generation artificial discs are also intended to exert a positive influence on the sagittal balance of the (cervical) spine. Likewise, with 3rd generation artificial discs, the requirement of avoiding adjacent level degeneration and disease should be optimal, if there are no predominant genetic influences. The rate at which postoperative heterotopic ossifications can be significantly reduced with a 3rd generation artificial cervical disc must be demonstrated by clinical-radiological results over time. Known counterarguments to total disc implantation, such as a significant tendency to form spondylophytes, should also be taken into account for 3rd generation artificial cervical discs.

Design of the frisbee Artificial Cervical Disc and its Functional Performance

Proven traditional materials were used in the newly developed three-part artificial cervical disc known as frisbee. Both prosthetic plates consist of the titanium alloy TiAl6V4 which has significantly fewer artifacts on CT and MRI as compared to the cobalt-chromium alloy that was often used for disc prostheses. The non-luxating sliding core of the frisbee moving between both prosthetic plates consists of ultra-high-molecular-weight polyethylene. (Figure 2)

With the frisbee, there cannot be metal-metal bearing wear with danger of extensive revision surgery to decompress the spinal canal.[24] In comparison to ceramic slide bearings, there is no risk with the frisbee of splintering within the intervertebral space.[25]

The coating of the prosthetic plates of the frisbee does not include the fins and instrument recesses. It is performed with titanium plasma spray (TPS), the same as it is used for the M6-C and Prodisc-C. In the robot-assisted process, porous pure titanium layers are applied reproducibly (DOT GmbH, Rostock, Germany). The primary position stability of the frisbee is thus increased as the result of the rough surface, in addition to the 2 fins for fixation of the prosthesis. Long-term stabilization is guaranteed as a result of bone growth into the porous titanium layer.

The primary characteristic of the frisbee is based on its component design and the resultant biomechanical functionality in interaction with the 3 prosthetic components in 2 sliding areas. In the cranial sliding area, a design deviating from the spherical ball-and-socket principle has been devised (patents US 7,833,273; EP 1816989). The convex "spindle" of the sliding core moves in a concave recess in the upper prosthetic plate which is modified in the design as compared to the spindle shape. Soft limitation of axial rotation along the y-axis of the modified White and Panjabi coordinate system[22] is included. (Figures 3, 4)

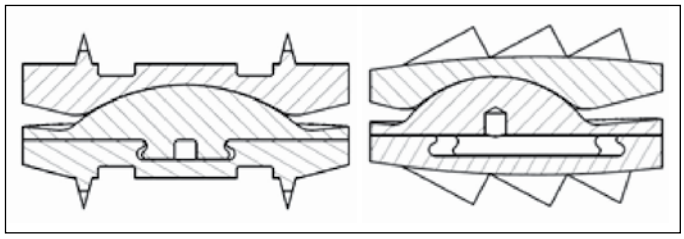

Figure 2. Frisbee. Middle frontal plane (left), middle sagittal plane (right).

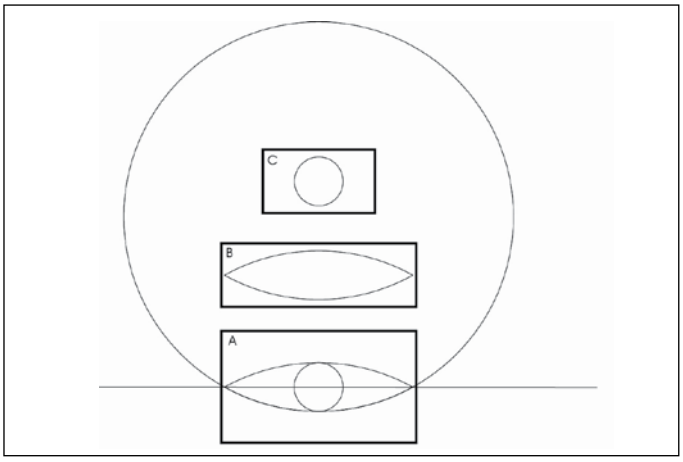

Figure 3. (A) Derivation of the spindle principle. (B) Frontal and transverse sections. (C) Sagittal section.

Physiologic segmental motion with varying ROM in extension, flexion, lateral bending and axial rotation is enabled along with coupled motions, due to the design of the cranial sliding area. In the caudal sliding area of the frisbee, a translational shifting of the sliding core in the anterior and posterior direction takes place depending on the force applied during extension and flexion based on the component design (patents US 13/365,308; PCT/EP2012/051815).

The design of the sliding areas and edge configurations of the frisbee serve to avoid hypermobility of this artificial cervical disc to

protect the facet joints on the same level which are physiologically included in the motion. In summary, it was attempted to physiologically align the design of the frisbee in regard to all 12 directions of motion of the modified three-dimensional coordinate system of White and Panjabi[22] (Figure 1), including a minimal translational motion along the y-axis through the elastic properties of the ultra-high-molecular-weight polyethylene of the sliding core.

The following parameters for the size, height and angle as well as for the maximum motions for the frisbee were adopted from and established from scientific literature and from clinical experience:

1. Footprints: 13x16 mm, 15x18 mm, 17x20 mm;
2. Heights: 5.5 mm, 6.5 mm, 7.5 mm;
3. Angulations of the prosthetic plates: 0°, 7° (per prosthetic plate 3.5°);
4. ROM: Extension/flexion +/-9°, lateral bending +/-7°; axial rotation +/-6°;
5. Translation: Caudal flat sliding area: The sliding core moves on the caudal prosthetic plate ventrally 1 mm and dorsally 0.5 mm.

Cranial convex-concave sliding area: The upper prosthetic plate moves on the sliding core ventrally and dorsally in each case with 0.86 mm offset as well as to right and left side laterally 1.05 mm in each case. Thus the maximum offset possible in anterior-posterior motion is 3.22 mm and in the laterolateral motion is 2.1 mm.

To 3. Angulations of the prosthetic plates:_For the segmental lordotic angle, two possibilities were considered during the development of the prosthesis: One, creating the angle via the two prosthetic plates, and one, via the sliding core. (Figure 5)

Using a finite element model, it was calculated whether an angled prosthetic plate or an angled sliding core provides more safety. The respective 3D model with the angled sliding core and then the angled prosthetic plate was provided with a fixed bearing on the caudal prosthetic plate and subjected to a vertical force of 100 N. The horizontal force was measured needed to shift the cranial prosthetic plate by 2 mm dorsally. The result demonstrates that with an angled prosthetic plate the needed force for plate dislocation is 20% higher. (Figure 6)

Prevention of postoperative kyphosis: In the sagittal plane 0° and 7° (2 x 3,5°) prosthetic plates are available. The 7° frisbee allows a maximum of 2° flexion by which substantial segmental kyphosis is avoided. At same time the segmental ROM is unchanged. (Figure 7)

To 4. ROM: With the frisbee the ROM of the cervical intervertebral discs from C3 to T1 can be simulated. The segmental motion values are identically to White and Panjabi.[22] A deviation from the individual segmental ROM is only seen in levels C3-C4 and C4-C5. However, these levels only represent 6% of artificial cervical disc implantations (Bryan FDA approval IDE study). The segments C5-6 and C6-7 involve more than 90% of artificial cervical disc implantations and have a deviation in segmental mobility per direction of motion (e.g. in extension/flexion) of a maximum of only 2°. (Table 1)

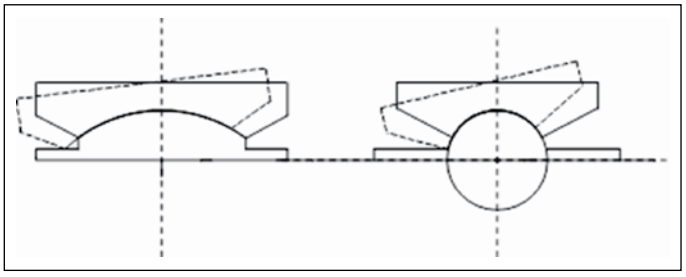

Figure 4. Functional principle of the cranial sliding area of the frisbee with frontal plane (left) and sagittal plane (right).

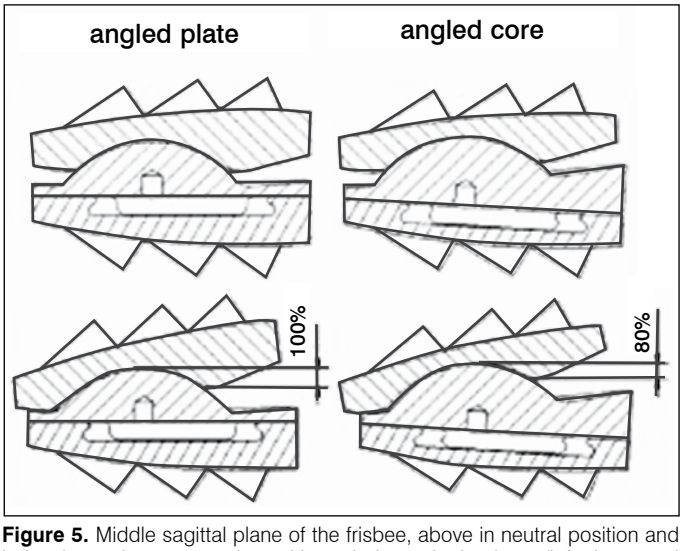

Figure 5. Middle sagittal plane of the frisbee, above in neutral position and below in maximum extension, with angled prosthetic plates (left above and below) and an angled core (right above and below). Percentage covering of the convexity of the angled sliding core is 80% in comparison to the angled prosthetic plates with 100%.

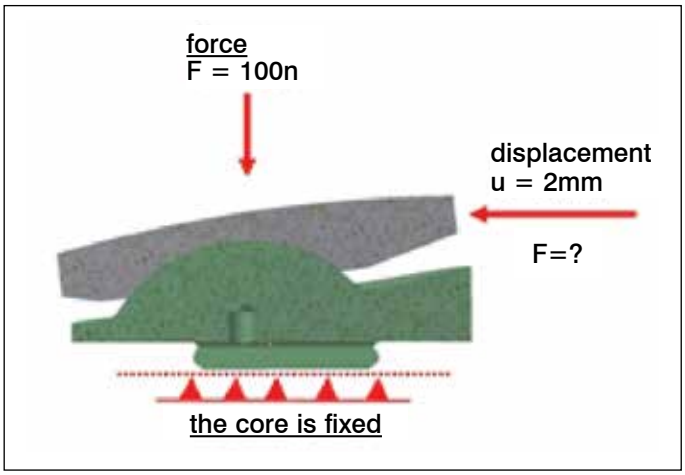

Figure 6. Finite element model of the frisbee (middle sagittal plane) with angled sliding core and cranially as well as ventrally applied forces.

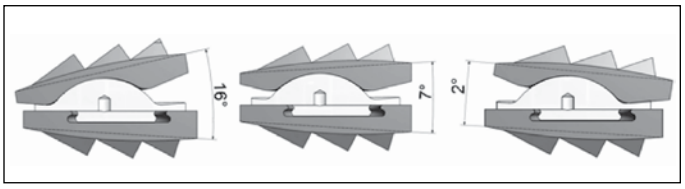

Figure 7. Middle sagittal plane of the frisbee with two 3.5° angled prosthetic plates. Extension=lordosis (left), zero position (middle), flexion=kyphosis (right). ROM in extension/flexion: 16/0/2.

In vitro Investigation with the frisbee

Six frisbee implants underwent a wear test according to ISO 18192-1.[26] This test is a standard test for receiving CE certification and also a basic test for an approval by the U.S. Food and Drug Administration. The set-up and also the implementation of the test is based on the physiological processes in the human body. It can be assumed that the results of the in-vitro testing represent the worst-case behavior *in vivo*.

ISO 18192-1 Wear Test: The objective of this mechanical test was to examine the wear characteristics of the frisbee. The test of the six frisbee implants was performed over 10 million cycles. Prior to the test, the sliding cores were gamma sterilized (25-50 kGy) and stored for 25 days in calf serum as specified in the Standard ISO 18192-1. The prosthetic plates were mounted in POM test blocks (polyacetal). The entire set-up was placed in the test machine, the geometric center of the sliding body was correspondingly adjusted in the center of rotation of the machine and then the test was performed at 1 Hz[27]. (Figure 8)

Table 1. Segmental ROM of White/Panjabi 1990 (W/P) in comparison to the frisbee, deviation of the frisbee of White/Panjabi and frequency of implantation of artificial cervical discs (*Bryan FDA approval IDE study).

Segment	Extension / Flexion		Deviation	Lat. Bending (total)		Deviation	Rotation (total)		Deviation	Frequency in % in 242 implantations*
	W/P	frisbee		W/P	frisbee		W/P	frisbee		
C3-C4	15	18	-3	22	14	-8	14	12	+2	1.1
C4-C5	20	18	+2	22	14	-8	14	12	+2	5
C5-C6	20	18	+2	16	14	-2	14	12	+2	57.9
C6-C7	17	18	-1	14	14	0	12	12	0	36

The test machine was stopped after 0.5 million cycles, 1 million cycles and thereafter after every 1 million cycles. The lower endplates with the PE-cores were removed from the test blocks and cleaned and dried. The following analyses were carried out:

Weight and height measurements of the sliding cores and photographs of the surfaces of the cores and prosthetic plates. (Figure 9)

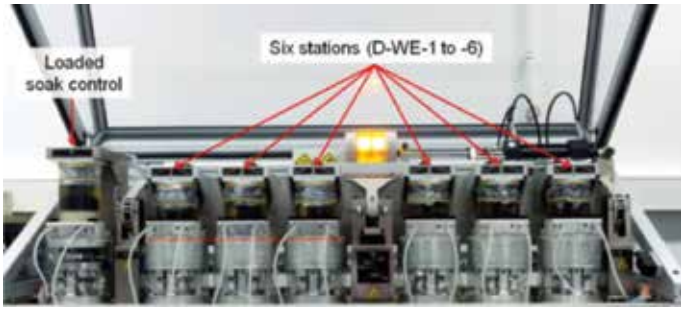

Figure 8. Test machine for testing according to ISO 18192-1 for wear characteristics of the frisbee (SpineServ GmbH & Co. KG, Ulm, Germany).

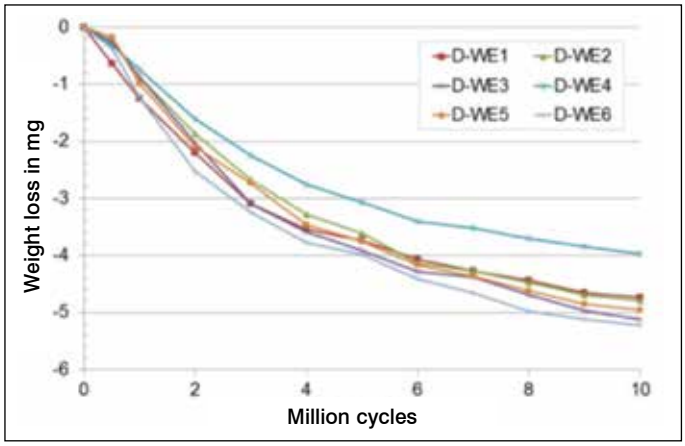

Figure 9. Cumulative weight loss (=wear) of six frisbee implants in mg according to ISO 18192-1 during the test over 10 million loading cycles (SpineServ GmbH & Co. KG, Ulm, Germany).

RESULT

After 10 million cycles, an overall weight reduction of 4.8 mg on average (= 0.48 mg / million cycles) was measured. The height of the sliding cores decreased after 10 million cycles in mean by 0.12 mm. The mean height loss per million cycles was accordingly 0.01 mm.

DISCUSSION

The new artificial cervical disc frisbee meets the basic requirements of a 3rd generation artificial cervical disc. Frisbee maintains the physiological range of motion in all planes (extension, flexion, lateral bending, axial rotation, translation). Based on its design frisbee distributes the mechanical forces and protects the facet joints from abnormal stress. The influence of the frisbee on the adjacent cervical segments can be evaluated after clinical application.

The convex sliding area of the frisbee is designed as a variant of a spindle. The differently shaped concave sliding area allows soft limitation of axial rotation of the spindle along the y-axis of the modified White and Panjabi coordinate system.[22] The rotational ROM of the frisbee around the x- and z-axis is limited due to the convergence in the edge areas with the result of physiological ROM. The edge areas are correspondingly designed for a potential contact of prosthetic components.

It was initially intended to construct an angled sliding core for the frisbee to adapt to the segmental lordosis. However, provocation tests in the finite element model for dislocation of the cranial prosthetic plate in the sagittal plane demonstrated that with an angled prosthetic plate the overlap of the spindle-shaped convexity and the concavity is more secure than with an angled sliding core. Thus, angled prosthetic plates can better avoid dislocation during e.g. whiplash.

The 2 x 3.5° prosthetic plates are preferably used for cervical segments which could be predisposed to kyphotic positioning. In the case of ventral contact of the adjacent edges of the components, a maximum of only 2° flexion respectively kyphosis is possible which does not allow decompensation of the sagittal balance of the cervical spine. A risk of facet joint subluxation during flexion as a result of hypermobility as can be the case with 1st and elected 2nd generation prostheses is not expected with the frisbee. The facet joints are also protected in this regard with the frisbee.

Taking the necessary material strengths into account the lowest height of the frisbee as three-component prosthesis is 5.5 mm. The desired variable center of rotation with a stress-relieving influence on the facet joints is achieved via the three components of the frisbee that are in motion with each other.

A total disc design with 100% correlation to the individual segmental motion parameters in extension/flexion, lateral bending and axial rotation does not appear to be possible, taking the scientific literature into account. However, near correlation according to White and Panjabi[22] has been achieved with the frisbee. Its ROM in the 3 directions of motion shown in table 1 corresponds with the surgical levels C5-6 and C6-7 which make up 93.9% of all disc implantations.

The ROM of the frisbee as a plus deviation in comparison to the physiological range is a maximum of 2 degrees, based on all surgical levels of the cervical spine. This low number should be disregarded, particularly when compared to the hypermobile 1st generation artificial cervical discs. The cervical segments other than C5-6 and C6-7 can also be treated with the frisbee, since the minus deviations, as a reduced ROM, are a maximum of 8 degrees in only one segmental direction of motion. This does not represent any risk for overload of the adjacent segments due to the respective total segmental ROM.

The degree of translation of the frisbee can be seen in connection with the vertebral body width, according to which a translation range up to 20% should not represent any instability.[28] Increased loads in the facet joints which occur during translational motions in the sagittal plane can be absorbed by the frisbee in cooperation with the upper convex-concave and the lower flat sliding area. Overall, it can be assumed that the motions of the frisbee fluidly merge as a coupled motion.

The wear test of the frisbee demonstrates mean values of 0.48 mg/million cycles. For the Prodisc-C 2.49 mg/million cycles are described (PMA P070001, approval of the Prodisc-C Total disc Replacement by the U.S. Food and Drug Administration). This different result is notable, since the frisbee, in contrast to the Prodisc-C, does not have any spherical design of the articulation partners and additionally the frisbee has 2 areas of motion. It can be assumed that the source of the good result of the frisbee is its design with resultant physiological behavior of this total disc.

With exclusively self-adjusting hypermobile artificial cervical discs, particularly those of the 1st generation, there is always the risk of postoperative segmental mal-positioning which can affect the overall alignment of the cervical spine and its balance. As a result of the ROM limitation of the frisbee in all directions of motion, this artificial cervical disc may be advantageous for multilevel surgeries as well as for the treatment of adjacent segment disease for which the available literature includes artificial discs as treatment option.[29]

The instrument set for the Frisbee is suitable for its implantation and explantation. Fritsch and Pitzen[30] indicate a preference for disc prostheses over fusion surgeries because they see the possibility of a safe and low-risk revision operation for total discs. The sliding core of the frisbee can be changed separately. This option has been taken into account for revision surgeries in e.g. older patients.

Precise implantation of the frisbee is necessary to achieve the desired physiological functionality over the long term. The facet joints are protected by the frisbee's segmental ranges of motion. The normal frisbee function is a requirement to determine whether the high rate of postoperative heterotopic ossifications [29]f can be reduced as a result of physiological segmental motion.

In this work the design and *in vitro* results of the new artificial cervical disc frisbee are presented. Generally, improved clinical results can be expected with implant designs for physiological ranges of motion. With the frisbee as first 3rd generation total disc, cervical total disc replacement can enter a new phase.

All the authors declare that there is a potential conflict of interest referring to this article.

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