Research Article

Analysis of Requirements for an Artificial Intervertebral Disc with Selected Mechanical Properties

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Abstract

Intervertebral disc degeneration is an important social and economical problem. Presently available artificial intervertebral discs (AIDs) are insufficient and the main surgical intervention is still spinal fusion. The objective of the present study is to present a list of requirements for the development of an AID which could replace the human lumbar intervertebral disc and restores its function. The list addresses geometry, stiffness, range of motion, strength, facet joint function, center of rotation, fixation, fail safety and implantation technique. Date are obtained from literature, quantified where possible and checked for consistency. Endplate size is a weak point in existing AIDs. These should be large and fit vertebral bodies to prevent migration. Disc height and wedge angle should be restored, unless this would overstretch ligaments. Finally, stiffness and range of motion in all directions should equal those of the healthy disc, except for the axial rotation to relieve the facet joints.

Keywords: Intervertebral disc, AID, Stiffness, geometry, Strength

1. Introduction

The intervertebral disc (IVD) consists of a gelatinous nucleus pulposus, surrounded by a fibrous annulus fibrosus. This particular construction can withstand the high loads acting on the spine during everyday life (Nachemson A, *et al,* 1966), (Wilke HJ, *et al,* 1999) while giving the vertebral column its mobility. IVD degeneration is a frequently occuring pathology with important social and economic consequences, as it is a major cause of occupational disability. In the case of symptomatic IVD degeneration, surgical intervention is necessary. Unless the pathology is limited and localised, total IVD replacement is inevitable.

The vertebral column consists of 24 separate vertebrae and the sacrum, connected by intervertebral discs, ligaments and muscles. Replacing one part of the vertebral column with a mechanically different part could affect the whole system negatively. As an example, a frequently practiced surgical solution is fixation of the intervertebral joint. Besides loss of mobility, extra loading or movement of the adjacent discs could result in increased disc degeneration at these levels (Quinnell RC and Stockdale HR, *et al, 1981*). An artificial intervertebral disc (AID) mimicks the mechanical properties of the IVD, meaning that mechanics around the spinal column are unchanged

and stability is unaffected, while motion between vertebral bodies is still possible.

The aim of the present paper is to provide directions for improvement of existing AIDs and their future development. Therefore, a list of specifications for the development of an AID has been derived from an extended literature survey of IVD properties. The following requirements have been selected as critical items in the development of an AID:

1. Geometry
2. Stiffness
3. Range
4. Strength
5. Center of rotation
6. Fixation to the adjacent vertebra
7. Function of the facet joints
8. Failsafety
9. Surgical procedure

Where possible, these variables are quantified using literature data. Qualitative adjustment is suggested whenever applicable.

2. Materials and Methods

An extensive literature study was performed to retrieve data for the requirements an artificial intervertebral disc has to satisfy. All data were checked on consistency and for each of the requirements, properties were given which

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are applicable to an artificial intervertebral disc. Guidelines for the development of new or for the improvement of existing AIDs are given.

3. Results and Discussions

3.1 Geometry

Boundaries for the AID geometry are determined by the endplates of the adjacent vertebral bodies and the IVD space Fixation of the AID to the endplates is most critical for successful intervention. For maximum grip between the AID and the bones, the shape of the AID endplates should be complementary to the surface of the adjacent bones. The size of the vertebral body endplates has been studied extensively, using radiographs (Amonoo KH, *et al*, 1991), (Gilad Iand Nissan, *et al,* 1986) cadaveric specimens (Linton AE, Levy ME, DiGiovanni BF, Scoles PV, *et al,* 1988) CT and MRI scans (Aharinejad S, *et al*, 1990). The results of these studies are comparable. The size of the vertebrae increases ~15 % from T12 to S1. The caudal lumbar vertebrae are ellipse shaped whereas the cranial lumbar vertebrae are kidney shaped. The vertebral endplates are slightly concave, but this has not been quantified in the literature, through it has been shown that concavity increases with age (Twomey LT and Taylor JR, *et al,* 1987).

To restore the mechanics of the spine, the AID should fully restore height and wedge angle of the healthy situation. The height of human lumbar IVD's has been studied extensively using lateral radiographs (Gilad Iand Nissan, *et al*, 1986)), and MRI and CT scans (Aharinejad S, *et al,* 1990) (Table 1). The small variation in average measured IVD height between studies is probably due to radiographical magnification bias. Also, in radiographs, the measured distance is mostly the largest lateral diameter of the vertebrae. However, the distance to the indent of the "kidney" is important for the fit of the AID.

Table. 1. Range and average values for lateral and sagittal diameter, disc height and wedge angle of lumbar intervertebral discs (T12/L1 – L5/S1) (Amonoo KH, *et al,* 1991), (Aharinejad S, *et al,* 1990).

S.No	Dimensions/Values	Range	Average
1	Lateral Diameter (mm)	35-63	50
2	Sagittal Diameter (mm)	27-45	35
3	Height (mm)	6-14	10
4	Wedge Angle (Degrees)	6-14	Table 2 and 3

During disc unloading (e.g. during bed rest), the disc attracts water and swells while during loading of the disc, water is expelled again. This diurnal volume variation (on the average 20 % in L3-L4 to L5-S1) (19), is accounted for by IVD height rather than by disc diameter. As a result, distance between the transverse processi before and and after bedrest varies 1.7 mm (L1-L2 to L3-L4) (20).

From measurements of anterior and posterior disc height in combination with the anterior-posterior diameter the IVD wedge angle could be calculated. (Chen MW, Yang SW, Lee MC, *et al,* 1994) studied differences in wedge angle between upright standing and 60º flexion. The total lumbar disc angle decreased with 42º for men and 46º for women.

Table. 2. Intervertebral disc wedge angle (in degrees), calculated from anterior, posterior disc heights and anterior-posterior diameters (Amonoo KH, *et al,* 1991), (Aharinejad S, *et al,* 1990), (Tibrewal SB and Pearcy MJ, *et al,* 1985).

S..No	1	2	3	4	5
Level	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1
Tibrewall	6.7	10.8	13.6	14.4	15.3
Nissan	3.7	5.1	5.5	10.9	15.4
Aharinejad	-1	0.1	0	0.1	0
Amonoo kuofi Males	10.4	11	10.3	10.4	12.2
Amonoo kuofi Females	11.3	9.9	12.1	12.4	14.2

Mean values are calculated from all papers except (Aharinejad S, *et al,* 1990) According to most studies, the IVD is wedge shaped in neutral position with the anterior height larger than the posterior height (Amonoo KH, *et al,* 1991), (Aharinejad S, *et al,* 1990), (Tibrewal SB and Pearcy MJ, *et al,* 1985).The wedge angle increases from T12 to S1 (Table 2) and with age (Table 3). (Aharinejad S, *et al,* 1990) found wedge angles less than 1 degree, which distinctly differs from the numerous other findings on this topic.

Table.3. Average Wedge Angles (in Degrees) for all levels of lumbar intervertebral discs

S..No	Age	Wedge angles Males	Wedge Angles Females
1	10-20	8.1	8
2	20-30	8.2	9.7
3	30-40	9.6	11.7
4	40-50	12.8	13.6
5	50+	15.8	17

Calculated from data of (Amonoo KH, *et al,* 1991)

3.2 Stiffness

IVD stiffness (Table 4) is important for the shock absorbing ability of the vertebral column, which is largely accounted for by the IVD mechanical properties (Chen MW, Yang SW, Lee MC, *et al,* 1994). The stiffness of the IVD has been studied in vitro (White AA and Panjabi MM, *et al,* 1990) (Brown T, Hansen RJ, Yorra AJ, *et al,* 1957) data that roughly describe the relationship between stiffness and compression are 800 N/mm at loads up to 1000 N, and 2000 N/mm at loads over 4000 N (McGlashen KM, Miller JA, Schultz AB, Andersson GB,

et al, 1987).This non-linear progressive stiffness of the IVD and ligaments facilitates small movements around the neutral situation, and restricts larger movements. Unfortunately, a comprehensive description of the relationship between stiffness and compression has not been found in the literature. Probably the most important reason for discrepancies between the aforementioned studies is that test circumstances varied with respect to the time and rate of disc loading, and with respect to the final load applied on the disc. Because the disc exhibits visco-eleastic mechanical behavior, time-dependency is an important variable when determining IVD stiffness. For appropriate deformation of the spinal column and therewith appropriate loading of surrounding soft tissues, the stiffness of the AID and the IVD should be comparable.

Table.4. Average stiffness and stiffness ranges (between brackets) of a lumbar motion segment (White AA and Panjabi MM, *et al,* 1990), (Pearcy MJ and Tibrewal SB, *et al,* 1984). Note that these data are simple representations of complex spinal behavior

S..No	Force/Moment	Stiffness
1	Tension	770 N/mm
2	Compression	2000(700-2500) N/mm
3	Anterior Shear	121 N.mm
4	Posterior Shear	170 N/mm
5	Lateral Shear	145 N/mm
6	Flexion	1.36(0.8 -2.5) Nm/deg
7	Extension	2.08 Nm/deg
8	Lateral Bending	1.75 Nm/deg
9	Axial Rotation	5.00 (2.0-9.6) Nm/deg

3.3 Range of Motion

The range of motion (ROM) of the IVD was studied in vitro (Adams MA and Hutton WC, *et al,* 1986) and in vivo using lateral radiographs (Chen YL and Lee YL, *et al,* 1997) and skin markers.

Table.5. Range of motion (ROM) and its range in degrees for lumbar

Motion	L1-L2	L2-L3	L3-L4	L4-L5	L5-S1
Axial rot.	2(1-3)	2(1-3)	2(1-3)	2(1-3)	1(1-3)
Lat.bending	6(3-8)	6(3-10)	8(4-12)	6(3-9)	2(2-6)
Flex.+Ext.	12(5-16)	12(5-16)	15(6-17)	16(9-21)	17(10-24)
Flexion	8(5)	10(2)	12(1)	13(4)	9(6)
Extension	5(2)	3(2)	1(1)	2(1)	5(4)

The results are comparable. (Kapandji IA, *et al,* 1974) showed that the ROM decreases to 60 % in 70 years old males. ROM data obtained (White AA and Panjabi MM, *et al,* 1990), (Pearcy MJ and Tibrewal SB, *et al,* 1984) who distinguished flexion and extension, are given in. An AID should allow for the same range of motion as the natural IVD, to restore full functionality of the spine. However, it

should be noticed that an overly flexible motion segment may increase the chance of spinal instability. Data are obtained from a review by White White AA and Panjabi MM, *et al,* 1990). Data from Pearcy (30, 31) are presented separately to distinguish flexion from extension.

3.4 Strength

One should distinguish loads that frequently occur during everyday life, such as walking and lifting small weights, from rare extreme loads, i.e. those that occur while lifting heavy objects or falling. The first type of load determines the AID fatigue strength, whereas the second determines the maximum strength of the AID, both of which are important failure criteria. The maximum strength of the AID has been studied in several ways:
1. Measurement of the load on the IVD in vivo (Nachemson A, *et al,* 1966), (Wilke HJ, *et al,* 1999).
2. Measurement of the failure load of the IVD in vitro (White AA and Panjabi MM, *et al,* 1990).
3. Measurement of the failure load of the vertebra in vitro (Jager M and Luttmann A, *et al,* 1992).
4. Calculation of the load on the IVD with mathematical models (Ito M, Tadano S, Kaneda K, *et al,* 1993)

In vivo intradiscal pressure on L3-L4 is approximately 1000 N in a standing position, increasing to 3000 N in a sitting, leaning forward position or carrying 20 Kg (Nachemson A, *et al,* 1966), (Wilke HJ, *et al,* 1999).They found an increase in intradiscal pressure during sleep up to 240 % at the end of the sleep period, presumably because of rehydration.

Table.6. Fatigue test loads for walking and lifting activities and maximum test load for the lumbar artificial disc

Properties/Values	Fatigue strength Walking	Fatigue strength Lifting	Minimum Strength
Compression	200-2250 N	150-1250 N	8 kN
Lateral Shear	-100-100 N	-450-450 N	2
Sagittal Shear	-100-100 N	-450-450 N	3
Flexion	0-2°	0-4°	14°
Extension	0-1°	0-2°	5°
Lateral Bending	0-1°	0-2°	6°
Rotation	0-1°	0-1°	3°

Failure load according to Brown (Brown T, Hansen RJ, Yorra AJ, *et al,* 1957) is 5700 N, which is in agreement with the range found by Adams: 6400 ± 2450 N in compressio and 33 ± 12.8 Nm in flexion. Both studies show rupture of the endplates prior to IVD failure. The maximum strength is needed for an AID is also determined by the failure load of adjacent vertebral bodies. Although Whit concluded that the strength of the vertebrae is lower than that of the IVD (Table 5), (Jager M, Luttmann A, *et al,* 1992) determined that the maximum failure load of the lumbar vertebrae equals 8000 N, which

exceeds the 6400 N disc failure load as found by Adams . Global forces that act on the IVD can also be estimated with numerical models in which the structures of the spine are represented by springs and dashpots. The results of these studies vary due to different assumptions, such as working distance of muscles, stiffness of the ligaments, speed of lifting and way of lifting. Despite these assumptions, the highest loads that were reported from these computations are 7500 N in compression (Frigo C, *et al,*1990) 3000 N in anterior posterior and 2000 N in lateral shear (Marras WS and Granata KP, *et al, 1997).*

These values are in close agreement with the failure loads of (Jager M, Luttmann A, *et al,* 1992). Therefore, not taking a safety factor into account, assuming a minimum failure load for the AID of 8000 N in compression, 3000 N in anterior posterior shear and 45 Nm in anteflexion, is reasonable (Table 6). Maximum and minimum peak compression loads on L5-S1 while walking are 2.07 and 0.2 times bodyweight, respectively (Khoo BCC, Goh JCH, Bose K, *et al,* 1995*)* maximum peak shear load is 0.63 times bodyweight. (Ambrosio L, *et al,* 2000) used the load on the IVD while lying supine (200 N) and lifting a weight of 20 kg (2250 N) (Nachemson A, *et al,* 1966) for fatigue testing of an AID. For average fatigue torques and rotations of the IVD, no data were found in the literature.

The number of walking cycles is ~2*106 per year, and the number of lifting cycles is ~125*103 per year (Kostuik JP, *et al,* 1997). Therefore, in a fatigue test, an AID should be loaded with 80*106 sinusoidal cyclic loads (2 Hz) between 150 and 1250 N (Z 0.2 - 1.8 * 70 kg) in compression and between –450 and +450 N of shear load to represent 40 years of walking, followed by 5*106 sinusoidal 0.5 Hz cyclic loads between 200 and 2250 N in compression to simulate lifting weights .

3.5 Center of rotation

In flexion, the center of rotation moves to the anterior side of the vertebral column, in extension to the posterior side, and during lateral bending and axial rotation, the center of rotation moves to the opposite side of the spinal column (White AA and Panjabi MM, *et al,* 1990). The advantage of the movement of the center of rotation is that the working distance of the spinal muscles and ligaments increases during these actions. Therefore, loads are reduced (Kostuik JP, *et al,* 1997), (Farfan HF, *et al,1978).* For this reason, and to minimize kinematic changes of the spine, the center of rotation of the AID preferably mimics this behavior.

3.6 Fixation

Dislocation of a disc may result in serious damage to vital systems such as the spinal cord and large veins and arteries. Directly after implantation, a firm initial fixation is required, which must last for at least 20 years. Long term fixation can probably be improved by stimulation of bone ingrowth, using specific coatings. Similar techniques are widely used in other orthopedic implants.

3.7 Facet joints

Facet joints are small, stabilizing articulations between the vertebral bodies, located at the latero-posterior sides of the nerve root. The orientation of the joint surface, and therewith the direction in which movements are enabled, differs with position in the spinal column. In the lumbar spine, the orientation of the facets limits axial rotation, posterior-anterior shear and extension. Flexion and lateral bending are less restricted (White AA and Panjabi MM, *et al,* 1990). In neutral position, facet joints account for 15 % of the total load, whereas in extension and axial rotation, this increases to 40 % (Adams MA and Hutton WC, *et al,* 1983). Disc space narrowing, which is seen in degenerated discs, increases facet joint loading (Dunlop RB, Adams MA, Hutton WC, *et al,* 1984). In degenerated discs, the facet joints are often arthritic and joint contact is painful. Therefore, the ideal AID would account for the function of degenerated facet joints (Butler D, Trafimow JH, Andersson GB, McNeill TW, Huckman MS, *et al,* 1990) thus relieving these joints.

3.8. Surgical procedure

The surgical replacement procedure must exclude the chance of possible damage to surrounding tissues such as the spinal cord and large vessels, and limit interaction with nearby muscles and ligaments. A less obvious, but important consideration, is to prevent spinal ligaments from overstretching during insertion of the AID, which predisposes ligament ossification in the long run.

The operating procedure should further minimize the chance of misaligning the lower and the upper AID fixation in relation to the vertebrae. Since only a small operating space is available to the surgeon, positioning is difficult. As disc positioning as well as initial fixation is of ultimate concern for successful replacement, repositioning must be avoided. Therefore, the insertion must be unambiguous.

Conclusion

Based on the assumption that an AID should mimick the regular mechanical IVD behavior, feasibile suggestions for the design of an AID are presented, as wel as suggesting means to prevent AID failure. These suggestions include geometry, stiffness, ROM, strength, center of rotation, fixation, facet joint function, failsafety and surgical procedure. Failure of clinically used prostheses is apparent when judged according to this list. The following criteria and proposals are noteworthy:

1. For optimum fixation, the AID should closely fit the vertebral endplates , whereas the AID needs support from the cortical shell to prevent it from migration. Therefore, AID diameter increments should be less than 4 mm.
2. The AID should restore loss of disc height only if that does not increases disc height by more than 2 mm, to prevent spinal ligament overstretching.

3. Stiffness in flexion, extension and lateral bending is less critical than in compression, because of the contributions of ligaments and muscles.

4. For this reason, rotation in these directions should not be limited by stiffness or ROM of the AID. Thus the chance of overloading of the fixation is decreased.

5. Minimum AID failure strength in compression is 8 kN (vertebral body collapse), in lateral and sagittal shear 2 and 3 kN, respectively.

6. The center of rotation of the AID should move with rotation of the motion segment similar to the natural disc, to increase muscle working distance and consequently decrease disc loading.

7. The Charité prosthesis does not call for this criterion. Ultimately, an AID incorporates facet joint function. Possible means are discussed, but these principally interfere with prior requirements.

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