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ORIGINAL ARTICLE

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History, design and biomechanics of the LINK SB Charité artificial disc

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Abstract The SB Charité I artificial disc was developed in 1982 by Schellnack and Büttner-Janz and modified as the Mark II version in 1984. Both types were manufactured in the former German Democratic Republic (GDR). Today's design, the SB Charité III, was first produced by LINK in 1987. Five sizes of the artificial disc in various angulations are available today, with a double coating of titanium/calciumphosphate. Designed with a three-component set-up, the SB Charité mimics the physiological segmental motion. The possibility of translation in the SB Charité provides proper biomechanical function and protects the zygapophysial joints. Results of biomechanical testing showed a sufficient cold-flow resistance of the UHMWPE (**U**ltra **H**igh **M**olecular **W**eight **P**olyethylene) sliding core and confirmed the negligible abrasion rate. The LINK SB Charité disc is a safe and effective operative treatment for discogenic low back pain. Long-term results (10 years and more) have been published.

Keywords History · Materials · Bioactive coating · Translation · Zygapophysial joints

Introduction

In 1982 Schellnack and Büttner-Janz initiated the development of the functional artificial disc, the SB Charité I (Fig. 1A) at the Charité Hospital in Berlin [11]. The idea was based on the "low-friction" principle, which had proven to be successful in total joint replacement: an UHMWPE (**U**ltra **H**igh **M**olecular **W**eight **P**olyethylene) sliding core articulates between two highly polished metal endplates, imitating the movement of the nucleus within its annular containment.

In September 1984, following mechanical testing at the Institut für Leichtbau und ökonom, Verwendung von Werkstoffen, Dresden [10], the SB Charité I artificial disc was implanted for the first time at the Charité Hospital in Berlin. The endplates of this model were made of 1-mm-thick URX2CrNiMoN 18.12 steel and the sliding core was produced from Chirulen UHMWPE. For fixation in the bony vertebral endplates, the artificial disc incorporated first 11 and later 5 sharp anchoring teeth for cementless fixation.

In 1985, due to axial migrations, the artificial disc was modified to SB Charité II (Fig. 1B). It was based on the same functional principle as type I, but the metal endplates were enlarged with bilateral "wings", to improve the support of the implant on the bony endplates of the vertebral bodies. The endplates incorporated three ventral and two dorsal anchoring teeth. Mark II was manufactured of stainless steel and later of EMO titanium sheeting (only for biomechanical testing) [10]. Both the mark I and the mark II implants were manufactured in the former German Democratic Republic (GDR) only, and were never commercially available. The usage was confined to the Charité Hospital.

Fractures in Mark II endplates and insufficient instrumentation for implantation were the reasons that the authors contacted LINK for production of a state of the art implant version of the artificial disc, the design of which has basically remained unchanged since LINK started production in 1987.

The endplates of the LINK SB Charité III disc (Fig. 2) are of cast CoCrMo alloy (ISO 5832/IV; ASTM F75–82)

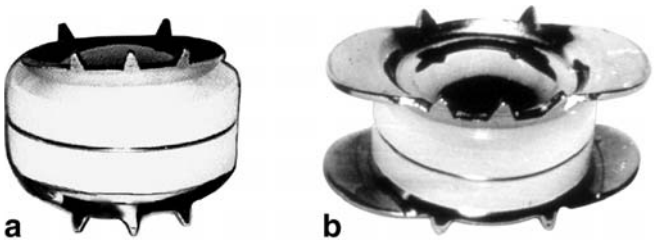

Fig. 1 **A** SB Charité I. **B** SB Charité II

Fig. 2 SB Charité III

for optimal static mechanical properties, each with three anchoring teeth ventrally and dorsally. Originally three sizes of metal endplates in parallel and 5° angulation were produced [11]. In 1998 a size 4, and in 1999 an even larger size 5, was added to allow for an optimal choice of the largest endplate giving best possible support on the cranial and caudal vertebral body (Fig. 3).

To improve lordotic reconstruction, additional angulated endplates of 7.5° and 10° were introduced in 1999. Endplates of the same size but with different lordotic angulations may be combined with each other, allowing an even more precise reconstruction of the lumbar lordosis. UHMWPE sliding cores (ISO 5834/II; ASTM 648–83) of various heights are available for each endplate size to allow for physiological restoration of the intervertebral disc space (Fig. 3).

Since 1987, approximately 4000 SB Charité artificial discs have been implanted, and spine surgeons in Germany, France, the UK and the Netherlands have reported [12, 15, 16, 21] on results of 10 years or more follow-up.

The bioactive coating

To improve the anchoring of the endplates and to establish a mineralized connection between bone and implants, the endplates receive on their outside a "bioactive double coating" (Fig. 4). This concept has been successfully tested in an animal study [24, 25] and in non-cemented joint replacements such as pressfit hip cups, ankle joint prostheses and dental implants [23].

The coating consists of three layers. The first two layers are of commercially pure titanium (Ti) – the first layer provides a special strong bond between the cobalt-chrome endplate and the coating, and the second layer of plasma-sprayed Ti provides the desired pore size of 75–300 µm. The third coating consists of a layer of calcium phosphate

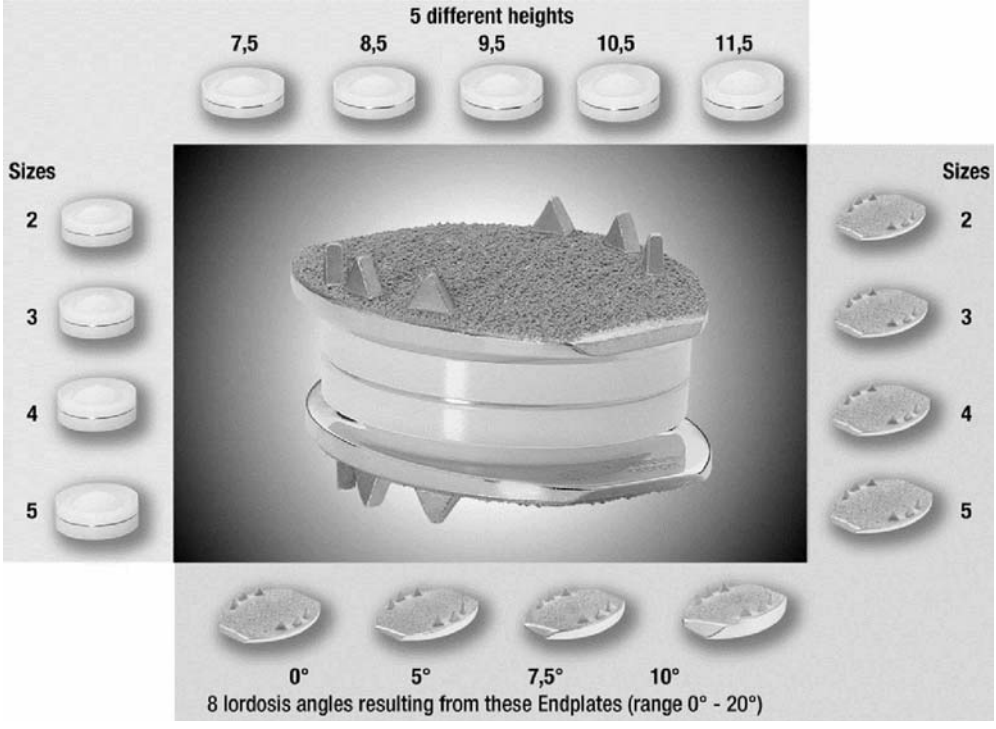

Fig. 3 Range of size, CoCr endplates and UHMWPE (**U**ltra **H**igh **M**olecular **W**eight **P**olyethylene) sliding cores

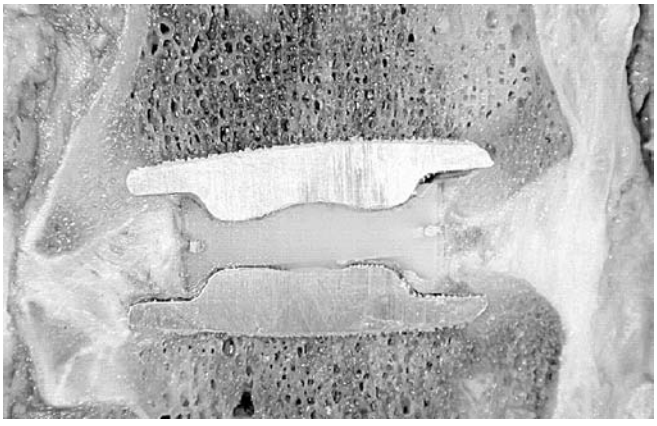

Fig. 4 The SB Charité "bioactive double coating" showed mean ingrowth of 47.9% in a baboon study (coronal diamond cut section, courtesy of Dr. McAfee, Baltimore)

(CaP). This is applied to the Ti surface in an electrochemical process that results in:

1. A thin layer of 10–25 µm
2. The retention of the open-cell structure of the Ti coating
3. A mechanically strong bond, which is necessary to cope with the stresses applied on the coating during implantation

The open-cell porous structure provides an optimal base for the ingrowth of bone cells. The attachment of osteoblasts on the structured surface is accelerated by the bioactive CaP coating (Fig. 5). This avoids at the same time the growth of connective tissues onto the implant.

Biomechanics

Sagittal rotation, lateral rotation, axial rotation and range of motion

Flexion and extension in the lumbar spine constitutes an arc-like motion combining sagittal rotation with sagittal translation [27]. The position of the instantaneous axis of rotation (IAR) point is not constant, and changes depending on the joint position.

This important aspect of spinal biomechanics is replicated in the functional motion of the SB Charité, due to its three-component set-up, which incorporates a floating sliding core, whose convex surfaces are encased in the concave cavities of the metal endplates (Fig. 6).

In vitro evaluations carried out by Ahrens [5, 24] of the mobility of the L4/L5 motion segment in fresh frozen cadavers with most ligamentous structures intact have revealed a similar mobility in those with and those without implanted SB Charité disc, in extension and flexion as well as right and left bending.

Only figures for the range of motion (ROM) in torsion (Table 1) for moments greater than 5 Nm were different. This seems to be related to the severed anterior ligament, the ventrally incised annulus fibrosis and the removed disc tissue. Clinical experience established that the soft-tissue structures adapt to that situation over a period of time.

Clinical evaluations have confirmed the values Ahrens found; David and Lemaire have both documented retained motion in their medium- and long-term follow-ups [14, 21].

Translation and the zygapophysial joints

Translation is a movement that causes all points in a body to move in parallel in the same direction and to the same extent as the force [7]. During flexion in an intervertebral segment two types of movement take place:

1. The center of nucleus moves dorsally
2. The cranial vertebral body translates ventrally

The major movements of an intervertebral segment in flexion and extension are sagittal rotation plus translation. The center of rotation changes and the path of the various centers of rotation is a centrode [8, 18] (Fig. 7).

In flexion and extension, the unconstrained sliding core of the SB Charité mimics this kind of movement (Fig. 8).

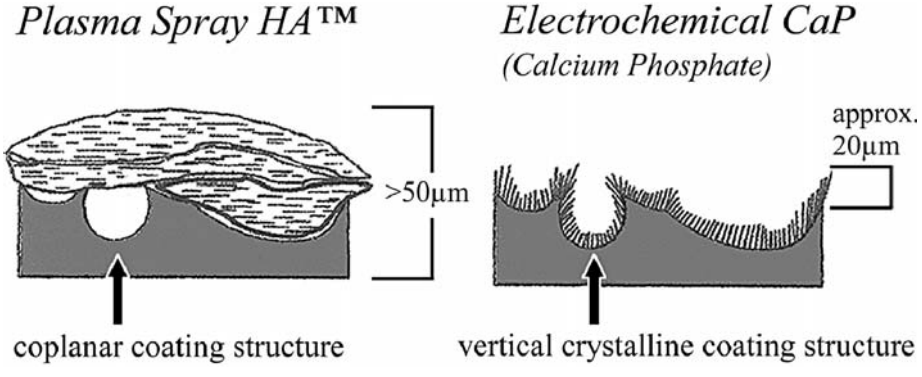

Fig. 5 CaP coating on porous implant surface

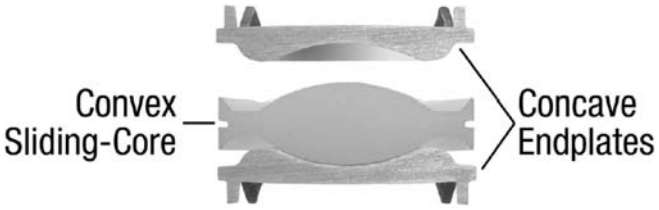

Fig. 6 Free-floating biconvex sliding core encased in concave endplates

Table 1 Mean range of motion in degrees (±SD) at level L4-L5, as published by Ahrens et al. [5]

	Maximum load (Nm)	Lumbar disc	Artificial disc
Extension	12	3.49 (0.82)	3.27 (0.83)
Flexion	12	7.72 (1.74)	9.78 (1.48)
Left flexion	8	2.78 (1.78)	2.37 (0.57)
Right flexion	8	5.24 (2.54)	7.41 (2.65)
Torsion	7	1.66 (0.74)	3.01 (0.73)

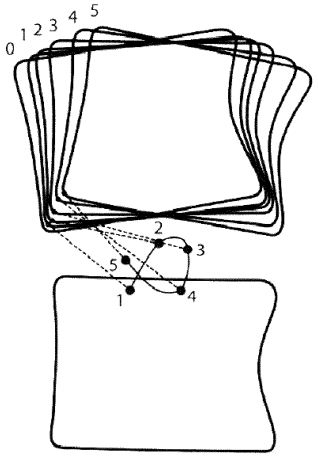

Fig. 7 Rotation and translation in the natural disc

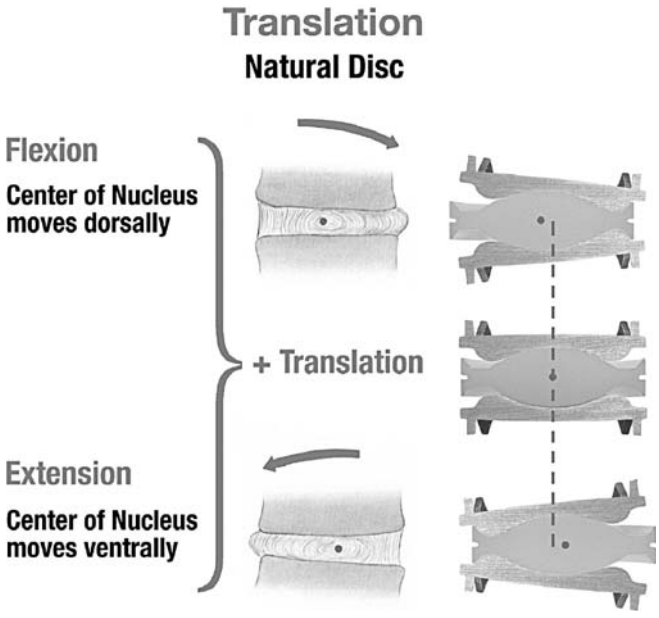

Fig. 8 SB Charité artificial disc showing rotation and translation

In lateral bending, coronal rotation is combined with translation. The mobile sliding core of the SB Charité mimics such movements as well.

In axial distraction or compression there is a possibility of axial translation. Such translation is possible in the sliding core of the modular SB Charité artificial disc, as it is attached to neither the superior nor the inferior endplate of the artificial disc.

If a vertebral body slides forward, the inferior articular processes are resisted by the superior articular processes of the inferior vertebral body. This resistance is transmitted to the vertebral body through the pedicles and the posterior elements and anterior vertebral column interact [9]. Such motion can be duplicated in the SB Charité without unphysiological stress, only due to the unconstrained three-component set-up. An artificial disc must allow the abovementioned motions simultaneously, otherwise zygapophysial joints and/or disc prostheses undergo unphysiologic/mechanically unfavorable stresses. Flexion, for instance, combines [7, 9]:

1. Upward sliding movement of inferior articular processes
2. Tension of zygapophysial joint capsule
3. Tension of ligaments of intervertebral joint: (i) supraspinous and interspinous ligament, (ii) ligamentum flava
4. Contribution of longissimus thoracis pars lumborum muscle

Adams et al. calculated that the disc contributes 29% of resistance to flexion, while the capsule contributes 39% and the ligaments 32% [1]. Consequently, one can state that capsule and ligaments together dominate the action of movement. Thus the soft tissue structures under high stress must have a compensating counter element in the anterior vertebral column to avoid strain and noxious movement. In the natural disc it is the nucleomobility, in the SB Charité this compensating element is the unconstrained sliding core.

Joint replacement in diarthrodial joints has led this approach to mimicking physiologic movement. For instance, mobile bearing knee designs offer the advantage [19] of maximum conformal geometry, while protecting the interface between bone and implant from high stress, and by following the pattern of movement that the ligaments dictate, they offer advantages in cases of component malalignment.

And just like the contemporary mobile bearing knee designs (Fig. 9), the SB Charité artificial disc has a mobile sliding core which, in its degree of mobility, defines the required interaction between soft tissues, facet joints and

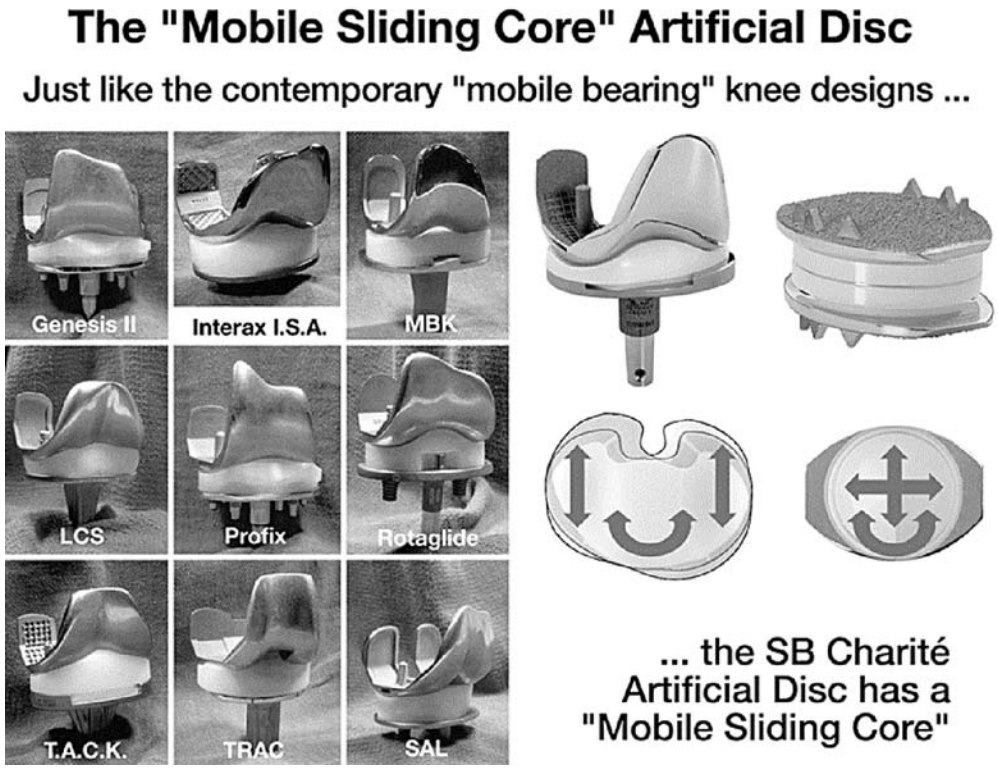

Fig. 9 Just like the contemporary "mobile bearing" knee designs, the SB Charité artificial disc has a "mobile sliding core"

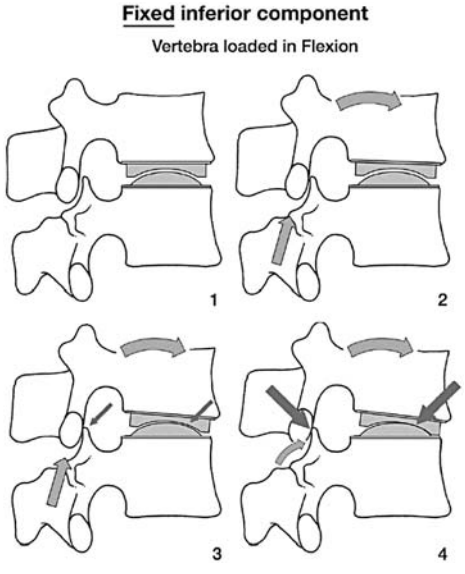

Fig. 10 Fixed inferior component: vertebra loaded in flexion

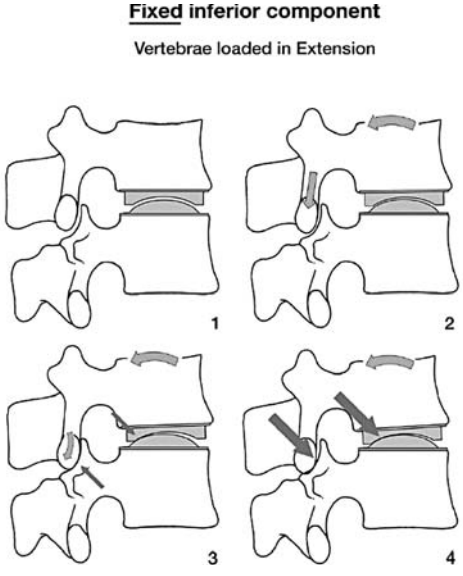

Fig. 11 Fixed inferior component: vertebra loaded in extension

implant geometry, to maintain a stable articulation and thus a physiologic restoration of the lumbar segment.

If the vertebra were loaded in flexion and the artificial disc's components allowed no translational movements, what would happen to the zygapophysial joints? The answer is: impingement and stress rising ... due to the inability of the disc's intermediate components to move posteriorly (Fig. 10).

In extension similar kinematics apply in reverse sequence (Fig. 11).

Nature has used the simple ball and socket joint in the vertebra, but only in species where weight bearing is not important, for example in fish, and just to provide mobility of the vertebral column. Wherever weight bearing is important, intervertebral adjustment is required to compensate for the rocking movements of the vertebrae [7].

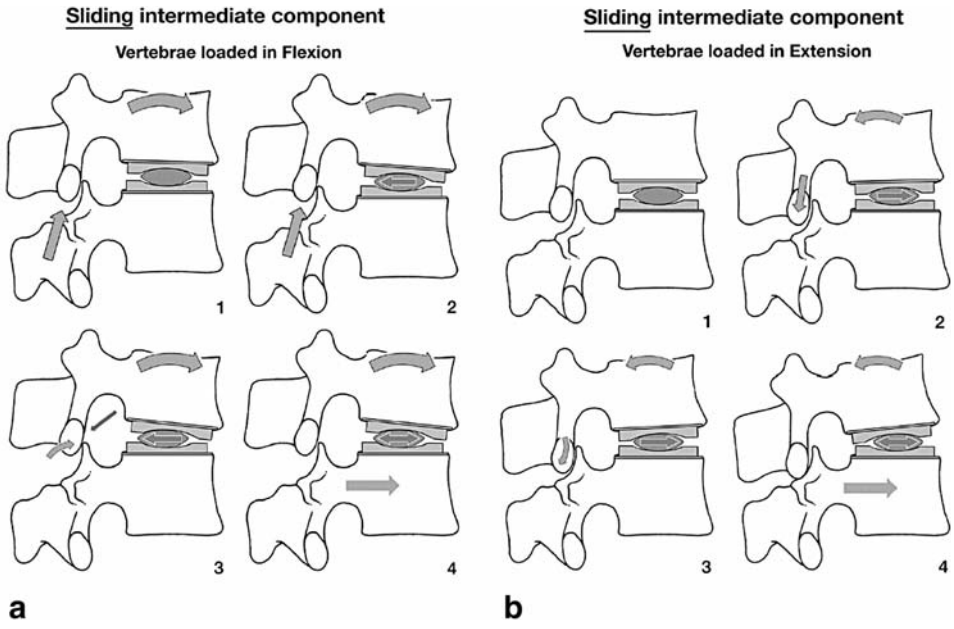

Fig. 12 **A** Sliding intermediate component: vertebrae loaded in flexion. **B** Sliding intermediate component: vertebrae loaded in extension

In a biomechanically sound artificial disc set-up, a sliding component would give way, allowing adjustment of the two adjacent vertebral bodies to each other and avoiding stress risers in the zygapophysial joints (Fig. 12).

Proper biomechanical function and the best possible relationship between anterior (implant loaded) and posterior elements requires, of course, correct implant positioning, which means central positioning in the sagittal and coronal planes. This is one of the basic requirements for successful disc replacement, and is especially necessary to avoid facet problems, as clinical follow-up reports have documented [12, 15, 16, 21, 22].

Biomechanical testing

Several biomechanical tests have been performed with the SB Charité artificial disc. As no mechanical problems with the cobalt-chrome endplates have ever been reported, tests concentrated on the endurance of the UHMWPE sliding core [2, 3, 4].

The University of Kiel as well as the Orthopedic Research Laboratory of the Mt. Sinai Medical Center in Cleveland/Ohio independently performed FDA- (Food and Drug Administration)- required dynamic tests under similar conditions: sliding cores size 2 (second smallest size), 7.5 and 9.5 mm in height were tested with 2.5- and 4.5(!)-kN loads.

Kiel concluded: "None of the specimens tested failed," and "For all testing phases and loads, the creep rates were found to be low" [17]. Cleveland stated: "...under normal in vivo conditions the permanent deformation of the core is not expected to reduce the available articulating surface or result in premature failure of the device due to significant cold-flow or delamination" [28].

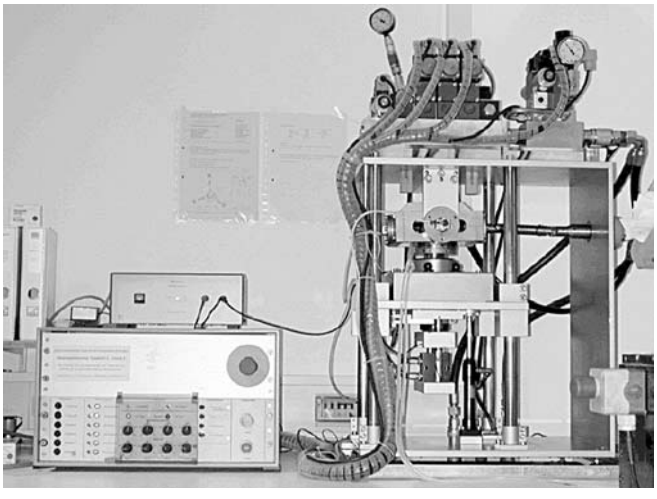

Fig. 13 Simulator test set-up at the Laboratory for Biomechanic Testing, Munich

Most recently, a functional 10 million cycles simulator test was performed at the Laboratory for Biomechanical Testing Grosshadern/Munich (Fig. 13).

The report stated: "An extremely mild abrasive wear was recorded, of negligible volume..." and, "The result of this tribologic investigation is considered to be very positive, especially in light of the 10 million cycles and the demanding test set-up" [20].

Clinical experiences have confirmed the results of such tests. Staudte as well as Zeegers reported that no polyethylene wear particles were detected when surrounding tissues taken during revisions were histomorphologically examined, provided the implants had been properly sized and implanted (personal communications, H-W Staudte/W Zeegers, 1998).

Whether or not wear debris is produced due to improper size or position, progressive bone lysis as seen in patients with aseptic loosening of joint replacements in diarthrodial joints is still unlikely, and has not been reported. This is most probably due to the absence of synovial membrane in the intervertebral joint [29].

Such bone resorbing factors as interleukin-1 (IL-1), interleukin-6 (IL-6), tumor necrosis factor-X (TNF-X), prostaglandin E_2 (PGE_2) and collagenase are produced by activated macrophages and fibroblasts [6, 13, 26]. As the synoviocyte-containing membrane, resembling macrophages and fibroblasts, is not present in amphiarthrosis [A], it can be hypothesized that such synovial absence is the reason for the absence of the "particle disease" in the intervertebral space.

To avoid cold-flow of the polyethylene core, it is important to always choose the largest possible size of implant and to use the appropriately angled endplates, so that the internal surfaces of the endplates encase the UHMWPE sliding core in a parallel fashion, thus distributing the forces evenly.

Conclusion

Biomechanical tests and more than 10 years of clinical experience at various centers have demonstrated that the LINK SB Charité artificial disc is a safe and effective operative treatment for pain of discogenic origin, provided the indications are right, the recommended intervention techniques are followed and implant choice is appropriate.

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