Development, in vitro and in vivo evaluation of a new artificial disc prosthesis (Kineflex/Centurion disc) and the relevant insertion instrumentation for the human lumbar spine

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A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand,
in fulfillment of the requirements for the degree of
Doctor of Philosophy

Johannesburg, 1st November 2008

DECLARATION

I, Ulrich Hähnle, declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Ulrich Hähnle 27 October 2008

I certify that the studies contained in this thesis have the approval of the Human Research Ethics Committee of the University of the Witwatersrand, Johannesburg.

Human Research Ethics Committee protocol number:
Protocol M03-06-13 Investigator: Dr U.R. Hähnle
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Hospital approval: Nedcare Linksfield Hospital, signed by the Hospital General Manager, B Bedford

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DEDICATION

First of all I want to thank my wife, (Prof.) Karen Sliwa, for her emotional and professional support. Without her, I would not have started this project, never mind bring it to an end.

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PUBLICATIONS AND PRESENTATIONS ARISING FROM THIS STUDY

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Ulrich R. Hähnle, Karen Sliwa, Ian R. Weinberg, Barry M.B.E .Sweet, Malan de Villiers, Geoffrey P. Candy. Lumbar Disc Replacement for Junctional Decompensation After Fusion Surgery: Clinical and Radiological Outcome at an Average Follow-Up of 33 Months. SAS Journal, Summer 2007;1:85-92. DOI:SASJ-2007-0006-RR.

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Congress presentations 2003:

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Hähnle UR and Weinberg IR. Lumbar disc prosthesis as salvage procedure for failed adjacent level surgery. SA Spine Society Congress, Johannesburg, June 12-14, 2003.

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Hähnle UR and Weinberg IR. Lumbar disc replacement as salvage procedure for failed posterolateral fusion surgery. 49th SAOA Congress, Cape Town, September 1-5, 2003.

Hähnle UR and Weinberg IR and De Villiers M. Centurion Disc – a new mechanical lumbar disc prosthesis. 49th SAOA Congress, Cape Town, September 1-5, 2003. Poster.

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Hähnle UR and Weinberg IR. Lumbar disc replacement as salvage procedure for fusion surgery. SA Spine Society Congress, Windhoek, June 17-19, 2004.

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Hähnle UR and Weinberg IR. Lumbar disc replacement as salvage procedure for fusion surgery. 50th SAOA Congress, Pretoria, September 6-10, 2004.

Hähnle UR and Weinberg IR and De Villiers M. Short term results with the Centurion Lumbar Disc. 50th SAOA Congress, Pretoria, September 6-10, 2004.

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Hähnle UR and Weinberg IR. Lumbar disc replacement for junctional decompensation after fusion surgery.
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Hähnle UR and Weinberg IR and De Villiers M. One to two year results with the Kineflex (Centurion) lumbar disc prosthesis. P70: World Spine III, Rio de Janeiro, Brazil, 31 July- 3 August 2005.

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Hähnle UR, De Villiers M, Weinberg IR. Kineflex (Centurion) lumbar disc prosthesis: two year results. Spinal Arthroplasty Society (SAS 6), Montreal, Canada, May 9-13, 2006.

Hähnle UR and Weinberg IR. Disc replacement after fusion surgery: correlation between clinical outcome and spinal/pelvic alignment. P036: Spinal Arthroplasty Society (SAS 6), Montreal, Canada, May 9-13, 2006.

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Congress presentations 2007:

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Hähnle UR, Weinberg IR and Candy GP. Juxta-fusional lumbar disc replacement: Correlation between clinical outcome and Spinal/Pelvic alignment. SA Spine Society Congress, Durban, South Africa, June 7-9, 2007.

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Hähnle UR, Sliwa K, Weinberg IR, De Villiers M and Candy GP. Is degenerative spondylolisthesis a contra-indication for total disc replacement? Kineflex Lumbar Disc in seven patients with 24 months follow up. P62 Spinal Arthroplasty Society (SAS 8), Miami, USA, May 6-9, 2008.

ABSTRACT

Background:
Lumbar disc replacement is a rapidly expanding surgical treatment modality for long-standing back and leg pain due to intervertebral disc degeneration. Compared to fusion surgery, it has the advantage of preserving segmental mobility, but convincing evidence of superiority over fusion surgery is missing.

As part of this research project, I participated in the development of a new intervertebral disc prosthesis, with several international patents attached to the design of the prosthesis, the instrumentation and the insertion technique. The Kineflex (Centurion) lumbar disc is a mechanical, un-constrained, re-centering disc prosthesis developed in South Africa. After the development and manufacturing of the disc, prototype test racks were custom-made at the premises of the manufacturer and the disc was extensively tested for mechanical wear and fatigue. The first implantation took place in October 2002. I prospectively captured all cases performed by our centre, with documentation including demographic data, co-morbidities, clinical history, symptoms and signs. The completed consent forms were filed. The outcome was monitored, pre-operatively and in follow-up, with complete radiological documentation of all radiographs on JPEG files. Clinical outcome results were documented using two different internationally validated questionnaires as well as our own questionnaire, which expands further on work and demographic details, previous operative and conservative treatment, and satisfaction with the treatment outcome.
The aim of the this project was to develop a disc prosthesis that is suitable and safe for human implantation into the lumbar spine disc space, even in severely advanced disc degeneration and to verify this in the outcome studies presented in this thesis. Existing indications and contra-indications for artificial disc replacement were critically evaluated regarding their validity for this particular implant.

Results:
Chapter 3 elaborates on the extensive pre-clinical mechanical wear and fatigue testing protocol to which the Centurion (Kineflex) lumbar disc prosthesis was

subjected. The results of this testing protocol, together with our early clinical outcome results, formed the basis for the awarding of the European quality recognition (CE-Mark). In these extensive *in vitro* studies, we were able to show the durability of the Kineflex disc prosthesis in the long term. This, together with our initial clinical outcome results, formed the basis for the acceptance into a "prospective, randomized, multicenter *Food and Drug Administration investigational device exemption study* of lumbar total disc replacement with the KINEFLEX Lumbar Artificial Disc *versus* the CHARITÉ™ Artificial Disc".

Chapter 4 is compiled from an invited submission to a new book on motion preservation surgery in the human spine, edited by leading spine surgeons in the field (James J. Yue, Rudolf Bertagnoli, Paul McAfee, and Howard An) and published by Elsevier Publishers: Chapter 42: Kineflex. In this chapter, an overview is given of the ideas behind the Kineflex disc development, as well as of the insertion instrumentation used for disc implantation. It further reports on early clinical outcome results of the first patients implanted with the device in our centre (the first 40 implantations worldwide were all performed by me).

Chapter 5, our first peer reviewed international publication, reports on clinical and radiological 2-year outcome results of our first 100 patients. With the Kineflex implant, we could demonstrate equally good radiological placement accuracy in patients with severe and less severe disc degeneration of the index level, rendering the implant suitable even in severe degeneration of a spinal motion segment.

Chapter 6 and Chapter 7 of this thesis consist of two further peer-reviewed publications. They both report on so-called "off-label" patient sub-groups in our disc replacement series.

In Chapter 6 we present the second published series on a larger group of patients presenting with adjacent segment disease after previous lumbar fusion surgery as well as the first publication, which investigated the radiological changes in alignment parameters secondary to the disc replacement surgery in this patient group.

Chapter 7 consists of the first published series on patients with “degenerative spondylolisthesis” treated with disc replacement surgery. A detailed description of the operative reduction technique is provided, which is unique to the Kineflex disc and its insertion instrumentation. In this pilot study, two-year results on a limited patient group are presented.

This thesis concludes with the overall discussion in Chapter 8. It outlines the current knowledge on artificial disc replacement and places my results into perspective with recent discoveries published in the literature. It finishes with my assessment of what future research should concentrate on.

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NOMENCLATURE

ALIF	Anterior Lumbar Interbody Fusion
ASD	Adjacent Segment Disease
ASTM	American Standard for Testing and Material
CCM	Cobalt Chrome Molybdenum
CE	Conformit Europeane
DDD	Degenerative Disc Disease
DHR	Disc Height Reduction
DPQ	Dallas Pain Questionnaire
DSPL	Degenerative Spondylolisthesis
FDA	Food and Drug Administration
FSU	Functional Spinal Unit
HREC	Human Research Ethics Committee
Kineflex Disc	Centurion Disc
KPD	Kineflex Prosthetic Disc
LBP	Low Back Pain
LL	Lumbar Lordosis
MRI	Magnetic Resonance Investigation
ODI	Oswestry Disability Index
OT	Osteotomy
PI	Pelvic Incidence
PLIF	Posterior Lumbar Interbody Fusion
PT	Pelvic Tilt
ROM	Range Of Motion
SF 36	Quality of life score
SMS	Spinal Motion Segment
SLL	Segmental Lumbar Lordosis
SS	Sacral Slope = Sacral Tilt (ST)
ST	Sacral Tilt = Sacral Slope (SS)
TDR	Total Disc Prosthesis
TDP	Total Disc Replacement
TLIF	Transforaminal Lumbar Interbody Fusion
VAS	Visualized Analog Score

1. INTRODUCTION AND LITERATURE REVIEW: SURGERY FOR LOW BACK PAIN

1.1. Aetiology and treatment of low back pain

1.1.1. Epidemiology and social impact of low back pain

During their lifetime, 70 - 85% of people have back pain at some stage. Low Back Pain (LBP) is the major cause for absenteeism from work in western societies. In Sweden, 11 - 19% of all annual sickness leave is taken by people with back pain. In the USA, back pain is the most common cause of activity limitation in people younger than 45 years, the second most frequent reason for visits to a physician, the fifth ranking cause for admission to hospital, and the third most common cause for surgical procedures. About 2% of the US workforce is compensated for back pain each year (Andersson, et al., 1999).

Sixty to seventy percent of back pain patients recover by six weeks and 80 - 90 % by 12 weeks. Recovery after 12 weeks is slow and uncertain. Fewer than half of those individuals disabled for longer than six months return to work; after two years of absence from work, the return-to-work ratio is close to zero. Compensation has a negative influence on the length of disability. Patients with lumbar sprains and strains recover within 14.9 months from injuries that occur on-duty, but within 3.6 months from injuries that happen off-duty. Patients, who had an operation, returned to work at 9.3 and 4.4 months respectively (Andersson, et al., 1999).

A recent systematic review on LBP costs in different reported data from Australia, Belgium, Japan, Korea, the Netherlands, Sweden, the UK and the United States (Dagenais, et al. 2008[2]) showed that the largest portion of direct medical cost was spent on physical therapy and in-patient services, followed by pharmacy and primary care. The yearly per capita cost of LBP is substantial in these countries (Australia - 474 AUD; Netherlands - 399 Euro; Sweden - 381 Euro; UK - 209 Pounds; US - 335 USD) (only direct costs), but the separation into direct and indirect costs varied widely between studies and countries. In 1998, the direct health care expenditure in

the United States for individuals with back pain was estimated to be over 90 billion US $ (Luo, et al. 2004[3]).

1.1.2. Aetiology of low back pain

The cause and therefore the treatment of "mechanical" low back pain remains unsolved, despite almost a century of endeavour. It is now generally accepted that some kind of failure of the intervertebral disc is central to causation (Mulholland RC, 2008[4]).

In 1950, Barr suggested in a review article that backache was often associated with mechanical instability of a degenerative disk lesion (Barr JS, 1950[5]).

In 1954, Harris and MacNab fully addressed the central role of the disc in causing low back pain and sciatica. Although the term instability was used in the paper, it did not suggest that excessive movement is present - indeed translational movement is deemed to be unusual. The term "unstable" was used to indicate a disc whose movement was irregular (Harris & McNab, 1954).

In 1964, Harmon (1964) described the clinical triad of spinal instability including: low back, gluteal and thigh pain as follows: "Spinal instability refers to a low back-gluteal-thigh clinical triad of symptoms that may be accompanied (overt cases) by incapacitating regional weakness and pain. This was the effect of disc degeneration with or without disc hernia. Some could be asymptomatic or slightly symptomatic when instability was compensated by muscle and ligament control. It does not refer to spinous process or laminal hypermobility, which some surgeons like to demonstrate on the operating table; nor does this clinical concept parallel the common spinal hypermobility, which was the product of spinal intervertebral disc degeneration, demonstrable in flexion-extension filming of the region, since the anatomic hypermobility is not always productive of symptoms."

Influenced by the increasing influence of basic science and mechanical engineering, Pope and Panjabi developed a biomechanical concept of spinal instability developing as a consequence of failure of spinal restraining structures resulting in a loss of

stiffness (Pope & Panjabi, 1985[8]). Panjabi later concluded that increased movement was not necessarily a feature of what he termed instability, but a reduction of the neutral zone was (Panjabi MM, 1992[9]).

However, in a more recent paper, he has abandoned the concept of instability altogether and ascribes chronic back pain as being caused by ligamentous sub-failure injuries leading to muscle control dysfunction (Panjabi MM, 2006[10]).

The term instability is still widely used in degenerative disc disorders, indicating the fact that disc degeneration leads to decreased, rather than increased movement, as the term instability would imply. Despite the introduction of pedicle screw into fusion surgery, with significantly increased rigidity and decreased non-union rates, clinical results of fusion surgery in low back pain has not improved. It was well recognized that clinical success was unrelated to the success of the fusion. Pseudarthrosis was as common in successful patients as it was in those who had failed (Mulholland RC, 2008[4]).

In his review article, Mulholland (2008[4]) further elaborates on the mechanism by which pain was generated in the intervertebral disc. He mentions that although there was no correlation between the degree of degeneration and the severity of back pain, it was well recognized that changes in the disc play a major role in low back pain. The disc has two biomechanical roles: it must transmit load and it must allow a controlled range of movement, so that such movement does not compromise the adjacent neural elements. The normal disc behaves like a fluid filled bag and transmits load uniformly across the surface of the disc and to the end-plate. In any position of the spine, load is transmitted uniformly over the end-plates.

In any diathrodial joint (hip, knee, etc.), high spot loading is avoided by the design of a joint that guarantees an even pattern of load transmission. Disturbance of the anatomy of the joint, such as meniscectomy in the knee, or destruction of the cartilage by disease (arthritis, infection) in other joints, leads to disturbance in normal weight transmission, and produces pain. An appropriately planned osteotomy, which alters the weight transmission, might result in pain relief. If we accept that in load-

bearing joints overall an altered load bearing pattern produces pain, then we can more easily accept that this concept also applies to the disc. This load transfer is to the underlying vertebra. The vertebrae are well innervated and sensitive to excessive pressure. Another important consequence of the uniformity of distribution of load transmission across the surface of the disc is that it transmits load to the annulus, producing a tension in the annulus and converting it into a load bearing structure. It is established that disc degeneration alters the isotropic nature of the disc and, as a consequence, load transmission over the end-plates becomes irregular, leading to high spot-loading, particularly when associated with certain positions (Mulholland RC, 2008[4]).

In the 1990s, Mcnally et al (1992 & 1996) developed a technique of performing a profilometry immediately before routine discography on all patients undergoing fusion surgery. They could demonstrate that discs with missing nuclear support (annular loading) or discs with very focal areas of high load were the painful discs. (Mcnally & Adams, 1992[11]; Mcnally, et al.1996[12]).

1.1.3. Benefits of fusion surgery

Spinal fusion as a treatment for back pain was in vogue from the beginning of the last century, with little thought given to what the source of the pain might be. None of the papers dealing with fusion mention abnormal movement (instability) as a cause of pain until the nineteen-fifties (Mulholland RC, 2008[4]).

Fusion surgery has been accepted as the "Golden Standard" for treatment of disabling low back pain, but scientific evidence to support this is still scarce. Spinal fusion emerged early in the last century as a means of dealing with spinal infection, later being extended to fractures and tumors, and then to cases of spinal deformity. The intention was to restore segmental stability and spinal alignment. Spinal fusion for degenerative disease is a more recent extension of the indication. Nonetheless, it is one that became established by default and in the absence of any viable alternative. One might argue that if ethics approval for this procedure were sought now, this would be unlikely to be forthcoming (Turner, et al. 1992[13]).

Recuperation is lengthy and slow, and return to work is considerably delayed. The posterior approach to the spine inevitably causes damage to the paravertebral muscles, which are so important for subsequent functional recovery. Harvesting autologous bone from the pelvis, for which there is no scientifically proven, satisfactory substitute, can cause chronic donor site pain. The reported incidence of these complications varies (Boeree, N. 2007[14]).

Two randomized studies have failed to detect a definite, significant advantage of spinal fusion surgery over state of the art, conservative treatment, including aggressive exercise and cognitive therapy. (Brox, et al. 2003[15]) (Fairbank, et al. 2005[16]). Nevertheless, both studies suffered from severe limitations. The follow-up was short, being one and two years respectively. The first study had only 64 patients randomized to the two groups. In the Fairbank study, the crossover of 28%, from the "Intensive Rehabilitation Group" to the Spinal Stabilisation Group, was unacceptably high.

Recently, Anderson et al (2008[17]) published a long term follow up (11-13 years) of patients who originally had been randomised to two groups: one had undergone uninstrumented posterolateral fusion, the other had undergone instrumented posterolateral fusion with pedicle screw instrumentation. They managed to follow-up results on 83% (107 patients) of their original study cohort. Patients maintained significant improvement in Dallas Pain Questionnaire (DPQ), Oswestry Disability Index (ODI) and SF36 - quality of life score. About 70% of patients in both groups answered positively to the global outcome question. This was despite a high percentage of patients having undergone previous decompression surgery. Furthermore, there was no significant difference between the two groups (Andersen, et al. 2008[17]).

1.1.4. Long term problems with lumbar fusion

1.1.4.1. Adjacent Segment Degeneration (ASD)

ASD means the degeneration of the intervertebral disc next to a spinal fusion. It was first described in the 1950s, but it was only in the 1980s and 1990s that it became a major consideration (Leong, et al 1983[18]; Lehmann, et al. 1987[19]; Penta, et al. 1995[20];

Hambly, et al 1998[21]; Kumar, et al. 2001a[22]; Gillet, et al. 2003[23]; Park, et al. 2004[24]). With the increase in fusion surgery, surgeons realized that ASD might pose a serious problem in the long term.

Lehmann (Lehmann, et al. 1987[19]) presented a cohort of 62 patients with an average follow-up of 33 years after a posterior lumbar fusion. Fifteen percent had undergone repeat lumbar surgery, 42% had spinal stenosis, and segmental instability was present in 45%. In many patients, the ASD was not clinically symptomatic.

Kumar et al. published a matched control study in 2001 with patients undergoing surgery for DDD; one group with fusion, the other without fusion. At 30 years mean follow up, using validated outcome questionnaires, they found similar clinical outcomes in patients in the two groups (fusion group and non-fusion group), despite an incidence of ASD twice as high in the fusion group as in the non-fusion group (Kumar, et al. 2001a[22]).

In a literature review of 22 retrospective studies on ASD after lumbar spinal fusion, Park et al. (2004) detected a wide range of radiolocical ASD reported (5 - 100%). In contrast, the reported incidence of symptomatic ASD is only 5 - 19%). Suggested risk factors for ASD were: instrumentation, fusion length, sagittal mal-alignment, facet injury during surgery, age and pre-existing degenerative changes. (Park, et al. 2004[24])

In two studies, the patients were treated with Anterior Lumbar Interbody Fusion (ALIF) surgery (Leong, et al. 1983[18]; Penta, et al. 1995[20]). At 13 and 10 years post-operatively, the fusion rate was 55% and 84% and ASD was present in 52% and 32% of patients, respectively, with no difference in single and multiple level fusions. No cases of impotence occurred in Leong's study and non-union did not jeopardize the clinical outcome (Leong, et al. 1983[18]). Nevertheless, spinal stenosis at the adjacent level was rare (Penta, et al. 1995[20]).

Schulte et al., after an almost 10 year follow-up, re-examined a group of 40 patients who had undergone a 360 degree fusion (2/3 for Degenerative Disc Disease (DDD) - Group 1); 1/3 for lytic spondylolisthesis - Group 2). Clinical outcome showed an improvement of 44.6% in ODI and 43.8% in VAS, with a tendency towards better

results in Group 2. Fusion rate was 95%. Disc height of the first cephalad adjacent segment in all patients was reduced by an average 20% (second cephalad level 15%). A tendency towards more Disc Height Reduction (DHR) in the degenerative group was observed. Advanced age correlated with advanced DHR. Multiple-level fusion led to a more pronounced DHR than 1-level fusion. There was no correlation between the clinical outcome and DHR (Schulte TJ, et al. 2007[25]).

Jun Young Yang (2008) determined the impact of ASD on clinical outcome in patients who had undergone 1, 2 or 3 level posterolateral fusion for degenerative spondylolisthesis, spinal stenosis or degenerative lumbar kyphoscoliosis. He graded ASD according to the UCLA grading scale for intervertebral disc degeneration. After short follow-up they found that ASD is more severe in multi-level fusion surgery and clinical outcome deteriorated with the severity of change in ASD (Yang JY, et al. 2008[26]).

1.1.4.2. Sagittal imbalance

There is increasing evidence that loss of lumbar lordosis or sagittal imbalance are contributing factors in the development of low back pain (Lazennec, et al. 2000[27]; Kumar, et al. 2001b[28]; Jang, et al. 2007[29]; Soegaard, et al. 2007[30]); but it was only recently that Roussouly presented a classification of sagittal lumbar alignment (Roussouly, et al. 2005[31]).

TDR, as the ALIF procedure, by restoration of anterior disc height, more than posterolateral fusion, has a stronger potential than posterolateral fusion procedures to normalise sagittal imbalance through a single approach (Hähnle, et al. 2007[32]).

1.1.5. Summary on fusion surgery

Whereas a successful fusion reliably protects the neural structures at the fused levels and abolishes the pain originating from abnormal motion at that particular FSU, there are considerable drawbacks associated with fusion, viz.:

- By abolishing motion in one FSU, the other lumbar FSUs have to compensate for the loss of motion, leading to ASD.
- An inadequate restoration of the sagittal spinal balance during fusion surgery may promote the early onset of ASD.
- Posterior fusion surgery, unless performed in conjunction with posterior OT surgery, has a limited potential of treating the flat back deformity that is often associated with DDD.
- Posterolateral fusion surgery causes significant damage to the spinal muscles and it carries considerable risk of developing non-union.
- Posterior spinal fusion surgery has the potential for spinal nerve root injury. This risk increases in cases where extensive recess decompression is required or when instrumentation is added.
- Anterior fusion surgery is very powerful in restoring lumbar lordosis. The non-union rate is considerable, especially in multilevel anterior fusion surgery.
- Combined anterior and posterior fusion surgery can achieve good spinal balance with high fusion rates, but it is large surgery, with the combination of risks for complications resulting from the anterior and posterior surgery.

Therefore, the potential short and long term morbidity arising from fusion surgery is significant and other treatment modalities will need to be explored. It is due to this associated morbidity, that motion preserving spinal surgery is currently experiencing a revival.

1.2. Development of the Kineflex disc prosthesis

1.2.1. History of spinal disc replacement

As described earlier, adjacent level degeneration is a major concern in lumbar fusion operations (Lehman, et al. 1987[19]; Lazennec, et al. 2000[29]; Kumar, et al. 2000a[22]; Gillet P, 2003[23]; Park, et al. 2004). Artificial lumbar discs are an alternative to arthrodesis. The purpose of Total Disc Replacement (TDR) is to restore the intervertebral segment and protect the adjacent levels against non-physiological loading conditions. The first description of surgical insertion of a lumbar prosthetic nucleus replacement, using a steel ball, was published by Fernström (Fernström U, 1966[33]). It failed clinically, essentially because of subsidence of the implant into the bony end-plate. Modern types of total lumbar disc replacement commenced in 1984 with the insertion of the first generation Charité disc prosthesis (Charité SB I) developed by Büttner-Janz and Schnellnack (Büttner-Janz, et al. 1987[34]). The ingenious "sliding core" articular mechanism of this device was interposed between two bottle-cap shaped disc end-plates. The first results on 16 patients were published in 1987 (Büttner-Janz, et al. 1987[34]; Büttner-Janz & Schnellnack, 1990[35]). The subsidence at the bone end-plate interface led to the second (Charité SB II) and third (Charité SB III) generation articulated lumbar disc prosthesis. The second generation disc had wings added to increase the bearing surface and avoid subsidence into the bony end-plate. Breakage through these wings and subsidence still occurred in this model (Charité SB I). The mechanism of the prosthesis was carried through to the third generation device that is still being used today (Charité SB III: De Puy, Raynham. Mass, US). This third generation disc has been used since 1987 and intermediate and long term results are available (Griffith, et al. 1994[36]; David, 1999[37]; Lemaire, et al. 2005[38]). Final (two year) results of randomized FDA (Food and Drug Administration) trials in North America have been published (Blumenthal, et al. 2005[39]; McAfee, et al.2005[40]).

Subsequently, more constrained lumbar disc prostheses were developed. One of these prostheses was recently approved (Prodisc: Synthes, West Chester, PA, US) and others are currently being evaluated in FDA studies, (Maverick disc: Medtronic, Memphis, Tenn, US; Flexicore disc: Stryker Spine, Allendale, New Yersey). The only other disc with long term follow up currently available is the lumbar Prodisc

(Marnay T, 2002[41]). Despite improvement in the disc insertion techniques and designs, difficulties persist with the correct midline and posterior placement of the prostheses within the disc spaces, even in experienced hands (McAfee, et al. 2005[40]).

1.2.2. Indications for lumbar disc replacement

Despite 20 years of experience with TDR, no general consensus exists about indications and contra-indications of TDR (Huang, et al. 2004[42]; McAfee PC, 2004[43]; Wong, et al. 2005[44]).

Strict guidelines were laid down in the US-FDA trials regarding indications and contra-indications for total disc replacement (Blumenthal, et al. 2005[39]) (Table 1.2.2.). Multiple European centres have used total disc replacement for a much wider range of indications. In terms of these so-called "off-label" indications, only a limited number of outcome results have been published in recent years (Bertagnoli, et al. 2006[45]).

Table 1.2.2: Inclusion and exclusion criteria of lumbar TDR (adapted from Blumenthal et al., 2005)

Inclusion criteria	Exclusion criteria
-Age 18 to 60 yrs	-Previous thoracic or lumbar fusion
-Symptomatic DDD confirmed by discography at L4, L5, or S1	-Current or prior fracture
-Single-level DDD at L4–L5 or L5-S1 degeneration.	-Symptomatic multi-level
-Oswestry score $\geq$ 30	-Non-contained herniated nucleus pulposus
-VAS score $\geq$ 40 (of 100)	-Spondylosis
-Failed $\geq$ 6 mos of appropriate non-operative care	-Spondylolisthesis > 3 mm
-Back and/or leg pain with no nerve root compression	-Scoliosis > 11°
-Able to tolerate anterior approach	-Mid-sagittal stenosis < 8 mm
-Able and willing to comply with follow-up schedule	-Positive straight leg raise
-Willing to give written informed consent	-Spinal tumor
	-Osteoporosis, osteopenia
	-Metabolic bone disease
	-Infection
	-Facet joint arthrosis
	-Psychosocial disorder
	-Morbid obesity
	-Metal allergy
	-Use of a bone growth stimulator
	-Participation in another study
	-Arachnoiditis
	-Chronic steroid use
	-Autoimmune disorder
	-Pregnancy
	-Other spinal surgery at the affected level (except discectomy, laminotomy/ectomy, without accompanying facetotomy or nucleolysis at the level to be treated)

1.2.3. Development of the Kineflex disc prosthesis

The aim in designing the Kineflex disc was to develop a wear-resistant prosthesis with motion properties close to a human FSU. A simple, non-traumatic insertion technique should facilitate its use, even in severely degenerated and collapsed disc spaces.

The Kineflex Disc Prosthesis represents a Chrome-Cobalt Molybdenum (CCM-Carpenter Technologies, Biodur Plus; USA), un-constrained but re-centering disc prosthesis with a mobile centre of rotation. The mechanism comprises two metal end-plates articulating over a sliding core that is positioned between the end-plates. It allows 12 degrees of movement into flexion, extension and left and right side bending. The inferior end-plate has a retaining ring that limits the excursion in the inferior articulation to 2 mm in all directions and prevents dislodgement of the sliding core. The mechanism therefore only allows around 3.5 mm of translation before, by distraction of the disc space, a re-centering force is produced which counteracts further translation (**Figure 1.2.3 a-c**). The disc is inserted as a single unit, with a freely mobile articular mechanism during the final insertion process, to facilitate posterior placement within the disc space (**Figure 42–1. in Chapter 4.2.)**.

Figure 1.2.3. a-c: Illustration of Kineflex core motion

Illustrate the core motion of the Kineflex prosthetic disc (KPD).

(Note: As the KPD arthroplasty is symmetrical, the following analysis is equally applicable to flexion and extension)

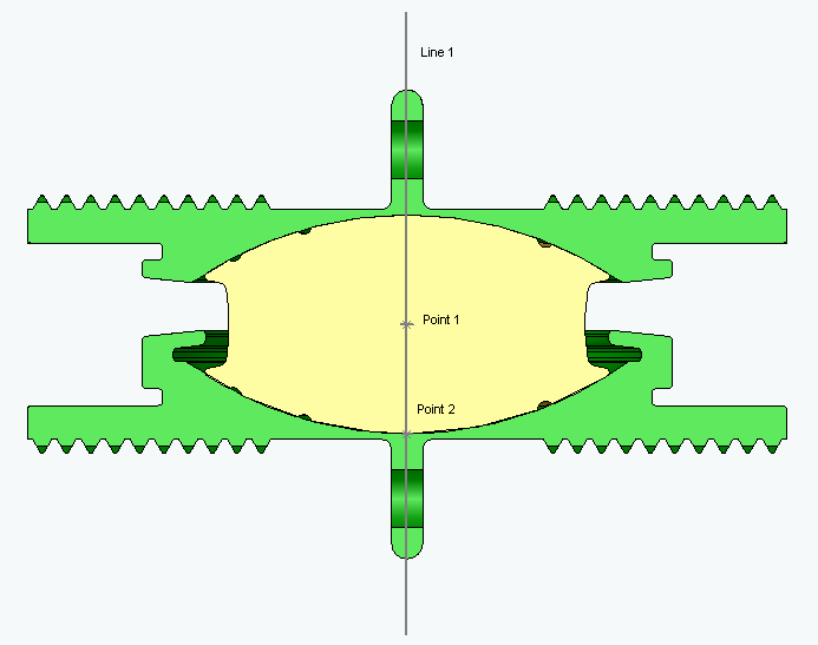

Figure 1.2.3.a: Cross - section of the KPD in neutral position

The core motion is limited in the inferior articulation by the retaining ring of the inferior endplate. The superior articulation has no retaining ring.

Line 1 shows the assembly center: Point 1 is the core center while Point 2 is the point on the lower disc endplate where the lower disc articulation cuts the assembly center and contacts the core.

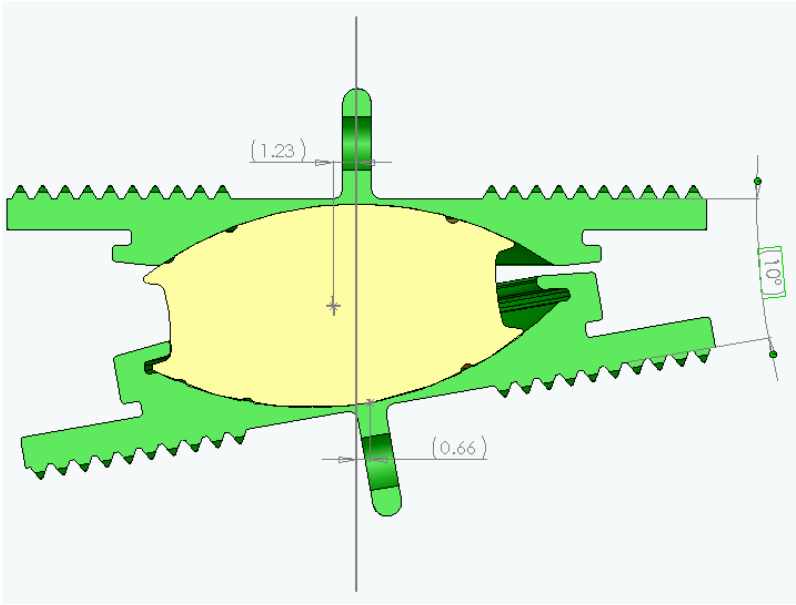

Figure 1.2.3.b: KPD at 10° right sided inclination

shows the Kineflex lumbar disc with a 10° articulation towards the right. It is shown that the core moves, from the disc assembly center, 1.24 mm away from the inclination side while point 2 moves 0.59 mm towards the inclination side. There is contact between the core and the lower endplate on the left side of the assembly.

In contrast to this, analysis of Figure 1.2.3.c shows the assembly with a right side core contact.

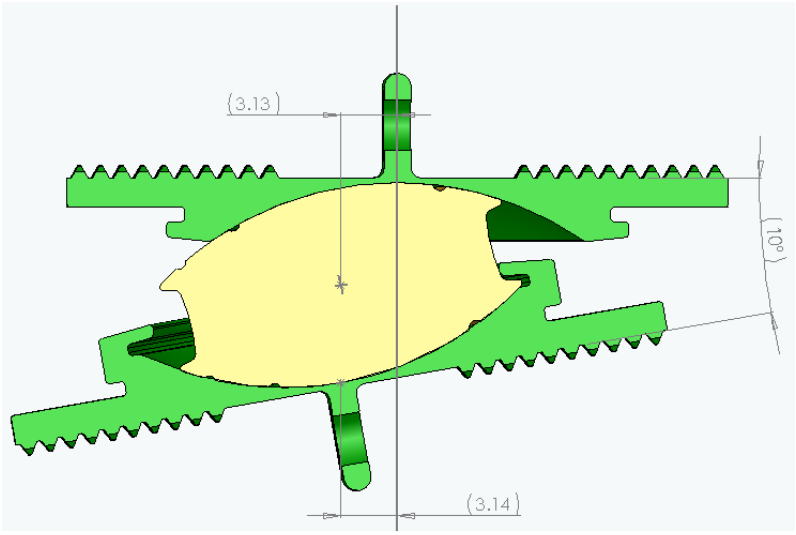

Figure 1.2.3.c: KPD at 10° right sided inclination and translation

shows the Kineflex lumbar disc with a 10° articulation and additional maximal translation of the top endplate towards the right. It is shown that the center of the core

and Point 2 on the inferior endplate both move away from the disc assembly center, 3.1 mm away from the side of inclination. The contact between the core and the lower endplate on the right side of the assembly prevents further translation unless the inclination increases.

Karin Büttner-Janz (2008[46]), the pioneer of modern type total disc replacement (TDR), recently sub-categorized TDR into 3 groups, viz.:

i. Functional three-component prostheses
ii. Functional two-component prostheses
iii. Functional one-component prostheses classified

The Kineflex lumbar disc prosthesis (Spinal Motion; CA; USA) falls into group A. It was, after the Charité Artificial Disc Prosthesis (De Puy Spine, Inc., Raynham, MA), only the second functional three-component prosthesis design. Later designs in this sub-category are the Mobidisc (LDR, Troyes, France), the Activ-L (Aesculap spine, Tuttlingen, Germany), the Dynardi (Zimmer Spine, Minneapolis, MN), the Secure-C (Globus Medical, Inc., Audubon, PA) and the Baguera (International Center Cointrin, Geneva, Switzerland).

Before engaging in the development of the Kineflex (Centurion) lumbar disc prosthesis, I had considerable surgical experience with anterior and posterior lumbar fusion surgery for DDD and with the Charite SB III Disc prosthesis. The Charite prosthesis comprises an ingenious, sliding core mechanism as articulation. Despite my satisfaction with the basic mechanism of the prosthesis, I found several design features of the Charite disc considerably limited the potential indications for the prosthesis in DDD and jeopardized the exact placement of the prosthesis, viz.: 1) The anchoring spikes on the prosthetic end-plates made midline, as well as posterior placement within the disc space, close to the natural centre of rotation, difficult to achieve. In stiffer and more collapsed disc spaces, this could lead to sub-optimal placement or end-plate fractures during insertion. 2) The insertion instrumentation was relatively bulky and wider than the actual implant, which significantly impeded visualisation when inserted through minimal invasive surgical approaches. 3) The insertion instrumentation held the implant end-plates rigidly and parallel throughout

the entire insertion process, therefore creating difficulties in narrow and stiff disc spaces in preserving the integrity of the bony end-plates of the disc space during the insertion process.

At the onset of the development of the Kineflex disc prosthesis, there existed two further mechanical discs with wider distribution, i.e. the lumbar ProDisc (Synthes, West Chester, PA, US) and the Maverick Disc prostheses (Medtronic, Memphis, Tenn, US). Both comprised of a "ball and socket" articular mechanism. The mechanism allowed translation within the joint only when coupled with flexion, extension or side-bending within the joint or by partial disengagement between the articular surfaces (semi-constrained). Their pattern of motion is, therefore, significantly different to the natural motion pattern of a human spinal motion segment (SMS) (Moumene M, Geisler FH, 2007[47]).

Table 1.2.3 below reflects the limitations I encountered with the available mechanical lumbar disc implants, available at the onset of the development of the Kineflex (Centurion) lumbar disc prosthesis. It describes the changes incorporated in the design of the Kineflex lumbar disc prosthesis in order to improve on these limitations.

Table 1.2.3: Limitations of available mechanical disc implants

Prosthesis model	Feature	Resulting limitation	Solution
Charite SBIII	V- shaped anchoring teeth	Teeth restrict posterior placement within the disc space	Multiple small, machined teeth
	V- shaped anchoring teeth	Teeth don't always follow the pre-cut grooves, resulting in difficulties in maintaining coronal plane direction during insertion process	Midline fin

	Sharp leading edge of the prosthetic end-plate	Danger of bony end-plate violation during insertion process	Bevelled leading edge of the prosthesis
	Rigid fixation of prosthesis by insertion instrumentation	Danger of bony end-plate violation during insertion process	Modular fixation of prosthetic end-plates during the insertion process
ProDisc L +Maverick Disc	Fixed centre of rotation	Motion pattern of prosthesis differs from natural SMS	Sliding core
ProDisc L +Maverick Disc	Large midline fin	Danger of vertebral splitting in double level disc replacement	Small, narrow midline fin
ProDisc L +Maverick Disc	Large midline fin	Restriction in seating the prosthesis fully into disc space	Small, narrow midline fin
ProDisc L	Clip-in polyethylene core	Danger of disengagement	Sliding core dislodgement avoided by retaining ring
+Maverick Disc	Very posterior articulating mechanism	Need of osteotomy in wedged, narrow disc spaces in order to seat the prosthesis	Less back-seated articular mechanism and freed prosthetic end-plates during insertion process

1.3. Framework for how the various chapters of the thesis contribute to the overall integrated argument of the thesis

After initial planning of a new prosthesis, together with my neurological colleague, Dr Ian Weinberg, we approached Dr Malan De Villiers (PhD), an engineer and CEO of Southern Medical (Centurion, Gauteng), which is South Africa's leading designer and manufacturer of medical implants. Together we designed the "Centurion disc prosthesis" (later re-named the "Kineflex disc prosthesis"), as well as the insertion instrumentation (8 patents in my name).

The aim in the development of this prosthesis was: a motion pattern close to the natural disc motion; an insertion technique that allows accurate placement within the disc space, even in patients with very advanced disc degeneration; and to explore the use of disc replacement in problems that are often considered as contra-indications to total disc replacement (disc height narrowing to less than 5 mm, previous fusion surgery and degenerative spondylolisthesis).

A portion of the pre-clinical in vitro studies have been published in the book chapter on the Kineflex disc published with Elseviers. (Hähnle, et al. 2008[48])

Chapter 3 expands on the extensive pre-clinical testing, which is the portion of the results that has not been published. Due to the results of this testing protocol, together with our early clinical outcome results, the Kineflex disc is currently Conformit Europeane (CE) certified. These results also formed the foundation for the inclusion of the Kineflex into a prospective, randomized, multi-center "Food and Drug Administration Investigational Device Exemptions Study" of lumbar total disc replacement comparing KINEFLEX Artificial Disc versus CHARITÉ™ Artificial Disc. The recruitment phase of the study has been completed and the two-year results of two US centres have recently been presented (Guyer, 2008 [49]).

Chapter 4 features the book chapter that we published with Elsevier (Hähnle, et al. 2008[48]). It describes the development of the prosthesis and instrumentation, outlines

the material testing and presents early results of the first patient treated with the Kineflex lumbar disc.

Chapter 5 consists of the first (Hähnle, et al. Winter 2007[32]) of three publications in the SAS Journal, the official publication of the Spine Arthroplasty Society (SAS). It describes discs and the implantation technique of the Kineflex disc, which differs significantly from the insertion technique of earlier implants. A detailed description of the insertion procedure with intra-operative, radiological imaging is given and the two-year clinical and radiological results of the first 100 patients are presented. As with artificial implants in other joints, outcome depends on the accuracy of placement within the disc space (McAfee, et al. 2005). Ideal positioning within the disc space is difficult to achieve, especially in very collapsed and rigid disc spaces. In our publication, therefore, a comparison is done in terms of the prosthetic placement accuracy in cases with advanced disc space collapse and cases with lesser disc space narrowing. We further compare our placement accuracy achieved to the placement accuracy published in terms of another implant (McAfee, et al. 2005). Our clinical outcome was compared to the outcome of other disc prostheses, mostly in patients with significantly less advanced disc degeneration (Siepe, et al. 2006).

Chapter 6 and 7 incorporate two of our publications, both of which were so called off-"label indications" for lumbar TDR.

Chapter 6 reports on the results of TDR in patients who had previously undergone lumbar fusion surgery of other lumbo-sacral spinal levels (Hähnle, et al. Summer 2007[50]). Although TDR has been used by other surgeons for this indication, little was previously published.

Chapter 7 consists of the second publication of an "off-label" indication. It explains the insertion and reduction technique used to treat patients with lower grade Degenerative Spondylolisthesis (DSPL) (Hähnle, et al. Summer 2008[52]). It comprises a pilot study with a small number of patients enrolled. Prior to our report, there had been no results on this particular patient group.

Chapter 8 is a comprehensive discussion of the thesis and its relation to the existing knowledge. It finishes with an outlook of the direction of future research into this matter.

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2. METHODS

2.1. Study objectives

In this chapter, the overall design idea of the prosthesis and the design of the clinical study are outlined. I further elaborate on aspects that are only superficially covered in the different publications referred to in Chapter 3.

I have already described the intellectual background leading to the development of the Kineflex disc prosthesis (Chapter 1, Sections 1.2 and 1.3). A detailed description of the material and methods applicable to the specific aspects of this work will follow in the remaining chapters, as outlined in Chapter 1, Section 1.3. I therefore limit myself in the present chapter to an outline of the research, with further detail presented in the subsequent chapters.

My intellectual ownership in the design of the Kineflex disc prosthesis is documented in the patents relating to the prosthesis and its insertion instrumentation and a brief description of the final product follows.

The Kineflex (Centurion) Disc Prosthesis (Spinal Motion; CA; USA) represents a Chrome-Cobalt Molybdenum (CCM- Carpenter Technologies, Biodur Plus; USA), un-constrained but re-centering disc prosthesis with a mobile centre of rotation (see Figure 42–1. in Chapter 4). The mechanism comprises two metal end-plates articulating over a sliding core that is positioned between the end-plates. It allows 12 degrees of movement into flexion, extension and left and right side bending. The inferior end-plate has a retaining ring that limits the excursion in the inferior articulation to 2 mm in all directions and prevents dislodgement of the sliding core. The mechanism therefore only allows 4 mm of translation before, by distraction of the disc space, a re-centering force is produced that counteracts further translation. The disc is inserted as a single unit with a freely mobile mechanism during the final insertion process to facilitate posterior placement within the disc space. The disc was originally named “Centurion”, as it was developed in Centurion (between Pretoria and Johannesburg, in South Africa).

The objective in the design of this implant was to develop a lasting, wear-resistant prosthesis. The design of the implant and the insertion instrumentation ought to facilitate reliable midline and posterior placement of the implant within the disc space, even in severely degenerative disc spaces. This placement should be easily achieved through a minimally invasive approach.

The objectives of this study were: to investigate the properties of the implant; to evaluate the insertion technique; and to assess the clinical and radiological outcome in patients with degenerative disc disease as well as the relevant sub-groups within this patient group.

As most aspects of the Material and Methods are described in the results section that contains the various publications, I will follow with a description of the aspects that have been neglected in the result chapters (Chapters 3 - 7) and only summarize the other parts (Sections 2.2 and 2.3).

2.2. Informed consent

Ethical clearance for the study was obtained from the University of the Witwatersrand (WITS) Ethics Committee on 27 March 2003 (protocol number: M03-06-13 & Protocol M080557). It was amended on 5 April 2004 by the Internal Review Board of the Nedcare Linksfield Hospital; this is the hospital at which all procedures have been performed. A second, revised, ethical clearance was obtained from the WITS Ethics Committee on 19 June 2008.

The study has been conducted in accordance with the ethical standards laid down in an appropriate version of the 1964 declaration of Helsinki. All patients received written information and signed a consent form.
Before engaging in surgical treatment, patients were informed about the lack of experience with this particular disc implant (Kineflex disc) and about the limited world-wide long term results (over 10 years) of lumbar total disc replacement as a treatment for back and/or leg pain. The alternative surgical treatment options were

discussed (fusion, decompression and disc replacement with an alternative prosthesis).

2.3. Clinical study design and patient enrolment

This study was a single centre, prospective, observational study.

The primary clinical outcome measures for this study were pain relief and functional improvement, as assessed by the Oswestry Disability Index (ODI) (Fairbank & Pynsent, 2000[1]), the Visual Analoque Pain Score (VAS) and our own questionnaire.

The primary radiological outcome measures are outlined in Chapter 2, Section 2.3.6.

2.3.1. Recruitment of patients and therapeutic work-up

Patients were recruited from in and out-patients seen for purposes of consultation by myself or Dr Ian R. Weinberg.

During clinical examination, the patients had to physically indicate the painful areas of the back and lower limbs. This was followed by palpation of the inter-spinous spaces in both standing and prone positions to determine the pain levels. Routine spinal examinations followed.

Before the surgical index procedure, all patients had experienced severe, disabling low back pain (LBP) of at least one year duration and/or leg pain of over 6 months duration. When patients had significant neurological deficits or neurological deterioration during the course of conservative treatment, the conservative treatment might have been shortened. All patients underwent at least six weeks of an active, physiotherapeutically supervised, exercise orientated, treatment program Diagnostic and therapeutic cortisone injections into the facet joint, sacro-iliac joints, the disc or the epidural space were performed when indicated.

2.3.2. Inclusion criteria

Inclusion criteria for the study were: age of 18 - 65 years; symptomatic single or multi-level degenerative disc disease at the L2/L3, L3/L4, L4-L5 or L5-S1 levels confirmed on x-rays, magnetic resonance imaging and provocative discography in selected cases. Further inclusion criteria included: mechanical back and leg pain, recurrent disc herniation, broad based central disc herniation without sequestration; and junctional failure after previous fusion. All patients had failed conservative treatment of at least 6 months. Only the symptomatic levels on clinical examination and/or discography were replaced.

2.3.3. Exclusion criteria

Exclusion criteria were: osteoporosis, tumor, infection, spondylolisis of the level, bony spinal stenosis, sequestrated disc prolapse tracking up or down behind the vertebral body, severe obesity, structural deformity, previous retroperitoneal surgery, vascular pathology and previous wide laminectomy with destabilization of the facet complex. Advanced facet arthritis was not an exclusion criterion unless osteophyte formation from the facet resulted in bony canal or recess stenosis. Spinal or lateral recess stenosis caused by soft tissue (disc, ligamentum flavum or joint capsule) was not considered a contra-indication for disc replacement if proper decompression during surgery, by means of direct or indirect decompression, could be anticipated on pre-operative imaging.

2.3.4. Study visits

Patients were seen; pre-operatively, at 6 weeks, at 3 months, 6 months, at one and two years in conjunction with the regular follow-up examinations. In addition to the outcome data, general demographic information and operative data, as well as data pertaining to radiological examination, were collected. The follow-ups formed part of our routine, standard-of-care and follow-up visits.

2.3.5. Clinical outcome measures

The primary clinical outcome measures for this study were pain relief and functional improvement as assessed by the Oswestry Disability Index (ODI) (Fairbank JC,

Pynsent PB. 2000[1]), the Visual Analoque Pain Score (VAS) and our own questionnaire. The questionnaires were completed by patients pre-operatively, at 6 weeks, at 3 months, at 6 months, and yearly in conjunction with regular follow-up examinations.

The questionnaire was our own, designed by myself and Dr I. Weinberg, and has not been validated. It captured general demographic information regarding marital status, number of children, work status, recreational sport activities, the reason for stopping sport activities, intake of alcohol and cigarettes as well as drugs and medicine. Pre-operatively, the questionnaire screens for previous conservative treatment, pain duration and pressure experienced in the work process. Pre-operatively and post-operatively (follow-up) it incorporates a detailed scoring of pains and weaknesses (see appendix).

During follow–up, the patient is asked about satisfaction with the treatment outcome (options: excellent, good, fair, poor) and whether he or she would undergo the same operation again or recommend it to friends (options: yes; don't know; no).

2.3.6. Radiological examination

All patients had a pre-operative magnetic resonance investigation (MRI) or lumbar myelography followed by computer tomography (Myelo-CT) or both. Pre-operative, at 3 months, at one year, and yearly the following radiographs were taken: Antero-posterior (AP), a lateral standing radiographs (which included the bottom end-plate of the T12 vertebra and the top half of both femoral heads), lateral flexion/extension radiographs and a lateral whole-spine standing radiograph (kyphosis X-ray). At all other follow-ups (2 weeks, 6 weeks and 6 months), only standing AP side-bending and lateral flexion/extension radiographs of the lumbar spine were performed. Oblique standing radiographs were only done pre-operatively.

Pre-operative discography was only performed in cases when, after clinical examination and radiographic evaluation, doubt persisted about inclusion or exclusion of a lumbar level in the operation. The amount of disc space narrowing, the presence or absence of spondylolisis, the mobility of the motion segment, and the

radiological stability of the relevant spinal level were carefully assessed on the plain radiographs. The disc quality, the amount of canal and recess encroachment by the disc, the facet joints and the ligamentum flavum were determined on MRI. The degree of facet arthritis and modic changes were also assessed.

Pre-operative disc height at the operated level was measured by 2 different observers on lateral standing radiographs at 3 points (anterior, middle and posterior) and averaged and corrected by the magnification error (McAfee PC et al. 2005[2]). Radiographic placement accuracy: The exact central placement of all disc implants in the coronal and mid-sagittal plane was determined and categorized, as described by McAfee (McAfee PC et al. 2005[2]), into ideal, sub-optimal and poor placement. The mid-sagittal plane on lateral radiograph is defined as 2 mm posterior to the middle of the vertebral body in the sagittal plane. The coronal plane on anteroposterior radiographs is the exact center line of the vertebral body (McAfee PC et al. 2005) or interpedicular midpoint (Mistry & Robertson, 2006[3]). The center of the core of the artificial disc was placed: within 3 mm of exact central placement in both the coronal and midsagittal planes in Group I (ideal placement); from 3-5 mm from exact central placement in Group II (sub-optimal placement); and over 5 mm from exact central placement in Group 3 (poor placement). If the two axes are rated in different groups, the rating of the placement was determined by the poorer rating. The measurements were checked by two different observers, then averaged and corrected by the magnification error (McAfee PC et al. 2005[2]).

2.3.7. Surgery

All surgery was performed in Nedcare Linksfield Hospital. I personally performed or directly assisted Dr Ian Weinberg in all surgical procedures. Two anaesthesists and two scrub sisters formed part of the operative team.

All operations were performed on a translucent electrical table under radiographic image control. Intra-operative cell-saving was used in all patients. After a transverse midline incision of between 5 and 9 cm, depending on patient size and number of levels to be exposed, the rectus sheet was opened parallel to the linea alba and the rectus muscle was retracted laterally. The spine was approached retroperitoneally, partially incising the transversus abdominis fascia from the arcade ligament cranially.

After mobilization of the major vessels, Hohman retractors, attached to a frame retractor, were used to maintain exposure throughout the procedure.

After a midline anuloplasty (a trap-door-like opening of the annulus of the disc), the disc nucleus, the inner layer of the annulus and any sequestrated disc material were removed. The end-plates were prepared using a Cobbs instrument and curettes to remove the cartilaginous end-plates and to prepare the bony end-plates. Osteotomes and burrs were occasionally used to remove big osteophytes or to prepare the end-plates in cases of significant end-plate sclerosis. This was followed by sequential distraction of the disc spaces using wedge distracters of increasing sizes. The midline was determined on AP radiographs using a specially designed and patented midline finder. The insertion of the disc followed the principle described in the relevant publications, as the technique varies slightly with the indication for the surgery (see Material and methods in the result section (Section 3.2-3.5)).

2.3.8. Post-operative mobilization

Patients were routinely allowed to ambulate the day after surgery without bracing, initially under supervision of a qualified physiotherapist. Patients started supervised gait training, isometric muscle strengthening and stretching exercises as from day 1 post-operatively. At discharge, patients were instructed to walk every day and they were allowed to sit as long as they felt comfortable. Cycling on a stationary bike was encouraged after removal of stitches at 12 days after the operation. Low-impact sport was allowed at 6 weeks and impact sport at 3 - 4 months.

All employed office workers were allowed to return to work at 4 weeks, provided they could sit for prolonged periods without additional discomfort. Manual workers were kept off work for 6 weeks post surgery and were then allowed to go back onto light duty (no lifting of objects weighing more than 10 kg, no vibration, only limited bending and no running) for the next 6 weeks.

2.4. References: Methods

1. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine*. 2000;25:2940-2952.
2. McAfee PC, Cunningham BW, Holtsapple G, et al. A prospective, randomized, multicenter Food and Drug Administration Investigational Device Exemption Study of lumbar total disc replacement with the Charité artificial disc versus lumbar fusion: Part II: Evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. *Spine*. 2005;30:1576-1583.
3. Mistry DN, Robertson PA. Radiological landmark accuracy for optimum coronal placement of total disc arthroplasty. *J Spinal Disord Tech*. 2006;19:231-236.

3. Results: Pre-clinical, in vitro testing of the Kineflex lumbar disc prosthesis

3.1. Kineflex M lumbar intervertebral disc prosthesis: Development of wear protocol and protocol for static compression testing

3.1.1. Description of the Kineflex M intervertebral lumbar disc prosthesis: Development of in vitro test protocol

The Centurion intervertebral prosthesis consists of two cobalt chrome molybdenum (CCM) end-plates positioned on either side of a cobalt-chrome-molybdenum core. The articulating surfaces are polished CCM against polished CCM; the bone integrating surfaces are plasma sprayed with titanium.

The goal of the tests was to simulate the load and movement to which the prosthesis would be exposed under *in vivo* conditions and to verify the prosthesis' ability to withstand static and fatigue load conditions as well as determine the wear characteristics of the prosthesis.

Custom equipment was used to test the prosthesis under a simultaneous combination of flexion/extension, lateral bending and rotational movement (wear tests). Further custom test benches were used to perform compression under a Z-axis load (fatigue tests). Fatigue tests included mono-axial cyclical testing for compressive and compressive-shear modes.

Five test samples were tested for the wear test; five test samples were tested for the compressive fatigue test under each load condition. The tests were conducted over 10 million cycles at a constant frequency of 5 Hz - well within the frequency range of previous metal on metal prosthesis testing.

Test samples, with respect to the articulating surfaces, were faithful replicas of production discs. The non-articulating surfaces were modified to allow fixtures to be attached for testing purposes.

Since all Kineflex discs utilized the same core, variations in thickness to match the dimensions of the anatomic space were achieved by varying the end-plate thickness. Thus, there was not a distinct difference amongst the cores regarding thickness for different disc heights and sizes. Additionally, while end-plate sizes varied to accommodate different sized vertebrae, the articulating surface area (i.e. the part of the articulating surface that is in direct contact with the core) remained constant. Thus, because there is only one articulating surface size across all end-plate-core combinations, and the articulating surface was the critical design parameter for purposes of mechanical performance in dynamic testing, the core end-plate combination in this test provided the smallest available articulating surface. It should be noted that the end-plates had to be modified on the non-articulating sides to accommodate fixation to the spinal simulation equipment, consistent with applicable draft ASTM standards (ASTM F04.25.05.01[1]).

3.1.2. Rationale of load condition imposed for wear studies: lexion/Extension, Lateral Bending and Rotation

The prostheses were tested under a constant Z-axis load of 1200N. A maximum load condition of the lower lumber discs has been defined as being that load exerted when a person is in a hunch-back position and lifting an additional load of 20kg. This condition results in a force of 2700N on the FSU (Functional Spinal Unit) according to Nachemson (Nachemson A, 1966[2]) and 4140N according to Wilke (Wilke et al 1998[3]).

According to Wilke, the standing position is defined as a 100% load condition; other body-positions are a percentage in relation to the 100%. The 100% or standing position represents the normal load. This load was determined to be approximately 22% of the maximum load of 4140 N (911 N); 22% of the maximum load of 4140 N is 911 N. A vertical load of 1200N was chosen as the test rig load. The 1200N load condition was well in excess of the *in vivo* condition when viewed in terms of an average load over 10 years, but was applied to gain experience as to the disc wear under excess loading. Due to the angle of articulation a shear, load is generated concurrently in the prosthesis during the cycle of articulation.

The disc is symmetrical in the X-X and Y-Y directions. The test was carried out in combined flexion-extension (X-X) and lateral bending (Y-Y), combined with simultaneous rotation around the axis of symmetry (Figure 3.2.1.a-c).

The disc combinations all utilized the same core. The articulating geometry of all discs was, therefore, constant across the range of disc sizes and hence only one combination required evaluation.

Wear debris was collected and analyzed to give an indication of debris load and particle geometry for comparison to debris loads found in other arthroplasties.

3.1.3. Rationale of loading cycles imposed: wear test

According to Eijkelkamp (2001[4]), the number of walking cycles of an average person is 2,000,000 per year and the number of lifting cycles is 125,000 per year. A compromise for a wear test should lie somewhere between the former figure, at a low degree of articulation, and the latter figure, at a high degree of articulation. The proposed test is to be carried out for 10 million cycles, which is deemed to represent a minimum of 10 years of *in vivo* use.

Analysis of the test specimens was performed at every 1,000,000 cycles. This included a dimensional check with specific reference to meniscal height and diameter to comment on possible creep deformation of the meniscus.

3.1.4. Rationale of articulating limits imposed: Flexion/Extension, Lateral bending and Rotation

The range of motion limits of the normal spinal motion segment (SMS) have been studied by various researchers (Dvorak , et al. 1991[5]; Pearcy, et al. 1984[6]; Putto, Tallroth K. 1990[7]; Hayes, et al. 1989[8]). From these studies, it can be seen that the range of motion at the disc level reduces after arthroplasty (De Kleuver M, et al. 2003[9]).

In the case of a walking cycle (gait), the motion is less than 2□ in total (see table below) in any of the three planes, namely flexion-extension, lateral bending and axial rotation (Table 3.4.1).

Table 3.1.4: Summary of combined segmental motion (ROM) during gait, as found by various researchers (in degrees)

Study	Flexion/extension	Lateral b ending	Axial rotation
Vogt, et al. 2001[10]	0.5	0.8	1.0
Cromwell, et al. 1989[11]	1.2	2	2.7
Callaghan, et al 1996[12]	1.9	1.2	2.45
Taylor, et al 1996[13]	1.0	3.0	1.6
Average Total ROM	1.15	1.75	1.94

Gait is the predominant cyclical load condition and a range of motion to simulate this condition is, therefore, appropriate for implant wear assessment. To simulate a worst-case gait load condition, a movement in excess of the published data was therefore applied. A total cyclical ROM of 14.2□ of lateral bending, combined with a cyclical ROM of 14.2□ of flexion/extension bending and 8□ of rotation, were applied simultaneously. The relative phase of the flexion/extension, lateral bending and axial rotation movements were based on human gait studies – see Figure 2 below. These represent movement in the 3 planes for the full spinal lumbar region during fast walking. The proposed wear test would emulate the phasing, whereby F-E and rotation is in phase and lateral bending out of phase. Because the amount of wear debris generated is a product of the applied load and the sliding distance, combining the high load with maximal simultaneous motion in flexion-extension and rotation in this manner was believed to substantially exaggerate the amount of wear that would be generated under actual *in vivo* conditions. A gait simulator had been constructed to replicate this movement.

3.1.5. Rationale for the analysis of testing

Results were analyzed to establish whether the implants' intended physical performance would be compromised by cyclic loading. It was established whether dimensional changes were such that the intended ROM could be sustained, or implant

stability lost. Further, the wear rate and wear particle size distribution were compared to published data to establish whether any adverse biologic reaction should be anticipated.

3.2. Methods: Kineflex Disc: Set-up of wear and compression testing

3.2.1. Test bench set-up (gait simulator)

The gait simulator consisted of a loaded vertical arm that pivots on the assembled artificial disc (Figure 3.3.2.).

The articulating motion for the flexion/extension test was introduced by means of a horizontal arm connected to an eccentric pin on a wheel that was rotationally driven by an electric motor. The lateral bending motion was introduced by means of the same drive chain, but was applied to the inferior end-plate. The phasing of the 3 desired motions could be adjusted and remained synchronized for the duration of the wear test (Figure 3.2.1.a-c).

The loads were imposed on the prosthesis via a combination of 20kg and 15kg weights combined with the load of the vertical arm.

The test specimens were tested in a physiologically buffered 0.9% saline held at 37^{o}C ± 3^{o}C to simulate the body fluids such that the implant would function under *in vivo* conditions.

The following components were used in the test set-ups:

- AC electric motor
- Electronic speed controller
- Electric fluid heater
- Filter with in-line pump

A VVVF speed controller was used to bring down the frequency to 5Hz.

SPINAL DISC WEAR LOAD SIMULATION

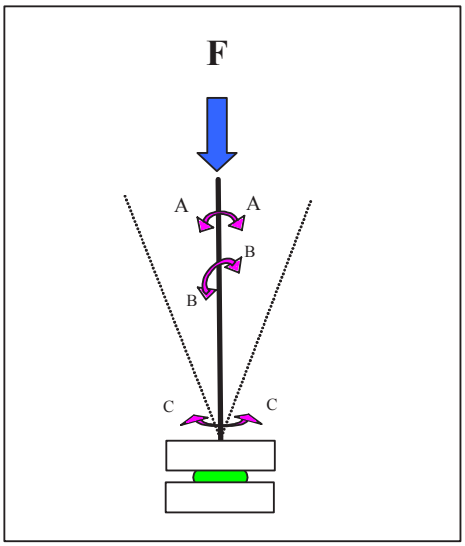


Figure 3.2.1.a: Flexion/Extension and lateral bending combined with rotation

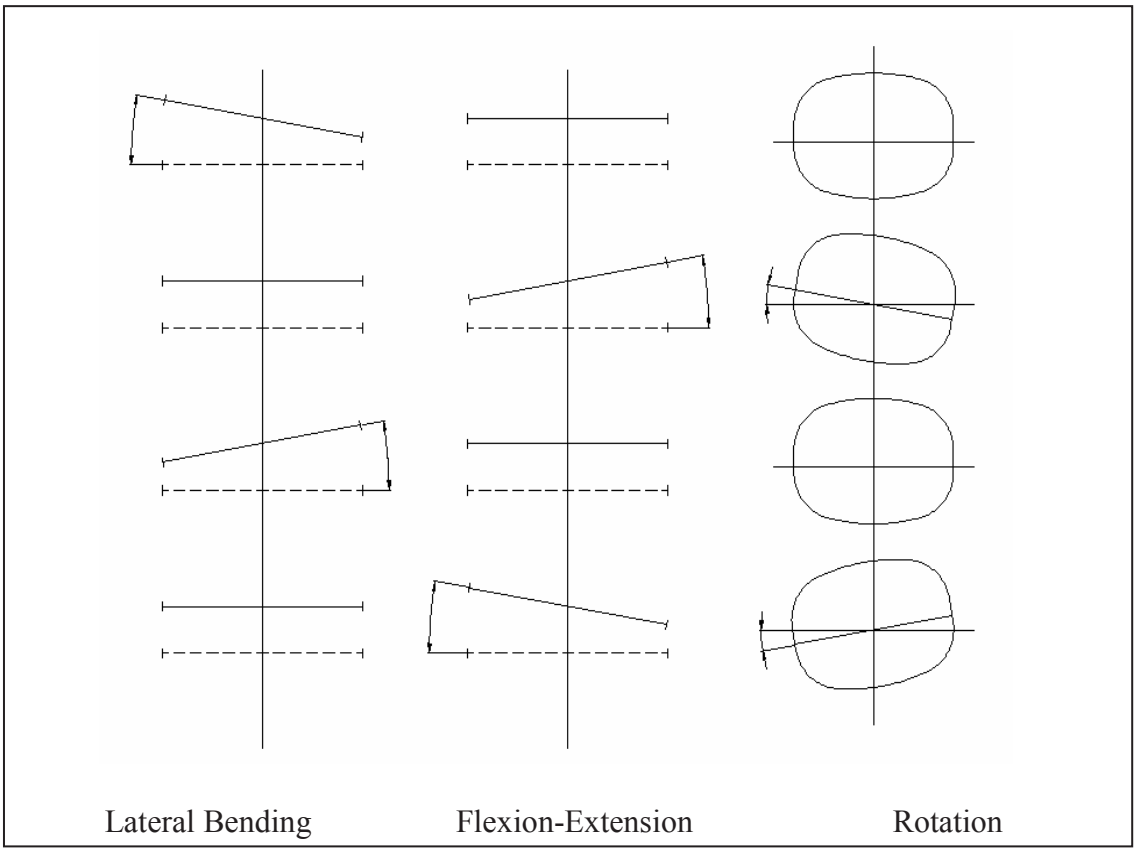


Figure 3.2.1.b: Side and top views of motion generation

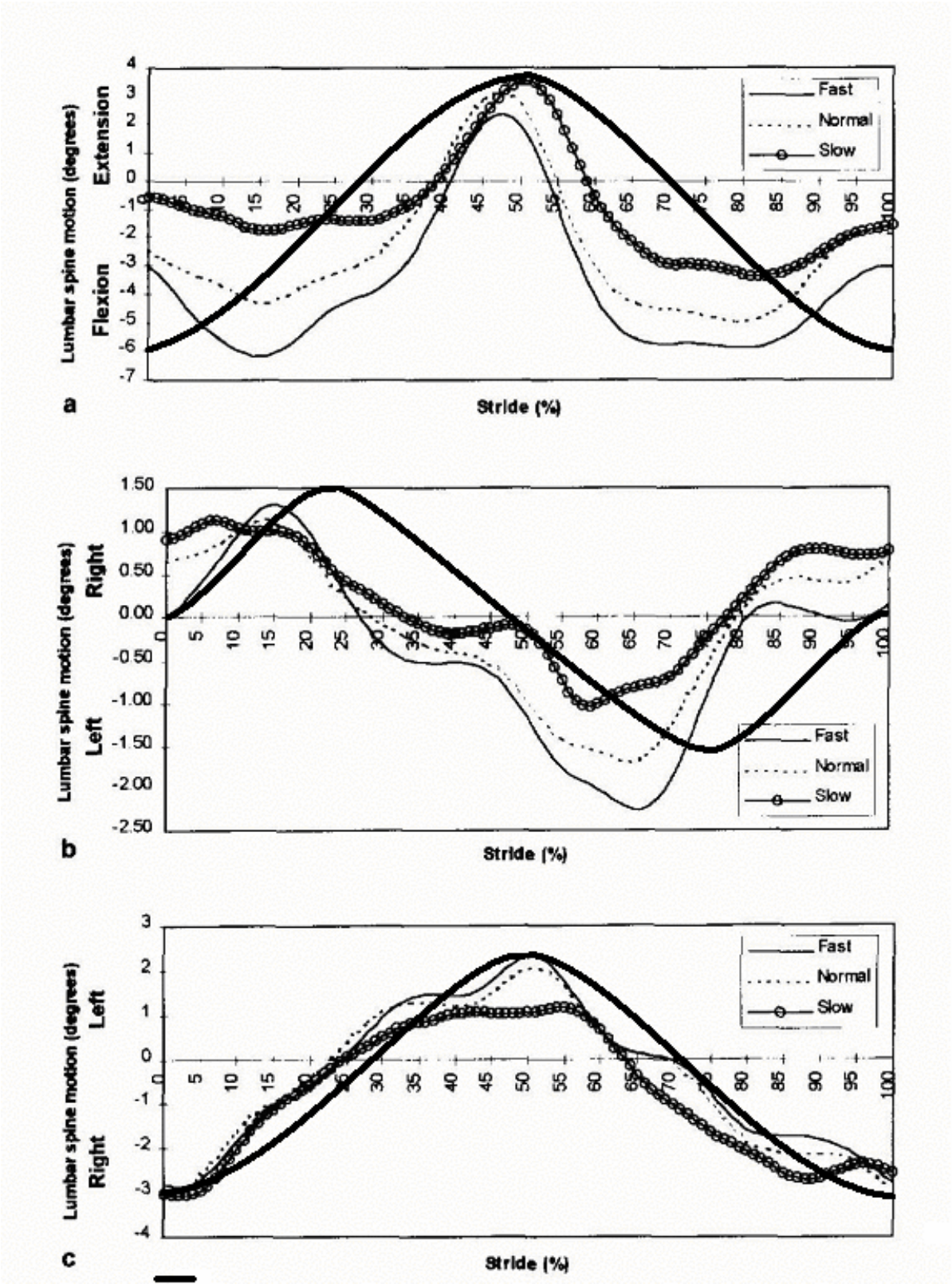


Figure 3.2.1.c: Concurrent (a) F-E, (b) Lateral Bend and (c) Rotation of Lumbar Spine for the sum of all 6 lumbar levels during gait (Cromwell et al. 1989[11]), with phasing of lumbar spine gait simulator superimposed.

3.2.2. Test criteria

3.2.2.1. Pre-test Set-up

1. Receipt of two CCM disc end-plates: Ø 40mm x 5mm with articulating surfaces finished as per normal manufacturing procedure, inclusive of sterilization.
2. Receipt of CCM menisci finished as per normal manufacturing procedure, inclusive of sterilization.
3. Removal from packaging and weighing of the discs x 2 per test rig to three decimal places (Sartorius TE313S).
4. Weighing of the menisci x 1 per test rig to three decimal places.
5. Dimensional check of height and diameter of meniscus.

3.2.2.2. Gait simulation wear test set-up

Five spinal motion simulators were utilized in the testing of the disc prosthesis and a sixth static load soak control was subjected to the applied load for the corresponding testing times.

The test prostheses were evaluated in reservoirs of physiologically buffered saline, which were maintained at 37□ ± 2□C by means of thermostatically controlled submersed heaters.

Electronic cycle counters confirmed the number of cycles to which test prostheses were subjected. The test frequency was maintained at 5Hz by adjustment of electronic speed controllers.

At every 1 million cycles, the following data was determined or collected:

1. Weight loss of prosthesis components.
2. Dimensional checks of the core, being the total height and the overall diameter.
3. One 60ml sample of physiologically buffered saline per simulator reservoir. At intervals of 2, 5, 8 and 10 million cycles, one sample per simulator was subjected to particle isolation and wear debris analysis.

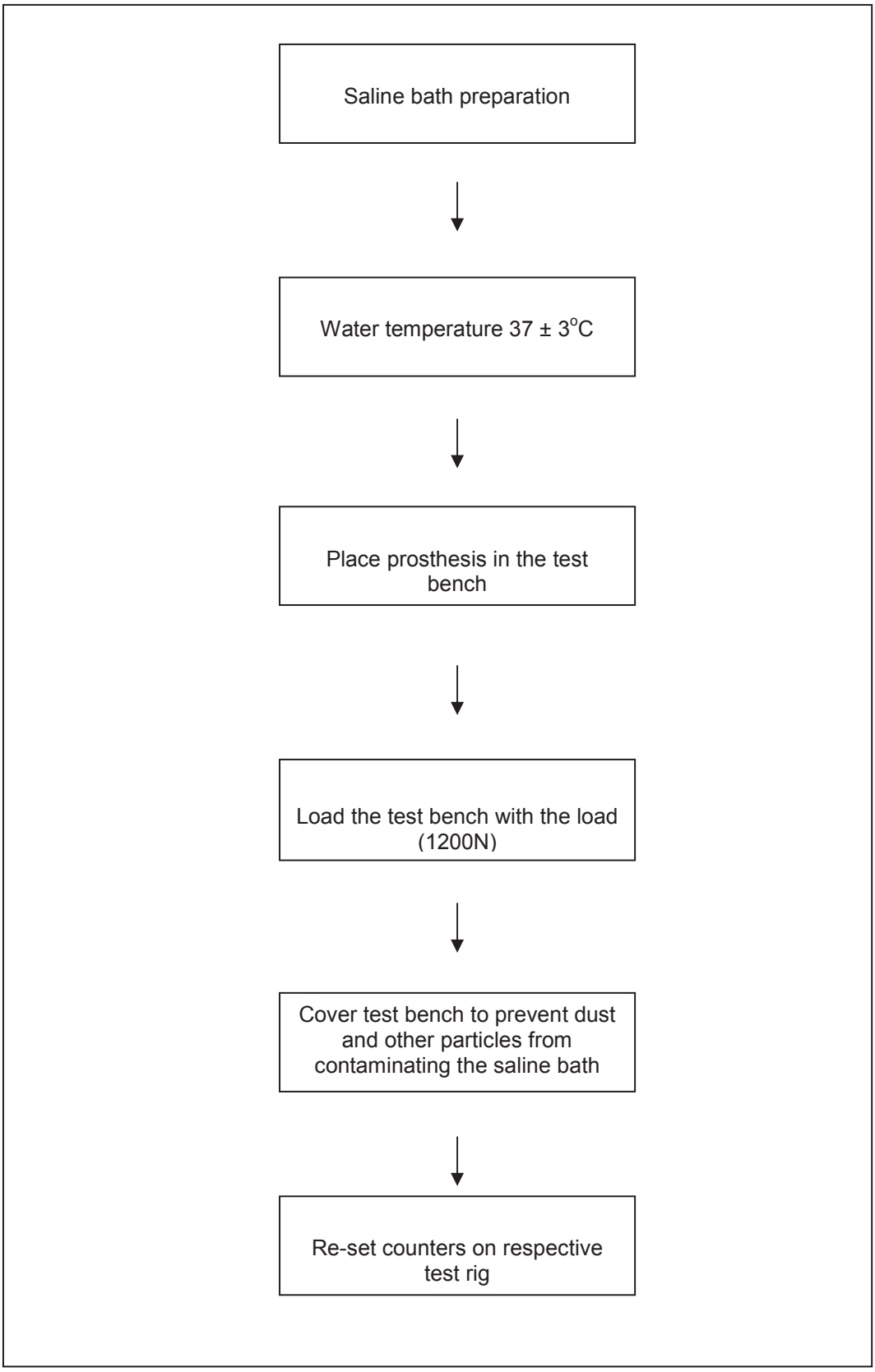


Figure 3.2.2: Gait simulation wear test – set-up

3.2.2.3. Test

After every 1,000,000 cycles, the following procedures were followed on each of the test benches:

1. Cleaning of discs and meniscus ultrasonically.
2. Weighing of discs x 2 to three decimal places (g).
3. Weighing of meniscus x 1 to three decimal places (g).
4. Dimensional check of height and diameter to three decimal places (mm).

The difference in weight was utilized to correctly determine weight loss due to wear. A visual inspection of the test specimens was carried out and recorded to ascertain the extent of visual damage. A photographic record was compiled for reference.
The saline medium was filtered at 2 million, 5 million, 8 million and 10 million cycles through sequential filters of 10 micron, 1 micron and 0.1 micron (Endo, et al. 2001[14]; Tipper, et al. 2001[15]; Tipper, et al. 2000[16]) Analysis of wear debris quantum, size and geometry was carried out.

3.2.2.4. Test result assessment

Upon each completion of the tests (i.e. after the 10 million cycles were completed) the following parameters were calculated for each test: The weight of test samples at all intervals of wear and fatigue testing were verified on a Sartorius CP4235 validated scale to an accuracy of ±0.001g. This took place in a temperature-controlled room.

1.	Mass reduction	[mg]
2.	Percentage mass reduction	[%]
4.	Wear Rate = Volume loss due to wear/Sliding distance	[mm^3/m]
5.	Wear Factor = Volume loss due to wear/(Sliding distance x Load)	[mm^3/Nm]
6.	Dimensional changes (creep indication)	[mm]

The results were analyzed to establish whether the implants' intended physical performance was compromised by cyclic loading. It had to be established whether dimensional changes were such that the intended ROM could be sustained, or implant stability was lost. Further, the wear rate and wear particle size distribution had to be

compared to published data to establish whether any adverse biological reaction was anticipated.

3.2.3. Static tests

Static tests were carried out in 2 configurations (Figure 3.2.3.1 & Figure 3.2.3.2), as described below.

3.2.3.1. Normal load

A normally loaded disc mechanism was at 90 degrees to disc end-plates, with the end-plates parallel to each other.

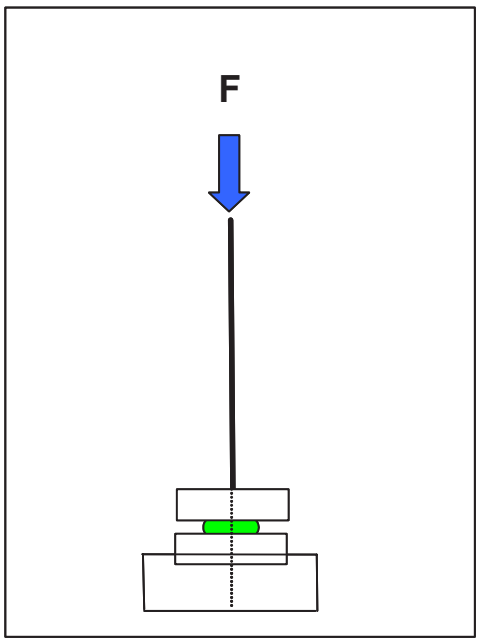
3.2.3.2. Shear load

The disc mechanism in an extreme lordotic position of 10 degrees, with axial loading applied to simulate the worst *in vivo* shear condition. This is the *in vivo* position in which shear resistance is required.

The tests carried out had to include a pre-determination of the test fixture stiffness. The actual device configuration had to then be loaded at a rate not exceeding 25mm/min until functional failure was attained. Load and displacement data were recorded. The following parameters were determined as an average of 5 test samples for each condition, as per 3.2.3.1. and 3.2.3.2.:

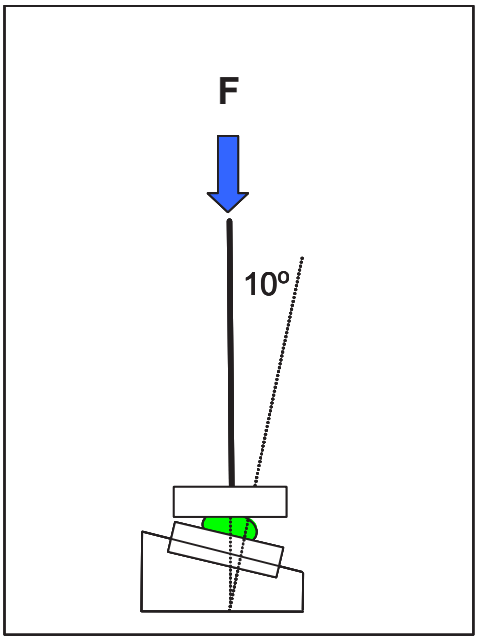
- Load-displacement curves;
- Yield displacement;
- Yield load;
- Ultimate displacement;
- Ultimate load;
- Device stiffness;

The ultimate load was recorded as input for fatigue test loading purposes.



Normal Loading

Figure 3.2.3.1: Compressive fatigue



Lordotic Loading

Figure 3.2.3.2: Shear fatigue

3.2.4. Rationale for mono-axial fatigue tests

Cyclical compression tests for the case of a normally loaded disc as well as a disc in a lordotic position (see paragraphs 3.2.3.1 and 3.2.3.2 above) were carried out. This gave an indication of the fatigue properties in a correctly implanted disc as well as for

instances where a pronounced lordosis were encountered and the meniscal spacer position would therefore not lie horizontally.

The test medium was physiologically buffered saline (0.9%) and a test frequency of 5Hz was applied. The purpose of this test was to confirm a load-cycle to failure plot and to comment on the suitability of the fatigue resistance of the device for in vivo use. Five samples in each configuration were tested.

The fatigue tests were carried out under a cyclic load condition of 200N to 2000N over 10,000,000 cycles. The condition of the prosthesis was recorded for every 1 million cycles. This included a visual integrity check as well as a dimensional verification.

For the purposes of this test, a failure mode was defined as a visible deterioration of the meniscal spacer or end-plates evidenced by cracking, spalling or creep of magnitude that prevents the prosthesis from articulating freely or maintaining its structural integrity.

3.2.5. Torsion test

This device was unconstrained in axial rotation and therefore no torsion test was required (ASTM[1]).

3.3. Results of accelerated wear test

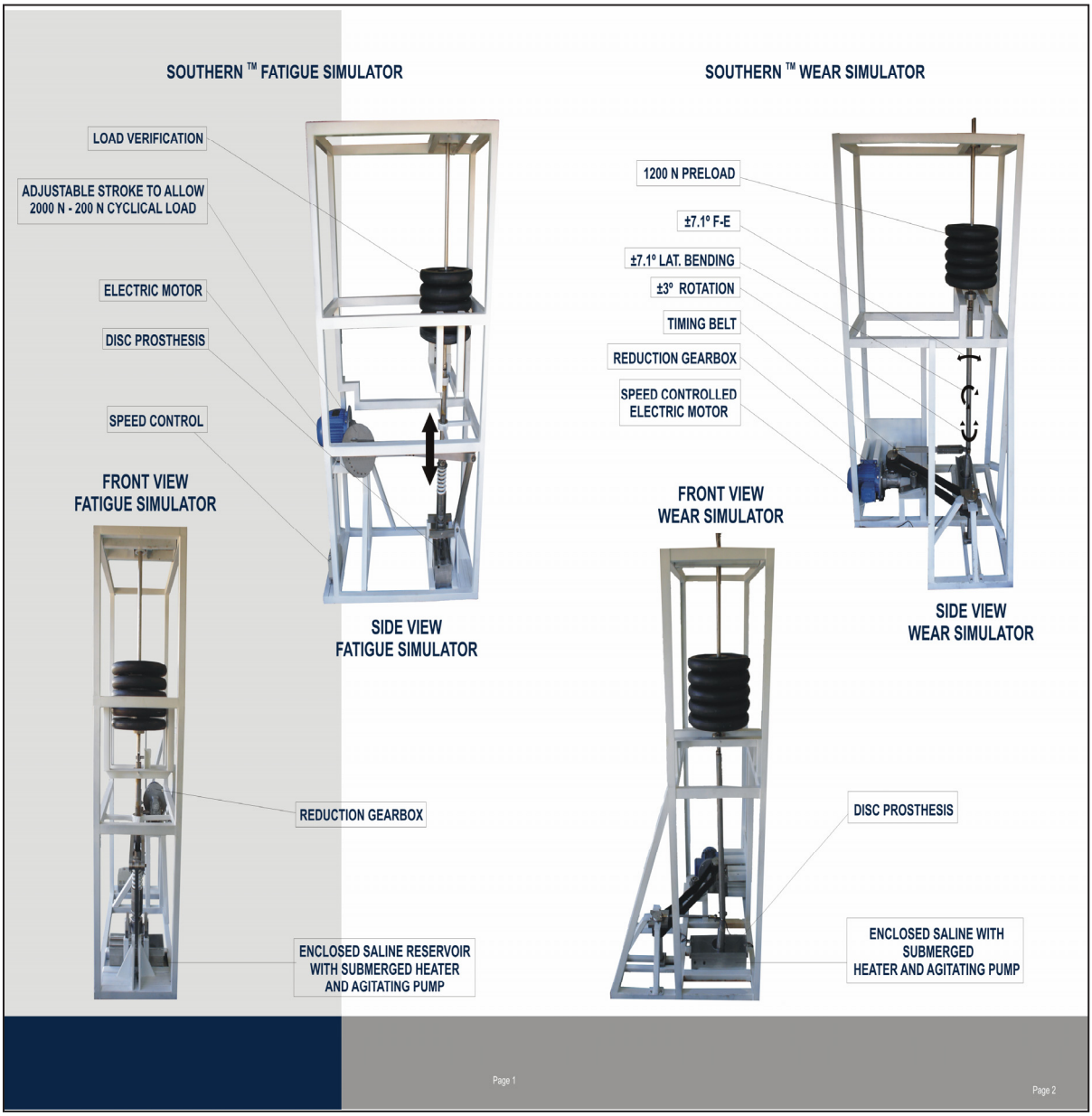
3.3.1. Wear test protocol

The wear tests described herein were carried out in accordance with the protocol: Methods: Kineflex Disc: Set-up of wear and compression testing (Chapter 3.2).

3.3.2. Description of the test equipment

Spinal simulators were constructed, which enable a variety of loading conditions and ranges of motion to be applied to the prosthesis. The simulator design has been illustrated in drawings appended hereto as Figure 3.3.2. It allows for cyclical motion to be applied under a constant load in the three degrees of freedom of the Functional Spinal Unit (FSU).

Figure 3.3.2: Lumbar Spinal Fatigue Simulator Illustration



The load was accurately applied by means of weights that were loaded onto the articulating arm of the simulator. The parameters applied were:

Loading	:	1200N
F-E Range	:	+7.1□ to -7.1□
Lateral Bending Range	:	+7.1□ to -7.1□
Rotation	:	+4□ to -4□

3.3.3. Weight verification

The weight of test samples at all intervals of wear and fatigue testing was verified on a Sartorius CP4235 validated scale to an accuracy of ±0.001g. This took place in a temperature-controlled room.

3.3.4. Results of wear testing

The following tables (3.3.4.a-k) summarize results achieved for the accelerated wear testing.

Table 3.3.4. a-k: Results of accelerated wear testing

a) COMMENCEMENT OF TEST: 3 AUGUST 2004

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.483	-	27.203	-	29.044	-	10.48	-	19.41	-
2	16.497	-	27.403	-	29.323	-	10.49	-	19.39	-
3	16.222	-	27.542	-	29.075	-	10.49	-	19.40	-
4	16.368	-	27.694	-	29.314	-	10.50	-	19.40	-
5	16.448	-	27.223	-	29.035	-	10.51	-	19.43	-
Average	16.404		27.413		29.158		10.49		19.41	

b) ONE MILLION CYCLE PARAMETERS: 5 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.474	0.009	27.197	0.006	29.038	0.006	10.44	0.04	19.41	0.00
2	16.492	0.005	27.399	0.004	29.319	0.004	10.47	0.02	19.39	0.00
3	16.210	0.012	27.538	0.004	29.070	0.005	10.43	0.06	19.40	0.00
4	16.361	0.007	27.691	0.003	29.308	0.006	10.46	0.04	19.40	0.00
5	16.439	0.009	27.219	0.004	29.031	0.004	10.46	0.05	19.43	0.00
Average	16.395	0.008	27.409	0.004	29.153	0.005	10.45	0.04	19.41	0.00

c) TWO MILLION CYCLE PARAMETERS: 8 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.466	0.008	27.194	0.003	29.034	0.004	10.40	0.04	19.41	0.00
2	16.483	0.009	27.394	0.005	29.315	0.004	10.42	0.05	19.39	0.00
3	16.204	0.006	27.534	0.004	29.067	0.003	10.40	0.03	19.40	0.00
4	16.355	0.006	27.686	0.005	29.303	0.005	10.42	0.04	19.40	0.00
5	16.432	0.007	27.217	0.002	29.027	0.004	10.41	0.05	19.43	0.00
Average	16.388	0.007	27.405	0.004	29.149	0.004	10.41	0.04	19.41	0.00

d) THREE MILLION CYCLE PARAMETERS: 10 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.461	0.005	27.191	0.003	29.029	0.005	10.37	0.03	19.41	0.00
2	16.479	0.004	27.391	0.003	29.310	0.005	10.39	0.03	19.39	0.00
3	16.200	0.004	27.530	0.004	29.065	0.002	10.37	0.03	19.40	0.00
4	16.350	0.005	27.683	0.003	29.299	0.004	10.38	0.04	19.40	0.00
5	16.427	0.005	27.213	0.004	29.024	0.003	10.38	0.03	19.43	0.00
Average	16.383	0.005	27.402	0.003	29.145	0.004	10.38	0.03	19.41	0.00

e) FOUR MILLION CYCLE PARAMETERS: 13 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.458	0.003	27.189	0.002	29.027	0.002	10.35	0.02	19.41	0.00
2	16.477	0.002	27.388	0.003	29.306	0.004	10.38	0.01	19.39	0.00
3	16.196	0.004	27.530	0.000	29.060	0.005	10.35	0.02	19.40	0.00
4	16.344	0.006	27.681	0.002	29.296	0.003	10.36	0.02	19.40	0.00
5	16.422	0.005	27.209	0.004	29.022	0.002	10.35	0.03	19.43	0.00
Average	16.3794	0.004	27.399	0.002	29.142	0.003	10.36	0.02	19.41	0.00

f) FIVE MILLION CYCLE PARAMETERS: 15 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.455	0.003	27.186	0.003	29.025	0.002	10.33	0.02	19.41	0.00
2	16.472	0.005	27.383	0.005	29.304	0.002	10.35	0.03	19.39	0.00
3	16.192	0.004	27.528	0.002	29.058	0.002	10.32	0.03	19.40	0.00
4	16.342	0.002	27.680	0.001	29.292	0.004	10.32	0.04	19.40	0.00
5	16.418	0.004	27.207	0.002	29.017	0.005	10.32	0.03	19.43	0.00
Average	16.376	0.004	27.397	0.003	29.139	0.003	10.33	0.03	19.41	0.00

g) SIX MILLION CYCLE PARAMETERS: 17 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.453	0.002	27.182	0.004	29.020	0.005	10.30	0.03	19.41	0.00
2	16.469	0.003	27.379	0.004	29.302	0.002	10.33	0.02	19.39	0.00
3	16.185	0.007	27.527	0.001	29.056	0.002	10.28	0.04	19.40	0.00
4	16.338	0.004	27.678	0.002	29.291	0.001	10.29	0.03	19.40	0.00
5	16.415	0.003	27.206	0.001	29.013	0.004	10.30	0.02	19.43	0.00
Average	16.372	0.004	27.394	0.002	29.136	0.003	10.30	0.03	19.41	0.00

h) SEVEN MILLION CYCLE PARAMETERS: 20 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.448	0.005	27.180	0.002	29.016	0.004	10.27	0.03	19.41	0.00
2	16.462	0.007	27.377	0.002	29.301	0.001	10.29	0.04	19.39	0.00
3	16.183	0.002	27.524	0.003	29.055	0.001	10.28	0.00	19.40	0.00
4	16.333	0.005	27.676	0.002	29.288	0.003	10.25	0.04	19.40	0.00
5	16.411	0.004	27.204	0.002	29.008	0.005	10.27	0.03	19.43	0.00
Average	16.367	0.005	27.392	0.002	29.134	0.003	10.27	0.03	19.41	0.00

i) EIGHT MILLION CYCLE PARAMETERS: 22 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actua	LOSS
1	16.444	0.004	27.175	0.005	29.013	0.003	10.25	0.02	19.41	0.00
2	16.456	0.006	27.372	0.005	29.299	0.002	10.25	0.04	19.39	0.00
3	16.177	0.006	27.522	0.002	29.051	0.004	10.25	0.03	19.40	0.00
4	16.330	0.003	27.673	0.003	29.284	0.004	10.24	0.01	19.40	0.00
5	16.402	0.009	27.202	0.002	29.006	0.002	10.22	0.05	19.43	0.00
Average	16.362	0.006	27.389	0.003	29.131	0.003	10.24	0.03	19.41	0.00

j) NINE MILLION CYCLE PARAMETERS: 25 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.438	0.006	27.172	0.003	29.010	0.003	10.22	0.03	19.41	0.00
2	16.450	0.006	27.370	0.002	29.297	0.002	10.23	0.02	19.39	0.00
3	16.170	0.007	27.519	0.003	29.049	0.002	10.21	0.04	19.40	0.00
4	16.325	0.005	27.668	0.005	29.283	0.001	10.22	0.02	19.40	0.00
5	16.396	0.006	27.198	0.004	29.003	0.003	10.19	0.03	19.43	0.00
Average	16.356	0.006	27.385	0.003	29.128	0.002	10.21	0.03	19.41	0.00

k) TEN MILLION CYCLE PARAMETERS: 28 AUGUST

Simulator	MASS (g)						DIMENSIONS (mm)			
	CORE		SUPERIOR END-PLATE		INFERIOR END-PLATE		CORE HEIGHT		CORE DIAMETER	
	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS	Actual	LOSS
1	16.431	0.007	27.168	0.004	29.008	0.002	10.19	0.03	19.41	0.00
2	16.446	0.004	27.367	0.003	29.294	0.003	10.20	0.03	19.39	0.00
3	16.169	0.001	27.516	0.003	29.046	0.003	10.21	0.00	19.40	0.00
4	16.318	0.007	27.666	0.002	29.279	0.004	10.20	0.02	19.40	0.00
5	16.392	0.004	27.196	0.002	29.002	0.001	10.16	0.03	19.43	0.00
Average	16.351	0.005	27.383	0.003	29.126	0.003	10.19	0.02	19.41	0.00

3.3.5. Discussion of wear test results

Figure 3.3.5.a summarizes the average mass loss of the **core** over 10 million cycles. The mass loss of the core over 10 million cycles was 52 mg, or an average of 5.2 mg/M cycles. This equates to a loss of 0.3% of the entire core over 10 million cycles. The volumetric loss after 10 million cycles was 6.28mm^3, or an average of 0.628mm^3/M cycles.

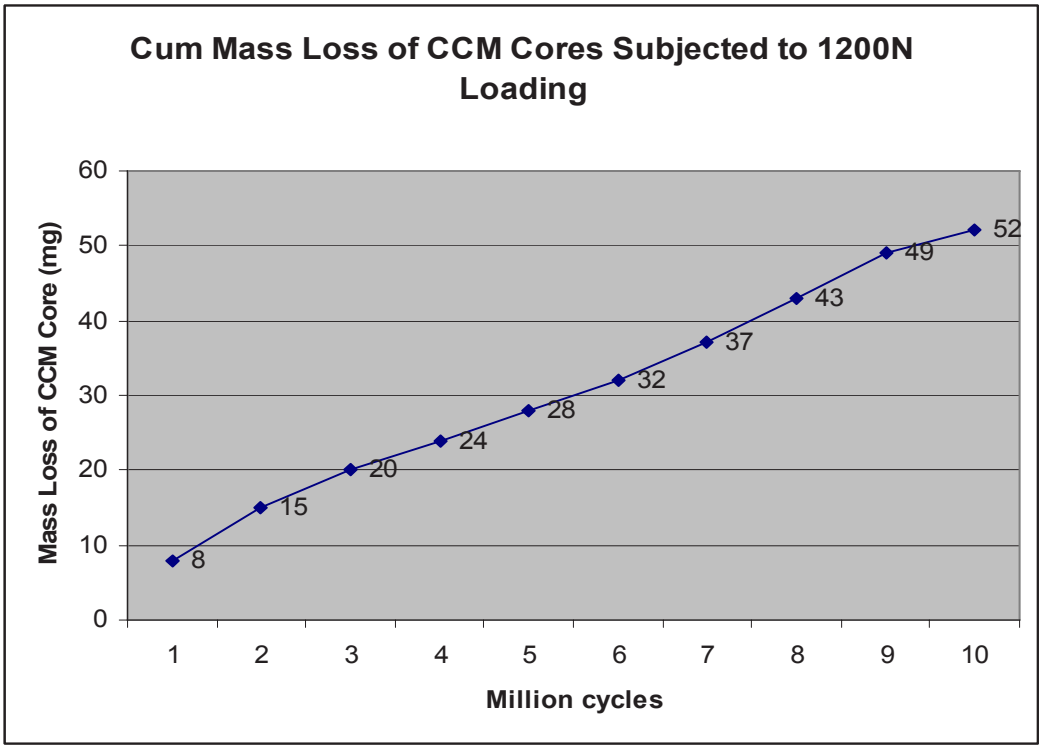


Figure 3.3.5.a: Cumulative mass loss in mg of core when subjected to 1200N loading

Figure 3.3.5.b summarizes the average mass loss for the full disc construct over 10 million cycles.The volumetric loss after 10 million cycles was 13.88mm^3.
The mass loss after 10 million cycles was 115 mg, for an average of 11.5 mg/M cycles. This equates to a loss of 0.1% of the entire disc over 10 million cycles. The volumetric loss after 10 million cycles was 13.88mm^3, for an average volumetric loss rate of 1.388mm^3/M cycles.

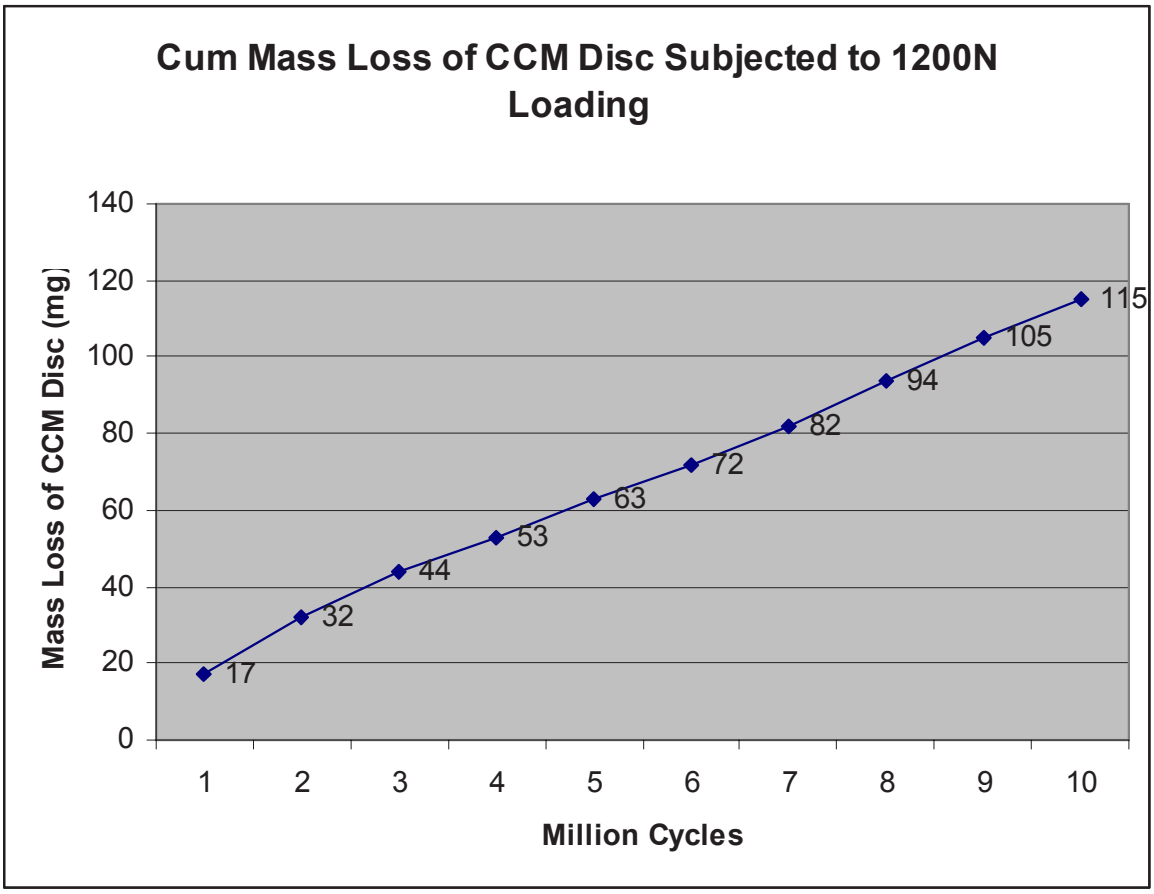


Figure 3.3.5.b: Cumulative mass loss of disc prosthesis when subjected to 1200N loading

The wear particle generation shows a decrease over the first 3 million cycles, followed by a relatively linear wear trend over subsequent cycles. The mass loss equates to 0.3% of the entire core and 0.1% of the entire disc over 10 million cycles. Factors that may have contributed to this trend are:

1. Magnitude of applied loading conditions.
2. Spinal simulator constructs of different test facilities would vary from facility to facility and to this extent comparative testing of different prostheses in future in the same facility would be informative.
3. The use of buffered saline in comparison to bovine serum is known to increase wear rates.

Wear particles fall within reported results for wear tests of other metal on metal (M-O-M) prostheses, with specific reference to M-O-M hip prostheses, for which the most literature is available.

A mass balance calculation (weight loss calculated from wear debris versus weight loss physically measured) shows good correlation and this comparison is included in the wear particle analysis report.

3.4. Result of static compression testing

3.4.1. Introduction

The test was performed in accordance with ASTM F-04.25.05.01 Draft I (February 2003) Item Z8924Z.

The inter-vertebral prosthesis consists of two end-plates positioned on either side of a meniscal core. Tests were conducted on Cobalt Chrome Molybdenum (CCM) end-plates with a CCM core.

The goal of this test was to determine the mechanical performance of the inter-vertebral prosthesis under compression. Two tests were performed on the materials configuration. The first test was conducted with the end-plates parallel throughout the test. In the second test, the bottom end-plate with retention was rotated to a 10º angle in relation to the top end-plate. The top end-plate was unconstrained in the horizontal plane.

All samples were previously unused parts and of standard production quality. The assembled lumbar prosthesis was placed in an Instron machine with a 0-100kN compression load capacity. In test one, the assembly was compressed until the end-plates touch; 25kN is achieved or mechanical failure occurs on any of the three components i.e. the two end-plates or the meniscal core. In test two, the assembly was compressed to a minimum of 10kN or until mechanical failure occurs. Mechanical failure was defined as a permanent deformation or breakage of any of the

three components. A total of five assembled samples were tested in each of the two tests.

The results reported in this report were load vs displacement results and the deformation of the samples at various intervals of the tests. The height of every meniscus was measured before and after the test for the five samples in test 1.

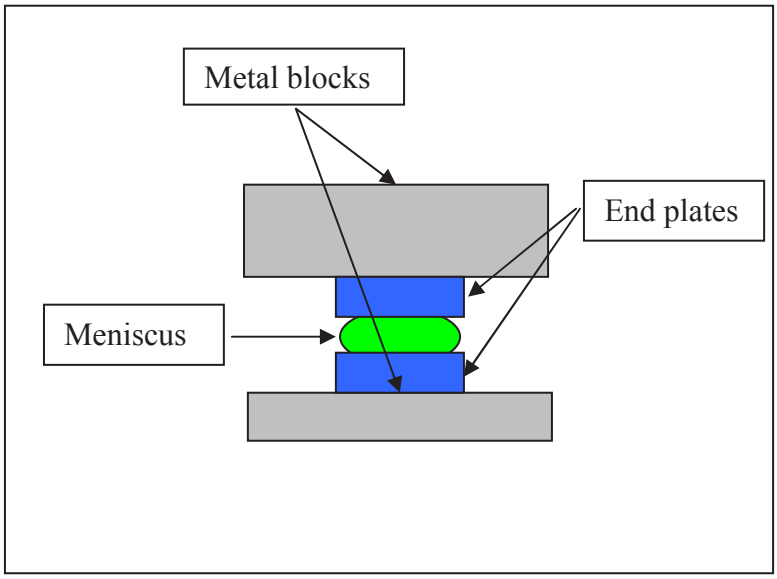
3.4.2. Rationale of load condition imposed

The test was conducted in an Instron machine capable of compressing the assembled prosthesis to 100kN. The load carrying capacity of the vertebral bone had been estimated to be approximately 5000N – 8200N[17]. Any load borne by the prosthesis in excess of this value would, under *in vivo* conditions, entail damage to the vertebrae. Compression of the discs was to increase until mechanical failure or a pre-set ultimate load was reached. During the test, the load was constantly monitored and plotted against the displacement.

3.4.3. Test bench set-up

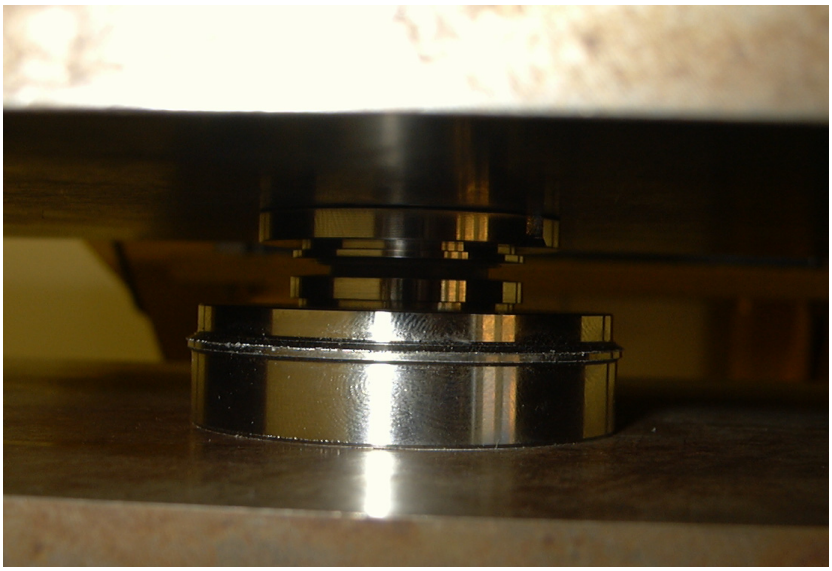
Figure 3.4.3.a: Test 1 - Compressive load

The assembled artificial disc is placed between the metal blocks in the Instron machine with the end-plates parallel to another as indicated in the schematic below.



Schematic 3.4.3.a: Assembled prosthesis in the Instron machine

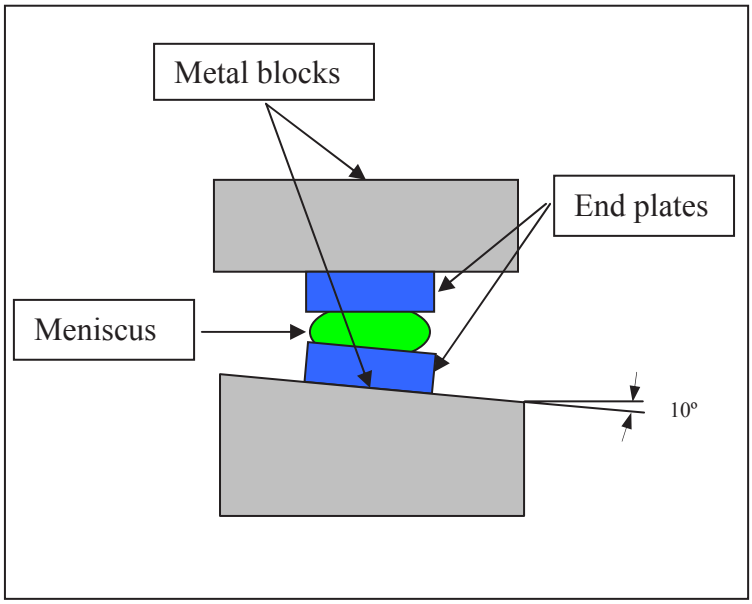
The load was imposed vertically on the prosthesis. The force was increased at a displacement rate of 25mm/min.



Picture 3.4.3.a: Assembled prosthesis in the Instron machine

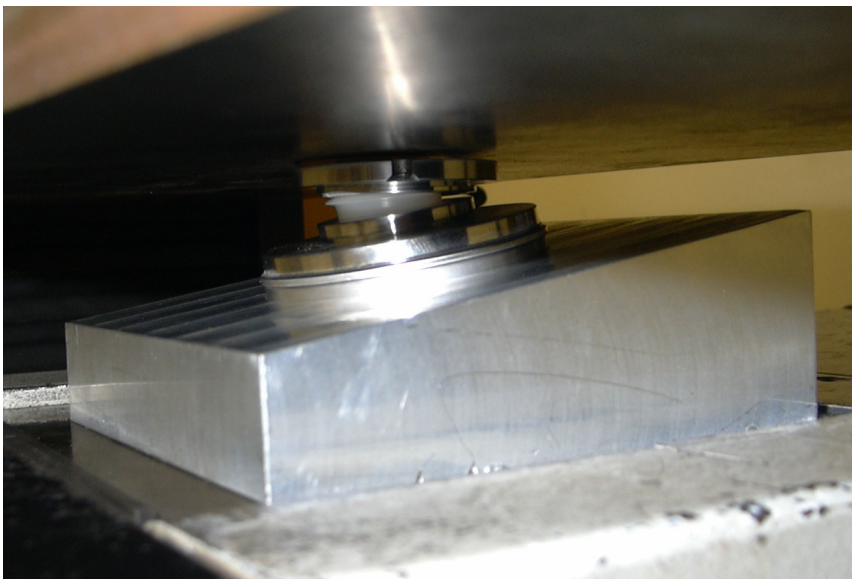
Figure 3.4.3.b: Test 2 - Shear load

The assembled artificial disc was placed between the metal blocks in the Instron machine with the end-plates at a 10º angle to one another, as indicated in the schematic below.



Schematic 3.4.3.b: Assembled prosthesis in the Instron machine at 10º

The load was imposed vertically on the prosthesis. The force was increased at a displacement rate of 25mm/min.



Picture 3.4.3.b: Assembled prosthesis in the Instron machine at 10º

3.4.4. Test results

3.4.4.a: Test 1 - compressive load

Figure 3.4.4.a: Average displacement of the device under compression

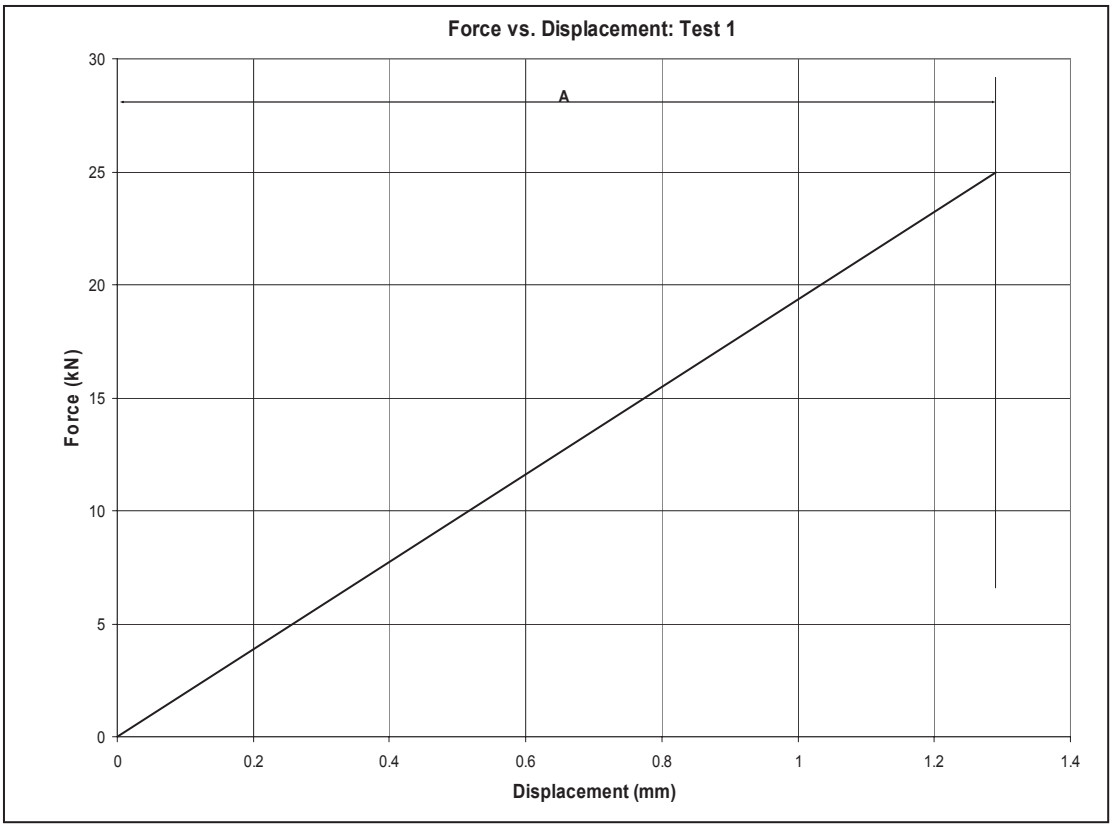


Figure 3.4.4.a: Load vs displacement for CCM disc and CCM core

The height of the assemblies was measured before the test commenced and within 5 minutes upon completion of compression. In Test 1, no height reduction occurred on any of the five samples.

3.4.4.b: Test 1- shear load

Figure 3.4.4.b: Average displacement of the device under compression with a 10º angle between the end-plates.

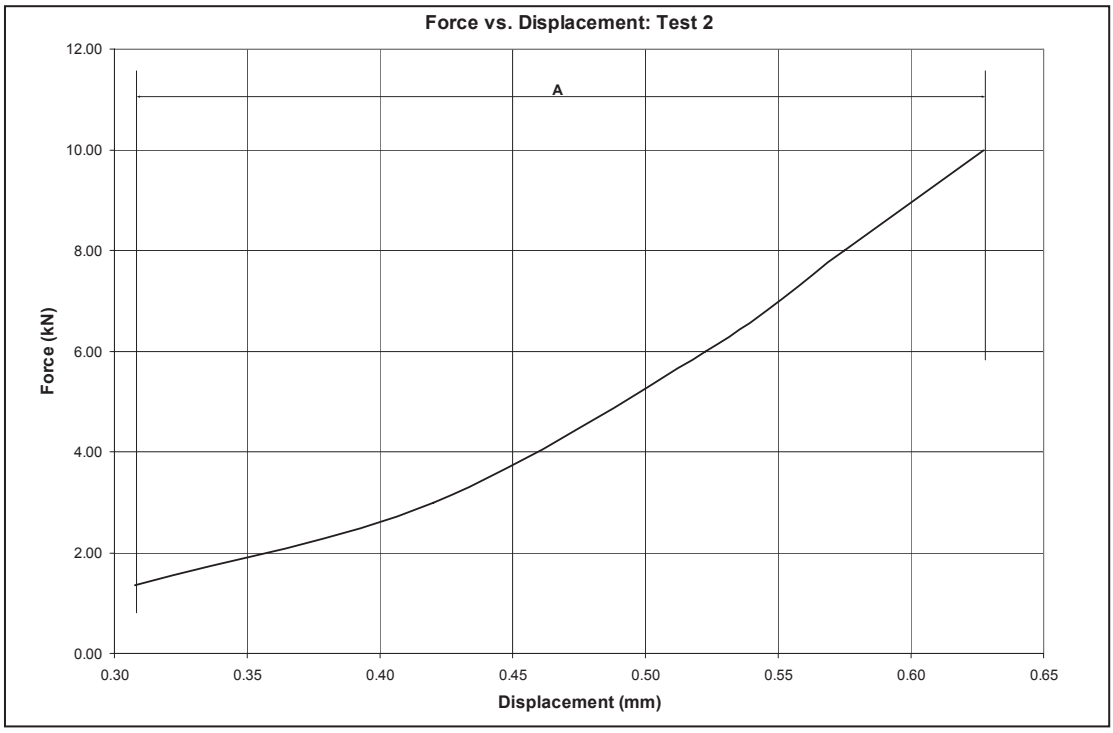


Figure 3.4.4.b: Load vs displacement for CCM & CCM core at 10º

The results of Test 2 are shown in Figure 3.4.4.b. This graph is divided into two regions, each representing a phase through which the test samples went.

The regions represent the following:

- Region A: On average, the first 0.31mm of vertical displacement of the test, the core rotated within the bottom end-plate up to an average applied load of 1.36kN (highest result is 1.74kN at 0.36mm and the lowest result 1.3kN at 0.3mm).
- Region B: Due to the angled assembly, the core rotated within the cup of the end-plate until the final position was found where the meniscus could not rotate any further. A linear elastic region was evident thereafter. The test was restrained to a maximum of 10 kN and no mechanical failure of the CCM end-plates or CCM cores was noted.

3.4.5. Discussion

Test 1 - Compressive load

In Figure 3.4.4.a, it can be seen that the samples remain within the elastic region of the materials. Recoverable strain occurs in this region. All loads applied on the assembled samples were in excess of 25kN. The average displacement at 25kN load is 1.29mm.

Test 2 - Shear load

The graph in Figure 3.4.4.a: is divided into two regions, each representing a phase through which the test samples went. Region A represents the rotation of the core within the bottom end-plate until the final position; Region B represents the linear elastic displacement. No mechanical failure occurred.

3.4.6. Conclusion

The cumulative mass loss of the disc was 0.3 % for the core and 0.1 % for the entire disc prosthesis at the end of the 10 million cycles. This had no impact on the integrity or function of the disc prosthesis.

The results of the static testing showed that the assembled CCM end-plate with CCM core prosthesis recovered within the elastic region after a load of 25kN was imposed axially. No visible or measurable deformation or deterioration was recorded.

The shear test result was carried out with a 10^{o} inclination between the two end-plates. No constraint was placed on the top end-plate without the retention. The test showed an elastic region of the CCM core up to the tested10kN.

Under the maximum load, reported by Wilke H-J[3] (1998), of 4140N when lifting 20kg in a hunch-backed posture, the Kineflex-M lumbar prosthesis will not permanently deform, nor will any temporary deformation result in constraint of movement of the prosthesis.

3.5. References: Results: Pre-clinical, in vitro testing of the Kineflex lumbar disc prosthesis

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4. RESULTS: BOOK CHAPTER (ELSEVIER): James J. Yue, Rudolf Bertagnoli, Paul McAfee, and Howard A. *Motion Preservation Surgery of the Spine: Advanced Techniques and Controversies.* CHAPTER 42: KINEFLEX: Ulrich R. Hähnle, Malan De Villiers, and Ian R. Weinberg

4.1. Introduction

In the middle of 2006, I was approached to write the chapter of a new book on motion preservation surgery in the human spine, edited by leading spine surgeons in the field (James J. Yue, Rudolf Bertagnoli, Paul McAfee, and Howard An) and published by Elsevier Publishers. By then, I had presented extensively at national and international meetings (see Publications and Presentations) on surgical outcome with different lumbar disc prostheses, primarily with the lumbar Kineflex intervertebral disc prosthesis. The book chapter elaborates on the ideas behind the development of the prosthesis, the pre-clinical testing in the laboratory, the properties particular to the device and the insertion technique. It then follows with the clinical short-term outcome studies of the first patients, who had by then completed a 2-year follow-up.

Co-authors are Malan de Villiers (PhD), who performed a large part of the pre-clinical testing and who is a co-developer of the prosthesis, and Dr Ian R. Weinberg, who is my partner in practice, co-developer of the prosthesis and co-investigator in the clinical trials.

The book was published in June 2008 and I received a complimentary copy from the publisher, which can be reviewed.

CHAPTER 42

Kineflex

Ulrich Reinhard Hähnle, Malan De Villiers, and **Ian R. Weinberg**

KEY POINTS

- The Kineflex disc is a recentering, unconstrained, metal-on-metal mechanical disc prosthesis.
- A cervical and a lumbar disc are currently Conformit Europeane (CE) certified and are also being evaluated in U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA) randomized, controlled trials.
- The Kineflex disc was designed primarily for patients with advanced motion segment degeneration using a simple insertion technique allowing powerful distraction and posterior placement within the disc space.
- The insertion of the assembled prosthesis enables free articulation of the end plates, allowing the superior and inferior end plates to be advanced independently.
- Good short-term clinical results have been achieved at a minimum follow-up of 2 years.

INTRODUCTION

Adjacent-level degeneration is a major concern in lumbar fusion operations.[1,2] Lumbar artificial disc replacement is an alternative to arthrodesis. The purpose of the intervention is to restore the intervertebral segment stability and mobility and protect the adjacent levels against nonphysiological loading conditions. Surgical insertions of lumbar disc prostheses using a steel ball were first published by Fernström.[3] It failed clinically essentially because of subsidence of the implant into the bony end plate. Modern-type total lumbar disc replacement commenced in 1984 with the insertion of the first generation CHARITÉ (DePuy Spine Inc., Raynham, MA) disc prosthesis (CHARITÉ SB I).[4] The mechanism of the prosthesis was carried through to the third-generation device that is still being used today (CHARITÉ SB III).

Subsequently more constrained lumbar disc prostheses have been developed. Three of these prostheses are currently being evaluated in U.S. Food and Drug Administration (FDA) studies (ProDisc, Synthes, West Chester, PA; Maverick disc, Medtronic Sofamor Danek, Memphis, TN; FlexiCore disc, Stryker Spine, Allendale, NJ). Despite major advances in the disc insertion technique and design, difficulties persist with the correct midline and posterior placement of the prosthesis within the disc spaces, even in experienced hands.[5]

The Kineflex disc prosthesis was originally named Centurion disc. It was developed in Centurion, located between Pretoria and Johannesburg in South Africa. The main objectives in the development of this prosthesis were an unconstrained/semiconstrained but recentering mechanism, to facilitate reliable midline and posterior placement of the implant within the disc space in severely degenerated disc spaces and to develop a simple and safe implantation technique, with the implantation being executed through a minimal invasive approach.

INDICATIONS/CONTRAINDICATIONS

Inclusion criteria at our center were age of 18 to 65 years, mechanical back and leg pain, symptomatic single or multilevel degenerative disc disease at the L2-L3, L3-L4, L4-L5, or L5-S1 levels confirmed on x-ray studies, magnetic resonance imaging, or provocative discography. Further inclusion criteria included recurrent disc herniation, broad-based central disc herniation without sequestration, and junctional failure after previous fusion. In all patients, supervised conservative treatment of at least 6 months had failed. Only the symptomatic levels on clinical examination and discography were replaced.

Exclusion criteria were general contraindications, such as severe obesity, osteoporosis, tumor, or infection. Spinal exclusion factors were thoracic kyphosis of more than 60 degrees, idiopathic lumbar scoliosis of more than 30 degrees, previous wide laminectomy with destabilization of the facet complex, spondylolisis or spondylolisthesis, greater than Meyerding Grade 1 of the level to be replaced, bony spinal stenosis, and sequestrated disc prolapse tracking up or down behind the vertebral body. Other contraindications were previous retroperitoneal surgery, advanced vascular pathology, and single kidney.

Advanced facet arthritis was not an exclusion criterion unless osteophyte formation from the facet resulted in bony canal or recess stenosis. Spinal or lateral recess stenosis caused by soft tissue (disc, ligamentum flavum, or joint capsule) was not considered a contraindication for disc replacement if proper decompression during surgery, by means of direct or indirect decompression, could be anticipated on preoperative imaging.

DESCRIPTION OF THE DEVICE

The Kineflex disc (Spinal Motion, Inc., Mountainview, CA) represents a disc prosthesis with a mechanism that is unconstrained but

re-centering, resulting in a mobile center of rotation. The amount of constraint lies between the CHARITÉ disc prosthesis and Mobidisc (LDR, Troyes, France) on the unconstrained side and the ProDisc, Maverick, and FlexiCore disc prostheses on the constrained side. The mechanism comprises two metal end plates congruently articulating over a sliding core that is positioned posterior to the center of and in between the end plates (Fig. 42–1). The inferior end plate has a retaining ring that limits the excursion of the inferior articulation and prevents dislodgement of the core. The superior end plate has no retaining ring. The angle of motion allowed by the articulating mechanism from the neutral position is 12 degrees into flexion-extension, left or right side bending. This is true for the lumbar as well as for the cervical disc (Kineflex|C).

The end plates and core are made of cobalt-chromium-molybdenum alloy (Biodur CCM Plus, Carpenter Technologies, Reading, PA).

The integrating side of the end plate, facing the bony end plate, is flat and oval shaped, and has a small 1.5-mm wide midline fin with an oblique leading edge and two transverse holes which follows a pre-cut insertion groove but also allows self-cutting of a groove if required. The side of the end plate has multiple machined sharp serrations for primary fixation. Only the central portion of the surface adjacent to the center fin is smooth to allow riding of the adjacent prosthesis along the 'slotted end plate distracter.' The entire leading edge of the end plates is beveled toward the bone side, to avoid cutting into the bony end plate during the insertion procedure.

Both the inferior and superior end plates are manufactured in three different sizes (small, medium, and large). The inferior end plate is manufactured in three different angles coupled with three different heights (0 degree, 5.5 mm; 5 degrees, 6.5 mm; and 10 degrees, 7.25mm). The superior end plate has no angle but two different heights (5.5 to 6.5 mm). As a result, the overall height of the prosthesis ranges from 11 mm to 13.75 mm.

BACKGROUND OF SCIENTIFIC TESTING/CLINICAL OUTCOMES

Preclinical Testing

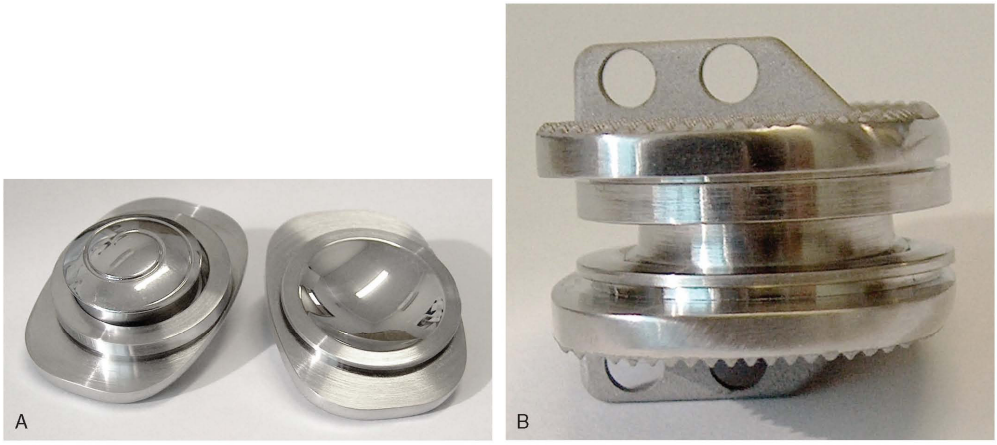
Substantial preclinical mechanical testing was performed on the Kineflex arthroplasty, including static testing, monoaxial fatigue testing, and wear testing. All tests were performed using finished, sterilized devices, with the 5-×40- mm end plate size and a core. As noted earlier, there is only one core size; therefore, the size of the load-bearing area on each end plate, which conforms to the core, is the same for all end plate diameters.

Static Compression and Static Shear Testing

Static compression and shear testing were performed in accordance with American Society for Testing and Materials F-04.25.05.01 Draft I (February 2003) Item Z8924Z. The tests were conducted in an Instron machine, and compression of the six disc samples were increased until mechanical failure or a preset ultimate load was reached. The yield displacement, yield load, ultimate displacement, ultimate load, and stiffness were recorded. The results demonstrated that there was no height reduction in any of the samples as would be expected with a metal-on-metal construct. All loads applied to the assembled samples were in excess of 25 kN. Thus, because the maximum load-carrying capacity of vertebral bone is approximately 5 to 8.2 kN,[6] the compressive strength of the Kineflex Prosthetic Disc (KPD) substantially exceeds that of the vertebral bone.

Dynamic and Shear Fatigue Testing

Samples were tested under cyclic axial and shear compressive loading to assess the suitability of the fatigue resistance of the device for in vivo use. Samples were immersed in a physiologically buffered saline bath at 37°C throughout the test to simulate in vivo conditions. A test frequency of 5Hz was applied. Loads varied



■ **FIGURE 42–1.** Kineflex metal-on-metal **(A)** mechanism. **(B)** Unit assembled.

cyclically between the maximum value of 2,000 N and 10% of the maximum, or 200 N. When viewed in terms of an average in vivo load, the results demonstrated no measurable dimensional changes in either the end plates or the core in what equates to 10 years of usage.

Wear Testing

To evaluate the amount and size of wear particles that may be generated by the arthroplasty in vivo, five test samples were cyclically loaded in a multiaxial motion simulator for 10 million cycles. Testing was performed at a frequency of 5Hz. A constant 1,200-N load was applied throughout the wear test. A total cyclic range of motion of ± 7.1 degrees of lateral bending, a cyclic range of motion of ± 7.1 degrees of flexion-extension bending, and ± 4 degrees of axial rotation were applied.

Test specimens were immersed in a 37°C saline bath throughout testing to simulate in vivo conditions. After every 1,000,000 cycles, the disc and meniscus were weighed, and a dimensional check of height and diameter was performed. Visual inspection was also performed, and a photographic record was compiled.

Weight and dimensional measurements of the prosthesis (end plates and core) performed after every million cycles showed an average volumetric wear rate of 1.39 mm^3 per million cycles. Mass loss was approximately 115 mg, for an average of 11.5 mg per million cycles. This represents a loss of only approximately 0.1% of the total prosthesis mass over 10 million cycles. Dimensional changes in the core were small, with an average height loss of less than 0.3 mm; no core exhibited any change in diameter. The degree of dimensional change observed with respect to core height does not interfere with the functionality of the device.

The mean wear particle size was approximately 0.5 μm across all samples. Analysis of the form factor of the wear particles indicates that they were generally slightly elongated. Evaluation of the particles showed that they had a flake-like morphology when greater than 1 μm in size, but were granular when less than 1 μm in size.

In vivo animal data demonstrating that wear debris of this type and quantity are unlikely to generate an adverse biologic response is available. Cunningham et al[7] evaluated the neural and systemic tissue response to cobalt alloy particulate debris in an in vivo rabbit model up to 6 months. They placed 4 mg of cobalt alloy particles directly on the dura and compared the results with rabbits that had a sham procedure of dural exposure alone. All cobalt alloy particles used were less than 5 μ in diameter, and 70% of all particles were between 2 and 3 μ in diameter. It should be noted that although the majority of particles were in the 2- to 3-μ range, more than 1.03 × 1010 submicron particles were injected.

At 3 months, the number of macrophage-expressing cytokines localized within the spinal cord and overlying tissues indicated no significant differences compared with the control group.

Despite regions heavily laden with metallic particulate, histiocystic reaction, and cytokine activity, the spinal cords indicated normal distribution of myelin and the intracellular neurofibrilla network. There was no evidence of cellular apoptosis, and all specimens were characterized as without significant histopathologic changes.

The quantity of particles applied in the Cunningham study, together with the one-time application of these particles directly to the dura, represents an extreme worst-case scenario compared with the anticipated wear of the Kineflex over time. The Cunningham study used a single application of particles, compared with the gradual release of particles over time that would be expected in vivo. Based on these results, there is low risk of any adverse biologic response to the wear particles generated by the Kineflex, even under the worst-case conditions of the in vitro wear test with respect to loads, motions, and the saline lubricant environment.

Biomechanics of the Kineflex Lumbar Disc Prosthesis

The design of the Kineflex prosthesis allows for high congruence of articulating components over its full range of articulation. However, the three-part design allows for a self-centering but relatively unconstrained motion, which enables translation of end plates with respect to each other, as opposed to ball-and-socket (two-part) designs, which are highly constrained. The instantaneous axis of rotation of the functional spinal unit (FSU) does indeed also incorporate a translating component, which is essential to allow flexion-extension motion in the three-point support structure of the FSU. The in vitro biomechanics of the Kineflex prosthesis was evaluated in harvested spines and compared with untreated harvested spines by Denis Di Angelo et al,[8] who concluded that there was no significant difference in the motion response between the Kineflex disc and the harvested spine conditions except in extension, where the motion was 73% of the untreated condition. The center of rotation of the Kineflex disc is located posterior of center, which also mimics the FSU condition.

Clinical Testing

The primary clinical outcome measures for this study were pain relief and functional improvement as assessed by the Oswestry Disability Index (ODI) and our own questionnaire. Questionnaires (ODI and our own questionnaire) were completed by the patient preoperatively, at 6 weeks, 3 months, 6 months, and yearly in conjunction with the regular follow-up examinations. In addition to the outcome data, general demographic information, operative data, and data pertaining to radiologic examination were collected.

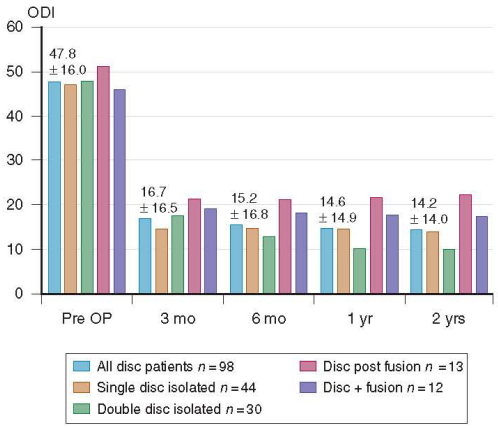
Our own questionnaire was designed by first and last authors and has not been validated. The patient is asked about his or her satisfaction with the outcome of the treatment operation (options: excellent, good, fair, poor) and to state if he or she would undergo the same operation again or recommend it to friends (options: yes, don't know, no). Furthermore, the patient is asked to gauge his or her pain in the last 2 weeks preoperatively and at the time of completing the questionnaire on a scale of 1(no pain) to 10 (pain as bad as it can be). No differentiation between leg and back pain is made.

Clinical Presentation and Evaluation

Baseline characteristics of the study population are shown in Table 42–1. Our first 100 patients have reached 2-year follow-up. They constitute a heterogenous study population, with 41% having undergone previous open lumbar surgery (see Table 42–1).

TABLE 42–1. Preoperative Data of Study Population (n = 100 Patients)

Factor	Number of Patients (n = 100)
Gender	
Male	57
Female	43
Age (years)	44.9 (23–63)
Height (cm)	174.6 ± 9.6 (154–196)
Weight (kg)	81.3 ± 15.6 (47–138)
Pain duration (month)	63.5 ± 74.6 (5–400)
Nonoperative care	
Physical therapy	99
Chiropractic	61
Acupuncture	25
Previous surgery	
Rizotomy	15
Discectomy	32
Laminectomy	20
Fusion	13
Smoking	39
Nonsmoking	61



■ FIGURE 42–2. Oswestry Disability Index (ODI) preoperatively and at different follow-up intervals.

Clinical outcome assessment was available for 99 of 100 patients at 1 year and at 97% at 2 years.

Sixty-nine patients underwent single-level disc replacements, and 31 patients had two levels replaced. Three of the patients with single-level surgery later received a second-level lumbar disc replacement at 7, 9, and 10 months after the index procedure, respectively. Twelve patients underwent fusions at another level (hybrid cases) during the index procedure. Four of these patients had previous discectomies. Thirteen patients presented with adjacent level disc disease after previous instrumented posterolateral fusion surgery (one to seven previous operations). Another 28 patients in this series, who underwent single- or double-level disc replacements, had one to four previous discectomies or laminotomies, or both (see Table 42–1).

Operative times, estimated blood losses, and postoperative hospital stays are shown in Table 42–2.

Recovery and Patient Satisfaction

Hospital stay averaged 2.8 ± 0.8 days (2 to 8 days). Eighty-six patients were in employment at the time of the operation (Fig. 42–2). All but one patient went back to their previous occupation at an average of 31.0 ± 16.1 days.

TABLE 42–2. Mean Operative Time, Blood Loss and Length of Hospital Stay

Factor	Number of Patients
Operative time (minutes): all patients	130 (45–400)
Operative time (minutes): single-level patients (48% at L4-L5 level)	95.3 ± 28.3
Estimated blood loss (milliliters): all patients	282 ± 301
Estimated blood loss (milliliters): single-level patients (48% at L4-L5 level)	145.7 ± 153.2
Hospital stay (days) all patients	2.86 ± 0.8

The pain score (scale from 1 to 10) of all patients decreased from 9.16 ± 1.00 preoperatively to 2.88 ± 2.34 at 1-year follow-up (2.78 ± 2.2 at 2 years).

The ODI improved significantly from 47.8 ± 16 to 14.6 ± 14.9 at 1 year (14.2 ± 14.0 at 2 years) (P <0.01) (see Fig. 42–2).

Patients with double-level disc replacement scored better regarding pain score improvement as well as ODI improvement at 1 year as compared with those patients with single-level disc replacements (P <0.01) (see Fig. 42–2).

Patients in the isolated single- or double-level disc replacement group had poorer outcome scores if they had undergone previous discectomies and/or laminectomies (n = 28) compared with patients without previous surgery (control: n = 46). Their ODI improved from 50.3 ± 19.2 to 16.5 ± 17.2 (control: from 46.1 ± 15.3 to 11.0 ± 15.3 and their pain score from 9.17 ± 1.2 to 3.1 ± 1.9 (control: 9.06 ± 1.1 to 2.41 ± 2.2) at 1 year.

At 1 year, 87% (at 2 years 90%) of patients considered their result good or excellent, and 90% (92% at 2 years) would undergo the same operation again or recommend it to friends.

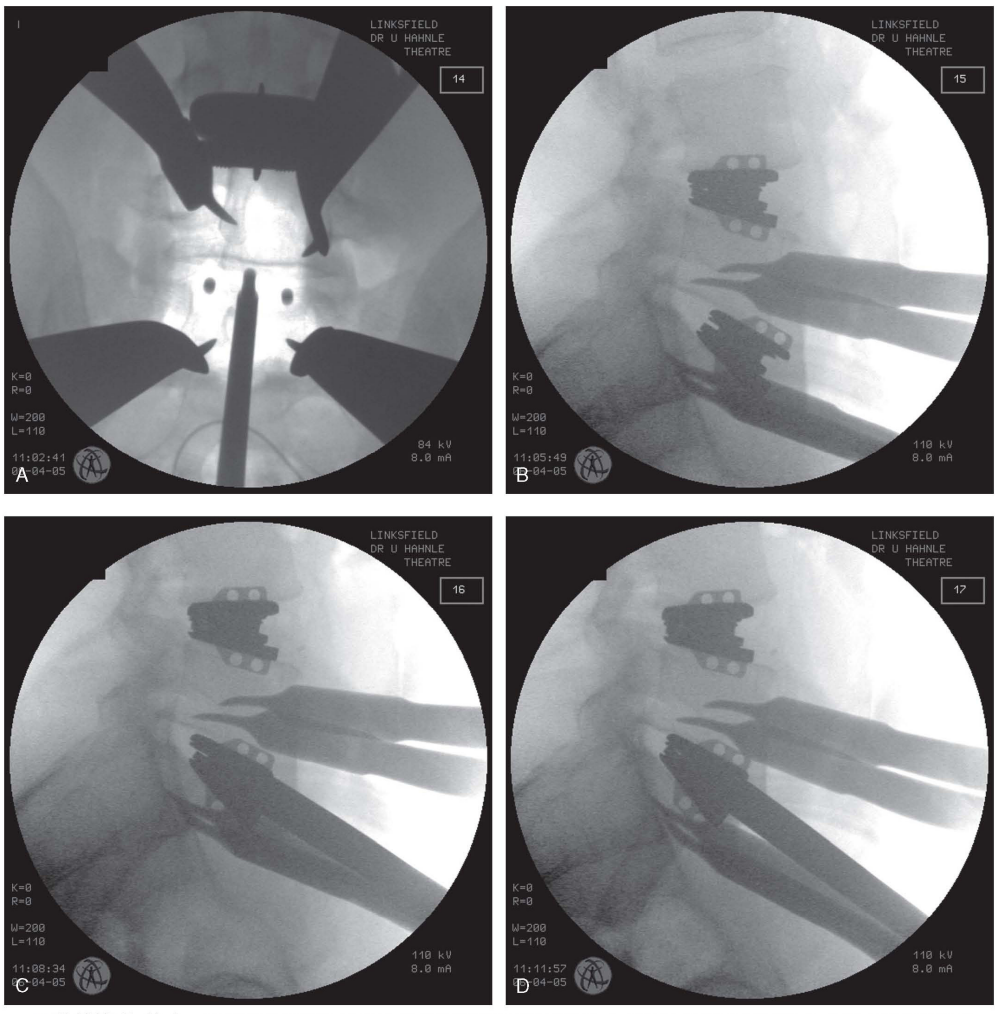
OPERATIVE TECHNIQUES

In our center, all procedures are performed on an electrical radiolucent table with the patient in supine position under general anesthesia. Image control is used preoperatively to determine the level of the skin incision and to preoperatively adjust rotation of the patient's disc space to be instrumented. Cell saver, to harvest the patient's red blood cells and to re-transfuse (if necessary), is used routinely. For a right-handed surgeon, the procedure is performed from the right side of the operation table. In case of a right-sided retroperitoneal approach, the exposure is performed with the surgeon standing on the left, only to change to right side once the spine is reached. A transverse skin incision centered over the midline is used in one- to three-level exposures.

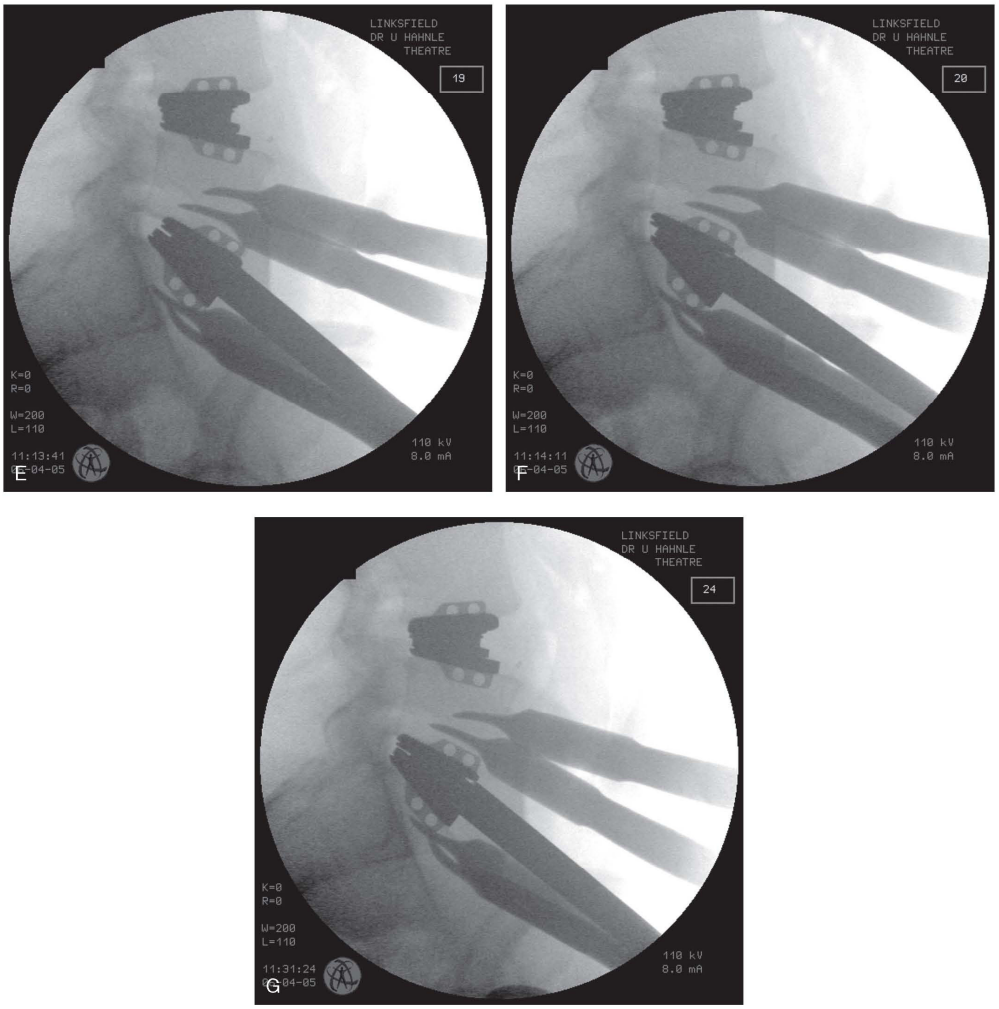
Depending on the level, a left- or right-sided retroperitoneal approach is performed along the posterior rectus sheet. For levels L4-L5 and higher, the transversus abdominis fascia may have to be incised from the arcade ligament cranially after mobilization from the peritoneum. Segmental vessels are ligated, if required, and the large vessels are mobilized off the relevant disc space. The level to be instrumented is verified under image control. Hohmann retractors are used for exposure and attached to the frameretractor throughout the insertion process. After midline annuloplasty, the nucleus, the inner layers of the annulus, and the cartilaginous end plate are removed. This is followed by sequential stretching of the disc space using wedged end plate distracters. If necessary, any sequestrated disc pieces or osteophytes are removed.

Insertion of the Prosthesis

The disc is inserted as a single unit with a freely mobile mechanism during the insertion process to facilitate posterior placement within the vertebral disc space (Fig. 42–3). During insertion, the end plates of the prosthesis can be advanced individually, rotating



■ **FIGURE 42–3.** Insertion technique as seen on intraoperative radiographs. **A,** Midline finder in position. **B,** Initial engagement of the prosthesis into the disc space. **C, D,** Sequential advancement of the prosthesis into final position.



■ **FIGURE 42–3. Cont'd.** **E** to **G,** Sequential advancement of the prosthesis into final position.

in the sagittal plane around the core (see insertion video). Therefore, pressure at the bone/implant interphase at the leading edge of the prosthetic end plate is reduced during prosthetic end plate advancement. The Kineflex disc constitutes the only mechanical disc prosthesis for which final placement into the disc space is performed with a freed mechanism.

Insertion Procedure

The insertion instruments include the following items: wedge-shaped end plate distracters (three heights), vertebral end plate seizers (three seizes), one midline finder, end plate cutters (two heights), a slotted end plate distracter including guiding plates, and an initial as well as a final implant-insertion instrument (three sizes each). It further includes an implant-removal instrument.

After the disc space is prepared as described earlier, the final end plate size of the prosthesis is determined using the end plate seizers. This is compared with the preoperatively planned seize. The angle and height of the prosthesis were determined during preoperative planning. The height and angle might be adjusted only if the ease of insertion of the wedges differs from what was expected on preoperative planning.

The exact midline is determined under anteroposterior image control after insertion of the midline finder into the disc space. The lateral border of the vertebral body and the pedicles serves as reference and is related to the outer markers of the midline finder. The midline is marked with diathermy on the vertebral body.

On the electrically motorized table, the patient's lumbar area is extended, opening the prepared disc space. The midline grooves are cut using the vertebral end plate cutter. The correct size disc prosthesis is inserted halfway into the disc space. The slotted end plate distracter should be used if the anterior entry of the disc space is tight or recollapses. Through the slotted distracter, the disc is inserted halfway into the disc space, and the slotted distracter is removed.

From here on, the open final insertion instrument of the correct size is used to advance each end plate individually into the desired position. Owing to the unconstrained nature of the mechanism, the core acts as a hypomochlion (pivot), allowing the advancing end plate to pivot over the core and thereby reducing pressure on the leading edge of the end plate at the prosthesis/bone end plate interphase. This avoids end plate violation during the insertion process with possible subsequent subsidence.

The final end plate position is controlled under fluoroscopic imaging. The annuloplasty is closed using stay sutures. A 1/8-inch closed drain is left in the retroperitoneum, if required.

POSTOPERATIVE CARE

Postoperative mobilization: Patients are allowed to ambulate the day after surgery without bracing. Supervised gait training, isometric muscle strengthening, and stretching exercises start from day 1 postoperatively. At discharge (day 2 to 4 postoperatively), patients are instructed to walk every day and are allowed to sit as long as they feel comfortable. Cycling on a stationary bicycle, longer and faster walks, more vigorous isometric exercises, and hamstring and hip stretching exercises are encouraged after removal of stitches at 12 days after the operation. Light sports are allowed at 6 weeks. Impact sports are allowed only at 4 months in order to allow bony incorporation and remodeling at the implant bone interphase.

COMPLICATIONS AND AVOIDANCE

In our series of 230 patients studied so far, we have had no procedure-related deaths. In general, perioperative approach-related and implantation-related complications of the first 100 patients with 2 years follow-up, including reoperations, are described as follows:

Approach-related complications included two occurences of deep vein thrombosis, four venous vascular injuries (blood loss <500 mL), two transient neuropraxia of an L-5 nerve root, six patients with postoperative warmer left leg (one permanent).

Disc level-related complications were as follows: Three patients had disc-related complications requiring reoperations. One had an incomplete decompression and was redecompressed 2 days later. The same disc was reinserted. Another patient had a traumatic partial end plate protrusion at 4 weeks. The disc was removed and converted into an anterior fusion. In a third patient, with major subsidence, the disc was removed at 2 weeks, the vertebra was bone grafted, and a larger end plate disc inserted.

Three patients underwent a second-level disc replacement procedure. All reoperated patients were followed up further, and their assessment continued to be included in the outcome results.

DISCUSSION

The Kineflex disc prosthesis has three unique features that should be emphasized, because not all disc prostheses are the same: (1) The mechanism of the prosthesis is unconstrained and recentering, using a retaining ring on the inferior end plate to maintain the sliding core in position. (2) Two material options for the articulating surfaces are currently available (cobalt chrome on polyethylene as well as cobalt chrome on cobalt chrome). (3) It is the only mechanical disc in which the final seating into the disc space is accomplished with a fully freed articulating mechanism in order to take pressure off the implant/bone interface at the leading edges of the implant during the insertion. The aim is to minimize the danger of bony end plate violation.

The Kineflex disc is currently under evaluation by the FDA for the metal-on-metal articulation.

ADVANTAGES/DISADVANTAGES: KINEFLEX

Kineflex Lumbar Disc Prosthesis	
Metal-on-metal disc	
Unconstrained and recentering disc mechanism	
Machined pyramids of 0.6-mm height	
Flat prosthetic end plates	
Midline finder	
Insertion technique	
Advantages	**Disadvantages**
Minimal wear	No axial shock absorption other than by coupled motion
No risk of polyethylene wear particles	None
Motion pattern approximates natural disc motion	None
Translational forces are absorbed by unconstrained mechanism	Hypermobility can recur in preoperative hypermobile disc spaces
Greater ROM than constrained discs	If cartilage is left behind during end plate preparation, the primary fixation might be insufficient
Excellent primary fixation within the disc space	Initially, after insertion, load is concentrated on the perimeter of the prosthetic endplate
Prosthetic end plates do not "rock" over bony end plates if match is not perfect	None
Easy to find exact midline with the help of lateral markers	If disc material is left behind within the disc space, it may be carried into the spinal canal. This can be avoided by careful discectomy and end plate preparation.
As the articulating mechanism is released during the insertion process, the superior and inferior prosthetic end plates can be advanced independently during seating of the implant	

More than 50% of patients in our series had advanced disc degeneration, with disc space height less than 5 mm and some with advanced facet joint arthritis.[9] In significantly collapsed and rigid disc spaces, we specifically aim to achieve a posterior position of the prosthesis within the disc space in order to unload the facets. This has been difficult with other implants owing to the rigidly held implants during the insertion process. The Kineflex disc prosthesis is disconnected from its initial insertion tool after the initial engagement into the disc space. The final placement is done with a released prosthetic mechanism that facilitates the seating of the prosthesis, avoiding excessive pressure on the bony end plate during insertion. Although the achievement of a posterior position of the prosthesis within the disc space has not yet been systematically evaluated, it seems to be much easier to achieve than with other implants.

The operative time and blood loss are higher than in other studies.[10] Twelve of our patients had additional fusion surgery, including combined posterior and anterior osteotomy surgery with operative times of up to 7 hours.[11] These cases added to operative time and blood loss. However, for single-level disc replacements, the operative time and blood loss are comparable to other studies[10] (see Table 42–2). The use of Hohman retractors for exposure causes additional bleeding from the vertebral bodies but avoids slippage of the major veins into the operative field.

Postoperative hospital stay and return to work data compare favorably with other studies.[10] Ninety-eight percent of our patients went back to work at an average of 31 days after the operation.

The ODI and pain score improvements occurred early after surgery and were maintained at the time of 2-year follow-up (see Fig. 42–2). As previously described, the patients with double-level replacement[12] scored better in their 1-year clinical outcome parameters than the patients with single-level replacement after scoring poorer results at 3 months[13] (see Fig. 42–2). We had a 6% reoperation rate within 2 years. In three of our single-level replacements, we performed a second-level replacement within the first 2 years. In all three patients, this second level had been degenerative before the first procedure. Therefore, we now tend to be more aggressive in favor of second-level replacements as compared with single-level replacements.

The improvement in the pain score and ODI scores compare favorably with the literature.[10,12,13]

CONCLUSION

We achieved good short-term clinical results using the Kineflex disc in a heterogeneous patient group with a high number of patients with advanced disc degeneration, severe disc space narrowing, and previous fusion with lumbar flat back deformity. The independent advancement of the end plates allows seating of the prosthesis posterior into disc space with minimal trauma to the bony end plates.

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5. RESULTS: FIRST PUBLICATION:

Ulrich R. Hähnle, MD, FCS (Ortho), Ian R. Weinberg, MD, FCS (Neuro), Karen Sliwa MD, PhD, Barry M.B.E. Sweet, MD, PhD, and Malan de Villiers, PhD. Kineflex (Centurion) lumbar disc prosthesis: Insertion technique and two-year clinical results in 100 patients. ***SAS Journal.*** **Winter 2007**;1:28–35. DOI: SASJ-2006-0005-RR.

5.1. Introduction

Worldwide, this is the first peer-reviewed publication on the Kineflex lumbar disc prosthesis. It was published in the first volume of the SAS Journal, the official journal of the Spine Arthroplasty Society. The article presents the design and the insertion technique of the Kineflex lumbar disc prosthesis. It further investigates the radiological placement accuracy and two year clinical outcome of the first 100 patients treated.

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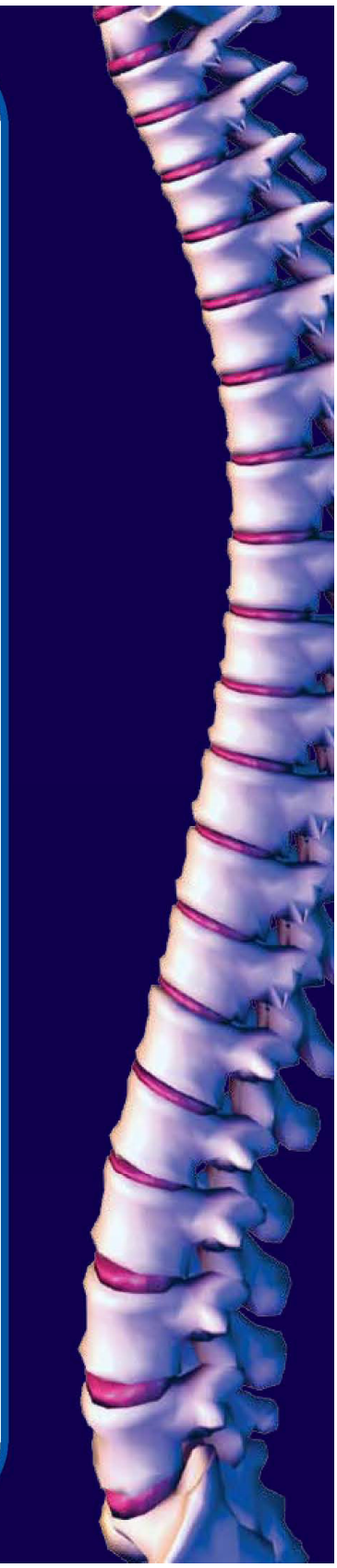

LUMBAR ARTHROPLASTY

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LUMBAR ARTHROPLASTY

Kineflex (Centurion) Lumbar Disc Prosthesis: Insertion Technique and 2-Year Clinical Results in 100 Patients

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ABSTRACT

Background

The Kineflex lumbar disc is a mechanical, unconstrained, re-centering disc prosthesis developed in South Africa. The first implantation took place in October 2002. We present a single-center, prospective, longitudinal study of the first 100 patients treated with the Kineflex lumbar disc. Our objective was to evaluate the insertion technique, clinical outcomes, and patient satisfaction at 2 years postimplantation in 100 consecutive patients with 132 (68 single- and 32 2-level) Kineflex lumbar disc replacements.

Methods

We determined the exact central placement of all disc implants in the coronal and midsagittal planes. We measured clinical outcome with the Oswestry disability index (ODI), our own questionnaire, and the time needed to return to work. All patients received radiological and clinical follow-up assessments for 2 years after the index procedure.

Results

Forty-three patients were female. The mean age of the patients at operation was 44.9 years (range, 23–63 years). Postoperative hospitalization averaged 2.8 days (range, 2 to 8 days). All patients who were employed before surgery returned to work 31 ± 16.8 days after the operation. Fifty-six percent of operated disc levels had intervertebral disc heights of less than 5 mm. A 2-year clinical outcome was available for 98 of the 100 patients (58 excellent, 30 good, 7 fair, 3 poor). The ODI score improved from 47.8 ± 16.0 preoperatively to 14.2 ± 14.0 ($P < .01$) at 2 years. At 2 years, 95% of disc implants were radiologically in the ideal position. The insertion technique, with a released prosthetic mechanism for final placement, allowed ideal placement in the sagittal plane in 98% of discs. The radiographic placement accuracy achieved was equal in patients with preoperative intervertebral disc height below and above 5 mm.

Conclusions

Good short-term clinical results were achieved with the Kineflex disc in a heterogeneous patient group with a high number of patients with advanced disc degeneration, severe disc space narrowing, and lumbar flat-back deformity. In this cohort, accurate implant placement could be achieved in our first 100 patients.

Clinical Relevence

This is the first report on the Kineflex mechanical lumbar disc prosthesis.

Key Words Kineflex disc, degenerative disc disease, lumbar disc prosthesis, insertion technique, unconstrained disc prosthesis, Oswestry disability index. ***SAS Journal.*** **Winter 2007**; 1; 28–35. DOI: SASJ-2006-0005-RR

Adjacent-level degeneration is a major concern in lumbar fusion operations.[1–4] Lumbar artificial discs are an alternative to arthrodesis (fusion). The purpose of total disc replacement is to restore the intervertebral segment and protect the adjacent levels against abnormal loading conditions. A description of the surgical insertions of a lumbar prosthetic nucleus replacement, with a steel ball, was first published by Fernström.[5] It failed clinically because of subsidence of the implant into the bony end plate. Modern total lumbar disc replacement commenced in 1984 with the insertion of the first-generation Charité disc prosthesis (Charité SB I, Raynham, Mass). The articular mechanism of this device was interposed between 2 bottle cap–shaped disc endplates. The mechanism

of the prosthesis was carried through to the third-generation device still in use today (Charité SB III). The first results, from 16 patients, were published in 1987.[6,7] The failure at the bone–endplate interface (subsidence) led to the second- and third-generation articulated lumbar disc prostheses (Charité SB II and III). The second-generation disc had wings to increase the bearing surface and avoid subsidence into the bony endplate. Breakage through these wings and subsidence still occurred in this model. The third-generation disc has been used since 1987, and intermediate and long-term results are available.[8–10] More recent publications report on prospective randomized cases in 2 US centers.[11,12]

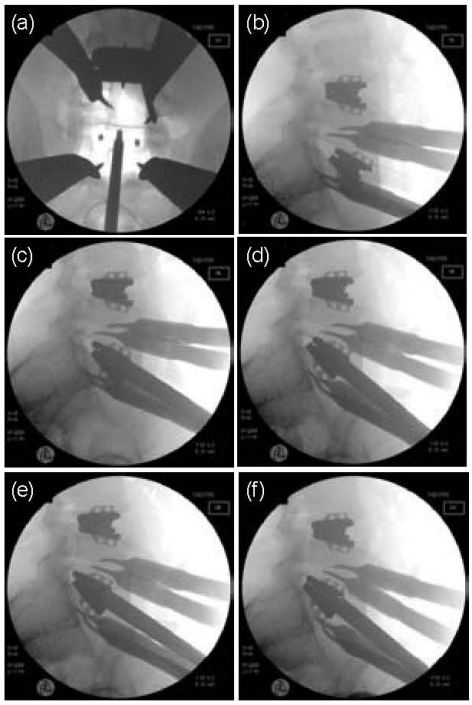
More constrained lumbar disc prostheses have been developed. The US Food and Drug Administration (FDA) recently approved one of these prostheses, ProDisc (Synthes, West Chester, Pa) and is evaluating Maverick (Medtronic Sofamor Danek, Memphis, Tenn); and FlexiCore (Stryker Spine, Allendale, New Jersey). Apart from the Charité disc prosthesis, the only other available disc with long-term follow-up is the lumbar ProDisc.[13,14] Despite improvements in disc design and insertion techniques, difficulties persist with the correct midline and posterior placement of the prostheses within the disc spaces, even in experienced hands.[12] No general consensus exists about indications and contraindications of total disc replacement.[15]

The Kineflex disc (SpinalMotion, Mountain View, Calif) is a chrome-cobalt-molybdenum (CCM) alloy (Biodur CCM Plus; Carpenter Technologies, Reading, Pa), unconstrained but re-centering disc prosthesis with a mobile center of rotation. The mechanism consists of 2 metal endplates articulating over a sliding core positioned between the endplates (Figures 1 and 2). It allows 12 degrees of movement into flexion, extension, and left- and right-side bending. The inferior endplate has a retaining ring that limits the excursion in the inferior articulation to 2 mm in all directions and prevents dislodgment of the sliding core. The mechanism therefore only allows 4 mm of translation before distraction of the disc space, at which point a re-centering force is produced that counteracts the translation. The disc is inserted as a single unit with a freely mobile mechanism during the final insertion process to facilitate placement posteriorly within the disc space. The disc was originally named "Centurion" because it was developed in Centurion (located between Pretoria and Johannesburg, South Africa). The objective in the development of this prosthesis and its insertion instrumentation was to facilitate, through a minimally invasive approach, reliable midline and posterior placement of the implant within the disc space even in severely degenerative disc spaces.

Figure 1

Kineflex metal-on-metal: mechanism, (b) assembled

Figure 2



Insertion technique as seen on intraoperative radiographs: (a) midline finder in position, (b) initial engagement of the prosthesis into disc space, (c–f) sequential advancement of the prosthesis into final position.

We present the properties of the implant, the insertion technique, and a 2-year clinical outcome of its first 100 patients and describe the relevant subgroups within this patient cohort.

MATERIALS AND METHODS

Our study consists of a single-center, consecutive, longitudinal series of the first 100 patients receiving 132 Kineflex lumbar disc replacements between October 2002 and May 2004. All discs were inserted by a single surgeon (U.R.H.). The primary

diagnosis was degenerative disc disease with mechanical back or leg pain in all cases. All data were collected prospectively.

During clinical examinations, the patients had to physically indicate the painful areas of the back and lower limbs. Palpation of the interspinous spaces in both standing and prone positions determined the pain levels. Routine spinal examinations followed.

Radiographic Evaluation

All patients had a preoperative magnetic resonance imaging (MRI), lumbar myelography followed by computer tomography (Myelo-CT), or both MRI and Myelo-CT.

Preoperative and postoperative (at 3 months and at 1 year) and yearly, anteroposterior, lateral standing radiographs including the bottom endplate of the T12 vertebra and the top half of both femoral heads were performed. Lateral flexion-extension radiographs were also performed at these follow-ups; in addition, a lateral whole-spine standing radiograph was included. At all other follow-ups (2 weeks, 6 weeks, and 6 months), only standing anteroposterior side-bending and lateral flexion-extension radiographs of the lumbar spine were performed. Oblique standing radiographs were only done preoperatively.

Preoperative discography was only performed in cases when, after clinical examination and radiographic evaluation, doubt persisted about inclusion or exclusion of a lumbar level in the operation. The amount of disc space narrowing, the presence or absence of spondylolysis, the mobility of the motion segment, and the radiological stability of the relevant spinal level were carefully assessed on the plain radiographs. Disc quality and amount of canal and recess encroachment by the disc, facet joints, and ligamentum flavum were determined by MRI. The degree of facet arthritis and modic changes were also assessed.

Preoperative disc height at the operated level was measured by 2 different observers on lateral standing radiographs at 3 points (anterior, middle, and posterior) and corrected by the magnification error.[12]

Radiographic Placement Accuracy

The exact central placement of all 132 disc implants in the coronal and midsagittal plane was determined and categorized, as described by McAfee et al.,[12] into ideal, suboptimal, and poor placement. The midsagittal plane on lateral radiograph is defined as 2 mm posterior to the middle of the vertebral body in the sagittal plane. The coronal plane on anteroposterior radiographs is the exact centerline of the vertebral body[12] or interpedicular midpoint.[16] The center of the core of the artificial disc was placed less than 3 mm of exact central placement in both the coronal and midsagittal planes in group I (ideal placement), 3 mm–5 mm from exact central placement in group II (suboptimal placement), and more than 5 mm from exact central placement in group III (poor placement). If the 2 axes were rated in different groups, the poorer rating determined the placement's rating. Two observers checked the measurements, which were then corrected by the magnification error.[12]

Clinical Evaluation

Inclusion criteria for the study were age of 18 years to 65 years, symptomatic single- or multilevel degenerative disc disease at the L2-L3, L3-L4, L4-L5, or L5-S1 levels confirmed on X rays, MRI, and provocative discography in selected cases. Further inclusion criteria included mechanical back and leg pain, recurrent disc herniation, and broad-based central disc herniation without sequestration and junctional failure after previous fusion. All patients had failed conservative treatment of at least 6 months' duration. Only the symptomatic levels on clinical examination or discography were replaced.

Exclusion criteria were osteoporosis, tumor, infection, spondylolysis of the level, bony spinal stenosis, sequestrated disc prolapse tracking up or down behind the vertebral body, severe obesity, structural deformity, previous retroperitoneal surgery, vascular pathology, and previous wide laminectomy with destabilization of the facet complex. Advanced facet arthritis was not an exclusion criterion unless osteophyte formation from the facet resulted in bony canal or recess stenosis. Spinal or lateral recess stenosis caused by soft tissue (disc, ligamentum flavum, or joint capsule) was not a contraindication for disc replacement if proper decompression during surgery (direct or indirect) could be anticipated on preoperative imaging.

The primary clinical outcome measures for this study were pain relief and functional improvement as assessed by the 1–100 Oswestry Disability Index (ODI)[17] and our own questionnaire. Patients completed both questionnaires preoperatively and at 6 weeks, 3 months, 6 months, 1 year, and 2 years in conjunction with the regular follow-up examinations. In addition to the outcome data, we collected general demographic information and operative data as well as data pertaining to radiological examination.

Our own questionnaire (designed by U.R.H. and I.R.W.) has not been validated. The questionnaire asked preoperative patients to gauge their pain in the past 2 weeks on a scale of 1 (no pain)

to 10 (pain as bad as it can be), to differentiate between back and leg pain and pain in different positions (lying, sitting, standing, walking). At follow-up visits we asked patients about their satisfaction with the outcome of the treatment operation (excellent, good, fair, poor).[18] We then asked patients if they would undergo the same operation again or recommend it to friends (yes, don't know, no).

Operative Technique

All operations were performed on a translucent electrical table under radiographic image control. We used intraoperative cell saving on all patients. After a transverse midline incision of between 5 cm and 9 cm, depending on patient size and number of levels to be exposed, the rectus sheet was opened, parallel to the linea alba, and the rectus muscle was retracted laterally. The surgeon approached the spine retroperitoneally, partially incising the transversus abdominis fascia from the arcade ligament cranially. After mobilizing the major vessels, the surgeon used Hohman retractors, attached to a frame retractor, to maintain exposure throughout the procedure. After a midline annuloplasty, the disc nucleus, the inner layer of the annulus, and any sequestrated disc material were removed. The endplates were prepared with a Cobbs instrument to remove the cartilaginous endplates and open curettes to prepare the bony endplates. Osteotomes and burrs were used rarely to remove big osteophytes or to prepare the endplates in cases of significant endplate sclerosis. This step was followed by sequential distraction of the disc space, with wedge distracters of increasing sizes. The midline was determined on anteroposterior radiographs with a specially designed and patented midline finder (Figure 2a). After the initial engagement of the assembled 3-part disc into the disc space (Figure 2b), with a fixed insertion device, the prosthetic disc mechanism was released. Further advancement into the disc space was accomplished with a released and fully mobile mechanism (Figure 2c–g). Our aim was to allow the leading edges of the disc to collapse, thus avoiding pressure and impact to the bony endplates of the vertebra. After closing the annuloplasty and final radiographic control, the surgeon closed the wound.

Postoperative Mobilization

Patients were allowed to ambulate the day after surgery without bracing. Patients restarted supervised gait training, isometric muscle strengthening, and stretching exercises from day 1 postoperatively. At discharge, patients were instructed to walk every day and were allowed to sit as long as they felt comfortable. Cycling on a stationary bike was encouraged after removal of stitches at 12 days after the operation. Light sports were allowed at 6 weeks, impact sports at 3–4 months.

All employed office workers were allowed to return to work at 4 weeks provided they could sit for prolonged periods without additional discomfort. Manual workers were kept off work for 6 weeks postsurgery and were allowed to go back on light duty (no lifting of more than 10 kg, no vibration, limited bending, and no running) for the next 6 weeks.

STATISTICAL METHODS

Data are presented as mean ± standard deviation. Group comparisons were made with a Mann–Whitney test or binomial test as appropriate. Wilcoxon matched-pairs test was used to compare baseline data with follow-up data. Data were analyzed on a personal computer with a commercially available statistical program (Statistica version 8; StatSoft, Tulsa, Okla). Significance was assumed at a 2-tailed value of $P < .05$.

RESULTS

Baseline characteristics of the study population are shown in Table 1. A 2-year full clinical outcome assessment was available for 98 of 100 patients. One patient was from a neighboring country and was only available for telephonic follow-up, and one patient was lost to follow-up.

Sixty-nine patients underwent single-level disc replacements and 31 patients had 2 levels replaced. Three of the single-level patients later received a second-level lumbar disc replacement at 7, 9, and 10 months after the index procedure, respectively. Twelve patients, who had a spondylolysis at a second level or had a transitional vertebra with abnormally developed facet joints, underwent fusions at that level during the index procedure. Four of these patients had undergone previous discectomies. Thirteen patients presented with adjacent level disc disease after previous instrumented posterolateral fusion surgery (1–7 previous operations). Another 28 patients in this series who underwent single or 2-level disc replacement had 1 to 4 previous discectomies or laminotomies (Table 1).

Operative times, estimated blood losses, and postoperative hospital stays are shown in Table 2.

Recovery and Patient Satisfaction

The average hospital stay was 2.8 ± 0.8 days (range, 2 to 8 days). Eighty-six patients were employed at the time of the operation. All went back to their previous occupation an average of 31.0 ± 16.8 days after the operation. The pain score (1–10) of all patients dropped from 9.16 ± 1.0 preoperatively to 2.83 ± 2.3 at 1 year and 2.78 ± 2.2 at 2 years follow-up ($P < .01$) (Figure 3).

The ODI improved significantly from 47.8 ± 16 preoperatively to 14.6 ± 14.9 at 1 year and 14.2 ± 14.0 at 2 years ($P < .01$)

(Figure 4). Eighty-seven percent of patients at 1 year and at 90% of patients at 2 years considered their clinical outcome to be good or excellent; 90% at 1 year and 92% at 2 years would undergo the same operation again or recommend it to friends.

Table 1

Preoperative Characteristics of Study Population (N = 100)

	No. or Mean ± SD (Range)
Gender	
Men	57
Women	43
Age, y	44.9 (23–63)
Height, cm	174.6 ± 9.6 (154–196)
Weight, kg	81.3 ± 15.6 (47–138)
Pain duration, months	63.5 ± 74.6 (5–400)
Non-operative care	
Physical therapy	99
Chiropractic care	61
Acupuncture	25
Previous surgery	
Rizotomy	15
Discectomy	32
Laminectomy	20
Fusion	15
Smoking status	
Smoking	39
Nonsmoking	61
Preoperative employment status	
Employed	86
Not employed	11
Disabled	2
Retired	1
Claim or compensation patients	8

Two-level disc replacement patients scored better on pain score improvement and ODI improvement at 1 and 2 years compared with single level disc replacements ($P < .05$) (Figures 3 and 4).

Patients who underwent isolated single or double level disc replacement who had undergone previous discectomies or laminectomies (n = 28) had similar outcome scores if compared with patients without previous spinal surgery (n = 46). Their ODIs improved from 50.3 ± 19.2 to 16.5 ± 17.2 (no previous surgery: from 46.1 ± 15.3 to 11.0 ± 15.3) and

Table 2

Mean Operative Time, Blood Loss, and Length of Hospital Stay (n = 100)

	Mean (Range)
Operative time, all patients, min	130 (45–400)
Operative time, single level patients, min (48% at L4/L5 level)	95.3 ± 28.3
Estimated blood loss, all patients, ml	282 ± 301
Estimated blood loss, single level patients, ml (48% at L4/L5 level)	145.7 ± 153.2
Hospital stay, all patients, days	2.86 ± 0.8

their pain score from 9.17 ± 1.2 to 3.1 ± 1.9 (no previous surgery: from 9.06 ± 1.1 to 2.41 ± 2.2) at 1 year.

Radiographic Placement Accuracy

Fifty-six percent of all operated disc levels had intervertebral disc heights of less than 5 mm. Of the 100 patients, 93 patients with 124 implanted disc spaces underwent a preoperative MRI; the remaining 7 patients only had a preoperative Myelo-CT. Eighty-three (67%) instrumented disc spaces in 72 (77%) patients showed adjacent modic changes on MRI scanning.

We determined and categorized the exact central placement of all 132 disc implants in the coronal and midsagittal planes. We assessed the radiographic accuracy of placement at 2 years. Most (125 [94.7%]) discs were placed in ideal position, 6 (4.5%) in suboptimal position, and 1 (0.76%) had early subsidence (poor placement). Three of the suboptimal placements were in the coronal and 3 (1 of them extruded) in the sagittal plane. Except in the patient who had a traumatic extrusion of the lower endplate, there were no delayed migrations (change of position of more than 2 mm). The 6 suboptimal placements were equally distributed between preoperative disc heights below 5 mm and above 5 mm, meaning there was no correlation between preoperative intervertebral disc height narrowing and decreased radiological placement accuracy.

Complications and Reoperations

There were no procedure-related deaths. Approach-related complications included 2 cases of deep vein thrombosis, 4 venous vascular injuries (blood loss <500 ml), 2 cases with transient neuropraxia of a L5 nerve root, and 6 patients with a postoperative warmer left leg (1 permanent).

Six patients (6%) required a reoperation. Three patients (3%) had disc level–related complications requiring reoperations as follows: One patient had an incomplete decompression and was re-decompressed 2 days after the index surgery. The same disc was reinserted. Another patient had a traumatic partial endplate protrusion at 5 weeks. The disc was removed and

converted into an anterior fusion. In a third patient, with major subsidence, the disc was removed at 2 weeks, the vertebra was bone grafted, and a larger endplate disc was inserted (see mention of poor placement accuracy in the previous paragraph).

Three patients (3%) underwent a second-level disc replacement procedure. All reoperated patients received further follow-up, and their assessments were included in the outcome results.

DISCUSSION

The Kineflex disc prosthesis has 3 features distinguishing it from other disc prostheses: (1) The mechanism of the prosthesis is unconstrained but re-centering, with a retaining ring on the inferior endplate to maintain the sliding core in position. (2) Two material options for the articulating surfaces are currently available (CCM on polyethylene and CCM on CCM). (3) The final seating into the disc space is accomplished with a fully released articulating mechanism to take pressure off the implant–bone interface at the leading edges of the implant during the insertion. The aim is to minimize the danger of bony endplate violation.

There are certain differences between the mechanisms in motion behavior of the Kineflex prosthesis and 2 other mobile core discs: the Charité prosthesis, already approved by the US FDA, and the Mobidisc (LDR Medical, Troyes, France), under investigation by the US FDA. Compared with the Charité disc, the mechanism of the Kineflex prosthesis has a stronger re-centering vector because of the more restricted inferior excursion. With creep occurring in the connection between the retaining ring and the inner core of the Charité disc, the re-centering force would further decrease. The Mobidisc has no intrinsic re-centering force within the limits of the excursion of the inferior articulation. No tilting of the sliding core occurs. When the Mobidisc reaches the limit of the inferior articulation, which happens unconstrained, there will be a sudden change in motion pattern. With further excursion the Mobidisc mechanism behaves like a semiconstrained prosthesis (e.g., ProDisc, Maverick). The US FDA is currently evaluating the metal-on-metal Kineflex disc.

More than 50% of patients in our series had advanced disc degeneration with disc space height of less than 5 mm, some with advanced facet joint arthritis. In significantly collapsed and rigid disc spaces, we specifically aim to achieve a posterior position of the prosthesis within the disc space to remove the load from the facets. This achievement has been difficult with other implants because of the rigidly held implants during the insertion process. The Kineflex disc prosthesis is disconnected from its insertion tool after the initial engagement into the disc space. The final placement is done with a released prosthetic mechanism allowing the leading edges to adapt to the contour of the bony disc space. This mechanism facilitates the seating of the prosthesis, avoiding excessive pressure on the bony endplate during insertion. Exact posterior position of the prosthesis within the disc space has been achieved and maintained in 98% of patients and therefore compares favorably with other implants.[12] The radiographic placement accuracy achieved was equally good in patients with preoperative intervertebral disc heights below and above 5 mm.

Operative time and blood loss were higher than in other studies.[10,11] Twelve of our patients had additional fusion surgery, including combined posterior and anterior osteotomy surgery, with operative times of up to 7 hours. These cases added to operative time and blood loss. The use of Hohman retractors for exposure causes additional bleeding from the vertebral bodies. However, for single-level disc replacements, the operative time and blood loss are comparable to other studies (Table 2).[10,11]

Postoperative hospital stay and return to work data compare favorably with other studies.[8–11] All patients who were previously employed went back to work an average of 31 days after the operation. The ODI and pain score improvements occurred early after surgery and were maintained at 1- and 2-year follow-up (Figures 3 and 4). Two-level replacement patients scored better on clinical outcome parameters than the single-level replacement patients. Similar results were shown by Bertagnoli et al.[19,20] but contradicted by others.[21] We only replaced the clinically or discographically confirmed disc level in 2-level and multilevel degeneration. Three of our single-level replacements required a second-level disc replaced during the 2-year follow-up period. Although we included multilevel disease in our series we did not perform surgery on all affected levels. We only included levels at L3-4 and cranial to it in cases when clinical examination, radiculopathy, or a significantly positive discogram demonstrated their role as pain generators.

The improvement in the ODI scores is comparable with that found elsewhere.[11,12,19,20] Of particular interest are the preliminary results in 13 patients who had junctional disc replacement after previous posterolateral instrumented fusion operations. These 13 patients had undergone 36 previous spinal procedures before the index procedure. All of these patients presented with significant flat-back deformities from inadequate restoration of lordosis during the previous

posterolateral instrumented fusion. One needs to consider that revision surgery in these patients has a high failure rate as far as patient satisfaction is concerned.[22–25] Salvage surgery usually includes combined anterior and posterior spinal surgery[23–25] or posterior extension osteotomies with extension of the fusion.[23]

In our opinion, an isolated single-level disc replacement after previous fusion surgery can only correct a limited degree of lumbar flat-back deformity. We therefore perform, at the time of the index procedure, an additional spinal osteotomy through the fusion site in cases with severe flat-back deformity. Eleven of 13 patients considered their 2-year outcome to be good or excellent, and 12 would undergo the same procedure again. Despite three reoperations in this subgroup, we consider junctional decompensation after fusion a good indication for total disc prosthesis provided that good spinal alignment can be achieved during surgery. Bertagnoli et al. presented larger numbers and longer follow-up times in this particular patient group,[26] with excellent clinical outcome. Other previous publications on disc replacement after fusion surgery had very short follow-up times or numbers of patients.[27,28]

Good short-term clinical results were achieved with the Kineflex disc in a heterogeneous patient group including a high number of patients with advanced disc degeneration, severe disc space narrowing, and previous fusion with lumbar flat-back deformity. Accurate placement of the prosthesis can be achieved in the sagittal and coronal planes.

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The institutional review board of the hospital where all the cases have been performed (Linksfield Park Clinic, Nedcare, Johannesburg, South Africa) approved this study, which was conducted in accordance with the ethical standards of the Declaration of Helsinki (2000).

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6. RESULTS: SECOND PUBLICATION:

Ulrich R. Hähnle, MD, FCS (Ortho), Karen Sliwa, MD, PhD, Ian R. Weinberg, MD, FCS (Neuro), Barry MBE Sweet, MD, PhD, Malan de Villiers, PhD, and Geoffrey P. Candy, PhD. Lumbar disc replacement for junctional decompensation after fusion surgery: Clinical and radiological outcome at an average follow-up of 33 months. ***SAS Journal*. Summer 2007;1:85–92. DOI: SASJ-2007-0006-RR.**

6.1. Introduction

This publication reports on our experience with the use of total disc replacement (TDR) in patients, who had previously undergone fusion surgery and had developed Adjacent Segment Disease (ASD). ASD is an "off-label' indication for TDR and only one previous publication had dealt with this particular problem in a larger patient group (Bertagnoli, et al. 2006). Our patient sample was published in the SAS Journal, the official journal of the Spine Arthroplasty Society.

SASJournal

LUMBAR ARTHROPLASTY

Lumbar Disc Replacement for Junctional Decompensation After Fusion Surgery: Clinical and Radiological Outcome at an Average Follow-Up of 33 Months

Ulrich R. Hähnle, MD, FCS (Ortho), Karen Sliwa, MD, PhD, Ian R. Weinberg, MD, FCS (Neuro), Barry MBE Sweet, MD, PhD, Malan de Villiers, PhD, and Geoffrey P. Candy, PhD

ABSTRACT

Background

Failed fusion surgery remains difficult to treat. Few published data on disc replacement surgery after failed fusion procedures exist. Our objective was to evaluate outcomes of junctional lumbar disc replacement after previous fusion surgery and to correlate outcome with radiological changes to parameters of sagittal balance.

Methods

Out of a single-center prospective registry of 290 patients with 404 lumbar disc replacements, 27 patients had had a previous lumbar fusion operation on 1 to 4 lumbar segments and had completed a mean follow-up of 33 months (range: 18–56). We correlated the clinical outcome measures (patient satisfaction, 10-point pain score, and Oswestry Disability Index [ODI] score) to parameters of spinal sagittal alignment (sacral tilt, pelvic tilt, pelvic incidence, and lumbar lordosis).

Results

Postoperative hospital stay averaged 3.3 days (range: 2–8). Previously-employed patients went back to their jobs with a mean of 32 days (range: 21–42) after the procedure. At the latest follow-up, 1 of the patients considered the outcome to be poor, 3 fair, 8 good, and 15 excellent. Twenty-four patients "would undergo the operation again." Average pain score decreased from 9.1 ± 1.0 (SD) to 3.2 ± 2.1 ($P < .01$). Average ODI decreased from 50.2 ± 9.9 preoperatively to 21.7 ± 14.2 ($P \leq .01$). We found the change in pelvic tilt to be an independent predictor of better clinical outcome by multivariate analysis ($P < .05$).

Conclusions

In patients with junctional failure adjacent to a previous posterolateral fusion, disc replacement at the junctional level(s), compared with osteotomy and fusion surgery, offers the advantage of maintaining segmental mobility and correcting the flat-back deformity through a single approach with less operative time and blood loss. Early- to intermediate-term results are promising. The influence of changes in spinal sagittal alignment on clinical outcome needs to be addressed in future research.

Clinical Relevance

This is the first study on "junctional disc replacement patients" correlating clinical outcome to changes in spinal/pelvic alignment.

Key Words Lumbar disc replacement, junctional disc replacement, spinal alignment. ***SAS Journal*. Summer 2007;1:85–92.** DOI: SASJ-2007-0006-RR

INTRODUCTION

Failed fusion surgery patients are difficult to treat. Adjacent disc decompensation with spinal stenosis and pain at the junctional levels are known sequelae after fusion surgery.[1–3] Although the association is not universally accepted,[4] previous fusion and lumbar flat-back deformity seem to contribute to low-back pain and accelerated wear of the adjacent motion segments.[1,3,5–7] Symptoms arising from loss of sagittal spinal alignment after previous fusion surgery remain therapeutically challenging, and long-term treatment results are satisfactory at best.[8–12] Because of the associated lumbar spinal flat-back deformity, extensive surgery with combined dorsal-ventral-dorsal, ventral-dorsal, or posterior osteotomy approaches, including an extension of the fusion, are usually applied as salvage procedures for these patients.[10–12] These procedures entail long surgery time with extensive blood loss and dangers to the spinal canal and nerve roots. Artificial disc replacement in this patient group offers a promising alternative to extensive

refusion surgery with the theoretical advantage of absorbing some of the junctional stresses.

Fernstrom[13] first published in 1966 on the surgical insertion of steel balls as nucleus prostheses, but lumbar disc replacement with a modern articulating disc only began in 1984 with the first implantation of the Charité SB I prosthesis performed by Büttner-Janz.[14] Since then, other more easily implantable discs have been developed (Charité SB III, DePuy Spine, Raynham, Massachusetts; ProDisc, Synthes Spine, West Chester, Pennsylvania; Maverick, Medtronic Sofamor Danek, Memphis, Tennessee; FlexiCore, Stryker Spine, Allendale, New Jersey; Kineflex, SpinalMotion, Mountain View, California). The indications and contraindications for artificial disc replacement remain controversial[15–17] despite more than 10 years of follow-up results.[18–20]

Detailed correlations between clinical outcome and changes in pelvic/spinal parameters have not been reported after lumbar total disc replacement. Although previous publications on radiological sagittal alignment changes after total disc replacement did not show significant changes in pelvic alignment parameters such as pelvic incidence (PI), pelvic tilt (PT), and sacral tilt (ST),[21,22] segmental lumbar lordosis (LL) at the replaced level has changed significantly.[21–23] Overall LL changed in 1 study[22] but not in others.[21,23] No findings of a correlation between clinical outcome and changes in pelvic/spinal parameters after total disc replacement have been published, nor have results regarding the influence of juxtafusional lumbar disc prostheses on the parameters of sagittal alignment.

The aim of our study was to determine the outcomes, pitfalls, and limitations of lumbar disc arthroplasty adjacent to an existing lumbar fusion. We looked at clinical outcome parameters such as surgery time, blood loss, complications, return-to-work time and ratio, patient satisfaction, pain score, Oswestry Disability Index (ODI) score, and reoperations. We also performed radiological outcome studies, looking at parameters of sagittal spinal alignment (pelvic incidence, PT, ST, and LL). We further correlated these radiological parameters to clinical outcome parameters.

MATERIALS AND METHODS

Out of an ongoing, longitudinal, single-center prospective study involving 290 patients to date, 27 patients had had a previous posterolateral lumbar fusion operation of 1 to 4 lumbar segments and a minimum follow-up of 18 months. As the index procedure, all patients received either a Charité or a Kineflex lumbar disc replacement adjacent to the previous instrumented fusions.

The primary clinical outcome measures for this study were pain relief and functional improvement as assessed by the ODI and our own questionnaire. Patients completed questionnaires preoperatively and at 6 weeks, 3 months, 6 months, and yearly thereafter in conjunction with the regular follow-up examinations. In addition to the outcome data, we collected general demographic information and operative data as well as data pertaining to radiological examination.

Inclusion criteria for the study were (1) previous lumbar fusion operation, (2) age of 18 to 65 years, and (3) symptomatic adjacent single- or double-level disc disease of the lumbar spine below the L1–L2 level confirmed on x-rays, magnetic resonance imaging, or computer tomography-myelography imaging. We performed preoperative discography only in cases when, after clinical examination and radiographic evaluation, doubt persisted about inclusion or exclusion of a lumbar level in the operation. We performed diagnostic facet joint infiltrations when junctional low-back pain was a significant symptom. Diagnostic (and therapeutic) sacroiliac joint injections were performed in most cases. Further inclusion criteria were mechanical back or leg pain, broad-based central disc herniation without sequestration, or sequestration in line with the disc space. All patients had failed supervised conservative treatment of at least 3 months, except for one patient who presented with progressive neurological deficits. Only the symptomatic levels on clinical examination and/or discography were replaced.

Exclusion criteria for junctional disc replacement were osteoporosis, tumor, infection, spondylolysis of the relevant level, bony spinal stenosis, sequestrated disc prolapse tracking up or down behind the vertebral body, morbid obesity (BMI ≥ 40), previous retroperitoneal surgery, vascular pathology, and previous wide laminectomy with destabilization of the facet complex. Advanced facet arthritis was not an exclusion criterion unless osteophyte formation from the facet resulted in bony canal or recess stenosis. Spinal or lateral recess stenosis caused by soft tissue (disc, ligamentum flavum, or facet joint capsule) was not a contraindication for disc replacement if proper decompression during surgery, by means of direct or indirect decompression, could be anticipated on preoperative imaging.

Two of the authors (Hähnle and Weinberg) designed our questionnaire; it has not been validated. The patients were asked about satisfaction with the outcome of the treatment operation (excellent, good, fair, or poor). The patients were asked whether they would undergo the same operation again or recommend it to friends (yes, no, don't know) and to gauge their pain at the time of completing the questionnaire on a scale of 1 (no pain) to 10 (pain as bad as it can be).

Clinical Evaluation

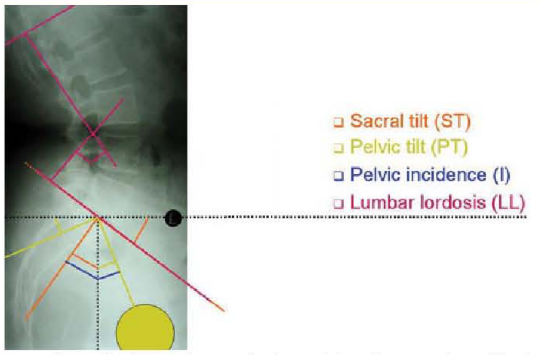
During clinical examinations, the patients physically had to indicate painful areas of the back and lower limbs. This was followed by palpation of the interspinous spaces in both standing and prone positions to determine the levels associated with pain. Routine spinal examinations followed.

Radiographic Evaluation

All patients had a preoperative magnetic resonance imaging or lumbar myelography followed by computer tomography.

Preoperatively and at 3 months, 6 months, and annually postoperative, we took anteroposterior and lateral standing radiographs, which included the bottom endplate of the T12 vertebra and the top half of both femoral heads. We also took a lateral whole spine standing radiograph. The patients were asked to stand straight with the arms crossed over the chest and knees fully extended. These follow-ups also included lateral flexion/extension radiographs. We based the spinal balance evaluation on the studies of Duval-Beaupere et al.[24–26] and Lazennec et al.[6] (Figure 1). We looked at pelvic incidence, ST, PT, LL (cephalad endplate L1–cephalad endplate S1), and segmental LL, which is the angle between the cephalad endplate of the level of the total disc replacement (TDR) to cephalad endplate S1 (TDR-S1) (or other reproducible marker within the fusion mass). If the femoral heads were not exactly superimposed on each other, the middle of the line connecting the centers of the femoral heads was used to determine the PI and PT. We correlated the clinical outcome of our patients with the radiological changes in spinal balance parameters.

Figure 1



Note. Yellow circle = hip joint; horizontal and vertical dotted lines cross the middle of the S1 endplate. Black circle was a label on the original X-ray.

Lumbar and pelvic spinal alignment measurements.

Operative Technique

We performed all operations on a translucent electrical table under radiographic image control with intraoperative cell-saving in all patients. A mini-retroperitoneal approach through a midline incision was used. After a midline annuloplasty, we removed the disc nucleus, the inner layer of the annulus, any sequestrated disc material, and posterolateral osteophytes. We prepared the endplates with curettes before sequential distraction of the disc space with wedge distracters of increasing size. The insertion technique was dependent on the implant used.

Postoperative Mobilization

Patients were allowed to ambulate the day after surgery without bracing. Patients restarted supervised gait training, isometric muscle strengthening, and stretching exercises from the first postoperative day. At discharge, patients were instructed to walk every day and to continue with isometric muscular exercises and stretching exercises, and they were allowed to sit as long as they felt comfortable. Cycling on a stationary bike was encouraged after removal of stitches at 12 days postoperation. Other nonimpact sports were allowed at 6 weeks and impact sports at 4 months.

All employed office workers were allowed to return to work after 4 weeks provided they could sit for prolonged periods without additional discomfort. Manual workers were kept off work for 6 weeks postsurgery and were then allowed to go back on light duty (no lifting of more than 10 kg, no vibration, only limited bending, and no running) for the next 6 weeks. Self-employed patients were allowed to return to work at their discretion, provided it would not result in additional discomfort.

STATISTICAL METHODS

Data were reported as mean ±SD with SAS 9.1 (SAS Institute Inc, Cary, North Carolina) for statistical analysis and comparisons. We compared changes in measured variables pre- and postoperation with a nonparametric Wilcoxon signed rank test ($P < .05$). We used regression analysis to determine variables that significantly influenced outcome, including pain.

RESULTS

Clinical Outcome

Table 1 summarizes the baseline data of our patients. The average age of the 27 patients was 49.2 years (range, 33–63 years). Thirteen patients were female. All patients presented with low-back pain over the lumbosacral junction radiating into 1 or both sacroiliac joints and buttocks. Twenty-four of the 27 patients presented with symptoms of spinal stenosis.

Seven patients underwent a junctional disc replacement with a Charité lumbar disc prosthesis and 20 patients with a Kineflex lumbar disc prosthesis. In 4 patients, a second-level disc prosthesis was inserted. An additional osteotomy (OT) and anterior or posterior fusion were performed during the index procedure in 4 patients (the OT group) to help with correction of the flatback deformities.

The average follow-up period lasted 32.9 months (range, 18–56). Successful outcome was achieved in 85% of the patients by the last follow-up (15 of the patients considered the outcome to be excellent, 8 good, 3 fair, and 1 poor) (Figure 2a). Twenty-four patients stated they "would undergo the operation again," 2 "did not know," and 1 of the patients stated that he "would not undergo the same operation again." The 10-point pain score decreased from 9.1 ±1.0 preoperatively to 3.2 ±2.1 ($P < .01$) at the latest follow-up. The ODI score decreased from 50.2 ±9.9 preoperatively to 21.7 ±14.2 ($P < .01$) (Figure 2b). The sacroiliac joint symptoms and the spinal stenosis symptoms disappeared or significantly improved in all patients after the index procedure.

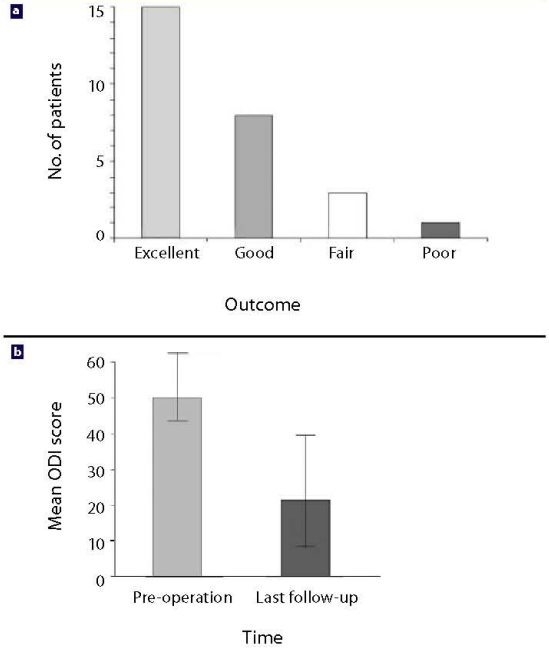
The average operation time was 134 ±80 min, and the average estimated blood loss was 290 ±335 mL, including the 4 patients with dorsal-ventral-dorsal and posterior osteotomy surgery at

Table 1

Preoperative Characteristics of Study Population ($n = 27$)

	No. or Mean ± SD ($n = 27$)
Male, no.	14
Age, mean ±SD, y	49.2 ±9.3
Height, mean ±SD, cm	171.2 ±8.3
Weight, mean ±SD, kg	80.7 ±17.6
Pain duration, mean ±SD, mo	51.1 ±58.1
Nonoperative care	
Physiotherapy	25
Chiropractic care	15
Acupuncture	7
Previous surgeries	
Discectomy	12
Laminectomy	23
Posterolateral fusion procedures	33
Posterolateral interbody fusion	1
Levels fused preoperatively	
1	18
2	8
3	0
4	1
Smokers	13
Preoperative employment status	
Employed	19
Not employed	3
Disabled	2
Retired	3
Claim or compensation patients	2

Figure 2



Clinical outcome at last follow-up (average 33 months, range 18–56 months, $n = 27$): (a) patient's satisfaction with the clinical outcome; (b) Oswestry Disability Index (ODI) (1–100) score.

Table 2

Mean Operative Time, Blood Loss, and Length of Hospital Stay ($n = 27$)

	Mean ±SD
Operative time, all patients, min	134 ±80
Estimated blood loss, mL	290 ±335
Dorsal-ventral-dorsal surgery/OT surgery, no. ($n = 27$)	4
Hospital stay, all patients, days	3.3 (1.1)

Note: OT = osteotomy.

the time of the index procedure. Postoperative hospital stay averaged 3.3 days (range, 2–8) (Table 2). All employed ($n = 22$) patients went back to their previous occupations an average of 32 days (range, 21–42) after the procedure. Four patients required subsequent reoperations (Table 3) (Figure 3).

Radiological Changes to Sagittal Alignment and Correlation with Clinical Outcome

From before the surgery to the latest follow-up, overall LL (L1–S1 level) increased by 10.4° for all patients and by 18.25° in the 4 patients with additional osteotomies (OT group); the segmental lordosis (TDR-S1) increased by 9.8°. The pelvic incidence remained unchanged. The ST increased by 5° (4.25° in the OT group), and the pelvic tilt decreased by 5° (Figure 4) (3.5° in the OT group).

Patients' outcome was correlated with the postoperative change of LL, ST (Figure 5), and PT (Figure 6) with univariate and multivariate analysis. Only the change in PT was found to be an independent predictor for improved clinical outcome in multivariate analysis after adjusting for age, sex, height, and weight ($P < .05$). Correlation for ST was statistically significant in the univariate ($P < .05$) analysis but just missed statistical significance in the multivariate analysis ($P < .08$). No correlations were found between clinical outcome and the increase or preoperative value of lumbar lordosis angles or the preoperative values of pelvic incidence.

DISCUSSION

We present our experience of lumbar disc replacement for junctional decompensation after previous fusion surgery. Similar to the outcome of the only larger series, published by Bertagnoli et al.,[27] in our series of 27 patients, good outcome was achieved in 85%

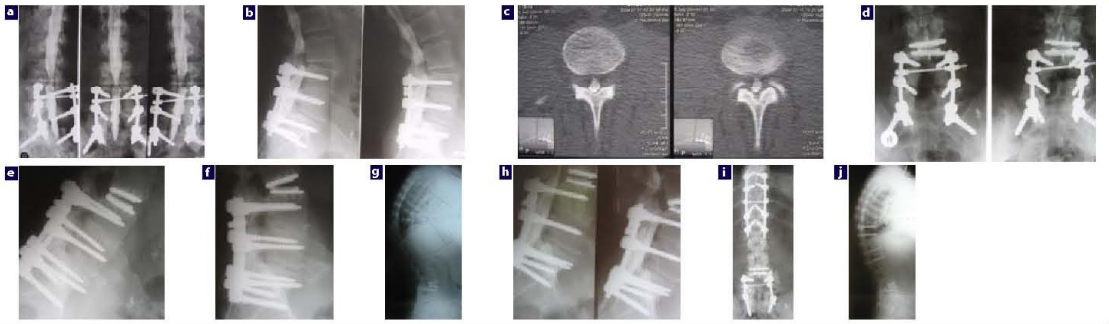
Table 3

Revision Surgeries

Time After Index Surgery	Problem	Treatment Applied
Patient 1: 2 days	Incomplete recess decompression	Removal of prosthesis, decompression, reinsertion of same prosthesis
Patient 2: 10 mo	Recurrent mechanical stenosis symptoms because of persistent flat back after disc prosthesis at L3–L4	Disc replacement L5–S1 + anterior cage at posterior fused L4–L5
Patient 3: 26 mo	Recurrent mechanical stenosis symptoms because of persistent flat back after disc prosthesis at L3–L4	Double posterior osteotomy (OT) (pedicle substraction OT L5 and multiple, limited OTs T9–L1)
	Additional thoracic kyphosis of 74°	See Figure 3
Patient 4: 41 mo	Persistent flat-back deformity and progressive instability at disc level with sciatica and low-back pain	Exchange prosthesis L4–L5 for higher-angled prosthesis of different make

Note. OT = osteotomy.

Figure 3



A case study demonstrating the limitations of a single-disc replacement in correcting a spinal flat-back deformity: (a–c) a 45-year-old obese male patient underwent posterolateral fusion in 1998 and had significant mechanical back and leg pain thereafter; he presented with bilateral foot drop and severe low-back pain 5 years later; (d–g) after junctional disc replacement the patient was doing well during follow-up until 2 years after the index surgery; (h) at 26 months post-index surgery the patient re-presented with spinal stenosis, a right-sided foot drop, and severe low-back pain; radiographs showed extended disc prosthesis and myelography confirmed spinal stenosis behind disc prosthesis; (i, j) after double osteotomy (OT) (pedicle substraction OT L5 and multiple lower thoracic OTs as well as a direct posterior decompression L3–L4), rebalancing of the prosthetic disc and complete relief from symptoms.

of the patients by the mean follow-up of 33 months. During the follow-up period, 4 patients underwent further surgery (Table 3).

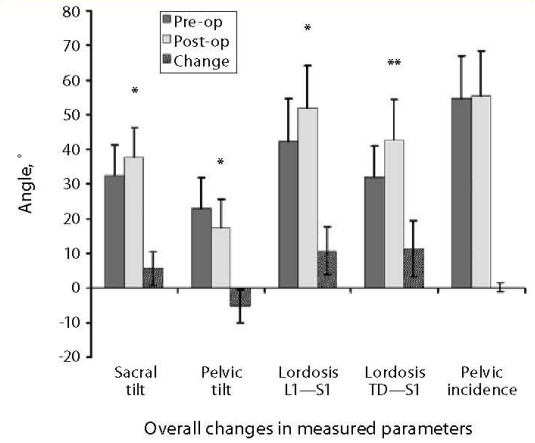
We used 2 different unconstrained disc prostheses: the Charité SBIII prosthesis in the first 7 patients and the Kineflex lumbar disc prosthesis in the last 20 patients. Because of the small number of patients in the former group, a statistically meaningful comparison between the 2 groups was not feasible.

We further analyzed parameters of sagittal spinal alignment in our juxtafusional disc replacement patient group and correlated these parameters to clinical outcome. The pelvic incidence of our patient group was similar to normal values.[26] The LL increased and the pelvic incidence stayed the same in all patients at follow-up. A stronger postoperative increase in ST and decrease in PT correlated with better clinical outcome. This result was not produced by the inclusion of the 4 patients with an additional OT (OT group), as the patients in the OT group had similar or lesser changes in their ST and PT. Lazennec et al.[6] found that in 81 patients who had undergone lumbosacral fusion, PT was significantly higher and ST significantly lower in patients with postfusion pain. No published results are available for patients after juxtafusional disc replacement.

Le Huec et al.[21] measured, preoperatively and postoperatively, parameters of sagittal spinal balance after total disc arthroplasty. He and others[22] found no significant changes in pelvic alignment parameters (ST and PT). The segmental lordosis increased at the level of the disc replacement,[21–23] but only Chung et al.[22] found a significant increase of the overall LL. Patients undergoing isolated single-level disc replacement are unlikely to present with a significant preoperative sagittal spinal imbalance. Patients undergoing disc replacement after a previous posterolateral fusion, as opposed to patients with previous anterior lumbar interbody fusion or 360-degree fusions, in most instances present with a lumbar flat-back deformity because of incomplete anterior column height restoration. The disc prosthesis then allows the possibility of correcting the sagittal deformity in part or in its entirety.

Four patients underwent reoperations during the follow-up period (Table 3). Except for 1 patient who had an inadequate recess decompression during the index procedure, the remaining 3 patients, after temporary relief of their symptoms, experienced recurring symptoms of spinal stenosis and lumbosacral pain with the disc prosthesis in an extended position on lateral standing radiographs. Two of these patients had an increased

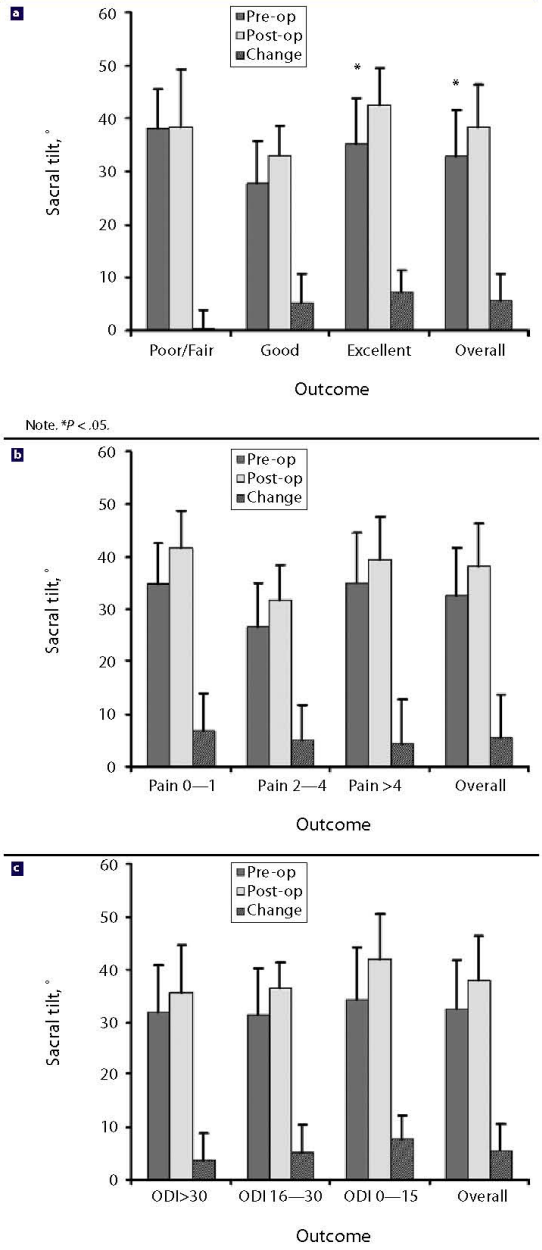
Figure 4



Note. TD = total disc. *$P < .05$; **$P < .01$.

Lumbar and pelvic parameters determined preoperatively and at latest follow-up.

Figure 5



Note. *$P < .05$.

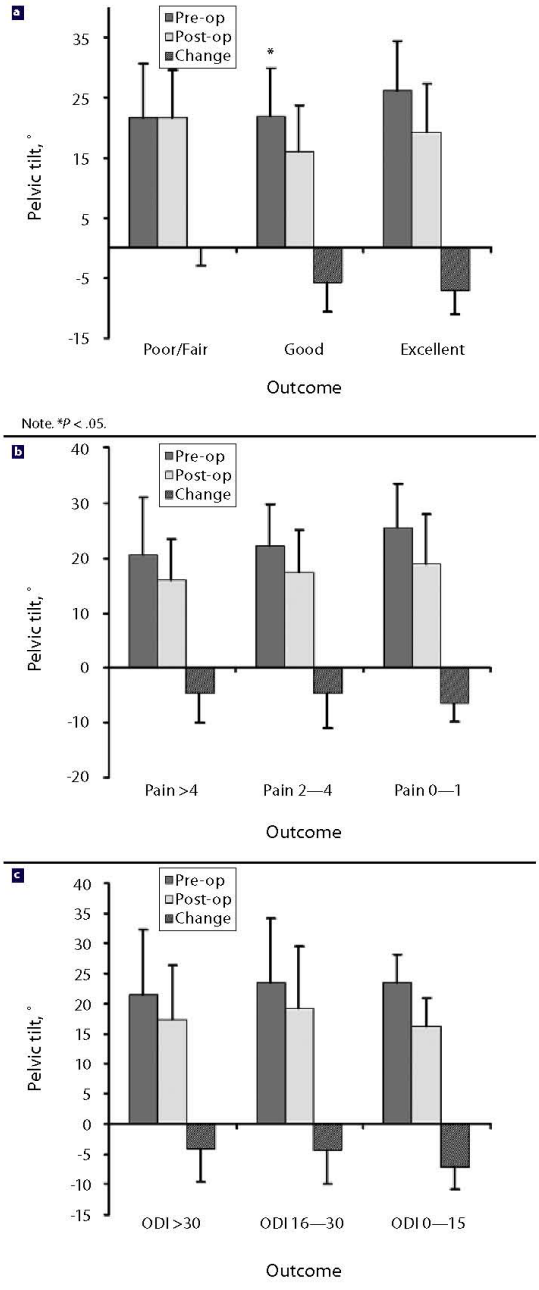
Changes in sacral tilt in relation to clinical outcome: (a) sacral tilt and satisfaction with surgical outcome; (b) sacral tilt and pain score; (c) sacral tilt and Oswestry Disability Index (1–100) score.

preoperative thoracic kyphosis, between 40° and 60° on lateral standing radiographs, both of which increased in later follow-up by more than 10° in the thoracolumbar junction area. The index level was significantly extended and in retrolisthesis on preoperative lateral standing radiographs in all 3 patients, the next cranial level in 2 of the patients. We therefore would consider osteotomy surgery or additional OT surgery for patients presenting with these radiological features. After reoperation, their PT decreased and ST increased significantly (not included in our calculations).

Treating "failed fusion surgery patients" requires consideration of the high rates of clinical complication and revision and of suboptimal results in patient satisfaction.[10,11,28–30] Extensive procedures are often required, incorporating combined anterior and posterior spinal surgery or posterior extension osteotomies with extension of the fusion surgery.[10–12,29,30]

To date, the authors have placed disc prostheses in 34 patients after previous lumbar fusion surgery and are generally impressed with the speed and extent of recovery as well as the satisfaction of these patients with the operation. We are aware of 3 publications on juxtafusional disc replacement.[27,31,32] The disc used by Enker et al.[31] consisted of an elastic rubber core interposed between 2 titanium endplates and was only used in 4 patients with junctional disc degeneration. Because of prosthetic failure it has long been withdrawn from the market. The study by Kim et al.[32] reflects the outcome of 5 patients with only 6 months of follow-up. Only Bertagnoli et al.[27] has published a larger series of patients with juxtafusional disc replacement and 2 years of follow-up with excellent clinical outcome. None of

Figure 6



Changes in sacral tilt in correlation to clinical outcome: (a) pelvic tilt and satisfaction with surgical outcome; (b) pelvic tilt and pain score; (c) pelvic tilt and Oswestry Disability Index (ODI) (1–100) score.

the publications comments on the changes of parameters of spinal and pelvic alignment in this patient group.

Most patients with previous posterolateral fusion surgery present with a lumbar flat-back deformity. Unless the sagittal balance is fully restored during prosthetic disc surgery, the replaced disc prosthesis would rebalance itself into an extended position with the upright standing patient. This can lead to excessive facet joint loading as well as continuous or recurrent spinal and recess stenosis symptoms caused by bulging of the posterior soft tissue structures into the spinal canal and closing of the foraminal exits in an extended position of the lumbar segment. In 3 of our 4 reoperation patients, the further surgeries were performed for this reason (Table 3).

It is our opinion that posterior placement of the prosthesis within the disc space, placement of a taller disc prosthesis, and the use of wedged endplates can correct the flat back only in patients with minor deformities. An additional osteotomy through the fusion mass should be considered in more severe sagittal imbalance. Whole-spine lateral standing radiographs should be used to asses the sagittal balance in all juxtafusion disc replacement patients preoperatively and at follow-up. As a working hypothesis we consider the following radiological parameters as risk factors for later decompensation and future clinical failure: a retroverted pelvis with increased pelvic tilt; an overextended disc or disc prosthesis with or without retrolisthesis at the index level and the more cranial lumbar levels; a hypermobile index level; and thoracic kyphosis, especially low in the thoracolumbar junction area.

Patients with junctional failure adjacent to a previous posterolateral fusion are a therapeutic challenge. Junctional disc replacement appears to be a good procedure after juxtafusional failure, provided a good sagittal balance is present or is restored during replacement surgery. Longer follow-up will be needed. There is a clear need for other investigators to report on their results with these patients.

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The IRB of the hospital where all procedures were performed (Nedcare Linksfield Hospital, Nedcare, Johannesburg, South Africa) approved this study, which was conducted in accordance with the ethical standards of the Declaration of Helsinki (2000). Informed written consent was obtained from all patients.

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7. RESULTS: THIRD PUBLICATION

Ulrich R. Hähnle, MD, FCS (Ortho), Karen Sliwa MD, PhD, Malan de Villiers, PhD, Ian R. Weinberg, MD, FCS (Neuro), Barry M.B.E. Sweet, MD, PhD, and Geoffrey P. Candy, PhD. Is degenerative spondylolisthesis a contraindication for total disc replacement? Kineflex lumbar disc replacement in 7 patients with 24-month follow-up. ***SAS Journal.*** **Spring 2008;2:92–100. DOI: SASJ-2007-0125-NT**

This publication summarizes our experience with the use of total disc replacement (TDR) in patients with degenerative spondylolisthesis (DSPL). DSPL is an "off-label" indication for TDR and no articles had previously been published on this particular indication. The study comprises a pilot study with only a limited number of patients involved. It was published in the SAS Journal, the official journal of the Spine Arthroplasty Society.

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LUMBAR ARTHROPLASTY

Is Degenerative Spondylolisthesis a Contraindication for Total Disc Replacement? Kineflex Lumbar Disc Replacement in 7 Patients With 24-Month Follow-up

Ulrich R. Hähnle, MD, FCS (Ortho),[a,b] Karen Sliwa MD, PhD,[a] Malan de Villiers, PhD,[c] Ian R. Weinberg, MD, FCS (Neuro),[b] Barry M.B.E. Sweet, MD, PhD,[a] and Geoffrey P. Candy, PhD [a]

ABSTRACT

Background
Degenerative spondylolisthesis is associated with a significant segmental kyphosis at the level of the listhesis. We treated 7 disc spaces with Grade 2 listhesis and/or kyphosis of the slipped disc level with Kineflex disc replacement.

Methods
Out of a single-center prospective registry, involving 310 lumbar disc replacement patients, 7 patients underwent a single-level Kineflex disc replacement at the level of a degenerative spondylolisthesis with either segmental kyphosis or a Grade 2 slip.

Preoperative and follow-up radiological parameters studied were: pelvic incidence, pelvic tilt, sacral slope, lumbar lordosis L1-S1, degree of segmental listhesis, segmental lordosis, and range of motion (ROM). Clinical outcome measures were Visual Analog Scale pain score (VAS), Oswestry Disability Index (ODI), and patient satisfaction.

Results
Five replacements were performed at the L4-L5 level, and 2 were performed at a L3-4 level, above a pre-existing L4-S1 posterolateral fusion. Mean age was 50 (32–62) years. Average follow-up was 23.8 ± 13.1 months. Six of 7 patients considered their outcome as good or excellent. The mean VAS score decreased from 8.4 ± 1.9 to 2.7 ± 2.2 ($P < .01$). The ODI decreased from 45.2 ± 9.9 preoperatively to 19.7 ± 12.8 ($P < .01$).

There were increases in lumbar lordosis (from 47.4o ± 10.6 to 61.3o ± 8.0 ($P < .03$)), in segmental lordosis (from 0.17° ± 7.0° to 16.4° ± 2.0° ($P < .03$)), and in sacral slope (from 34.5° ± 4.8° to 40.7° ± 4.5° ($P < .03$)). There were decreases in pelvic tilt (from 22.6° ± 6.3° to 15.5° ± 5.9° ($P < .05$)), and degree of segmental listhesis (from 24.4% ± 7.7 to 3.7% ± 3.4 ($P < .03$)). Pelvic incidence and ROM did not change.

Conclusions
Disc replacement resulted in significant improvement in clinical outcome and excellent sagittal balance and slip correction. However, the influence of improved sagittal spinal alignment on clinical outcomes needs to be investigated in larger studies including a control group.

Clinical Relevance
This study is the first focused on disc replacement in degenerative spondylolisthesis.

Key Words: Spondylolisthesis, total disc replacement, radiological outcome, clinical outcome. ***SAS Journal.*** **Spring 2008;2:92–100.** DOI: SASJ-2007-0125-NT

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Ulrich R. Hähnle, Ian R. Weinberg, and Malan de Villiers are co-developers of the Kineflex Disc Prosthesis and shareholders in Spinal Motion (Mountainview, California)

Institutional Review Board approval was obtained from the University of the Witwatersrand Ethics Committee.

INTRODUCTION

Degenerative spondylolisthesis (DSPL) is a condition where degenerative changes in disc and facet joint complex lead to vertebral displacement, resulting in spinal stenosis, recess stenosis, and segmental kyphosis.[1] Reports are mostly retrospective, and randomized studies have only compared surgical treatment consisting of posterolateral fusion with or without instrumentation and with posterior decompression alone.[2]

The influence of sagittal alignment on the generation of lower back pain (LBP) and degeneration of the lower back is not well understood. Despite existing suspicion that pre-existing differences in sagittal alignment may influence the occurrence of LBP and that outcome of fusion surgery may be dependent on restoration of lumbar lordosis during surgery,[3] only recently a classification system to measure and classify sagittal alignment has been published.[4] It has been applied to pathological conditions of the lumbar spine such as DSPL.[5]

Anterior lumbar interbody fusion (ALIF) surgery reliably corrects sagittal imbalance and listhetic slip in significant segmental kyphosis associated with DSPL.[1,6,7] Anterior column support was recommended by Sengupta and Herkowitz for patients with Grade 2 spondylolisthesis or higher or when kyphosis was present.[8]

Dynamic posterior motion preservation in DSPL renders significant clinical improvement despite minimal sagittal alignment changes[2,9-12] and despite increase in facet arthrosis.[11]

Despite the potential positive effect on spinal alignment and degree of spondylolisthesis, significant DSPL is considered a contraindication for total disc replacement (TDR). Complications from inadvertently instrumented spondylolytic disc spaces have been presented, but objective confirmation of the outcome of TDR in DSPL is missing.

The Kineflex disc prosthesis (Spinal Motion; Mountainview, California) is a chrome-cobalt-molybdenum (BioDur CCM Plus; Carpenter Technology Corp., Wyomissing, Pennsylvania), unconstrained but recentering disc prosthesis with a variable center of rotation. The mechanism comprises 2 metal endplates articulating over a sliding core, which is positioned between the endplates. It allows 12° of movement into flexion, extension, and left- and right-sided bending. The inferior endplate has a retaining ring that limits the excursion in the inferior articulation to 2 mm in all directions and prevents dislodgement of the sliding core. The mechanism therefore only allows 4 mm of translation before distraction of the disc space; a recentering force is produced that counteracts the translation. The disc is inserted as a single unit with a freely mobile mechanism during the final insertion process to facilitate placement posteriorly within the disc space. The objective in the development of this prosthesis was to facilitate reliable midline and posterior placement of the implant within the disc space in severely degenerative disc spaces, through a minimally invasive approach.[13]

The insertion technique of this disc prosthesis is unique. After the initial engagement into the disc space of the fully assembled 3-component prosthesis, the insertion tools allow independent advancement of the superior and inferior prosthetic endplates. During this process the advancing endplate pivots over the sliding core, taking pressure off the leading prosthetic endplate/bone interphase.[13] We therefore postulated that, through independent advancement of the inferior endplate, this particular disc prosthesis should be able to assist spondylolisthesis reduction during the insertion process.

We are reporting on the operative reduction technique in DSPL and on the outcome of 7 patients with either a Grade 2 spondylolisthesis and/or kyphosis of the slipped disc level and who were treated with Kineflex disc replacement.

MATERIAL AND METHODS

Out of a single-center prospective registry involving 310 lumbar disc replacement patients, 7 patients were retrieved from our databank of patients who had undergone a single-level Kineflex disc replacement at the level of a degenerative spondylolisthesis with either segmental kyphosis or a Grade 2 slip.

Operative Technique

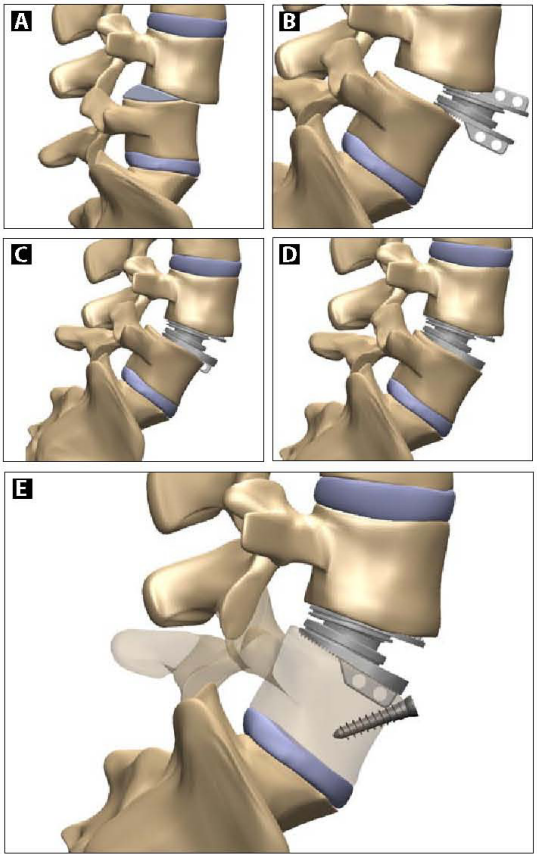
The operations were performed through a left-sided retroperitoneal approach, followed by the creation of a wide exposure of the disc space. After a midline anuloplasty, a complete nucleotomy was performed, and the inner, desiccated layers of the annulus were removed. The disc space was mobilized, and the bony endplates were prepared. The correct-sized prosthesis was selected. As hypermobility was an anticipated complication, the disc height selected was one size larger than we would have chosen in a standard disc replacement. After initial engagement of the prosthesis, the mechanism of the prosthesis was released, and the endplates were advanced until almost flush with the posterior wall of the inferior vertebral endplate of the cephalad vertebra. Thereafter, the inferior prosthetic endplate was further advanced until almost full spondylolisthesis reduction was achieved. Additional screw fixation of the inferior endplate was performed, whenever further primary fixation was thought to be necessary, in order to absorb excessive forces through the inferior prosthetic endplate/bone interphase (Figure 1).

Radiographic Evaluation

All patients had a preoperative magnetic resonance image (MRI) or lumbar myelography followed by computer tomography (CT), or both.

Preoperatively and postoperatively at 3 months, 6 months, and yearly, anteroposterior (AP), lateral standing radiographs that included the bottom endplate of the T12 vertebra and the

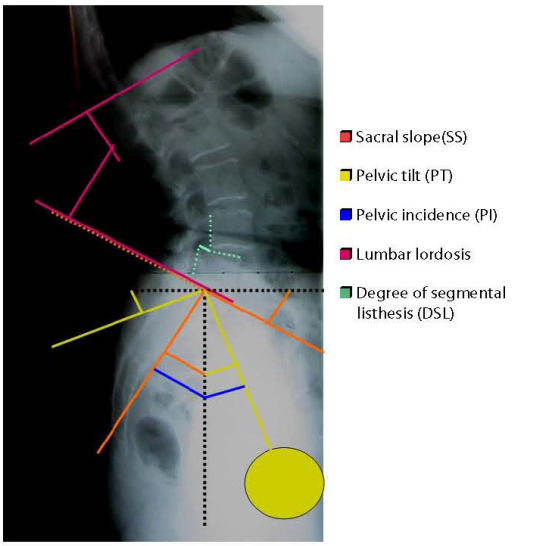
Figure 1. Insertion Technique



Position A: Spondylolisthetic disc space before operation. **Position B:** Initial engagement of the prosthesis into the disc space after full nucleotomy, disc space mobilization, and cutting of the insertion grooves. The further insertion is performed with a fully freed prosthetic mechanism. **Position C:** Advancement of the prosthesis into the disc space, until almost flush with the posterior wall of the cephalad vertebral body. The prosthetic endplates are individually advanced, alternating between top and bottom prosthetic endplate. **Position D:** Further advancement of the bottom prosthetic endplate, until almost flush with the posterior wall of the caudad; full reduction of the spondylolisthesis. During this advancement the inferior endplate pivots around the articulating mechanism of the prosthesis, reducing the pressure between the leading edge of the inferior prosthetic endplate and the bony endplate. Position E: Securing of the final reduced position by placement of a screw into the into the insertion groove of the inferior vertebra. This counteracts the displacing forces (For more information on insertion technique, see Hähnle et al.13)

top half of both femoral heads were performed. In addition, a lateral, whole-spine, standing radiograph was included. The patients were asked to stand straight with arms crossed over the chest and knees fully extended. Lateral flexion/extension radiographs were also performed at these follow-ups. The spinal balance evaluation was based on the studies of Duval Beaupere et al.[14-16] and Lazennec et al.[17] (Figure 2). We looked at pelvic incidence (PI), sacral slope (SS), pelvic tilt (PT),

Figure 2. Lumbar Disc Replacement in DSPL Measurements



Lumbar disc in DSPL-measured parameters. Pelvic incidence (PI), sacral slope (SS); pelvic tilt (PT), lumbar lordosis (cephalad endplate L1–cephalad endplate S1) (LL)

lumbar lordosis (cephalad endplate L1–cephalad endplate S1) (LL), and segmental lordosis (SL) within the instrumented disc space. If the femoral heads were not exactly superimposed on each other, the middle of the line connecting the centers of the femoral heads was used to determine the PI and PT. We further studied the degree of segmental listhesis (DSL) on a percentage basis. The range of motion (ROM) at the level of DSPL was measured on flexion/extension radiographs by 2 of the investigators (U.H. and I.W.), preoperatively by the Cobb method and postoperatively by the fin method.[18]

Clinical Evaluation

Clinical outcome was measured using the visual analogue pain score (VAS), Oswestry Disability Index (ODI),[19] patient satisfaction, and "return to work" data. Complications were described.

Statistical Analysis

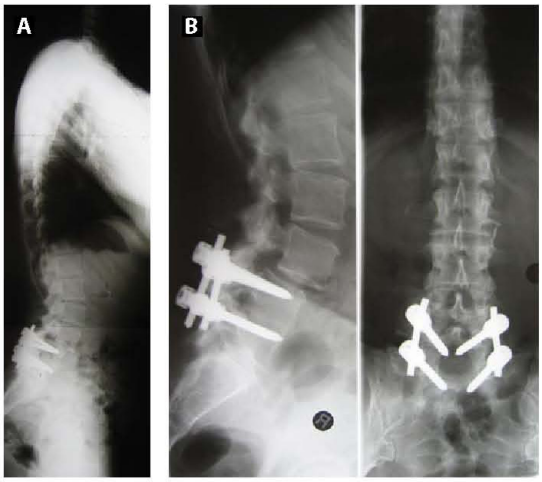
Data were reported as mean ± standard deviation with SAS V9.1 (SAS Institute Inc., Cary, North Carolina) for statistical analysis and comparisons. Changes in measured variables pre- and postoperatively were compared using a nonparametric Wilcoxon matched pairs test with a P value $< .05$ regarded as significant.

RESULTS

Seven patients were retrieved from our databank who had undergone a single-level Kineflex disc replacement at the level of a spondylolisthesis with either segmental kyphosis or

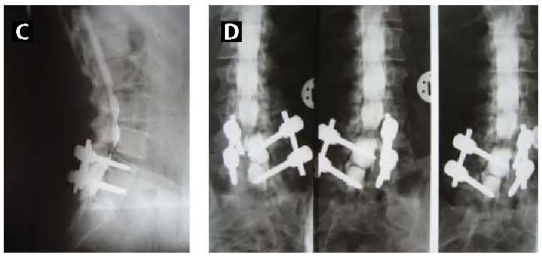
a Grade 2 slip or both and had undergone the index procedure at least 1 year before. They were called in for clinical and radiological follow-up; these patients form the base of this study.

Figures 3A and 3B.



43-year-old active lady with severe LBP and SS symptoms. Posterolateral fusion L4-S1 4 years before.

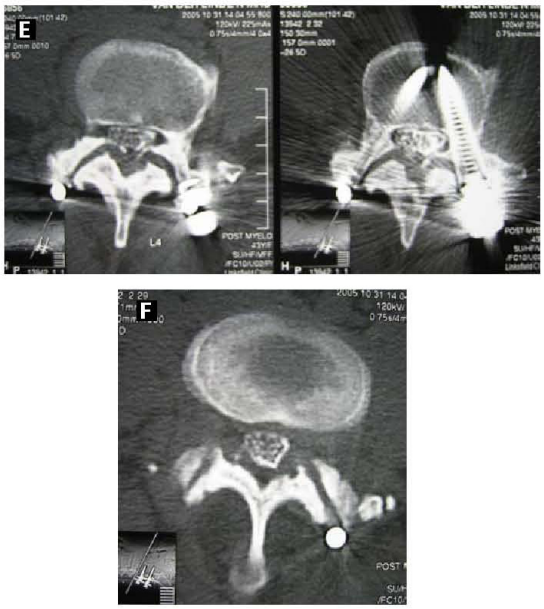
Figures 3C and 3D.



Myelogram confirms severe SS

Five disc replacements had been performed at the L4-L5 lumbar level. In one operation a posterior motion preservation device, inserted 2 years prior to the index operation, had first been removed through a posterior approach before the prosthetic disc insertion during the same anesthetics. Two disc replacements had been performed at a L3-L4 level, above a pre-existing L4-S1 posterolateral fusion (Figure 3). The average age at the time of the index procedure was 50 (32–62) years. Five of the patients were female. All patients had originally presented with symptoms of mechanical LBP and leg pain. Five patients had complained with symptoms of spinal stenosis.

Figures 3E and 3F.



CT Myelogram shows severe facet arthrosis.

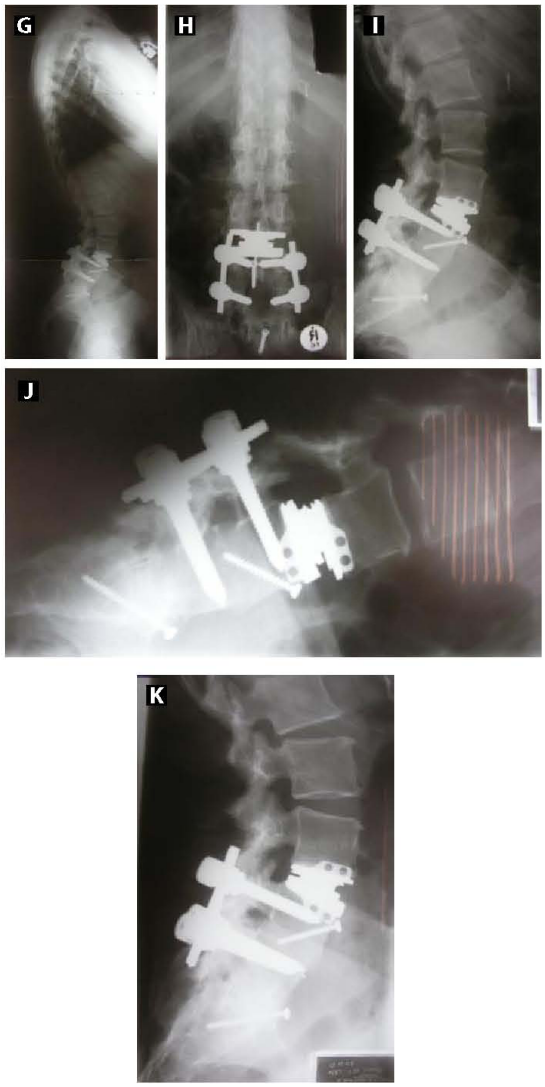
One of the 7 patients had a previous posterior dynamic system inserted by another surgeon 2 years prior to our operation. This person is not a DSPL patient, but the previous surgery resulted in a radiologically similar picture. The operation had left her with significant posterior distraction, segmental kyphosis, and instability. She refused fusion surgery. We therefore performed posterior implant removal followed by anterior TDR surgery.

The postoperative hospital stay averaged 3.3 days (2–8 days) with all patients returning to work after 27 days (3–42 days). The average follow-up was 23.8 ± 13.1 months. One of the patients considered the outcome as fair, 2 as good, and 4 as excellent. Six patients "would undergo the operation again," and one "doesn't know." The VAS score decreased from 8.4 ± 1.9 to 2.7 ± 2.2. The ODI decreased from 45.2 ± 9.9 preoperatively to 19.7 ± 12.8.

One patient was reoperated at 1 week postoperatively for partial extrusion of the inferior prosthetic endplate over the malpositioned buttress screw (Figure 4). One patient developed a left iliac deep vein thrombosis (DVT).

The lumbar lordosis (LL), segmental lordosis (SL), and sacral slope (SS) increased. LL increased from 47.4° ± 10.6° to 61.3° ± -8.0° ($P < .03$); SL from 0.17° ± 7.0° to 16.4° ± 2.0° ($P < .03$); and SS from 34.5° ± 4.8° to 40.7° ± 4.5° ($P < .03$). The pelvic tilt (PT) and the degree of segmental listhesis (DSL)

Figures 3G, 3H, 3I, 3J, and 3K.



2-year follow-up: good clinical (ODI = 22, VAS = 2) and radiological outcome.

decreased. PT decreased from 22.6° ± 6.3° to 15.5° ± 5.9° ($P < .05$); DSL from 24.4% ± 7.7 to 3.7% ± 3.4 ($P < .03$). The pelvic incidence (PI) did not change (preoperative PI was 56.25 while the latest follow-up was 56.5). The change in ROM was insignificant (11.9° ± 5.0° preoperatively to 11.6° ± 3.6° at the latest follow-up). Due to the small cohort no correlation could be drawn between clinical outcome and changes in radiological parameters.

DISCUSSION

The etiology of degenerative spondylolisthesis (DSPL) is poorly understood. Sagittal orientation of the facet joint has been implicated as a predisposing factor[20] but might be instead a consequence of the remodelling taking place during development of facet arthritis.[21] Controversy exists as to whether the pathology starts primarily in the facet joints[22] or within the intervertebral disc.[1] Whatever the etiology, the result is segmental spondylolisthesis, segmental kyphosis, spinal and recess stenosis, and facet joint arthritis.

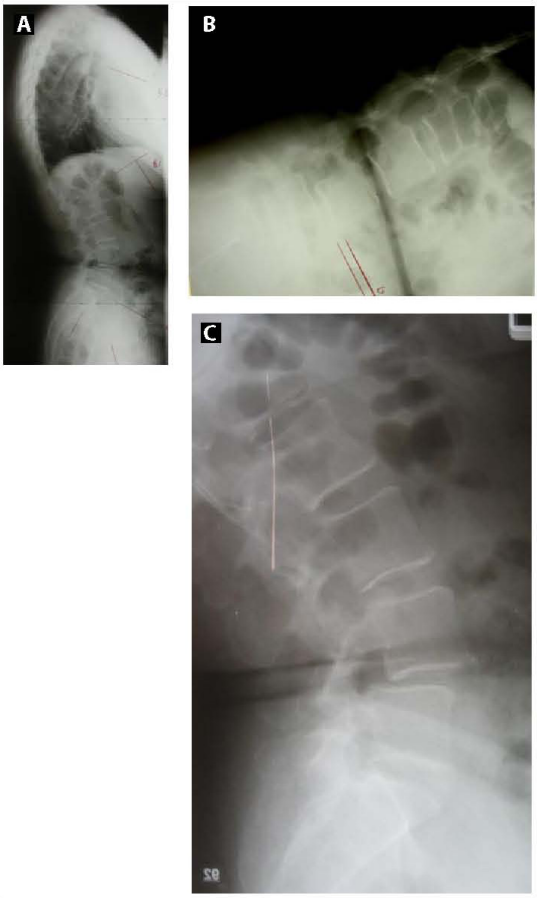
Our cohort of patients consisted of 3 different entities: degenerative spondylolisthesis proper, adjacent segment disease (ASD) with resulting (degenerative) spondylolisthesis at the adjacent segment, and 1 iatrogenic spondylolisthesis caused by an over-distracted posterior device. The resulting clinical and radiological picture is very similar. Clinical patients complained about mechanical LBP and leg pain, inability to stand or walk longer distances. Radiologically, the deformity resulted in low lumbar flat back deformities with compensatory retrolisthesis of the higher lumbar motion segments and flexion of the pelvis on lateral standing radiographs. In each of the 3 entities the resulting surgical treatment aim is similar: decompression of neural structures, stabilization of the motion segment, and restoration of the spinal balance. As we are primarily describing a surgical technique aimed to treat these different components, we considered it justifiable to sum these patients together.

Most surgical outcome studies on DSPL were retrospective and not controlled. Randomised studies have only compared surgical treatment consisting of posterolateral fusion with or without instrumentation and with posterior decompression alone.[2] Long-term outcome of surgical treatment seems more favorable with fusion than without fusion.[23,24]

Anterior lumbar interbody fusion (ALIF) surgery reliably corrects sagittal imbalance and listhetic slip in significant segmental kyphosis associated with DSPL.[1,6,7] Anterior column support was recommended by Sengupta and Herkowitz for patients with Grade 2 slips or higher or when frank kyphosis is present.[8]

More recently Choi and Sung reported on a large patient group, 14 patients with DSPL, using single-level standalone rectangular cages. At 27 months follow-up there was subsidence of over 2 mm in 77% of patients and a 13% nonunion rate, but neither correlated with recurrence of symptoms.[25] In ALIF there is a nonunion rate which might be asymptomatic,[25] but in case of a later established symptomatic anterior nonunion, supplementation with an instrumented posterior fusion does not always relieve the clinical symptoms. ALIF, as a standalone procedure, has a risk of anterior dislodgement in spondylolisthesis. Furthermore, the primary contact area of fusion cages is far less than the endplate surface area of the disc prosthesis.

Figures 4A, 4B, and 4C.

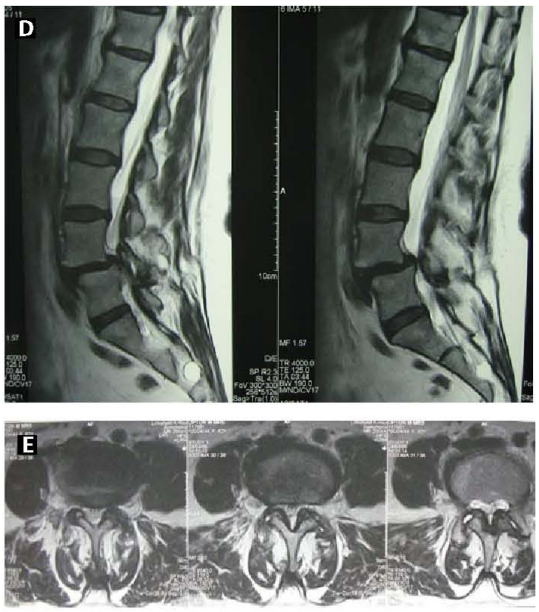


62-year-old patient with severe mechanical LBP and right-side leg pain for 2 years.

Brantigan et al.[26] reported 10-year results on a subgroup of an original US Food and Drug Administration trial, using carbon fiber posterior lumbar interbody fusion (PLIF) cages in conjunction with a posterior screw and plating system (360° fusion) with excellent clinical and radiological outcomes. McAfee et al.[27] reported on 120 patients with spondylolisthesis, half of them with DSPL, who were treated with a 360-degree fusion through a single posterior approach with a 98% fusion rate, good radiological outcome, and few complications.

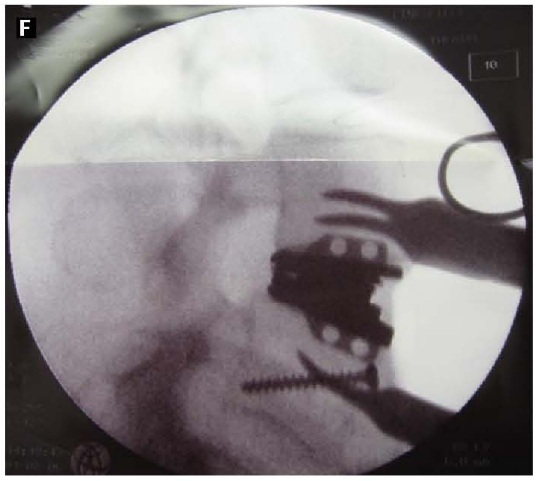
In a prospective study, Konno and Kikuchi[9] compared surgical decompression, together with posterior dynamic Graf ligament stabilization, to decompression surgery alone. They found better clinical outcome in the Graf ligament group. Significant clinical improvement was confirmed in other studies using dynamic stabilization,[2,10-12] despite an increase in facet

Figures 4 D and 4E.



MRI scanning shows partial reduction of listhesis in lying position, significant L4-L5 facet degeneration and DDD.

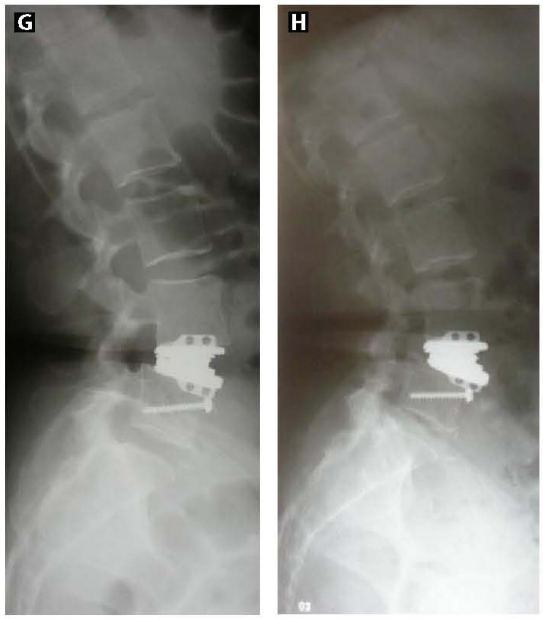
Figure 4 F.



Intraoperative radiograph shows good alignment and listhesis reduction.

arthrosis.[11] Posterior tension-band-like devices, in the absence of anterior support, should increase the load on the facet joints, and they are unable to significantly improve sagittal

Figures 4G and 4H.



(G) Partial extrusion of inferior prosthetic endplate at 2 days. (H) Further extrusion of inferior prosthetic endplate at 6 days.

alignment. Taking this into consideration, the improvement in clinical outcome in these patients is remarkable. Recently McAfee et al. reported clinical improvement with a motion-preserving facet replacement system (TOPS).[28]

Despite the success with posterior motion-preserving techniques in DSPL, even in the absence of spondylolisthesis and kyphosis reduction,[2,10-12] DSPL over 3 mm is considered a contraindication for TDR.[27] Nevertheless, objective confirmation of the outcome of TDR in DSPL is missing. Considerable reduction of the spondylolisthesis should be desirable in order to restore the normal 3-joint anatomy (disc and 2 facet joints) of the motion segment. This could not be achieved with posterior motion-preserving procedures.[2,10-12]

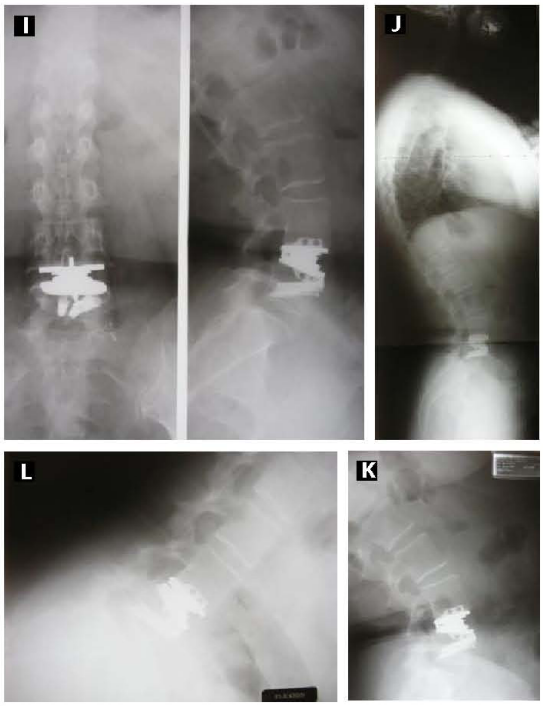
The potential advantages of disc replacement with an unconstrained disc and non-rigidly held prosthetic endplates during insertion are, at least in theory, the following (see also Figure 1 and Hähnle et al.[13]):

1) During the insertion process the prosthetic endplates can follow the shape of the bony endplates as they are able to pivot around the mechanism. The leading edge of a rectangular cage, or rigidly held disc prosthesis, is more likely to be impacted into the bony endplate, possibly resulting in endplate fracture and subsidence.

2) Once the Kineflex disc prosthesis is almost lying flush with the posterior vertebral body wall of the cephalad vertebra, the inferior endplate can be further advanced to facilitate reduction of the spondylolisthesis. As during this process part of the impact of the further advancement is absorbed in the prosthetic mechanism, the cephalad prosthetic endplate stays behind, avoiding protrusion of the superior prosthetic endplate into the spinal canal. With a cage or an unconstrained disc prosthesis, this manuever would easily result in impaction of the implant into the posterior part of the vertebral endplate of the cephalad vertebra (endplate fracture) or in protrusion of the implant into the spinal canal.

3) During mobilization of the patient the forces that could lead to expulsion of the inferior prosthetic endplate are at least partially dampened within the prosthetic mechanism, which allows translation but at the same time is recentering. Furthermore, flexion/extension motion through the operated segment does not lead to cyclical loss of contact (rocking) of the implant/bone surfaces and possible nonunion or nonintegration, as the contact is maintained by the adaptive movement of the prosthetic endplate.

Figures 4I, 4J, 4K, and 4L.



2 years after reoperation to reposition inferior endplate: excellent clinical (ODI = 0; VAS = 0) and radiological outcomes.

With the Kineflex insertion technique used, we achieved excellent sagittal balance and slip correction in all patients. The continuous advancement of the inferior prosthetic endplate, after seating the prosthesis close to the posterior edge of the apical vertebral endplate, allowed additional reduction of the spondylolisthesis. The postoperatively high translational forces on the inferior prosthetic endplate could be counteracted with additional screw fixation used as a buttress. No postoperative hypermobility developed at the replaced levels. One reoperation was performed early after the index procedure with excellent clinical and radiological final outcome (Figure 4).

The most common level in DSPL is the L4-5 motion segment. At this level dislodgement of the implant would be of particular concern because of the proximity of important vascular structures. We would generally try to avoid anterior revision surgery at this level after 17–18 days and would rather wait past 3 months when the postoperative inflammation has completely settled. We therefore performed our anterior revision surgery for partial endplate extrusion early, after the first follow-up at 8 days postoperatively, despite good clinical relief of symptoms at that early stage (Figure 4).

The indications for TDR have hardly been modified since the onset of modern type TDR over 20 years ago.[29] Only recently Siepe et al.[30] published clinical outcome of TDR dependent on indications. There is a need for arthroplasty surgeons to publish results of off-label TDR procedures, in order to establish their validity for different indications and in order to learn from the experience of other surgeons.

CONCLUSION

This is a pilot study with significant limitations: Only 7 patients were involved with no control group, and the follow-up is short. Early results are promising, but because of the limitations, one has to be careful about the clinical outcome results. With the insertion technique of the tested device we achieved excellent sagittal balance and slip correction in all patients. No postoperative hypermobility developed at the replaced levels. The influence of improved sagittal spinal alignment on clinical outcome needs to be investigated in larger studies.

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8. OVERALL DISCUSSION

8.1. Motion preservation surgery history

In the opening chapter of a recently published book on motion preservation, McKenzie (2008) compares the spine to a "multi-pinned ship's mast" with power, agility, endurance and grace to provide mobility with stability and freedom from pain. With damage to structure or rigging, it can still function after "bracing the mast" or "reefing the sails" and by careful, energetic sailing until it is "re-stepped by fixing" or fusion. His lesson learned from the past is that the spine cannot function at full purpose or in longevity without the essential duality of "stability and motion". When damage, disorder or discectomy leaves excessive motion at one of the spine's segments, it often spawns the corrosion of facet arthritis at the same level, with instability and breakdown at the next level or the levels beyond (McKenzie AH, 2008[1]).

Any form of decompression spinal surgery performed to a motion segment, without instrumentationis, at least in the short term, a motion preserving surgery, but fails to re-stabilize and to re-orientate the FSU.

Motion preserving spine stabilisation forms a rapidly evolving, fascinating part of modern surgical spine treatment. Intervertebral disc replacement comprises currently the largest portion of motion preservation surgery. Disc prostheses, made out of a variety of materials, implants with a variety of fixation principles and degree of constraint of the mechanism, and which use a range of insertion techniques, may render different clinical outcomes in different indications. We are only at the very beginning of understanding the advantages and limitations of TDR in surgery for a failed FSU. There is also limited understanding of the influence of different types of prostheses on the outcome in different clinical conditions.

Hip arthroplasty surgery has evolved from being highly experimental, in the form of tissue interposition arthroplasties at the change from the nineteenth to the twentieth century, to be a procedure considered as the "golden standard for the treatment of the

arthritic hip", with the highest patient satisfaction ratings of all orthopaedic procedures and with clear indication and acceptable complication rates (Learmonth, et al. 2007[2]).

We should not be discouraged by the upsets and setbacks of spinal arthroplasty, but rather try to learn from past failures. The purpose of total disc replacement is to restore the intervertebral segment and protect the adjacent FSUs against abnormal loading conditions. A first description of the surgical insertion of a lumbar prosthetic nucleus replacement with a steel ball was published in 1966 by Fernström (Fernström U, 1966[3]). Despite some excellent results, it failed because of subsidence into the bony end-plate due to failure of weight distribution at the prosthesis/end-plate interphase.

Modern total lumbar disc replacement procedures commenced in 1984, with the insertion of the first-generation Charité disc prosthesis by Karin Büttner-Janz. The prosthesis was later perfected, but the initial mechanism was carried through to the third-generation device, which is still in use today (Charité SB III) (Büttner-Janz, et al. 1987[4]; Büttner-Janz & Schellnack, 1990[5]).

Despite the 24-year history of modern type total lumbar disc replacement, which started with the development of the Charité disc prosthesis, there remains considerable controversy about the value, the indications and contraindications, the materials used and the amount of constraint within the prosthetic mechanism. Considering the complex nature of the FSU, we should expect that it will be some time before there is full understanding of the best prosthetic articulation of this joint (Sakalkale, et al. 2003[6]; Moumene & Geisler, 2007[7]).

8.2. Motion preservation surgery - what's different in the spine?

The motion of the FSU, compared to other weight bearing joints in the body, only exerts limited motion (less than 10 degrees in all directions). It comprises 3 articulations, viz.: the disc articulation in the front, and the paired facet joints in the back. The disc is not a classical, synovial joint. Therefore, unlike the hip joint (which constitutes a ball and socket joint), but similar to the knee joint, the FSU involves

joints other than the disc itself (the knee cap in the knee; the facet joints in the FSU). The restraints of the knee joint and FSU are mainly ligamentous and capsular. In the FSU, the disc itself - with its complex fibrous architecture of the outer annulus and the more pliable core providing tensioning of the annulus under load - forms part of the restraint of the articulation. The motion mechanism incorporates a variable centre of rotation. The FSU differs from hip and knee joints by the greater shock-absorbing properties within the joint and the fact that the FSU forms part of a sequence of similar looking joints, which are aligned within the spinal column, like a chain. Through its ligamentous and muscular support structures, the lumbar spine acts like an elastic spring.

It is the dependence on ligamentous restraints and the more complex motion patters that caused the knee joint replacement to lag behind the hip joint replacement before it became a reliable and lasting new joint. It involved going from more constraining prostheses to implants with lesser constraint and placing more emphasis on so-called soft tissue balancing.

TDR is only one motion preserving surgical approach used to try to resolve chronic LBP. Other procedures, like a large variety of pedicle screw based posterior shock-absorbing devices or interspinous spacer devices, address primarily the posterior elements of the motion segment. They all aim to reduce the mobility in the FSU, allowing motion through a limited and ideally painless range of movement. The advantage of posterior motion preserving surgery is the familiarity of most surgeons with the posterior approach; the disadvantage is the inability to address failure of the FSU close to the centre of motion and the inability to improve the sagittal balance (flat back deformity), which is one of the consequences of disc height loss in DDD.

8.3. Disc arthroplasty – what do we know?

Most lumbar fusions, today, are performed for degenerative conditions. There is an increasing focus on the disc as the source of lumbar pain. This provides many challenges as all discs degenerate with age, yet only a few cause significant debilitating pain. Strict adherence to mainstream indications and proper surgical techniques is essential. (Dunn RN, 2008[8]).

There is increasing evidence in the literature that positive spinal balance in spinal deformity correlates with an increase in spinal symptoms (Glassman, et al. 2005[9]; Kumar, et al. 2001[10]). This may well be the primary reason why circumferential fusion renders superior long term results and is more cost effective when compared to postero-lateral fusion alone (Soegaard, et al. 2007[11]).

Failed spinal fusion surgery is a serious professional challenge for the treating physician. In a recent publication, Shipley expertly dealt with the problem when describing a practical and very clinical approach (Shipley JA, 2008[12]).

Sagittal imbalance seems to be a common cause of failed back syndrome; complex posterior osteotomy, or combined posterior and anterior surgery, is often required to achieve adequate correction (Jang, et al. 2007[13]; Chang, et al. 2008[14]).

There is weak but increasing evidence that disc replacement, when compared to fusions, may be advantageous in protecting other lumbar levels from degeneration or at least in slowing down the incidence of ASD (Harrop, et al. 2008[15]; Chun-Kun, et al. 2008[16]). There are no publications on ASD, which provide a comparison of degeneration adjacent to disc replacement with the natural history of degeneration of this segment without surgery. Such studies would be useful in order to determine whether the added stiffness of the instrumented segment would lead to accelerated degeneration of the adjacent FSU or whether the change in spinal alignment to the adjacent segment might even be protective (Tournier, et al. 2007[17]; Hähnle, et al. 2007[18]).

After primary disc replacement surgery, no significant changes in overall spinal alignment parameters were demonstrated (Le Huec, et al. 2005[18]; Cakir, et al. 2005[20]), although internal realignment within the lumbar spine occurred. TDR resulted in increased lordosis in the lower (instrumented) part of the lumbar spine and decreased lordosis of the upper, non-instrumented lumbar area (Tournier, et al. 2007[17]).

It is also my own experience, that patients with severe disc degeneration in only the two caudal lumbar motion segments, on lateral standing radiographs, often show a

localized flat-back deformity in the lower lumbar spine. In the upper lumbar spine, a compensatory hyperlordosis with retrolisthesis of the otherwise normal upper lumbar levels develops. After disc replacement surgery, the lower lumbar lordosis increases, whereas the upper lumbar lordosis and the retrolisthesis decrease. The result is a reorientation within the lumbar spine with no or very small changes in the total lumbar lordosis.

In patients with "disc replacement after previous fusion surgery", we were able to show a significant change in spinal and pelvic alignment parameters after surgery (Hähnle, et al. Summer 2007[21]). The use of TDR in failed fusion surgery as cranial top-up, above an existing fusion, is a logical treatment in ASD. Apart from absorbing part of the stresses being transmitted to the cranial lumbar levels, TDR is able to improve the sagittal alignment by increasing anterior column height. Careful consideration of the overall sagittal spinal balance is of paramount importance in the planning of this procedure. The disc prosthesis comprises a mobile spacer that will passively adjust to a certain position by the restrained surrounding soft tissue structures in order to achieve a balanced position. Due to a flat back deformity within the fusion, the spinal balance is often significantly disturbed after previous fusion surgery.

Lumbar TDR still has considerable drawbacks. TDR can only approximate the natural motion of an intact SMS. The prostheses presently in use, in their material properties, differ significantly from the properties of the natural disc. The only prostheses with successful long term follow-up are mechanical discs (Lemaire, et al. 2005[22] ;Tropiano, et al. 2005[23]), which offer no elastic properties. Visco-elastic discs have, thus far, not rendered good sustainable long term results.

Anterior revision surgery, after previous anterior spine surgery for fusion or TDR purposes, presents a significant challenge to the access surgeon. Re-exposure of the spine requires mobilisation of the peritoneal sac as well as mobilisation of the major vessels and ureter, which are now strongly encased in fibrous tissue and firmly adherent to each other and the surface of the spine. Complications reported in the literature have varied widely, with vascular incidences ranging from 5% to 89%. The difference in complications results from the experience of the access surgeon, the pre-

operative planning and the inclusion of cases with lesser risk (as anterior revision of other levels than the index levels) (Brau, et al. 2008[24]; Nguyen, et al. 2006[25;] Punt, et al. 2008[26]; Wagner, et al. 2006[27]). The L4/5 disc space is the most difficult to revise; the L5/S1 is generally the easiest, except in patients with caudally situated venous confluents. A pre-revision venogram with contrast injected simultaneously into both femoral veins has greatly helped me to obtain an exact image of the venous vascular configuration in revision surgery. The future use of adhesion barriers in primary anterior spine surgery may reduce the dangers of anterior revision surgery (Patel, et al. 2008[28]). Revision surgery should only be undertaken by highly experienced vascular and arthroplasty surgeons.

From the onset of modern disc arthroplasty, the recommended patient age ranged from 18 - 50 (60) years. This recommendation includes considerably younger patients than recommended in any other arthroplasty; hip and knee arthroplasty is primarily performed in patients past the recommended age range for spinal arthroplasty. Considering the dangers of anterior revision surgery, this needs to be reconsidered.

8.4. Disc arthroplasty – the way forward

There is evidence in the literature that positive sagital balance is associated with an increase in lower back symptoms (Glassman S, et al. 2005[9]) and surgical flat back correction during fusion surgery positively correlates with improved clinical outcome of fusion surgery (Kumar, et al. 2001[10]). Only recently have classification systems been published for assessing sagital plane deformities (Roussouly, et al. 2005[29]; Jang, et al. 2007[30]). Jang et al. (2007) found that kyphosis at the T-L junction was particularly detrimental to the overall sagittal balance. There are no publications investigating the influence of pre-existing thoracic deformities on outcome of TDR.

Total disc replacement, by increasing the anterior column height can improve sagittal imbalance. Only a limited correction of flat back deformity within a FSU can be achieved. Where there is a need for stronger flat back correction, the insertion of a TDP will lead to hyper-extended disc prosthesis during upright standing posture. Over time, this will lead to over-stretching of the anterior soft tissue restraint structures and overloading of the posterior spinal elements. Recurrence of symptoms

(LBP and SS) will be the consequence. With increasing experience with the lumbar disc prostheses, I became more aware of the overall importance of the sagittal spinal balance in failed fusion surgery (Hähnle, et al. Summer 2007[21]). Long, whole-spine lateral standing radiographs should be performed on all patients undergoing lumbar TDR. Research is urgently needed into the influence of pre-existing thoracic and thoraco-lumbar kyphosis on the clinical and radiological outcome of disc replacement surgery.

Siepe et al. (2007) retrospectively analyzed their patient cohort after pro-disc insertion. With the pro-disc, they found a better outcome in L4/5 disc replacement when compared to L5/S1 disc replacement; the outcome was poorer with double level replacements when compared to single level replacements. They further investigated clinical outcome in relation to the initial clinical diagnosis and had the best outcome in patients with DDD and associated soft disc herniation (Siepe, et al. 2006[32]). These are important first steps towards the comprehension of what might determine the success of TDR. More research into indication related outcome will be required and the results need to be compared to conventional (fusion) treatment.

The clinical outcome has been shown to depend on the accuracy of placement of the disc prosthesis (McAfee, et al. 2005[33]; Moumene, Geisler. 2007[7]). Using the Kineflex lumbar disc prosthesis, we could achieve excellent placement accuracy in our patient cohort. The placement accuracy was equally good in patients with more advanced disc space collapse (Hähnle UR, et al. 2007[34]). We are of the opinion that the amount of disc space collapse should not necessarily influence the decision whether TDR can be performed.

Significant facet arthrosis is considered as contraindication for total disc replacement. There is no consensus on whether artificial disc replacement, or which type of disc prosthesis, increases or decreases facet loading. Fixed core implants seem to produce more facet joint incongruence during motion and they seem to be less tolerant towards slight misplacement within the disc space (Rousseau, et al. 2006[35]; Moumene, Geisler. 2007[7]).

Although it may be likely and logical, to date there is no proof that the amount of facet arthrosis has any influence on the clinical results of TDR. As described in our publication in Chapter 7, we implanted disc prostheses in seven selected patients with Grade 2 spondylolisthes and/or localised kyphosis - a condition widely considered as a contraindication for TDR. The condition is associated with significant facet arthritis, incongruence of the facet joint and a segmental kyphosis. The very particular insertion technique of the Kineflex disc prosthesis allowed an almost complete reduction of the deformity through a single access anterior approach and rendered excellent two year clinical and radiological results (Hähnle, et al. Winter 2007[18]). Further controlled studies will be required to confirm the viability of this procedure for DSPL.

A recent publication investigated the existing literature for factors that might affect the outcome of lumbar TDR. The authors concluded that there is only limited, lower level data available on most factors determining outcome and they found only weak evidence that TDR might prevent ASD (Zindrick, et al. 2008[36]).

8.5. Summary of this research project

As part of this research project, we developed a new intervertebral disc prosthesis with several international patents attached to the design of the prosthesis, the instrumentation as well as the insertion technique.

In extensive in vitro studies, we could show the durability of the Kineflex disc prosthesis over the long term. This, together with our initial clinical outcome results, formed the basis for the acceptance into a "prospective, randomized, multicenter *Food and Drug Administration investigational device exemption study* of lumbar total disc replacement with the KINEFLEX Lumbar Artificial Disc *versus* the CHARITÉ™ Artificial Disc".

As lumbar total disc replacement traditionally carried restrictive indications, our initial aim was to develop a prosthesis that could be used in a wider range of indications. In our studies we could demonstrate accurate placement even in severely collapsed disc spaces (Chapter 5). We successfully applied the Kineflex disc

prosthesis in patients with ASD who had undergone previous fusion surgery (Chapter 6) and in patients with DSPL, which both constitute contraindications for the insertion of artificial disc prosthesis.

The successful outcome in these off-label indications will have to hold up in long term follow-up and requires confirmation in larger, controlled trials, in order to determine what part of the traditional fusion surgery will finally be replaced by motion preserving surgery.

8.6. References: Overall discussion

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9. APPENDICES

9.1. Ethical clearances

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Hahnle

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M080557**
PROJECT	Retrospective analysis of clinical and radiological outcome of patients treated withthe Kineflex disc prosthesis between April 2002 and April 2008.
INVESTIGATORS	Dr U Hahnle
DEPARTMENT	Orthopaedics
DATE CONSIDERED	08.05.30
DECISION OF THE COMMITTEE*	Approved subject to Hospital permission being received

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 08.06.19 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr G Candy

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Hahnle

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M03-06-13

PROJECT A retrospective Comparison of the Subsidence Rate and the Accuracy of Midline Placement of 34 Consecutively Inserted Centurion Lumbar Disc Prostheses in 28 Patients With a Consecutive Sample of 61 Charite SB III Lumbar Disc Protheses in 50 Patients

INVESTIGATORS Dr UR Hahnle

DEPARTMENT School of Clinical Medicine, Johannesburg Hospital

DATE CONSIDERED 03-06-27

DECISION OF THE COMMITTEE Approved unconditionally

Unles otherwise specified the ethical clearance is valid for 5 years but may be renewed upon application
This ethical clearance will expire on 1 January 2008.

27/06/03

DATE 03-06-30 CHAIRMAN Mcshaelane (Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Dr UR Hahnle
Dept of School of Clinical Medicine Johannesburg Hospital
Works2\Iain0015\HumEth97.wdb\M 03-06-13

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DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress form. I/we agree to inform the Committee once the study is completed.

DATE 08/07/03 SIGNATURE

PLEASE QUOTE THE PROTOCOL NO IN ALL QUERIES .: M 03-06-13

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

9.2. Questionnaires

9.2.1. VAS

Pain Intensity Worksheet (VAS)

Lumbar

Subject Initials _____ Date of Birth: _____

Date of office visit _____

Visit Type: pre-op, post-op, 6 wks, 3 mo, 6 mo, 12 mo, 24 mo

Directions for Subject

Below is a scale with the left end of the scale indicating no pain and the right end of the scale indicating the worst pain possible. Please use this scale to record the *average* amount of back pain and leg (sciatica) pain you have had since your last visit (or for the past six months if this is the first time you are completing this scale) while you were at rest.

Make a circle around the number that corresponds to the level of pain.
0 – 10 scale (0= No pain, 10 = Worst pain)

0 1 2 3 4 5 6 7 8 9 10

_____ __
Subject Signature Date

Study Coordinator

Please note the value below

_____ ___
Study Co-ordinator Signature Date

9.2.2. ODI

Name _____ Address _____ Date _____

Date of birth _____ Age __ _____

Occupation _____ _____

How long have you had back pain? _____ Years _____ Months _____ Weeks
How long have you had leg pain? _____Years _____ Months _____ Weeks

THE OSWESTRY DISABILITY INDEX FOR BACK PAIN

This questionnaire has been designed to give us information as to how your back pain has affected your ability to manage everyday life activities. Please answer every section, and mark in each section the **one box** that applies to you. We realize you may consider that two of the statements in any one section relate to you, but please just mark the box that **most closely** describes your present day situation.

Section 1. Pain Intensity
A. I can tolerate the pain I have without having to use pain killers.
B. The pain is bad, but I manage without taking pain killers.
C. Pain killers give complete relief from pain.
D. Pain killers give moderate relief from pain.
E. Pain killers give very little relief from pain.
F. Pain killers have no effect on the pain and I do not use them.

Section 2. Personal Care (Washing, Dressing, etc)
A. I can look after myself normally without causing extra pain.
B. I can look after myself normally but it causes extra pain.
C. It is painful to look after myself and I am slow and careful.
D. I need some help but manage most of my personal care.
E. I need help every day in most aspects of self care.
F. I do not get dressed, wash with difficulty and stay in bed.

Section 3. Lifting
A. I can lift heavy weights without extra pain.
B. I can lift heavy weights but it gives extra pain.
C. Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, eg on a table.
D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
E. I can lift only very light weights.
F. I cannot lift or carry anything at all.

Section 4. Walking
A Pain does not prevent me walking any distance.
B. Pain prevents me walking more than 1 km.
C. Pain prevents me walking more than ½ km.
D. Pain prevents me walking more than ¼ km.
E. I can only walk using a stick or crutches.
F. I am in bed most of the time and have to crawl to the toilet.

Section 5. Sitting
A. I can sit in any chair as long as I like.
B. I can only sit in my favorite chair as long as I like.
C. Pain prevents me from sitting more than 1 hour.
D. Pain prevents me from sitting more than ½ hour.
E. Pain prevents me from sitting more than 10 minutes.
F. Pain prevents me from sitting at all.

Section 6. Standing
A. I can stand as long as I want without extra pain.
B. I can stand as long as I want, but it gives me extra pain.
C. Pain prevents me from standing for more than 1 hour.
D. Pain prevents me from standing for more than 30 minutes.
E. Pain prevents me from standing for more than 10 minutes.
F. Pain prevents me from standing at all.

Section 7. Sleeping
A. Pain does not prevent me from sleeping well.
B. I can sleep well only by using tablets.
C. Even when I take tablets I have less than six hours sleep.
D. Even when I take tablets I have less than four hours sleep.
E. Even when I take tablets I have less than two hours sleep.
F. Pain prevents me from sleeping at all.

Section 8. Sex Life
A. My sex life is normal and causes no extra pain.
B. My sex life is normal but causes some extra pain.
C. My sex life is nearly normal but is very painful.
D. My sex life is severely restricted by pain
E. My sex life is nearly absent because of pain.
F. Pain prevents any sex life at all.

Section 9. Social Life
A. My social life is normal and gives me no extra pain.
B. My social life is normal but increases the degree of pain.
C. Pain has no significant effect on my social life apart from limiting my more energetic interests, eg dancing, etc.
D. Pain has restricted my social life and I do not go out as often.
E. Pain has restricted my social life to my home.
F. I have no social life because of pain.

Section 10. Traveling
A. I can travel anywhere without extra pain.
B. I can travel anywhere, but it gives me extra pain.
C. Pain is bad, but I manage journeys over two hours.
D. Pain restricts me to journeys of less than one hour.
E. Pain restricts me to short necessary journeys under 30 minutes
F. Pain prevents me from traveling except to the doctor/hospital.

Comments _____

9.2.3. Own questionnaire: Pre-Op (Dr Uli Hähnle / Dr Ian Weinberg)

PRE-OP QUESTIONNAIRE - KINEFLEX DISC **L**umbar

To be completed by the patient (please ask when in doubt)

Name (Mr/Ms)_____ Date_____

Date of birth_____ Height (cm)_____ Weight (kg)_____

Single Married Divorced Widowed Other

Children: Number Age Sex

PROFESSION: Employed Self-employed Retired Specify:

Manual Office Driving (hrs/day)

PAST MEDICAL HISTORY

Previous Spine Operations: Year Operation Surgeon Result (good/poor)

1)_____

2)_____

3)_____

more_____

Previous other Operations: Gynaecologic:_____

Abdominal:_____

Others:_____

Other illnesses: Heart disease:_____

High blood pressure:_____

Diabetes:_____

Other:_____

HABITS: Smoking – No Yes (cigarettes per day)_____

Alcohol – No Yes (please specify)_____

Who referred you? (please specify)

Doctor Chiropractor Physiotherapist Patient Other

What **non-**operative treatment did you have before?

	Doctor	Chiropractor	Physiotherapist	Patients	Other
Treatment					
Duration					
Result?					

Medication:	**Name**	**Dose**	**times per day**	**per week**
Painkillers				
Anti-inflammatories				
Others				

Pain score:

Back: (please mark the severity of your back pain over the last two weeks from 0 - 10)

0 _____ 10

No pain Pain as bad as can be (please choose one number)

Leg: left right (please mark the severity of your pain over the last two weeks from 0 - 10)

0 _____ 10

No pain Pain as bad as can be (please choose one number)

Duration of pain: please insert numbers

☐ Years ☐ Months ☐ Weeks

Pain Severity: rate your pain 1 – 10

Lying 0 _____ 10

No pain Pain as bad as can be

Sitting	0 _____	10
	No pain	Pain as bad as can be
Standing	0 _____	10
	No pain	Pain as bad as can be
Walking	0 _____	10
	No pain	Pain as bad as can be

Weakness: Do you feel any weakness in your legs? No Yes left right

If yes, please specify.

When do you notice it most?

Work: Are you currently working? Yes No

Occupation_____

If no: Did you stop working because of back problems? Yes No

Do you feel pressurized at work? Yes No

Sport: Are you playing sport? Yes No

Which sports?_____

How often?_____

If not: Did you stop because of back problems? Yes No When?

Would you return to sport if your pain would allow it? Yes No

What do you expect from the treatment? (please describe in your own words)

Anything you think it would be important for us to know?

9.2.4. Own questionnaire: Post-op (Doctors U Hähnle and I Weinberg)

POST-OP QUESTIONNAIRE - **K**ineflex Disc **L**umbar

To be completed by the patient (please ask when in doubt)

Name (Mr/Ms)_____ Date_____

Date of birth_____ Height (cm)_____ Weight (kg)_____

Diagnosis_____

Procedure performed_____

Date of operation_____

Time since operation 6w 3m 6m 1y 2y 3y 5y 7y

QUESTIONNAIRE

Satisfaction with **outcome of treatment**

Excellent Good Fair Poor

Would you undergo the same operation again or recommend it to friends?

Yes Don't know No

Pain score (please grade your present pain) 0 = no pain 10 = Pain as bad as can be

General Before operation_____ Today_____

Specific today

Back pain	0	5	10
	No pain		Pain as bad as can be
Leg pain	0	5	10
	No pain		Pain as bad as can be
Stiffness	0	5	10
	No pain		Pain as bad as can be

Others (please explain):_____

Medication:	**Name**	**Dose**	**times per day**	**per week**
Painkillers				
Anti-inflammatories				
Others				

Work What work do (did) you do?_____

Do you feel like going back to your previous occupation? Yes No

If you are already back at work, when did you go back? Date_____

What are the remaining restrictions at work?_____

Sports What sports do (did) you do?_____ none

Do you feel like going back to your previous sport? Yes No

If you are back at sport, when did you go back Date_____

What are the remaining restrictions in sport?_____

What are the remaining restrictions in daily life? _____

_____

What did you **not like** about the treatment? _____

_____

What did you **like** about the treatment? _____

_____

What would you improve in work up and treatment? _____

_____

Other comments:_____

_____

9.3. Lumbar disc prosthesis - Patient consent (Doctors U Hähnle and I Weinberg)

KINEFLEX DISC REPLACEMENT- LUMBAR (GENERAL)

You are about to undergo a disc replacement operation. This operation is performed through a cut made between the bellybutton and the panty line. The bowels are moved to one side (together with their covering membrane) in order to reach the spine.

Once at the spine, the surgeon needs to move the big vessels (aorta and vena cava with its branches) temporarily out of the way in order to remove the disc and to insert the prosthesis (disc). There is the possibility of injury to the vessels and resultant significant bleeding. The nerves that supply temperature sensation to the legs, as well as the nerves to the sexual organs, also overlie the spine. They may be irritated or in rare cases permanently damaged during the operation. This may lead to a variety of neurological complications that might be permanent or transient (see neurological complications). Behind the disc lies the spinal cord enclosed in a fluid-filled membrane. Damage to the covering membrane or the nerves can occur during the operation. The prosthesis is placed within the disc space and will maintain the movement of the motion segment.

The disc that will be inserted, the Kineflex disc, is a new development. Our team has implanted over 400 Kineflex prostheses since October 2002. There is limited experience as regards the implantation and no long term results of this disc in people. The materials are well established and tested. The disc has also been tested extensively in the laboratory for wear and tear. The Kineflex disc is currently used in the US as part of a Food and Drug Administration (FDA) trial but is not approved for general use.

Disc replacements with similar discs have been performed in Europe for over 10 years with good results in follow up studies.

We believe that the Kineflex disc combines some advantages of the older disc prostheses while eliminating certain disadvantages.

The alternative operation is usually an anterior and/or posterior fusion operation, which are both well established procedures but carry certain risks and disadvantages.

On the following page you will find a summary of all the possible problems that can occur in relation to the operation.

We well understand that you may be anxious and afraid regarding the planned procedure. Please feel free to discuss all issues relating to this procedure with the doctor. He will be happy to elaborate further on the operation.

You are also welcome to discuss any other appropriate operation after discussion with your doctor.

Possible complications:

General:
- Death
- Neural (nerve) injuries with weakness of the legs
- Vascular injury with severe bleeding
- Need for blood transfusion
- DVT and emboli (blood clots in the legs with danger to circulation)
- Pulmonary embolism: blood clot in the lungs
- Bowel injury
- Infection
- Hernia through the wound

Specific:
- Impotence (loss of virility) – rare
- Paraplegia
- Urine and bowel incontinence
- Kidney, ureter or bowel injury
- Retrograde ejaculation (dry orgasm) in 2 - 7% of male patients
- Weakness or numbness of parts of the lower limbs

Warm feeling in left leg
Dural leak (leak of spinal fluid)
Implant loosening or breaking, non-union, with need for re-operation
Subsidence: sinking of the implant into the bone
Residual pain in the legs or back
Development of additional back or leg pain
Continuous back pain with the need for a later fusion operation

Any kind of anterior re-operation (revision operation) carries a much higher risk of the abovementioned complications, especially ureteric injury, vascular injury and abdominal organ injury.

I have read, understood and accept all relevant facts and possible complications relating to the Kineflex disc implant procedure.

NAME (print please)……..

SIGNATURE ……

DATE …….

WITNESS

NAME ……..

SIGNATURE……

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