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REVIEW

Design concepts in lumbar total disc arthroplasty

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Abstract The implantation of lumbar disc prostheses based on different design concepts is widely accepted. This paper reviews currently available literature studies on the biomechanics of TDA in the lumbar spine, and is targeted at the evaluation of possible relationships between the aims of TDA and the geometrical, mechanical and material properties of the various available disc prostheses. Both theoretical and experimental studies were analyzed, by a PUBMED search (performed in February 2007, revised in January 2008), focusing on single level TDA. Both semi-constrained and unconstrained lumbar discs seem to be able to restore nearly physiological IAR locations and ROM values. However, both increased and decreased ROM was stated in some papers, unrelated to the clinical outcome. Segmental lordosis alterations after TDA were reported in most cases, for both constrained and unconstrained disc prostheses. An increase in the load through the facet joints was documented, for both semi-constrained and unconstrained artificial discs, but with some contrasting results. Semi-constrained devices may be able to share a greater part of the load, thus protecting the surrounding biological structure from overloading and possible early degeneration, but may be more susceptible to wear. The next level of development will be the biomechanical integration of compression across the motion segment. All these findings need to be supported by long-term clinical outcome studies.

Keywords Lumbar · Disc arthroplasty · Biomechanics · Motion preservation · Spinal alignment

Introduction

Total disc arthroplasty (TDA) is currently widely used in Europe and in North America to treat chronic discogenic back pain, and several Investigational Device Exemption studies are currently in progress in the US. Satisfactory clinical outcomes as well as complications have been reported [63, 91, 96], pointing out the need for further investigations. The importance of patient selection was found to be a critical point: a class action lawsuit against the Charité artificial disc (Depuy Acromed Inc., Mountain View, CA, USA) is currently ongoing, due to low success rate and unexpected, potentially life-threatening complications. These problems may be related to overextending the indications and inappropriate patient selection. A number of biomechanical studies about lumbar TDA have been published, but the relationship between the different designs and the resulting biomechanics of the surgically changed spine has not been clearly described.

This paper reviews currently available literature on the biomechanics of TDA in the lumbar spine. The review is

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structured along the aims of TDA, related to the following biomechanical parameters:

- restoration of a physiological kinematics and mobility, avoiding segmental instability
- restoration of a correct spinal alignment
- protection of the biological structures, such as the adjacent intervertebral discs, the facet joints and the ligaments, from overloading and resulting accelerated degeneration
- device stability and wear.

The goal of the present review is to evaluate possible relationships between the aforementioned aims and the geometrical, mechanical and material properties of the various currently available disc prostheses, outlined in studies focusing on single-level disc arthroplasty. For this purpose, a PUBMED search (National Library of Medicine and National Institute of Health, USA) was performed in February 2007 and repeated in January 2008. Only papers written in English were reviewed. Search strings were “lumbar disc arthroplasty”, “lumbar artificial disc”, “lumbar disc replacement”, “lumbar disc prosthesis”. The search offered 668 papers; 77 papers were not published in English. About 498 papers did not contain relevant biomechanical information and have been excluded. Ninety-three papers were reviewed in total.

Restoration of a physiological kinematics and mobility

Many models of lumbar artificial discs are currently available; a summary of the disc prostheses, either commercially available or under clinical trial, which have been referenced in the papers included in the present review is reported in Table 1. The parameters usually employed to describe spine kinematics are the location of the instantaneous axes of rotation (IARs) and range of motion (ROM), both of which are related to the design of the disc prosthesis.

Instantaneous axis of rotation

The locations of the IARs for the lumbar spine in the different planes of motion have been identified in many studies, in both healthy and pathological conditions [70, 81, 95]. Figure 1 illustrates the IAR locations predicted in a recent study by Schmidt et al. [81] in the healthy lumbar spine.

A few biomechanical studies regarding the IARs after lumbar arthroplasty have recently been published (Table 2). Cunningham et al. [13] determined the locations of the IAR in flexion-extension, of eight spines implanted with the Charité disc prosthesis at the L4–L5 level. The measured IARs were located in the posterior third of the intervertebral space, similar to the physiological conditions. The same result was obtained by Kotani et al. [42] with a fabric disc prosthesis. Rousseau et al. [78] investigated the IARs of the L5-S1 motion segment after implantation of the semi-constrained prosthesis ProDisc and the unconstrained Charité. Both prostheses had no significant influence on the IAR locations in flexion-extension and lateral bending, despite their different design concepts. The authors demonstrated that the instantaneous axis of rotation does not necessarily correspond with the geometrical center of the spherical coupling for semi-constrained prostheses, in particular for shear and lateral bending loading conditions. These results, which seem counter-intuitive, were explained because of deformation of the articulating surfaces and micromotion at the device–endplate interface. However, the results may also be influenced by measurement errors, which cannot be neglected in the experimental estimation of the IAR location [81].

Range of motion (ROM)

In many studies, ROM restoration after lumbar disc arthroplasty was investigated by using radiographic

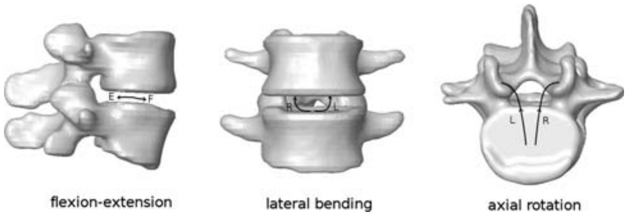

Fig. 1 Locations of the IARs in the lumbar spine [81]. *F* and *E* represent the IAR locations in flexion and extension respectively; *L* and *R* are the IAR locations in left lateral bending or left axial rotation (L) and right lateral bending or right axial rotation (R)

Table 1 Classification of the lumbar disc prosthesis that have been referenced in biomechanical papers

Name	Manufacturer	Classification
Flexicore	Stryker, Kalamazoo, MI, USA	Constrained
Maverick	Medtronic Ltd, Memphis, TN, USA	Semi-constrained
ProDisc	Synthes Inc., West Chester, PA, USA	Semi-constrained
Charité	Depuy Acromed Inc., Mountain View, CA, USA	Unconstrained
Acroflex (discontinued)	Depuy Acromed Inc., Mountain View, CA, USA	Unconstrained

Table 2 Published studies concerning lumbar kinematics after TDA

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Auerbach et al. [1]	Human	Radiographic	Motion	ProDisc (semi-constrained)	Fusion	Preserved motion at implanted and adjacent levels, as compared to fusion
Bertagnoli and Kumar [2]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Preserved average vertebral motion at the operated level
Bertagnoli et al. [4]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	3–7 degrees of motion in flexion-extension
Bertagnoli et al. [3]	Human	Radiographic	Motion	ProDisc (semi-constrained)	Smokers versus non-smokers	3–7 degrees of motion in flexion-extension
Cakir et al. [6]	Human	Radiographic	Segmental and total lordosis	ProDisc (semi-constrained)	–	Increased segmental lordosis, unchanged total lordosis
Cakir et al. [7]	Human	Radiographic	Method for measuring motion	–	–	Choice of different landmarks improves measure reliability
Chung et al. [9]	Human	Radiographic	Segmental and total lordosis	ProDisc (semi-constrained)	–	Increased segmental and total lordosis
Chung et al. [10]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Increased average motion from 9.7 to 12.7 degrees
Cinotti et al. [11]	Human	Radiographic	Motion	Charité (unconstrained)	–	Average 9 degrees of motion at the implanted level, 16 degrees at the adjacent levels
Cunningham et al. [14]	Non-human primate	In vivo, ex vivo (histopatologic and histomorphometric)	Motion, trabecular ingrowth	Acroflex (unconstrained)	–	Reduced motion; no evidences of pathological changes; heterotopic ossification
Cunningham et al. [13]	Human	Ex vivo	Motion, IAR	Charité (unconstrained)	Fusion, instrumented fusion	Preserved motion and IAR
Cunningham et al. [12]	Non-human primate	In vivo, ex vivo	Motion, bone ingrowth	Charité, Acroflex (unconstrained)	Intact	Acroflex motion smaller than intact and Charité; excellent bone ingrowth
Cunningham [16]	Human, non-human primate	In vivo, ex vivo (histopatologic and histomorphometric)	Motion, IAR, bone ingrowth	Charité, Acroflex (unconstrained)	Intact, fusion	Preserved motion and IAR, excellent bone ingrowth
Cunningham et al. [15]	Human	Radiographic	Motion	Charité (unconstrained)	Fusion	Normal motion distribution along the lumbar spine
David [17]	Human	Radiographic	Motion	Charitè(unconstrained)	–	Preserved motion
Delamarter et al. [19]	Human	Ex vivo	Motion	ProDisc (semi-constrained)	Fusion	1 operated level: preserved motion and coupling; 2 operated levels: not preserved motion and coupling in 50%

Table 2 continued

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Denozière and Ku [20]	Human	Computational	Motion, stability, ligament tensions, facet pressure	Ball and socket (semi-constrained)	Fusion	Greater risk of instability and further degeneration relative fusion
Dooris et al. [21]	Human	Computational	Motion, facet loads, intradiscal pressure, shear stresses	Ball and socket (semi-constrained)	–	Modification of the spinal bending stiffness in the sagittal plane
Eijkelkamp et al. [23]	–	–	Kinematics, load sharing, stability	–	–	Design guidelines for disc prostheses
Enker et al. [24]	Human	Radiographic	Motion, bone ingrowth	Acroflex (unconstrained)	–	Preserved motion, good bone ingrowth
Goel et al. [28]	Human	Computational	Motion, facet loads, intradiscal pressure, shear stresses	Charité (unconstrained)	–	Increased motion at the L5-S1 level in flexion-extension; decreased facet loads; higher shear stresses at the TDA L5 endplate relative to those at S1 interface
Hedman et al. [29]	–	–	Kinematics, endurance, safety	Generic	–	Design guidelines for disc prostheses
Hitchon et al. [30]	Human	Ex vivo	Motion	Maverick (semi-constrained)	–	Preserved motion
Huang et al. [34]	–	–	Constraint	Semi-constrained, unconstrained	–	Unconstrained disc prostheses may have a kinematical advantage; semi-constrained disc prostheses may protect the posterior structure in shear
Huang et al. [35]	Human	Radiographic	Motion, sagittal alignment	ProDisc (semi-constrained)	–	Preserved motion; improved global and segmental alignment
Huang et al. [33]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Radiographic follow-up was positively correlated with the clinical outcome
Huang et al. [36]	Human	Radiographic	Motion, adjacent level degeneration	ProDisc (semi-constrained)	–	Correlation between motion and adjacent level degeneration
Kadoya et al. [37]	Ovine	Ex vivo	Static, viscoelastic and fatigue properties; histological analysis	3D fabric disc (unconstrained)	–	Mechanical behavior similar to natural sheep disc; no debris detected
Kim et al. [39]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Reduced motion at L5-S1 implanted level

Table 2 continued

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Kosmopoulos et al. [40]	Human	Radiographic	Method for measuring motion	–	–	Patient should be parallel to the plate; the beam should be directed to the disc prosthesis
Kotani et al. [42]	Ovine	In vivo, ex vivo	Motion, histological analysis	3D fabric disc (unconstrained)	3D fabric disc with internal fixation	Biomechanical properties nearly equivalent to that of the natural disc; excellent fusion capacity
Kotani et al. [43]	Ovine	In vivo, ex vivo	Motion, histological analysis	3D fabric disc (unconstrained)	3D fabric disc with internal fixation	Reduced motion, excellent fusion
Kotani et al. [44]	Human	Ex vivo	Motion, IAR	3D fabric disc (unconstrained)	Intact, instrumented fusion	Motion and IAR equivalent to that of the intact spine
Le Huec et al. [50]	Human	Radiographic	Sagittal alignment	Maverick (semi-constrained)	–	Preserved global and segmental lordosis, decreased lordosis at the above level
Leivseth et al. [55]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Not preserved normal segmental rotational motion in the sagittal plane
Lemaire et al. [56]	Human	Radiographic	Motion	Charité (unconstrained)	–	Preserved motion in flexion-extension and axial rotation
Lim et al. [58]	Human	Radiographic	Method for measuring motion	–	–	Using the keels instead of the endplates for measuring the Cobb angles is recommended
Lim et al. [59]	Human	Radiographic	Errors in motion measures	–	–	Intraobserver variability: ±4.6 degrees; interobserver variability: ±5.2 degrees
McAfee et al. [61]	Human	Radiographic	Motion	Charité (unconstrained)	–	High accuracy during surgery induces better motion
McAfee et al. [62]	Human	Radiographic	Motion	Charité (unconstrained)	–	93.4% patients had motion over 7 degrees
Neal et al. [67]	Human	MRI	Motion, motion at the adjacent levels	–	–	Despite artifacts, MRI is a valuable tool for evaluating disc degeneration at the adjacent levels
Noailly et al. [68]	Human	Computational	Motion, stiffness	Novel composite disc	–	Higher stiffness than the intact disc
O'Leary et al. [69]	Human	Ex vivo	Motion	Charité (unconstrained)	Fusion + Charité	Preserved motion, not preserved motion patterns

Table 2 continued

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Panjabi et al. [72]	Human	Ex vivo	Motion	Charité (unconstrained)	Fusion	Preserved motion at implanted and adjacent levels (TDA); affected motion redistribution at adjacent levels (fusion)
Panjabi et al. [71]	Human	Ex vivo	Motion	ProDisc (semi-constrained)	Fusion	Preserved motion (TDA) as compared to fusion at all spinal levels
Putzier et al. [74]	Human	Radiographic	Motion	Charité (unconstrained)	–	Spontaneous ankylosis in 60% patients after 17 years
Rohlmann et al. [77]	Human	Computational	Motion	ProDisc (semi-constrained)	–	TDA height and position, ALL and AF removing affect the segment biomechanics
Rousseau et al. [78]	Human	Computational	Motion, IAR, facet forces	Charité (unconstrained) ProDisc (semi-constrained)	–	ProDisc: decreased facet forces, IAR variable; Charité: increased facet forces, IAR less variable
SariAli et al. [79]	Human	Computational	Motion	Charité (unconstrained)	Healthy volunteers	Single level TDA: preserved motion and coupling; double level TDA: not preserved motion and coupling in 50%
Sasso et al. [80]	Human	Radiographic	Motion	FlexiCore (constrained)	Fusion	Preserved motion in flexion-extension and lateral bending
Tortolani et al. [87]	Human	Radiographic	Heterotopic ossification	Charité (unconstrained)	–	Heterotopic ossification in 4.3% patients; all these patients had motion increase after surgery
Tournier et al. [88]	Human	Radiographic	Motion, disc height, sagittal balance	Charité (unconstrained) Maverick, ProDisc (semi-constrained)	–	Preserved motion and disc height, preserved sagittal balance, modification of the lumbar curvature
Vuono-Hawkins et al. [92]	Canine	In vivo, ex vivo	Motion, bone ingrowth	Elastomeric spacer	–	Increased motion, no significant bone ingrowth after 12 months
Zigler et al. [98]	Human	Radiographic	Motion	ProDisc (semi-constrained)	–	Preserved motion (average 7.7 degrees)

IAR instantaneous axis of rotation, *TDA* total disc arthroplasty, *MRI* magnetic resonance imaging, *ALL* anterior longitudinal ligament, *AF* annulus fibrosus measurements, laboratory experiments and computational models. The various disc prostheses were shown to preserve generally the mobility at a nearly physiological level, for both semi-constrained and unconstrained designs (Table 2). However, some dissenting findings are documented in the literature, in particular with reference to the unconstrained Charité disc prosthesis. Goel et al. [28] developed a finite element model of the lumbar spine including the Charité prosthesis at the L5-S1 level. The results showed an increase in ROM at the implanted level in flexion (18.9%) and in extension (43.4%), with consequent decrease in ROM at the adjacent levels. O'Leary et al. [69] conducted an experimental study on the Charité disc prosthesis implanted at the L5-S1 level, and reported an average ROM increase of 5.6 degrees in flexion-extension. However, computer simulations and in vitro experiments can only approximate the complex physiological loading of the human spine, especially compressive forces due to muscle activity. On the contrary, McAfee et al. [61], in a radiographic study on the same prosthesis, found a reduction in the flexion-extension ROM in 82.5% of the operated patients 24 months after the surgery, accompanied with the good clinical results. Nonetheless, the clinical outcome should be considered the principal functional measure.

Leivseth et al. [55] observed ROM values between 27% (L5-S1 level) and 64% (L2-L3) of the normal ROM, in 41 patients 24 months after implantation of the semi-constrained ProDisc. The authors postulated that the main cause of this phenomenon would be the soft tissue adaptation during the preoperative period. These changes, induced by restricted spine motion due to symptomatic periods of low back pain, are considered to be irreversible. This assertion appeared to be confirmed by the observed ROM decrease also at the adjacent levels.

Discussion

Most papers state that both semi-constrained and unconstrained disc prostheses are able to restore correct spinal kinematics, in terms of IAR and ROM. However, some dissenting findings have been reported, thus indicating that some aspects, namely the possible increase or reduction of the ROM, still need to be clarified. The reported difference between the geometrical center and the IAR location of semi-constrained disc prostheses need to be verified, in particular with reference to the possible measurement error in the estimation of the IAR position. Both ROM increase and decrease were reported in different papers; a clinical investigation about the actual incidence of these alterations in vivo is required. At present, we cannot state that the monitored ROM alterations are predictors for the clinical outcome.

Spinal alignment

Segmental lordosis is increased after lumbar TDA in most cases, for both semi-constrained [6] and unconstrained disc prostheses [31, 69]. Globally, preoperative insufficient segmental lordosis was found to be restored to a normal lordosis angle [57], while excessive segmental lordosis was observed in cases of normal lordosis in the preoperative stage [6]. However, the overall lumbar lordosis was preserved [6].

McAfee et al. [62] found iatrogenic lumbar scoliosis in an alarming number of patients subjected to lumbar TDA, with both semi-constrained and unconstrained disc prostheses. The actual incidence of this complication was not reported in the paper. The authors related this phenomenon to the rotational instability of the lumbar spine after "radical" preparation for TDA (discectomy, resection of the anterior longitudinal ligament, stretching of resection of the posterior longitudinal ligament, intervertebral distraction).

Discussion

The increase of the segmental lordosis is a rather frequent consequence of lumbar TDA, described in many papers, with possible clinical consequences. The clinical relevance of such a significant lordosis alteration needs to be evaluated in long-term follow-up studies. Up to now, no relation between the postoperative sagittal alignment and the prosthesis design has been demonstrated.

Iatrogenic lumbar scoliosis is documented in both patients with or without minor preoperative scoliosis, though only in a single case-report paper. A pre-existing minor scoliosis should be defined as an absolute contraindication for TDA; however, exclusion criteria for lumbar TDA generally admit scoliosis up to 11° Cobb angle [62]. Semi-constrained devices may help in the restoration of the rotational stiffness of the functional unit, as suggested by McAfee et al. [62].

Protection of the biological structures

Several papers addressing the estimation of loads and stresses acting in the lumbar spinal structures after TDA are currently available (Table 3). These studies are generally targeted to the investigation of the possible alteration of the forces transmitted through the facet joints and of the intradiscal stresses at the adjacent levels [76]. In fact, one of the premises of TDA is preventing the overloading of the surrounding biological structures, the main drawback of spinal fusion. However, some authors suggested that the increase in the biomechanical stresses after fusion may not have a real clinical significance [93], thus questioning the

Table 3 Published studies concerning loads, stresses and sagittal balance after TDA

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Cakir et al. [6]	Human	Radiographic	Sagittal balance	ProDisc (semi-constrained)	–	Increased segmental lordosis, overall lordosis preserved
Chung et al. [9]	Human	Radiographic	Sagittal balance	ProDisc (semi-constrained)	–	Increased segmental and overall lordosis
Denozière and Ku [20]	Human	Computational	Motion,stability, ligament tensions, facet pressure	Ball and socket (semi-constrained)	Fusion	Greater risk of instability and further degeneration relative fusion
Dooris et al. [21]	Human	Computational	Motion, facet loads, intradiscal pressure, shear stresses	Ball and socket (semi-constrained)	–	Modification of the spinal bending stiffness in the sagittal plane
Goel et al. [28]	Human	Computational	Motion, facet loads, intradiscal pressure, shear stresses	Charité(unconstrained)	–	Increased motion at the L5-S1 level in flexion/extension; decreased facet loads; higher shear stresses at the TDA L5 endplate relative to those at S1 interface
Huang et al. [34]	–	–	Constraint	Semi-constrained, unconstrained	–	Unconstrained disc prostheses may have a kinematical advantage; semi-constrained disc prostheses may protect the posterior structure in shear
Kadoya et al. [37]	Ovine	Experimental	Static, viscoelastic and fatigue properties; histological analysis	3D fabric disc (unconstrained)	–	Mechanical behavior similar to natural sheep disc; no debris detected
Ledet et al. [53]	Non-human primate	In vivo	In vivo interbody force	Instrumented interbody spacer	–	The baboon may be an appropriate animal model of the human lumbar spine
Le Huec et al. [52]	Human	Radiographic	Sagittal balance	Maverick (semi-constrained)	–	Preserved sagittal balance
Le Huec et al. [51]	Human	Radiographic	Sagittal balance, facet loads	Maverick (semi-constrained)	–	Facet loads may be not increased after implantation of a semi-constrained disc prosthesis
Lemaire et al. [56]	Human	Radiographic	Sagittal balance	Charité (unconstrained)	–	87% patients had a restoration of lumbar sagittal balance
Mathew et al. [60]	Human	–	–	ProDisc (semi-constrained)	–	Complication: bilateral pedicle fracture, probably related to the lordosis angle distribution of the prosthesis design
McAfee et al. [62]	Human	Ex vivo	Motion	Charité (unconstrained)	–	TDA accentuates scoliotic tendencies in the lumbar spine
Moumene and Geisler [66]	Human	Computational	Loading on the facet joints, stress on the polyethylene core	Unconstrained, semi-constrained	–	Unconstrained TDA unloads facet joints and presents decreased core stress as compared to fixed-core (semi-constrained) TDA
Rohlmann et al. [77]	Human	Computational	Alignment in standing position and flexion	ProDisc (semi-constrained)	–	Implant position strongly influences intersegmental rotation in standing and flexion

Table 3 continued

References	Model	Study type	Mechanical variables	Prosthesis	Compared to	Results
Rousseau et al. [78]	Human	Experimental	Motion, facet forces	Charité (unconstrained) ProDisc (semi-constrained)	–	ProDisc: decreased facet forces, IAR variable; Charité: increased facet forces, IAR less variable
Shim et al. [84]	Human	–	–	ProDisc (semi-constrained)	–	Case report of two split fractures of the vertebral body due to the keel design
Tournier et al. [88]	Human	Radiographic	Motion, disc height, sagittal balance	Charité (unconstrained) Maverick, ProDisc (semi-constrained)	–	Preserved motion and disc height, preserved sagittal balance, modification of the lumbar curvature
Trouillier et al. [89]	Human	Radiographic	Facet joint integrity	Charité (unconstrained)	–	Implantation of the disc prosthesis was not associated to increased loading in the facet joints
Van Ooij et al. [91]	Human	Radiographic	Degeneration, stability	Charité (unconstrained)	–	Observed complications: degeneration of adjacent discs, facet joint arthrosis at the implanted and other levels, subsidence
Wenzel and Sheperd [94]	Human	Computational	Contact stresses on the articulating surfaces	Ball-and-socket	–	Stresses below the fatigue strength of the employed materials

TDA total disc arthroplasty, *IAR* instantaneous axis of rotation

importance of motion preservation technologies in the protection of the biological structures.

Some papers describing numerical models of the lumbar spine after TDA are available in the literature. An increase in the ROM at the treated level was observed in some studies [20, 21, 28]. The hypermobility was related to a major increase of the forces in the facet joints, for semi-constrained disc prosthesis [20], with pressure values exceeding the ultimate strength of the articular cartilage. A strong sensitivity of the facet forces to the anteroposterior positioning of the disc prosthesis was also observed [20, 21]. The authors suggested the preservation of as much annulus as possible during surgery (in contrast to the mentioned radical preparation leading to iatrogenic scoliosis), as a good practice rule, in order to avoid instability and non-physiological loading on facet joints and ligaments [20]. Moumene and Geisler [66] estimated the effect of lumbar semi-constrained and unconstrained (mobile-core) artificial disc design and placement on the loading of the facet joints, using a 3D non-linear finite element model of the L4-L5 motion segment. Results showed that an unconstrained artificial disc design is less sensitive to placement and unloads facet joints, as compared to a semi-constrained design. Trouillier et al. [89] observed no significant increase in subchondral bone density 6 months after implantation of the unconstrained Charité disc prosthesis, and a significant decrease in 10/13 patients. These findings might indicate a reduced loading in facet joints, if compared to the preoperative conditions. Furthermore, the unconstrained design has been found to induce only marginal changes in the intradiscal pressures at the adjacent levels [28].

Contrarily, Rousseau et al. [78] described no significant alteration of the facet loads after implantation of the semi-constrained ProDisc device, in an ex vivo study employing thin pressure sensors. However, the unconstrained Charité disc prosthesis increased the facet load, in particular in lateral bending. According to the authors, this phenomenon is due to the contralateral movement of the core, which reduces the intervertebral height at the ipsilateral side, thus closing the corresponding facet joint.

Discussion

In general, most of the reviewed papers described an increase of the facet loads, for both semi-constrained and unconstrained artificial discs, but with some contrasting results jeopardizing a clear-cut statement. Oddly, only two papers addressed the quantification of the stresses in the adjacent levels [21, 28], despite the prevention of adjacent degeneration being probably the most important aim of TDA. In order to avoid spinal instability and excessive loads in the facet joints and the ligaments McAfee et al. [62] analyzed the possibility to introduce constraints in the prosthesis design. A more constrained design should be able to share a greater portion of load, thus decreasing the loads through the facet joints and in the ligaments, possibly allowing the restoration of a correct load sharing pattern. However, further studies, which directly determine of the influence of the prosthesis design on the segmental internal stress condition are required to demonstrate the validity of this assertion.

Device stability and wear

Device wear and stability are potentially problematic in lumbar TDA as in all tribological pairings, since the stresses inside the device and at the interface between the artificial disc and the endplates may reach high values in the lumbar spine (Table 4). A correct choice of biomaterials is a crucial determinant in the prosthesis performance. Commonly used material couplings are cobalt–chrome alloy/UHMWPE (Charité, ProDisc) and cobalt-chrome alloy/cobalt-chrome alloy (Maverick, Flexicore), both acknowledged to have good wear resistance.

Two in vivo studies conducted on non-human primates showed no signs of local or systemic accumulation of wear debris, no evidence of pathologic changes in tissues surrounding the disc prosthesis, and excellent osteointegration, after implantation of the Acroflex [12, 14] and the Charité [13] disc prostheses. Heterotopic ossification was observed in many specimens implanted with the Acroflex device, and was explained by the authors as due to the reduced ROM observed in flexibility testing. This disc prosthesis was later discontinued, due to a number of cases of minor defects in the polyolefin rubber core after 1 and 2 years [26, 85].

On the contrary, significant wear in lumbar disc prostheses was observed in other studies. Signs of wear were found in Charité disc prostheses retrieved from patients who underwent revision TDA surgery and conversion to fusion [46, 90], which showed surface damage as observed previously in both hip and knee replacements [46], with different extent and severity [90]. In 3/4 patients, implant wear was associated with biomechanical issues such as subsidence, migration, undersizing, and adjacent fusion [90]. Significant systemic release of cobalt and chromium ions was proven in the serum of 10 patients after implantation of the semi-constrained Maverick artificial lumbar disc [97]. The ion concentrations were similar to the values measured in total hip arthroplasty metal-on-metal, or exceeded these values.

Discussion

Generally, the published data are not exhaustive, but the problem of wear appears to be of significant importance for lumbar TDA, more than the device stability. Due to the lower stress sustained and the interface with the biological system, unconstrained designs appear to be more suitable than semi-constrained designs. However, as discussed in the previous paragraph, more constrained designs may be advantageous in terms of load sharing, protecting the surrounding biological structures from overloading. Because of the demonstrated potential for osteolysis in the spine [46], clinical problem related to wear may be of importance and need to be investigated with long term follow-up studies.

New ideas

Although most models of lumbar artificial discs can be related to the ball-and-socket design, either constrained, semi-constrained or unconstrained, some innovative ideas are currently emerging. Three new models currently under development or clinical investigation are subsequently described. The TrueDisc PL by Disc Motion Technologies (Boca Raton, FL, USA) is composed of two parts, each one mimicking a half disc, and can be implanted with a posterior access, thus reducing the invasiveness of the surgery [38]. The disc has been designed to be able to preserve the motion even if the two components are not implanted perfectly parallel. The M6 artificial cervical disc by Spinal Kinetics (Sunnyvale, CA, USA) includes a polymeric nucleus and a woven fiber annulus, thus replicating the structure and the biomechanics of a natural disc. The M6 disc is currently available for investigational use in the cervical spine; the lumbar artificial disc is under development. The Physio-L artificial lumbar disc (Nexgen Spine, Whippany, NJ, USA) has a polycarbonate polyurethane core connected to two porous titanium plates. The nucleus has been designed to closely match the mechanical properties of the healthy intervertebral disc, including the shock-absorption capability. This device is currently under clinical investigation [73]. All these models were presented at the main spine surgery conferences, but have not been documented in the currently available peer-reviewed literature.

Conclusions

Based on the present literature analysis, definitive conclusions cannot be drawn. Both semi-constrained and unconstrained lumbar disc seems to be able to restore nearly physiological IAR locations and ROM values; however, both increased and decreased ROM were observed. Segmental lordosis alterations after TDA were reported in most cases, for both constrained and

Table 4 Published studies concerning biomaterials, wear and osseointegration

References	Model	Study type	Observed variables	Prosthesis	Compared to	Results
Büttner-Janz et al. [5]	Human	Experimental	Static and dynamic strength	Charité (unconstrained)	–	Sufficient strength
Chang et al. [8]	Leporine	In vivo	Response to wear debris	Titanium particles	–	Minimal biological response
Cunningham et al. [14]	Non-human primate	Experimental, in vivo (histopatologic and histomorphometric)	Motion, trabecular ingrowth	Acroflex (unconstrained)	–	Reduced motion; no evidences of pathological changes; heterotopic ossification
Cunningham et al. [12]	Non-human primate	In vivo, ex vivo	Motion, bone ingrowth	Charité, Acroflex (unconstrained)	Intact	Acroflex motion smaller than intact and Charité; good bone ingrowth
Cunningham [16]	Human, non-human primate	In vivo, ex vivo (histopatologic and histomorphometric)	Motion, IAR, bone ingrowth	Charité, Acroflex (unconstrained)	Intact, fusion	Preserved motion and IAR, excellent bone ingrowth
David [18]	Human	Retrieval study, 1 patient	Wear	Charité (unconstrained)	–	Fractured polyethylene core, no wear debris observed
Edeland [22]	–	–	–	Composite	–	Proposal for material and design of a new disc prothesis
François et al. [25]	Human	Retrieval study, 1 patient	–	Maverick (semi-constrained)	–	Gross metallosis around the articulation of the prosthesis
Fraser et al. [26]	–	–	Shock absorption	Acroflex (unconstrained)	–	The design of the prosthesis is aimed to optimize the shock absorption capacity
Gloria et al. [27]	–	Experimental	Compressive stiffness, viscoelasticity	Composite polymer	–	Adequate static and dynamic mechanical properties
Hou et al. [32]	Non-human primate	In vivo, experimental	Biocompatibility, fatigue	Silicone	–	Good biomechanics, applicability and biocompatibility
Kadoya et al. [37]	Ovine	Experimental, in vivo	Static, viscoelastic and fatigue properties	3D fabric disc (unconstrained)	–	Mechanical behavior similar to natural sheep disc; no debris detected
Kostuik [41]	–	Experimental	Wear	Spring-based	–	Low wear if compared to hip prostheses
Kotani et al. [43]	Ovine	In vivo, ex vivo	Motion, histological analysis	3D fabric disc (unconstrained)	3D fabric disc with internal fixation	Reduced motion, excellent fusion
Kotani et al. [44]	Ovine	Experimental	Motion, histological analysis	3D fabric disc (unconstrained)	3D fabric disc with internal fixation	Biomechanical properties nearly equivalent to that of the natural disc; excellent fusion capacity
Kurtz et al. [45]	Human	Retrieval study, 1 patient	Wear, cracks	Charité (unconstrained)	–	Cracks in the polyethylene core, damage around the periphery of the core
Kurtz et al. [46]	Human	Retrieval study, 21 patients	Surface damage	Charité (unconstrained)	–	Observed surface damage
Langrana et al. [47]	–	Computational	–	Fiber-reinforced composite	–	Pioneering model of an artificial disc, including realistic material properties
Langrana et al. [48]	–	Experimental	Compression and torsion stiffness	Fiber-reinforced composite	–	Adequate stiffness can be achieved with the use of a composite material

Table 4 continued

References	Model	Study type	Observed variables	Prosthesis	Compared to	Results
Lee et al. [54]	–	Experimental	Mechanical properties of the disc	Fiber-reinforced composite	–	Manufacturing and testing of composite disc prostheses
Le Huec et al. [49]	–	Experimental	Shock absorption capacity	ProDisc (semi-constrained), Maverick (unconstrained)	–	The two devices have identical shock and vibration transmission properties
Mizuno et al. [64]	Murine	In vivo	Biochemical analysis	Tissue-engineered disc	–	Morphology and histology resembled those of the native intervertebral disc
Moore et al. [65]	Murine	In vivo	Response to wear debris	Polyolefin rubber	–	Rubber particles induce a localized tissue response consistent to a normal foreign body reaction
Revell et al. [75]	Porcine	In vivo	–	Tissue engineered disc	–	Engineered disc histology similar to a native intervertebral disc
Schmiedberg et al. [82]	–	Experimental	Wear	Spring-based	–	Analyses of wear debris with a new method
Shaheen and Sheperd [83]	–	Computational	Lubrication regimes	Generic ball-and-socket	–	Metal-metal and metal-polymer couplings are likely to generate wear debris; ceramic-ceramic coupling may reduce wear
Takahata et al. [86]	Ovine	In vivo	Bone ingrowth	3D fabric disc (unconstrained)	–	Excellent bone ingrowth
Van Ooij et al. [90]	Human	Retrieval study, 4 patients	Wear	Charité (unconstrained)	–	Wear present in all devices, with different extent and severity
Vuono-Hawkins et al. [92]	Canine	In vivo, ex vivo	Motion, bone ingrowth	Elastomeric spacer	–	Increased motion, no significant bone ingrowth after 12 months
Zeh et al. [97]	Human	Ion concentration analysis in serum	Co–Cr ion concentrations	Maverick (semi-constrained)	–	Co–Cr ion concentration significant, similar or exceeding typical concentrations after total hip arthroplasty

IAR Instantaneous Axis of Rotation

unconstrained disc prostheses. An increase in the load through the facet joints was documented, for both semi-constrained and unconstrained artificial discs, but with some contrasting results. Semi-constrained devices may be able to share a greater part of the load, but may be more subjected to wear. All these findings need to be supported by long term clinical studies.

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