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The Role of Physician Extenders in a Low Back Pain Practice

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Introduction

The vast majority of patients presenting to physicians with low back pain complaints are treated successfully in a nonoperative fashion. The medical care and treatment of the low back pain patient population are labor intensive with a low patient visit to surgery ratio. A successful and efficient spine surgery practice requires screening a large volume of patients before a surgical case is identified. The spine surgeon is often overwhelmed by a large quantity of referrals, leading to the task of having to actively manage both large numbers of nonoperatively and surgically treated low back patients. These patients generate large numbers of phone calls, follow-up visits, prescription refills, disability forms for Worker's Compensation, and personal injury claims, representing a significant expenditure of physician and staff time. In this environment, skilled physician extenders including physician assistants (PAs), physical therapists (PTs), and advanced nurse practitioners (APNs) are extremely effective in helping to successfully meet the increased requirements of low back patient management. This team approach frees up physician time and aid in the reduction of the waiting periods for specialized spine care. Furthermore, the additional attention that patients receive, as opposed to care delivered only by a single physician, is positively perceived by patients as comprehensive and thorough, high-quality healthcare.

There are several allied health professional categories. Some of them are properly trained and certified to perform, under supervision, many of the routine services that physicians would otherwise have to provide directly. They can substantially add to physician productivity, especially in a practice that sees a lot of managed care patients, and therefore, can function as physician extenders. Physician extenders include registered nurses, advanced nurse practitioners, physician assistants, physical therapists, and athletic trainers. How each of these healthcare professionals can function at a low back practice is dictated by state and local licensure and credentialing statutes. While all can function in the clinic, assisting in surgery is primarily limited to physician's assistants and certified surgical assistants. Whether their services can be reimbursed by insurance varies both within insurance policies and state mediated reimbursement policy. This discussion will focus on the role of nurses, physician assistants, and physiotherapists, assessing their function in the clinical and surgical environment of a spine surgery practice.

Allied Healthcare Professionals

Nursing

The oldest sense of "nursing" in the English language can be traced back to the fourteenth century and referred to a woman employed to suckle and care for a younger child. By the fifteenth century, nursing had evolved into the act of looking after another, not necessarily meaning a woman looking after a child [1]. Prior to the foundation of modern nursing, nuns and the military often provided nursing-like services [2]. Florence Nightingale, working to improve conditions of soldiers in the Crimean War, laid the foundation for professional

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nursing as we know it today [3]. Nursing has grown to be one of the most critical aspects of patient care and has become a government regulated profession, requiring appropriate licensure and credentialing. New Zealand was the first country to regulate nurses nationally in 1901. In the United States (US), North Carolina was the first state to pass a nursing licensure law in 1903.

Nurses are often placed in key management roles within health services and hold research posts at universities. The modern era has seen the development of several types of nursing degrees. With additional training, advance degrees to the nursing are available including nurse clinician and nurse practitioner categories. Each degree allows for more extensive clinical responsibilities, even approaching those of the primary care physician.

Physician Assistants

The shortage and uneven distribution of primary care physicians in the United States during the mid-1960s led to the creation of the first class of PAs in 1965. That class put together selected navy corpsmen who had received considerable medical training during their military service and during the war in Vietnam but had no comparable civilian employment. The curriculum of the PA program was based in part on the experience of the fast-track training of doctors during World War II [4, 5].

Physician Assistants are healthcare professionals licensed to practice medicine in the United States, under physician supervision. They are trained in intensive education programs accredited by the Commission on Accreditation of Allied Health Education Programs (previously the American Medical Association's Committee on Allied Health Education and Accreditation). Common services provided by a PA include taking medical histories and performing physical examinations, ordering and interpreting lab tests, diagnosing and treating illnesses, assisting in surgery, prescribing and/or dispensing medication, and counseling patients regarding diagnosis and treatment options. Physician Assistants can prescribe medications in forty-nine states [6].

In the United States, the PA model has proven to be a cost-effective way to train quality primary care providers with a high degree of acceptance of the PA role by patients and other healthcare providers. Several countries including the United Kingdom, Scotland, Canada, the Netherlands, Taiwan, South Africa, and Ghana are exploring the concept of the physician assistant as a way to quickly and efficiently train and employ autonomous and flexible health workers to address their nation's healthcare needs [7].

Because of their close working relationship with physicians, PAs are educated in the medical model designed to complement physician training. Upon graduation, physician assistants take a national certification examination developed by the National Commission on Certification of PAs in conjunction with the National Board of Medical Examiners. To maintain their national certification, PAs must log 100 h of continuing medical education every 2 years and sit for a recertification every 6 years. Graduation from an accredited physician assistant program and passage of the national certifying exam are required for state licensure.

Physician assistants can function to assist in patient care in both the clinic based and surgical environment. Almost universally their services are reimbursed adequately to cover the cost of their salaries and benefit packages.

Physiotherapists

The use of physiotherapists to see orthopedic outpatients was first described in 1989 [8]. In 1994, Hourigan and Weatherley reported a system to triage back pain by physiotherapists that eventually became widespread in United Kingdom and other countries [9]. According to this system, acute back pain outpatients are seen initially by a trained physiotherapist. The physiotherapist takes a careful history, performs a physical and radiological examination, and refers on to the spine surgeon only problematic cases and those potentially in need of surgery. Initially, all cases were discussed in resume with the consultant surgeon. However, as the physiotherapists became more experienced, the surgeon, in most cases, found that he/she was only sanctioning what has been proposed.

Certified Athletic Trainers

Certified athletic trainers help move patients faster through the appointment and treatment process, thereby

increasing physician productivity and efficiency and allowing the office to treat more patients in the same amount of time. They can reduce re-injury rates through patient instruction, reduce recovery time from nonsurgical injuries, and aid in the rehabilitate musculoskeletal injuries. Athletic training services are reimbursable by many insurance companies, and services are either directly billed or billed incident to physician services.

Physician Extenders' Tasks

Assisting in the Office

In an ideal setting, the low back pain patient/physician encounter would be limited to reviewing the pertinent medical history, the pertinent physical examination, the pertinent radiographic and medical tests, and spending the majority of time discussing with the patient the medical problem at hand and potential treatment modalities. The time requirements necessary to obtain and interpret the patient's pertinent medical history, physical examination, radiographic findings and medical tests are significant and can be overwhelming to daily practice patterns. Obtaining this information from the patient and organizing it prior to the physician's visit with the patient is one of the most valuable functions that a physician extender can provide in spine practice. By identifying pertinent findings which require further study (MRI, discogram, etc.), the practice efficiency is enhanced.

Physician extenders can also be used for telephone triage and assistance with the scheduling of patients' appointments. In busy practices with high telephone traffic, the PAs and NPs can assess the patient's problem and determine the urgency for the visit.

Initial Evaluation

History: The physician extender can facilitate the patient filling out intake forms while obtaining and reviewing a thorough past medical history. Important points of this process include determining associated diseases, medications, prior surgeries or interventions (such as physical therapy or injection therapy), and all pertinent information regarding patient's current chief complaints and organizing this for the physician in a standard fashion. The use of standard entry forms that include all of this information including a pain drawing is the basic requirement for the practice, and the physician extender can help to streamline this process for the patient and the physician.

Physical examination: Qualified physician extenders are skilled and competent to perform a thorough neurological and musculoskeletal physical examination. With pertinent physical findings provided by the assistant at the initial encounter, the physician is able to focus his or her time on the physical examination as it related to the patient's specific complaints. Again, a standardized office form that encompasses the complete examination highlighting positive findings is paramount for increasing efficiency.

Follow-Up Visits

Physician extenders can be effectively used in the clinical practice to see patients for follow-up clinic visits. Included in these visit categories are initial postoperative visits and follow-ups during ongoing nonoperative management. Follow-up visits to review test results (MRI, discogram, etc.) and outline treatment plans that may include surgical intervention are best handled by the physician, although the assistant can help to further explain the physician's discussion with the patient if the patient has extensive questions.

In Hospital Tasks

Most hospitals in the United States will credential nurses and physician assistants to function within the hospital environment. The assistant's interaction with the patient may include acute inpatient care and assistance in surgical procedures.

Physician extenders can assist in rounds on a daily basis, i.e., seeing patients and reviewing laboratory and radiographic data, while being legally and clinically qualified to write chart notes and orders. Most institutions require, however, close physician supervision of these functions, including daily cosigning of all orders and notes. To work effectively, open and timely communication must exist between the physician and the assistant. It is imperative that the physician maintains communication with the patient in order that the

patient does not perceive the assistant's presence as physician's neglect.

Hospital Medical Records

Credentialed, qualified physician extenders are capable, under physician supervision, to prepare most of the hospital required medical reports. These include histories and physicals, consultations, and discharge summaries. Most institutions will allow these to be dictated by credentialed health care professional such as APNs and PAs, while close physician supervision and cosigning of these documents are required.

Back Pain Clinics and Triage for Back Pain

The realization that one of the key factors that encourages acute back pain to become chronic is being off work led to the development of back pain screening clinics, as a system of triage, to reduce long waiting times for diagnosis and treatment. Triage is the medical model of diagnosis used to exclude serious pathology. As triage directs the management pathway, its role is to place the patients into groups at an early stage, identifying those who might benefit from surgery, and fast tracking them, identifying those who will benefit from conservative management and tracking them accordingly. Triage deals with identifying "red flags" denoting serious spinal pathology and "yellow flags" denoting the psychosocial factors, nerve root pain, cauda equina, and inflammatory disorders. Triage in low back pain clinics is traditionally performed by trained physiotherapists [10]. The introduction of these services, initially in the United Kingdom and subsequently in other countries, resulted in a reduction in the waiting periods for the specialized spine clinic, and a clinical and economical improvement in the care of those suffering from acute low back pain [11]. A potential disadvantage of this approach is that physiotherapists are less reliable than surgeons when conducting physical examination [12, 13].

Assistance in Surgical Procedures

Most institutions in the US require that surgical assistants be either other physicians, physician's assistants, or credentialed surgical assistants. The educational curriculum of PAs includes training in surgical assisting skills, which is recognized by most institutions and credentialing bodies. Nurses, however, are generally not allowed to function in this capacity unless they participate in extra training and are credentialed specifically as surgical assistants. Assistance in surgical procedures is beyond the basic training of registered nurses, nurse clinicians, or nurse practitioners. Physician's assistants and nurses, once credentialed as surgical assistants, may bill for their services and are recognized by most third-party payers. In this time of shrinking physician reimbursements, income received assisting in the operating room can be substantial and either partially offset or fully cover the costs associated with employing a physician extender. It is this financial incentive that supports the physician's assistant as a most desirable adjunct member of a health care team managing low back surgical practice in United States.

Other Clinical Tasks

In today's medical environment, there exists a multitude of patient contact tasks required in providing healthcare. These include dictating and completing the medical record for initial and follow-up office visits, effectively communicating with referring physicians and third-party payers, sorting through and evaluating test results including laboratory and radiographic studies, returning patient phone calls, coding and submitting physician charges for surgery, hospital consultations and prescription refills. In addition, the paperwork generated by disability and workers compensation claims is overwhelming, and the physician extender can be instrumental in efficiently managing this load.

Though crucial in providing quality healthcare, many of these tasks can be effectively delegated to qualified physician extenders, thereby freeing the physician to perform more of those tasks that he or she is uniquely qualified to perform.

Conclusions

Providing all of the necessary services required in the modern, tightly regulated, healthcare environment, can stretch physician time beyond that which is available.

Performing all required tasks leaves limited time for direct patient contact. Using a physician extender in a low back practice frees up the physician's time to focus his/her attention and skills on those patients who require a higher level of care and allow the practice to treat more patients daily. This shortens waiting period for specialized low back pain quality care, enables efficient and higher quality physician -patient contact, and possibly affects treatment outcomes. Furthermore, the additional attention the patients receive, when being treated by a medical team as opposed to a single physician, is positively perceived as thorough, comprehensive, quality healthcare.

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5.2 Clinical Factors that May Affect Outcome in Lumbar Total Disc Replacement. What Is the Evidence?

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Evaluating the scientific merit of a new technology early in its life cycle is important for a clinician considering incorporating these techniques into practice. The distinction between marketing hype and true scientific supporting evidence is sometimes blurred. Understanding the strength and quality of evidence that a new technique may have over older tried and established methods is paramount and understand the clinical value and risk benefit ratio of new techniques and the value such techniques may or may not give to one's practice and to patients.

The goal of evidence-based medicine is to apprize and use clinical research findings to aid making decisions about the care of individual patients. Evidence-based medicine (EBM) combines the physician's clinical experience, with the best available evidence, and patient values [1, 2]. The process of EBM involves translation of a specified problem into an answerable question and systematic retrieval of best evidence available [3]. Clinical findings are raked based on the strength of scientific methodology employed in performing research and developing conclusions. Using the EBM approach, clinicians can choose the best available evidence when making clinical decisions. Armed with this knowledge, the medical practitioner and the patient can make a well-informed decision.

In the ideal EBM model, the best available evidence from the literature is combined with clinical experience and patients' values. When dealing with new technology, there is, however, a lack of physician experience. Patient values may be artificially manipulated and overly optimistic due to marketing and advertising, leading to the misconception that "newest means best". Under such circumstances, it becomes even more imperative for a clinician embarking on the use of new technology, to fully understand what "best evidence" exists for newer techniques. This distortion of the related values of the EBM tripod, physician's experience, best evidence, and patient values, is obvious in the early introduction of motion technology. Few physicians have little if any experience with these techniques or devices. Patients have been bombarded by the lay press and manufacturers representations that artificial discs and other parts replacement of the spine will be the answer to their misery and disability. In an attempt to determine the level of the best existing evidence for several factors that may affect outcomes, the authors undertook this study. Understanding the strengths and weaknesses of the available literature can better allow the medical practitioner and the patient to make well-informed decisions regarding treatment options.

In an attempt to get to the heart of the existing evidence about a variety of clinical factors that might affect the outcomes of artificial disc replacement for the lumbar spine, we posed eleven questions and undertook a systematic review of the existing literature [4]. Those questions were grouped in three main categories: (a) patient selection issues, (b) surgical technique issues, and (c) motion technology issues. Sorting through medical literature to obtain answers can often be difficult. Research studies are susceptible to invalid conclusions resulting from bias, confounding or chance. With the introduction of evidence-based medicine techniques, however, the medical literature can be sorted into levels of evidence based on scientific merit. Higher level studies minimize bias, confounding and chance making their conclusions more likely reliable. By the very nature of their design, lower level studies do not address

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bias, confounding and chance making their results more prone to error. Higher level studies, however, may also have unavoidable methodological flaws. In the ADR literature, the Food and Drug Administration (FDA) Investigational Device Exemption (IDE) studies represent the highest quality evidence available [5, 6]. Those studies are randomized, controlled, and use validated outcome measures with a minimum of 2 year follow-up. Entry criteria and patient randomization for the studies is generally good. Lacking in all studies, however, is blinding. The reason for lack of blinding can be easily understood; nonetheless, this exerts a bias on outcome and should be considered when weighing their conclusions.

We performed a thorough review of the clinical literature between January 1990 and May 2007 on peer reviewed literature in English language [4]. Data that were only in abstract form was not used. Duplicate reports were eliminated if there were prior studies that presented the same group of patients and the most current report was used. If the authors reported a subset of a multi-centre study, the largest multi-centre series data available were used. Only studies including data addressing the above framed questions were included in this review.

We retrieved and reviewed 76 papers; 49 of them were excluded from our study as they did not include relevant information, or were duplicates [4]. The remaining 27 papers were ranked into appropriate evidence levels using the modification of Sackett grading system provided in the J Bone Joint Surg Am, January 2003 [7]. Briefly summarized, Level I studies are randomized, controlled clinical trials. Level II studies are prospective

Table 5.2.1 The articles included in this review were ranked by level of evidence, study design, follow-up, and outcome measures

Author	Level	No pts	Study design	F.U.	Lost at F.U. (%)	Outcome measures
Charité						
Tortolani 2007 [8]	I Prognostic	276	Prosp	2 years		Heterotopic ossification
Trouillier 2006 [9]	I Prognostic	13	Prosp	6 months		Facet subchondral bone density
McAfee 2005 [10]	I Therapeutic	205– 99	Prosp	2 years	8.5	ODI, SF36
Shim 2007 [11]	III Therapeutic	61	Retro	3 years	6.5	ODI
David 2007 [12]	IV Therapeutic	108	Retro	13.2 year	2	Non-validated
Putzier 2006 [13]	IV Therapeutic	71	Retro	17 years	25	ODI
Regan 2005 [14]	IV Therapeutic	100	Prosp	6–24 months		ODI
Lemaire 2005 [15]	IV Therapeutic	107	Retro	11.3 years	7	Non-validated
Van Ooij 2003 [16]	IV Therapeutic	27	Retro	7.5 years		Non-validated
Scott 2000 [17]	IV Therapeutic	14	Retro	18–68 months	28.50	Non-validated
Zeegers 1999 [18]	IV Therapeutic	50	Prosp	2 years	8	Non-validated
Lemaire 1997 [19]	IV Therapeutic	105	Retro	4 years		Non-validated
Cinotti 1996 [20]	IV Therapeutic	46	Retro	3.2 years		Non-validated
ProDisc						
Patel 2006 [21]	I Prognostic	52	Prosp	2 years		ODI, CT scan
Huang 2006 [22]	III Prognostic	64	Retro	8.7 years	34	Radiographic review
Huang 2005 [23]	III Prognostic	64	Retro	8.6 years	41	Stauffer-Coventry score, ODI
Siepe 2007 [24]	IV Therapeutic	99	Prosp	2 years		ODI
Siepe 2006 [25]	IV Therapeutic	94	Prosp	3 years	2	ODI, SF36
Chung 2006 [26]	IV Therapeutic	38	Prosp	37 months	5	ODI
Bertagnoli 2006 [27]	IV Therapeutic	22	Prosp	2 years	0	ODI
Bertagnoli 2005 [28]	IV Therapeutic	118	Prosp	2 years	12	ODI
Bertagnoli 2005 [29]	IV Therapeutic	29	Prosp	2 years	14	ODI
Tropiano 2005 [30]	IV Therapeutic	64	Retro	8.7 years	14	Non-validated
Tropiano 2003 [31]	IV Therapeutic	53	Prosp	1.4 years		ODI
Bertagnoli 2002 [32]	IV Therapeutic	108	Prosp	3months–2 years		ODI
Mayer 2002 [33]	IV Therapeutic	34	Prosp	1 year	23.5	ODI
Maverick						
Le Huec 2005 [34]	IV Therapeutic	64	Prosp	2 years	0	ODI

ODI oswestry disability index; *Prosp* prospective study; *Retro* retrospective study; *CT* Computed Tomography; *FU* Follow-up; *pts* Patients

non-randomized comparative studies. Level III studies are retrospective comparative studies or case-controlled studies. Level IV includes case series, with no comparison group. Level V evidence, which refers to expert opinions, was not included in the present study. Previous reviews on ADR were also not included. Articles were graded according to the type of study (therapeutic, prognostic, etc) and the level of evidence (I–IV) by two independent reviewers. We also listed other variables that may affect study quality, especially in level IV studies, such as the study design, follow-up period, percentage of patients lost at follow-up, and the use of validated outcome measures (Table 5.2.1).

Patient Selection Issues

(a) Is the outcome after single segment implantation similar to multi-segmental implantation? Ten level IV studies were found (Table 5.2.2). Three studies [20, 24, 26] report inferior results with multi-segmental implantations , while six studies [15, 18, 28–31, 33] report similar results . Therefore, available studies evaluating the question of single vs. multilevel surgery provide conflicting results.

(b) Does spinal level of ADR affect outcome? Two prospective, level IV studies were found. Regan et al. [13] in a study of 100 patients implanted with Charité, report no statistical difference in outcome when L4-L5 was compared to L5-S1 at 6–24 months of follow-up [14]. Siepe et al. [24] in a study of 99 patients with ProDisc II with a mean 2 year follow-up reported a trend towards better outcomes at L4-L5 when compared to L5-S1 [24].

(c) Does patients' age affect outcome? Eight level IV studies were found (Table 5.2.3). Younger age was a favourable predictive factor in three studies [18, 25, 34], while was a negative factor in one study [30]. Patient age did not affect outcome in four studies [17, 26, 27, 31]. Some authors report higher complication rates in older patients, as lordosis enhancement after implantation can exacerbate spinal stenosis, and compromised bone quality can increase the risk of subsidence [27]. In conclusion, the role of patients' age remains unclear; however, the possibility of higher complications and the morbidity of additional surgical interventions in older patients should be considered in decision making.

(d) Does prior surgery affect outcome? Twelve level IV studies were found (Table 5.2.4). Prior surgery had a negative effect on outcome in six studies [12, 20, 29–31, 34], while it had no effect on outcome in five studies [19, 25, 26, 28, 33]. In one study, prior surgery

Table 5.2.2 Effect of number of levels implanted in clinical outcomes

Author	Level	Study design	FU	No pts	Effect of multi-segmental implantation on outcome
Charité					
Cinotti 1996 [20]	IV	Retro	3.2 years	1 level: 36 2 levels: 10	Inferior results
Lemaire 2005 [15]	IV	Retro	>10 years	1 level: 54 2 level: 45	No difference
Zeegers 1999 [18]	IV	Prosp	2 years	1 level: 29 2 level: 18	No difference
ProDisc					
Siepe 2007 [24]	IV	Prosp	2 years	1 level: 79 2 level: 20	Inferior results
Chung 2006 [26]	IV	Prosp	2 years	1 level: 25 2 level: 11	Inferior results
Bertagnoli 2005 [28]	IV	Prosp	2 years	1 level: 106	No difference
Bertagnoli 2005 [29]	IV	Prosp	2 years	≥ 2 levels: 25	
Tropiano 2005 [30]	IV	Prosp	8.7 years	1 level: 35 ≥ 2 levels: 20	No difference
Tropiano 2003 [31]	IV	Prosp	1–2 years	1 level: 40 ≥ 2 levels: 13	No difference
Mayer 2002 [33]	IV	Prosp	1 year	1 level: 31 ≥ 2 level: 3	No difference

Table 5.2.3 Effect of patients' age on clinical outcomes

Author	Level	Study design	FU	No pts	Effect of age on outcome
Charité					
Zeegers 1999 [18]	IV	Prosp	2 years	46	Patients < 45 years had better outcome
Scott 2000 [17]	IV	Retro	4 years	14	Age > 45 did not affect outcome
ProDisc					
Siepe 2006 [25]	IV	Prosp	3 years	92	Patients < 40 years had better outcome
Tropiano 2005 [30]	IV	Prosp	8.7 years	55	Patients > 45 years had better outcome
Chung 2006 [26]	IV	Prosp	2 years	36	Age did not affect outcome
Bertagnoli 2006 [27]	IV	Prosp	2 years	22	Age did not affect outcome
Tropiano 2003 [31]	IV	Prosp	1.4 years	53	Age > 50 did not affect outcome
Maverick					
Le Huec 2005 [34]	IV	Prosp	2 years	64	Young patients had better outcome

Table 5.2.4 Effect of prior surgery on patients' outcome

Author	Level	Study design	FU	No pts with (+) or without (−) previous surgery	Effect of previous surgery on outcome
Charité					
Cinotti 1996 [20]	IV	Retro	3.2 years	(+) : 24 (−): 22	Negative effect
David 2007 [12]	IV	Retro	13.2 years	(+): 44 (−): 62	Negative effect in patients with > 2 previous surgeries
Zeegers 1999 [18]	IV	Prosp	2 years	(+): 27 (−): 33	Negative effect at 1 year No effect at 2 years
Lemaire 1997 [19]	IV	Retro	4 years	(+) : 55 (−): 50	No effect
ProDisc					
Bertagnoli 2005 [29]	IV	Prosp	2 years	(+): 17 (−): 12	Negative effect
Tropiano 2005 [30]	IV	Prosp	8.7 years	(+): 28 (−): 27	Negative effect
Tropiano 2003 [31]	IV	Prosp	1.4 years	(+): 11 (−): 33	90% satisfactory results 97% satisfactory result
Mayer 2002 [33]	IV	Prosp	1 year	(+): 9 (−): 25	No effect
Bertagnoli 2005 [28]	IV	Prosp	2 years	(+): 60 (−): 46	No effect
Siepe 2006 [25]	IV	Prosp	3 years	(+): 17 (−): 75	No effect
Chung 2006 [26]	IV	Prosp	2 years	(+):7 (−):29	No effect
Maverick					
Le Huec 2005 [34]	IV	Prosp	2 years	64	Negative effect

had a negative effect on outcome at 1 year and no effect at 2 years follow-up [18]. Most of the studies used non-validated outcome measures [12, 18–20, 30].

(e) Does preoperative facet degeneration affect outcome? Only one level IV study was found. Le Huec et al. [34] in a prospective study of 64 Maverick ADR reported that mild or moderate facet osteoarthritis (grade 1 or 2, on the 0–3 Fujiwara scale), did not influence outcome at 2 years follow-up. Patients with severe facet arthrosis had worse outcome, but their number was small to reach conclusive evidence. Therefore, the role of pre-existing facet arthrosis is still obscure. Pre-existing facet arthrosis is currently a contraindication to ADR; however, one study suggests that mild to moderate facet degeneration does not influence ADR outcomes [34]. Clinically significant facet arthrosis is reported to be present in 66% of patients undergoing fusion surgery [35]. Nevertheless, the extent of facet degeneration that can be accepted in motion preservation surgery remains to be evaluated, as most of the candidates for this surgery are expected to have some degree of facet arthrosis.

Surgical Technique Issues

(a) Does prosthesis positioning affect ROM or outcome? One level I study and seven level IV studies were found (Table 5.2.5). There is level I evidence that accuracy of placement affects both clinical outcome and range of motion after ADR [10]. Data from level IV studies are conflicting; three studies reported that placement can affect long-term outcome leading to the development of symptomatic facet arthrosis [12, 15] or decreased ROM [20], while four studies showed no effect [18, 21, 26, 34]. Therefore, higher level studies appear to support the importance of surgical precision upon clinical outcome.

Motion Technology Issues

(a) Does ROM of the implanted segment affect outcome? One level III and two Level IV studies were found (Table 5.2.6). A level III prognostic study reports

Table 5.2.5 Effect of implant positioning on Range of motion (ROM) and clinical outcome

Author	Level	Study design	FU	No pts	Effect of placement
Charité					
McAfee 2005 [10]	I	Prosp	2 years	276	Affects both outcomes and ROM
David 2007 [12]	IV	Retro	13.2 years	106	Anterior placement is correlated with the development of symptomatic facet arthrosis
Lemaire 2005 [15]	IV	Retro	10 years	100	All patients that developed facet arthrosis had non-ideal placement
Zeegers 1999 [18]	IV	Prosp	2 years	50	No effect
Cinotti 1996 [20]	IV	Retro	3.2 years	46	Affects ROM
ProDisc					
Patel 2006 [21]	IV	Prosp	2 years	52	No effect
Chung 2006 [26]	IV	Prosp	>2 years	36	No effect
Maverick					
Le Huec 2005 [34]	IV	Prosp	2 years	64	No effect if implant was between 0 and 7 mm from the posterior wall

ROM (Range of motion)

Table 5.2.6 Effect of range of motion after implantation on clinical outcome

Study	Level	design	FU	No pts	ROM	Effect of ROM on outcome
Charité						
Putzier 2006 [13]	IV Therapeutic	Retro	17 year	53	Functional–mobile implants: 17%	Patients with functional implants were less satisfied
ProDisc						
Huang 2005 [23]	III Prognostic	Retro	8.6 year	39	ROM>5°: 28%	Better outcomes with ROM >5°
Chung 2006 [26]	IV Therapeutic	Prosp	3 year	36		Better outcomes with higher ROM

that segmental ROM >5° was associated with a statistically significant but clinically modest better clinical outcome and a trend towards improved low back pain scores as compared to ROM ≤5° [23]. Similarly, a level IV prospective study reports that higher segmental motion after implantation was associated with better clinical outcomes [26]. On the contrary, another level IV retrospective study reports that patients with functional implants were significantly less satisfied than those with spontaneous ankylosis [13]. In conclusion, data from a level III prognostic study suggest that higher ROM of the implanted segment may be related with better outcomes. This is supported by a prospective level IV study [26], while contradicted by a retrospective level IV study [13].

(b) What is the fate of facets after the implantation? Two Level I, two level III and three level IV studies were found. Level I studies suggest no facet encumberment, as measured by CT osteoabsorptiometry of subchondral bone density [9], or facet changes measured on CT examination [21]. However, follow-up in both studies was short, ranging from 6 to 24 months (Table 5.2.7). Level III and level IV studies with longer follow-up suggest progression of facet arthrosis over time. Lemaire et al. [15] reported that patients who developed facet arthrosis had non-ideal anterior positioning of the prosthesis. Symptoms were developed in 36% of those patients. Prosthesis placement lateral to the ideal midline position was associated with development of symptoms. David [12] reported that 4.7% of patients required posterior fusion for symptomatic facet arthrosis within 3–12 years after implantation. Symptomatic facet arthrosis accounted for 45.4% of index level reoperation. This study also correlates the development of symptomatic facet arthrosis with anterior placement of the prosthesis. Similarly, Van Ooij et al. [16] in a series of 27 patients with unsatisfactory results after Charité disc replacement reported a 40.7% incidence of symptomatic facet arthrosis. The mean interval from surgery to facet arthrosis was 4.4 years. Shim et al. [11] in a level III comparative study reported no statistical difference of the facet degeneration between patients implanted with Charité and ProDisc.

In conclusion, several level IV studies report degradation of facet degeneration after the implantation [11, 15]. Furthermore, the commonest reason for conversion to fusion in long-term follow-up is the development of symptomatic facet arthrosis [12, 16]. Although it is theoretically postulated that prosthesis design and constrain may have a significant role in development of facet arthrosis, data from a level III comparative study show similar rates of facet degradation in a constrained vs. a semi-constrained device [11].

(c) What is the rate of heterotopic ossification, and what are their effects on ROM and clinical outcome? One Level I and four Level IV studies were found (Table 5.2.8). In a prognostic level I study, Tortolani et al. [8] reported a 4.3% incidence of heterotopic ossification at 2 year follow-up. The presence of heterotopic ossification did not significantly affect range of

Table 5.2.7 Incidence of radiographic and symptomatic facet degeneration

Author	Level	Study design	FU	No pts	Radiographic	Symptomatic
Charité						
Trouillier 2006 [9]	I	Prosp	6 months	13	No evidence of sclerosis of facet joints measured by CT osteoabsorptiometry	
Shim 2007 [11]	III	Retro	3 years		36.6%	
David 2007 [12]	IV	Retro	13.2 years	106		4.7%
Lemaire 2005 [15]	IV	Retro	10 years	100	11%	4%
Van Ooij 2003 [16]	IV	Retro	7.5 years	27		40.7% incidence of facet joint arthrosis among patients with unsatisfactory results
ProDisc						
Patel 2006 [21]	I	Prosp	6–24 months	52	0%	
Shim 2007 [11]	III	Retro	3 years		32%	

Table 5.2.8 Incidence of heterotopic ossification (HO) and its effect on range of motion (ROM) and clinical outcome

Author	Level	Study design	FU	No pts	H.O. (%)	Effect on ROM	Effect on outcome
Charité							
Tortolani 2007 [8]	I	Prosp	2 years	276	4.3	No effect	No effect
David 2007 [12]	IV	Retro	13.2 years	106	6.6	Negative	
Putzier 2006 [13]	IV	Retro	17 years	53	73	Negative	Negative
Lemaire 2005 [15]	IV	Retro	11.3 years	100	3		
Cinotti 1996 [20]	IV	Retro	3.2 years	46	15.2	Negative	No effect

Table 5.2.9 Reported rate of adjacent level degeneration (ALD) after ADR

Author	Level	Study design	FU	No pts	Radiographic ALD (%)	Surgery for ALD (%)
Charité						
Shim 2007 [11]	III	Retro	3 years	33	19.4	
David 2007 [12]	IV	Retro	13.2 years	106		2.8
Lemaire 2005 [15]	IV	Retro	11.3 years	100		2
Putzier 2006 [13]	IV	Retro	17 years	53	17	
Cinotti 1996 [20]	IV	Retro	3.2 years	10/46	0	
ProDisc						
Shim 2007 [11]	III	Retro	3 years	24	28.6	
Huang 2006 [22]	IV	Retro	8.7 years	42	24	
Bertagnoli 2002 [32]	IV	Prosp	3 months–2 years	108	9.2	

motion or clinical outcome. Five level IV studies were also found. Cinotti et al. [20] reported a 15.2% incidence of periannular ossifications; and 57% of patients with ossifications had spontaneous interbody fusion. However, periannular ossifications did not affect clinical outcome. David [10] reported partial ossification in 3.8% of patients and complete ossification with spontaneous fusion in 2.8% of patients. Ossifications occurred only in patients treated with postoperative brace and activities restriction, while it was not noted in patients who had early active physiotherapy [12]. Putzier et al. [13] reported that 60% of patients had spontaneous fusion and another 13% had signs of possible or likely motion impairment. Patients with functional implants without signs of heterotopic ossification were less satisfied than those with spontaneous ankylosis. Lemaire et al. [15] reported a 3% incidence of heterotopic ossification, without any cases of spontaneous arthrodesis. However, 9% of patients in that study had ROM <2°, which is beyond the measurement error accepted by the FDA.

(d) What is the incidence of adjacent level degeneration after ADR? Two level III and six level IV studies were found (Table 5.2.9). Cinotti et al. [20] reported a 0% incidence in 3.2 years of follow-up based on MRIs performed on 10 patients out of the 46 included in the authors' series. However, no selection criteria for the 10 patients were provided. Other studies with more than 3 years of follow-up, report that the incidence of ALD ranges between 17 [13] and 28.6% [11]. Additional surgery was required in 2–3% of patients in two series [12, 15].

(e) What is the effect of motion preservation on adjacent level degeneration? Only two level IV studies were found (Table 5.2.10). Data suggest that preservation of motion after ADR may reduce the risk for adjacent level degeneration [13, 22].

One of the main theoretical advantages of disc arthroplasty over spinal fusion is the prevention of the accelerated degeneration of the adjacent segments. The surprisingly high incidence of adjacent level degeneration reported in these studies suggests that disc arthroplasty may not have a protective effect on the adjacent segments as initially thought. In contrast, two level IV studies with long follow-up suggest that preservation of motion may have a prophylactic effect on adjacent discs

Table 5.2.10 Effect of motion preservation on the incidence of adjacent level degeneration (ALD)

Author	Level	Study design	FU	No pts	Radiographic ALD
Charité					
Putzier 2006 [13]	IV	Retro	17 years	53	20% in patients with spontaneous fusion 0% in patients with ROM >3°
ProDisc					
Huang 2006 [22]	IV	Retro	8.7 years	42	34% in patients with ROM <5° 0% in patients with ROM >5°

[13, 23]. Huang et al. [23] suggested that ROM ≥5° is a plausible crucial threshold to prevent adjacent level degeneration. The motion data provided to FDA from the IDE of Charité show that at 24 months after implantation 33% of patients had less than 5° of ROM [36]. Since it may take more than a decade for symptomatic junctional degeneration to develop, longer follow-up period is necessary to shed more light on the effect of ADR vs. fusion in randomized prospective trials.

Conclusions

Not surprisingly, the majority of the experimental studies were level IV, with only limited higher level studies. This reflects the difficulties in performing a randomized controlled trial, as well as the reluctance among clinicians and patients to deviate from their concepts of what the optimum treatment should be. In the absence of higher level studies, most of the best evidence concerning ADR comes from level IV studies (Table 5.2.1). Therefore, existing evidence does not allow drawing definite conclusions in the majority of the clinical questions regarding indications and factors that may affect outcomes. Where feasible, conclusions are mainly drawn from lower level, least reliable evidence. Highest quality data are short term and longer term data are of lower quality and in many instances conflicting. This lower level data, however, are plentiful and often quoted.

The clinician must understand when taking important clinical decisions that the scientific ground on which he/she is treading may not be as solid, as one would wish. There exist no long-term studies of high level scientific merit that demonstrate long-term efficacy of motion preservation technology over traditional techniques. Additionally, there exist limited data to suggest or support that junctional breakdown above fusions is clinically altered or is different from the normal degenerative process expected over ensuing period of time. There are limited data to suggest that motion technologies prevent the natural progression of degeneration, either at the index level or at adjacent segments, at this time. However, it is important to clarify that lack of evidence is not synonymous to lack of benefit. High-level studies with long-term follow-up are necessary to shed further light on important clinical issues.

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