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PRESENT STATUS OF TOTAL LUMBAR DISC ARTHROPLASTY(TLDA) USING NON-FUSION TECHNOLOGY

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Abstract: The paper presents a synthesis of the total lumbar disc arthroplasty (TLDA) results obtained in the last three years. The main objective of this paper is to underline the new trends in TLDA of international research in this field. The interverterbal devices taken into account are: ProDisc-L (Synthes-Stratec), Charité (Depuy Acromed), Maverick (Medtronic) and Kineflex (SpineCore). The first part of the paper consists in a short description of the mentioned devices. The second part is focused on a brief comparison between the disc implants, where the number of patiens, the follow-up period, the number of segments involved and the surgical aproach represent the major criteria of the analysing issue.

1. INTRODUCTION

The more incresing rate of back pain complications led to the developement of spine implantation technologies, which became a realistic solution for treating various disc degeneration problems.

Artificial disc replacement has been developed as an alternative to spinal fusion, with the goal of pain reduction or elimination, while still allowing motion throughout the spine. Another possible benefit is the prevention of premature breakdown in adjacent levels of the spine, a potential risk in fusion surgeries. Total lumbar disc arthroplasty (TLDA), also known as artificial lumbar disc replacement (ALDR), involves removal of the entire damaged intervertebral disc and the implantation of a prosthetic device in its place. The endogenous vertebral endplates and surrounding spinal ligaments are preserved in lumbar spine, helping to maintain the stability of the implant [23].

Possible candidates for TLDA have disc degeneration confirmed by medical history (X-rays, and other diagnostic imaging tools), posse one or more diseased disc and have failed at least six months of treatment including pain, medication, physical therapy, or back brace [4].

About ninety percent of all artificial disc replacement surgery is done on the lumbar spine, the L4/L5 disc being the most often replaced disc, closely followed by the L5/S1. Most disc replacement surgery is single level but about ten percent or more involve more than one level [26].

A decisive factor in evaluating spinal devices is the Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services. In a comprehensively phrasing, FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human veterinary drugs, biological products, medical devices, cosmetics, products that emit radiation, and tobacco products. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health [24].

2. METHODS

The present study involves a brief presentation and comparison between the most popular model designs used in TLDA: ProDisc-II (Synthes-Stratec), SB Charité-III (Depuy Acromed), Maverick (Medtronic) and Kineflex (SpineCore), concerning the treatment of degenerative disc disease (DDD).

The SB Charité-III artificial disc consists of three parts: two metal (cobalt-chrome alloy) endplates that are anchored to the top and bottom surfaces of the vertebrae and a plastic core (ultra-high molecular weight polyethylene or UHMWPE) that fits between the two endplates (figure 1). The plastic core and endplates help to restore the natural distance between the two vertebrae (disc height). The endplates can slide over the domed parts of the core, which can allow movement at the level where they are implanted [24].

Figure 1 – SB Charité-III

This lumbar disc has been used in Europe since the mid 1980s and has undergone three design revisions because of significant complications, and in 2004 the FDA approved it for use in the U.S.A.

Synthes-Stratec's ProDisc-II is a semi constrained three-part device (figure 2) and received the FDA approval in 2006. It has two metal endplates with a midline keel, small spikes for initial fixation to the vertebrae, and a plasma sprayed titanium coating on all bone-contacting surfaces to promote bony on growth. The superior endplate is a CoCrMo on UHMWPE, with the concave-shaped polished surface of the endplate acting as the "socket".

a. Exploded view ***b. Izometric view***

Figure 2 – Synthes-Stratec's ProDisc-II

The inlay is inserted between the two endplates and has the convex-shaped surface acting as the "ball", locking securely on the inferior endplate. The center of rotation of the implant is anterior to the center of rotation of the spinal segment, which means the loading of the facet joints is still significant.

The Maverick artificial disc solution is the first metal-on-metal, two-piece anterior lumbar disc prosthesis (figure 3). The endplates have a midline keel and surface coating for bone in-growth. It has a posterior center of rotation that matches the center of rotation

of the disc segment. This unloads the facet joints and reproduces near normal force transmission at the operated segment.

a. Assembled model ***b. Superior component*** ***c. Inferior component***

Figure 3 – Maverick artificial disc

SpineCore's Kineflex artifical disc is composed of two metal endplates and a round metal core, or spacer that can potentially allow preserving normal range of motion (figure 4). It uses a mobile bearing design, allowing translational movement within limits defined by a specially-designed retention ring. Kineflex features a metal-on-metal design of cobalt chrome to potentially minimize wear and improve longevity.

a. Assembled model ***b. Exploded view***

Figure 4 – Kineflex artificial disc

The previous introduction regarding the main TLDA devices is summarized in *table 1*, comprising a set of parameters of each model: materials, number of components, motion and present status.

Table 1. Main characteristics of TLDA devices

Device	Materials	No. of components	Articulation	Status
SB Charite-III	CoCrMo on UHMWPE	3	Mobile bearing (unconstrained)	FDA approval
Prodisc-II	CoCrMo on UHMWPE	3	Ball and socket (semi-constrained)	FDA approval
Maverick	CoCrMo metal-on-metal	2	Ball and socket (semi-constrained)	Clinical trial
Kineflex	CoCrMo metal-on-metal	2	Mobile bearing (unconstrained)	Clinical trial

The goal of obtaining a fairly realistic comparison between the effectiveness of the artificial discs necessitated certain key factors taken into account.

The follow-up period represents the time interval during which the subject is examined, subsequent to surgical intervention. Clinical trials, generaly, confirm the succes of implantation after twenty four months. It is considered sufficient to determine an answer regarding the pacient-implant status.

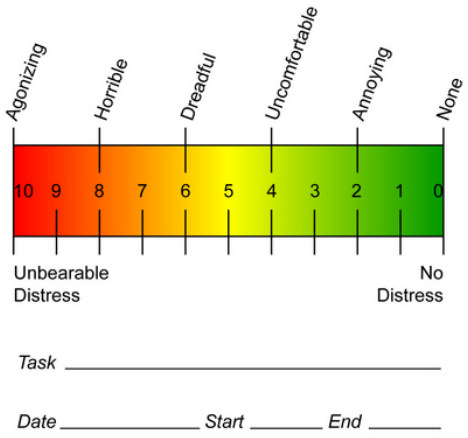
Having more individuals for TLDA leads to more precise statistics concerning the sustainability of the procedure, also assuring the quality of the product. Thus, the number of pacients is very important when differencing TLDA devices.

The lumbar arthroplasty may involve more than one intervention level (multilevel), in which case it has a direct impact on the pacinets' spine mobility recovering modality. The muscle system of each individual plays an important role in the surgical and postsurgical processes.

Health of the human body is preserved by the cell regeneration power, hereby the age of a person represents another major criterion in establishing the positive aspects of an artificial disc device. Statistically, most TLDA include patients over fifty years. Yet, accidents occuring at younger ages also imply the surgical procedure.

The Visual Analogue Scale (VAS) is a measurement instrument that tries to quantify a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured [7]. The VAS score is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end, determined by measuring in millimeters from the left hand end of the line to the point that the patient marks (figure 5).

The Oswestry Disability Index (ODI) is one of the most commonly used outcome measures for individuals with low back pain. The ODI is a self administered questionnaire and its scores are associated with degree of disability ranging from minimal to bedbound (figure 5.b). [7] [27]



a. VAS pain measurement

Section 1. – Pain intensity

I have no pain at the moment.	0
The pain is very mirl at the moment.	1
The pain is moderate at the moment.	2
The pain is fairly severe at the moment.	3
The pain is very severe at the moment.	4
The pain is the worst imaginable at the moment.	5

b. Example of ODI questionnaire

Figure 5. : Pain measurement indicators

3. RESULTS AND DISCUSSIONS

A synthetic comparison regarding the latest results of Charite, Prodisc, Maverick and Kineflex in TLDA is shown in *table 2*. [5], [8-20], [22]

Table 2. A brief comparison regarding the latest results in TLDA

TLDA device	Follow-up period [months]	Nr. of patients	Age	Nr. of levels	Type of levels		Indicators						Nr. of compl.	Success Rate [%]
							VAS			ODI				
							Pr-op	12m	24m	Pr-op	12m	24m		
SB Charite III	24	31	-	1	L4-L5	L5-S1	85	31.4	33.8	63.8	27.3	20.5	3	83.5
	12	17	41	1	L4-L5	L5-S1	Pr-op		12m	Pr-op		12m	-	-
							73		42	64		35		
	24	58	-	1	L4-L5	L5-S1	Pr-op		24m	Pr-op		24m	-	-
							83.4		30.2	60.5		24		
	60	90	-	1	L4-L5	L5-S1	Pr-op	24m	60m	Pr-op	24m	60m	38	57.8
							65	25	28	45	25	28		
ProDisc II	12	12	43	1	L4-L5		Pr-op		12m	Pr-op		12m	2	83.3
							7.9		4.4	67		43		
	24	54	-	1	L5-S1		Pr-op	12m	24m	Pr-op	12m	24m	2	97.4
							72	25	30	61	25	26		
	24	32	-	2	L4-S1		Pr-op	12m	24m	Pr-op	12m	24m	-	-
							70	35	30	61	31	32		
	24	38	45	1	L4-L5		5.3 decrease			25.7 decrease			1	-
				2	L4-S1									
				3	L3-S1									
Maverick	24	25	-	2	L4-L5	L5-S1	Pr-op	12m	24m	Pr-op	12m	24m	1	90
							74.1	27.9	20.1				1	84
	24	25	43	1	L4-L5	L5-S1	Pr-op	12m	24m	Pr-op	12m	24m	1	-
							56	15	15	7	3	2		
	24	57	-	1	L4-L5	L5-S1	Pr-op		24m	Pr-op		24m		
							83		23.7	58.9		21.4		
Kineflex	24	35	-	2	L4-L5	L5-S1	Pr-op	12m	24m	Pr-op	12m	24m	1	90.5
							83.9	27.3	26.9	61.1	20.4	19.3		
	12	17	41	1	L4-L5	L5-S1	Pr-op		24m	Pr-op		24m	-	-
							84		38	64		31		
	24	98	45	1	L4-L5		Pr-op		24m	Pr-op		24m	6	-
							9.17		3.1	50.3		16.5		
	12	44	-	1	L4-L5	L5-S1	Pr-op		12m	Pr-op		12m	-	-
							83		29	83		21		

All the four types of artificial disc replacement demonstrated safety, and shown efficacy with a statistically significant improvement at two year follow-up. Yet, the "Maverick"

demonstrated superiority in ODI measurements compared to the "Charite" or "Kineflex", and in VAS measurements compared to "Charite". At short-term follow-up, the "Kineflex" appears to be at least equivalent in outcome as the "Charite".

When attempting a comparison concerning the present matter, success is achieved if all the research data is available (mean age of patients, number of complications, rate of success, etc). Due to certain lack of information, the judgment of the study basically focuses on the ODI and VAS scores and the follow up period.

Surely, a larger sample size of subjects, together with a longer follow-up period may reveal more obvious differences between the artificial disc replacements devices.

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