BIOMATERIAL ASPECTS OF FAILED SPINAL IMPLANTS

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There are numberous indications for spinal fusion. Spinal instrumentations, aimed to correct deformity, to reduce listhesis, to maintain instability and also to accelerate and to shorten rehabilitation, were also many. This report was stressed mainly the detailed study of the most common and widely used spinal implant, Pedicle screw fixation system.

The principle of pedicle screw system, including its advantages and disadvantages was laid. Evaluation and comparison of mechanical properties of various popular pedicle implants, all of which made from stainless steel, were discussed. The study showed that the pedicle screw with rod systems (eg. ISOLA, TSRH,CCD) were stiffer than pedicle screw with plate system (eg. Steffee, Dyna-Lok). But in flexibility, the screw-plate systems were more flexible than the screw-rod systems. Fatigue life was longer in the rod systems, reaching one million cycles at 500 N. cycle load.

Screw breakage was the main concerned problem in the pedicle screw fixation system, reaching 7.1% in a megareview of almost six thousand patients. In order to improve stainless steel pedicle screw perfomance, Titanium based alloys were recently advocated. The Titanium alloys pedicle screw systems seemed to function better in preliminary laboratory testings in terms of stiffness, flexibility, bending strength and cycles to failure. The reasons to failure of biomaterials, as a spinal implant, either from stainless steel or titanium alloys were proposed.

INTRODUCTION

The goal of spinal fusion is to eliminate motion and provide increased resistance to external load. Spinal fusion using intrapedicular fixation was introduced by Roy-Camille et al.[16] in 1963. Since then, a number of fixation devices have been developed that rely on the pedicle screw as an anchor for the attachment of a rod or plate.

In general, Internal fixators for posterior spinal applications are aimed at short segment spinal defects such as disc degeneration, fracture, spondylolisthesis or tumor. The advantages of the internal fixators include

a) only two to three vertebrae are spanned
b) true three dimensional fixation is achieved
c) three dimensional adjustment is easily accomplished, allowing fracture or spondylolisthesis reduction to be readily performed.
d) attachment to vertebrae is by means of transpedicular screws eliminating deliberate encroachment into spinal canal
e) no spinal alignment between screw is needed (such as with holes or slots in a plate), allowing screw placement to fully conform to anatomic structure.
f) laminectomy sites and lumbosacral junction are readily instrumented.

PRINCIPLE OF PEDICLE SCREW SYSTEM

Many factors influence the holding strength of pedicle screws in vertebral bone. Fixation depends on the geometric characteristics of the screw and on the mechanical properties of the trabecular bone adjacent to the screw. Age-related bone loss diminishes the integrity of vertebral trabecular bone, leading to failure of screw fixation in the pedicle. Screw diameter, design, insertion technique, and insertion site may also affect fixation strength.

In clinical use, pedicular screws are subjected to complex cyclic forces that. combine transverse bending and axial pullout loads.[2] (Ashman 1989). In spinal fixation devices with an unconstrained screw-plate connection, such as the Lugue plate (Danek Medical, Memphis, Tennesse) and the AO notch plate (Synthes, Paoli, Pennsylvania), the major force acting on the pedicle screw is axial pullout[2]. Pedicular screws in internal fixators or plate fixation devices with constrained screw-plate or screw-rod connections, such as the Steffe plate (Acromed, Cleveland, Ohio), the AO Fixateur Interne (Synthes), and the Kluger Fixateur Interne (Endotec, Leverkusen, Germany), are subjected to both a large transverse bending force and pullout force[2].

How strong does a spinal implant really need to be? What should be the optimal design? What is the best material? These are still the unanswered questions.

APPROACH TO DESIGN

I. In vivo loads

The best answer to the question how strong should the implant be comes from the empiric clinical experience that has been accummulated in five areas.

First, posterior plates are typically attached (Roy-Camille 1979[15]) using 3.5-4.5 mm. cortical screws. Although ideally these screws are protected from all but pure tensile loads, in practice this seems to be quite unlikely, especially for the screws at the ends of the plates. These screws are almost surely exposed to some shearing and bending loads. Despite this, screw breakage has not been reported as a significant problem. Thus, whatever the in vivo loads are, 3.5-4.5 mm screws are strong enough to prevent breakage.

Secondly, in vivo bending of the plates themselves has not been reported to be a problem. Mechanical testing in vitro has shown that plastic deformation of the Roy-Camile plates occurs at only 11.3-nm (8.3 ft-lbs). For comparison this is even weaker than the bending strength (14.7 nm or 10.85 ft-lbs) of the 5-mm portion of the Schanz pins used in the external spinal fixator. These in vivo bending loads taken by the plate must less than 11.3 nm.

Thirdly, Cyron and lo-wakes (Cyran 1976)[7] have shown in vitro that spondylolysis can be produced with a mean moment of 35 nm for L5 and 28 nm for L1 vertebrae. These must represent upper limits to in vivo moments, since spondylolysis does not routinely develop after spinal injuries, even with complete paraplegia in which trunk muscle denervation may occur.

Fourthly, significant experience has been reported for facet joint fusions with a screw placed obliquely across the facet joint in conjunction with posterior bone graft for various nontraumatic conditions. Boucher[4] in 1959 encountered only two broken screws out of a total of 482. In the 150 patients of pennal et al (Pennal 1964) only one screw broke. The screws minor diameter in their studies was 1/8 inch.

Fifthly, the external spinal fixator[11] (Magerl 1984) utilized 6-mm Schanz pins thinned down to 5-mm along their anterior 6-cm. These pins, of course, are fully exposed to all the loads taken by the fixator. Breakage or bending of these pins has not been reported. Since the bending strength (load needed to produce plastic deformation) of the 5-mm portion of pin is 14.7 nm per pin or 29.4 nm per pair, it can be

seen that 5-mm certainly seems to be strong enough. If an even larger size could be used, the margin of safety would only increase.

II. Vertebral Morphometric constraints

The pedicle seems to be the strongest site accessible posteriorly through which to obtain a three-dimentionally grip onto the vertebra. The limiting factor to the size of the screw that can be placed from posteriorly through the pedicle into the vertebral body is the mediolateral width of the pedicle.

III. Pedicle screw design

Bone-screw interface strength is commonly the limiting factor in the overall strength of a stabilizing implant, at least over the first few days or weeks (fatigue of metal or resorption of bone may become a problem later on)

a) Optimizing pedicle screw pull-out strength requires a systemic study in which various screws design features are varied systemically. Pull-out strength depends on various combinations of pitch, minor diameter (root diameter) and tooth profiles (v-toothed Sherman screw, buttress-toothed AO screw) of various major diameters

b) Depth of screws penetrating into vertebra. How close to the anterior cortex should the tip of the pedicle screw be placed? The greater the depth of penetration, the more secure the screw grip on bone, but the greater risk of cortical breakthrough and damage to aorta of other structure.

IV. Articulating joint-system (plate, rod,clamp)

Some sort of mechanism is needed to rigidly link together the four pedicle screws after they are placed into the vertebra above and the vertebra below the site of instability. The four most important design objectives were felt to be adjustability, strength, compactness and security,

Adjustability in all three dimensions was sought, since this would simplify pedicle screw insertion : no special alignment between the screws would need to be maintained during their insertion. Adjustability also allows the reduction to be unconstrained and can be performed in a controlled fashion with the fixator already in place but before tightening the locking mechanism.

The strength of this ariculation should exceed that of the pedicle screw, so as not to become the limiting factor to overall implant

strength. Compactness is obviously for comfort and for normal muscle function. Security means that the likelihood for loosening be extremely low.

STUDY ON EVALUATION AND COMPARISON OF THE MECHANICAL PROPERTIES OF IMPLANTS

A considerable amount of spinal implant research has been devoted to the non-destructive mechanical or bone remodeling evaluation of pedicle screw inplant systems[5,9,12]. The following works have been done in evaluating and comparing the intrinsic mechanical properties of pedicle implant systems.

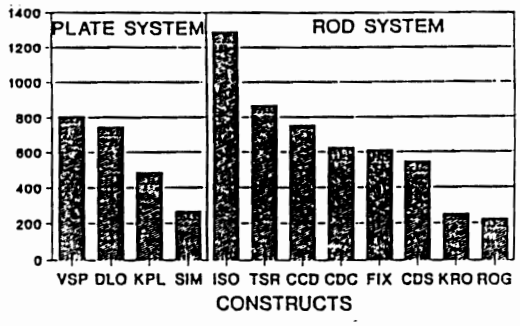
In 1992, Wittenberg et al[19] reported a biomechanical study of fatigue characteristic of four different thoracolumbar fixation devices using intrapedicular screw fixation, namely

...VSP bone plates attached to 7.0 mm VSP integral nut screw and washer (AcroMed Corp. Cleveland OH)
...AO Dick fixateur interne altached to 6.0 mm Schanz screws (Synthes, Bern, Switzerland)
...Kluger fixateur interne with 39-mm monoblock or six-hole telescopic rods and 6.0 mm screws. (Endotec, Leverkusen, Germany)
...a prototype of the Vermont fixator with a 4-cm rod and 6.0 mm screws. (Krag, Burlington, UT)

These devices were all designed having the same biomechanical principle of a constrained screw-rod or screw-plate fixation. The results showed that, although relatively large compressive sources and flexion movement were applied, the four devices provided equal stability to the destabilized segments because of their common design concept. The strain resulting across the fusion during loading was less than 10% for each spinal-implant construct. Therefore, characteristics other than initial flexibility and distraction should be analyzed before an implant device is made. Characteristics such as case of implantation, bulkiness or fatigue life may be more relevant.

In 1993, Cunningham et al[6] (Cunningham 1993) reported biomechanical evaluation of twelve different spinal devices in vitro employing pedicle screws and using static and cyclical testing parameters The results showed that in static testing

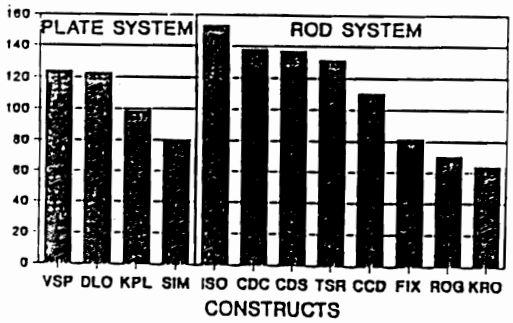
a) Stiffness



A bar graph demonstrating the stiffness (KN/M) values for twelve spinal systems.

The ISOLA, TSRH, CD standard rod and CD cold rolled rod were the stiffest rod systems with values greater than 130 KN/M. While the least stiff rod systems included the Kirschner and Rogozinski <70 KN/M. Both VSP and Dyna-Lok plate systems were the stiffest demonstrating no statistical difference. The Kirschner and Simmons were among the least stiff systems.

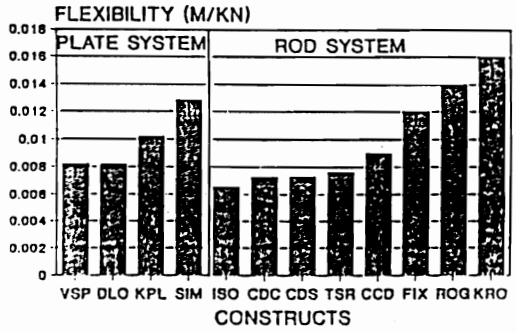
b) Bending Strength



A bar graph comparing the differences in bending strength (N) for twelve spinal systems.

For the rod systems, the ISOLA clearly demonstrated the highest bending strength (1289N) followed by the TSRH and CCD systems 866N and 753N respectively. The Rogozinski and Kirschner systems demonstrated lower bending strength of 223N and 250 N. Of the plate systems VSP and Dyna-Lok had higher bending strengths (807 and 746N) than the Kirschner and Simmons systems, however, were lower than their corresponding rod systems made by the same manufacturer.

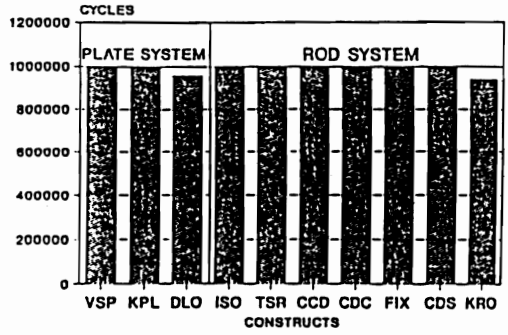
c) Flexibility



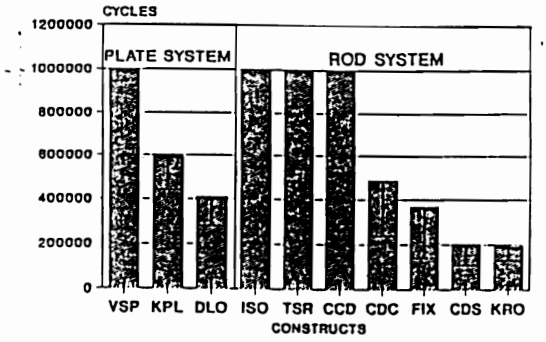
A bar graph demonstrating the flexibility levels (M/KN) for twelve spinal implant systems.

The flexibility values calculated are inversely proportional to the stiffness values. The Rogozinski and Kirschner systems were the most flexible while the ISOLA, CD standard, CD cold rolled, and TSRH systems were the least flexible. The VSP and Dyna Lok plates demonstrated more rigidity than the Kirschner and Simmons systems.

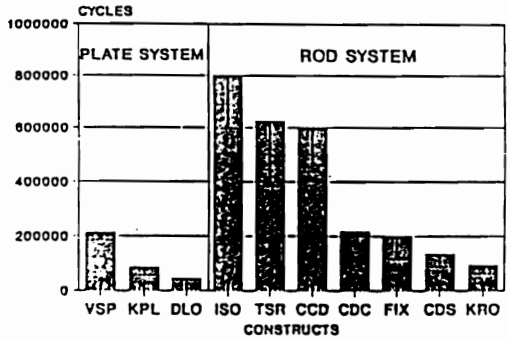
The result of fatigue testing showed that at the 400N level each device achieved one million cycles except for the Dyna-Lok and Kirschner Rod which both failed earlier. At 500N, the VSP system, ISOLA, TSRH and compact CD rod systems achieved the one million cycle limit, while the remaining constructs demonstrated mean failure ranging from 200,000 cycles, to 600,000 cycles. At 600N, the compact CD, TSRH and ISOLA systems demonstrated mean cycles to failure ranging from 600,000 to 800,000 cycles. The remaining devices hed failure ranges from 50,000 to 210,000 cycles.



Cyclic fatigue properties of ten spinal implant systems at a 400 N load leve.



A bar graph comparing the cyclic fatigue properties for ten spinal implant systems at a 500 N load level.



Cyclic fatigue properties for ten spinal implant systems at a 600 N load level.

Screw failure resulted from the cyclical compressive flexural load. All implant systems demonstrating pedicle screw failure had the same fracture location-- the junction of the upper screw thread and the collar. However, in the case of Dyna-Lok and VSP systems, fracture of the machine threaded portion of the screw just posterior to the integral nuts was the common fracture location. In the case of the CCD system, the spinal rod fractured. The point of fracture was adjacent to the screw/rod junction and located between the screws; however, there was no sign of permanent screw deformation.

In the study, Cunninghan clearly indicated that the rod constructs were biomechanically superior to plate systems under static and cyclical compressive flexural loading conditions. All implants evaluated demonstrated bending strengths below the normal load distribution through the anterior column of spine. This indicated that without adequate anterior column support, normal physiologic loads exceed the bending strengths of the implant systems evaluated.

Examples of clinical results of pedicle screw fixation

Authors	Temple 1994[17]	Millan 1994[13]	Hall 1996[10]
Type	Constrained	Unconstrained	Unconstrained
Trade name	Steffee	CCD	ISOLA
Patients	39	50	120
FU	2 yrs.	2 yrs.	2 yrs.
Fusion rate	92%	94%	91%
Clinical success	77%		87%
Screw breakage or looseness	5%	4.1%	6.9%
Device related problems	10%	6%	18%

The comprehensive literature review by Yahiro[20] in 1994 revealed that there were 5,756 patients with pedicle screw fixation devices reported in the 101 articles.

The literatures identified the following diagnoses that were treated with pedicle screw fixation deices:

1) Degenerative spondylolisthesis
2) Degenerative scoliosis
3) Degenerative disc disease
4) Spinal stenosis
5) Spondylolysis
6) Scoliosis
7) Spinal stenosis with scoliosis
8) Trauma, including fractures and fracture-dislocations
9) Post-traumatic instability
10) Post-traumatic deformity (e.g.,kyphosis)
11) Postlaminectomy spondylolisthesis
12) Low back pain
13) Preduarthrosis
14) Tumor (e.g.,metastatic, multiple myeloma)
15) Infection
16) Postsurgical failed back syndrome

The clinical results showed that there was overall fusion rate of 94.8%. There were 65 dural teas (1.1%) out of 5,756 patients, 99 neural injuries or neurological deficits (1.7%) , 410 patients with broken pedicle screws (7.1%), 12 patients with broken rods (0.2%) and 146 malpositioned pedicle screws (2.5%)

A ROOM FOR NEW BIOMATERIAL IMPLANT DEVICE : TITANIUM

As already known almost all the pedicular screw implant systems, curently in use, are made of stainless steels. The size and stiffness of these spine implants and their relationship to load sharing, stress shielding osteoporosis, rate of fusion mass incorporation, mechanical properties of the fusion, detrimental effects on adjacent segments of the spine and fatigue life of the implant are of clinical interest. The rigid fixation icreases spinal fusion rate. But the spinal implant constructs with high stiffness would reduce bone mass density and cause degenerative change at next proximal level. The less rigid systems fail early in cyclic loading. Ideally, a fixation device should support the spine until fusion, and then decay in stiffness.

New development of pedicular screw system is aimed at having more flexible implants by employing titanium alloys material in stead of stainless steel. The advantages of titanium alloys are (a) better resistance to crrosion (b) hight tensile strength (c) lower elastic modulus than stainless steel and (d) improved MRI Imaging. It seems that titanium alloys would be more biological and more biomechanical compatibility to spinal vertebrae than the stainless steel.

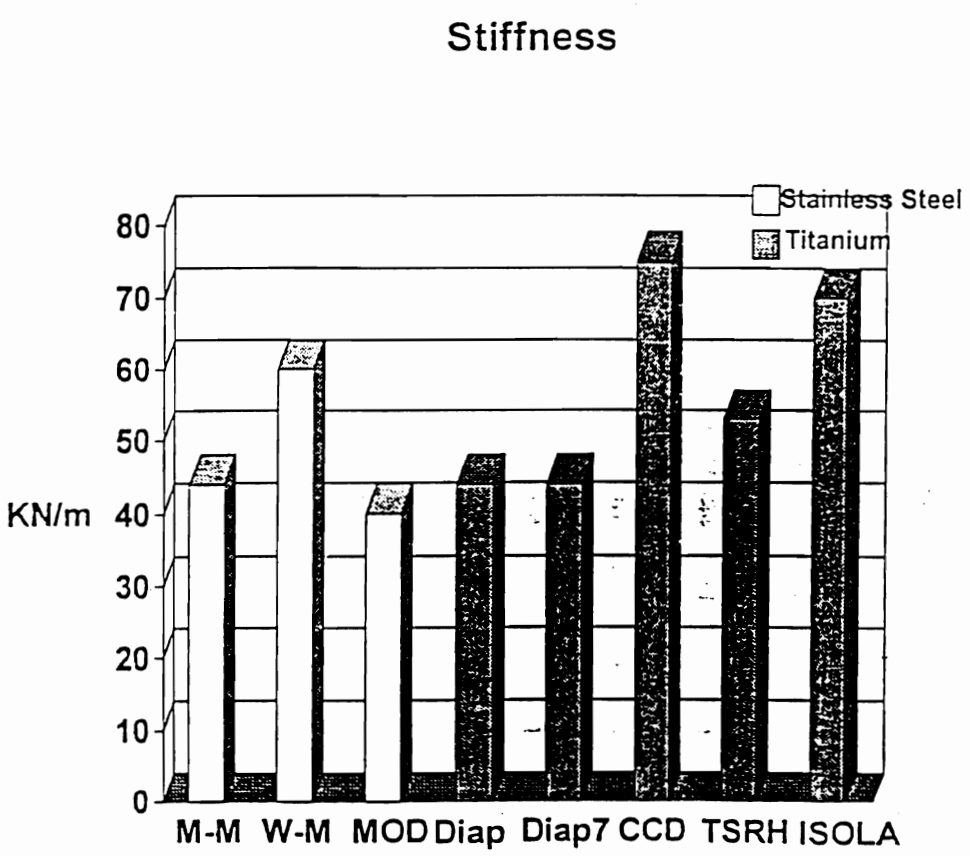
A study on a biomechanical comparison of five titanium and three stainless steel pedicle screw systems by Appleyard et al[1] in 1996 with static and dynamic tests was shown below.

STATIC RESULTS

(a) Stiffness

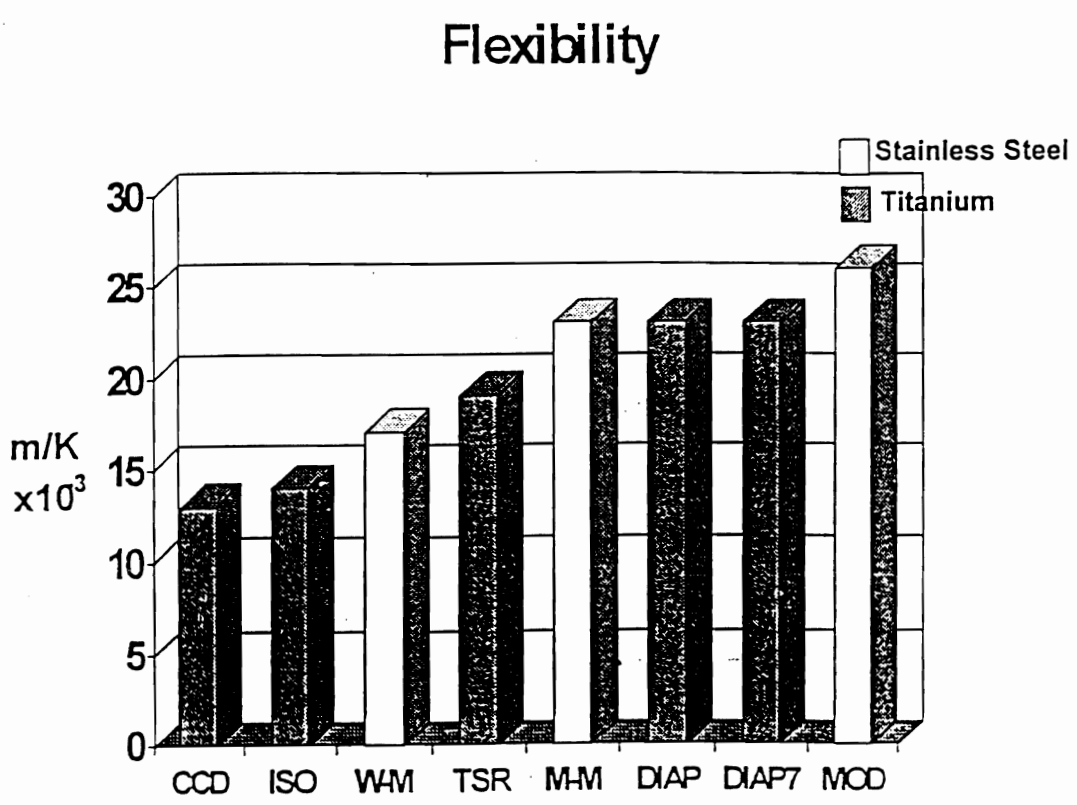
CCD, ISOLA, W-M, TSRH had high stiffness ranging 53-75 KN/m

MOD,DIAP,DIAP7 and M-M had low stiffness ranging 39-44 KN/m



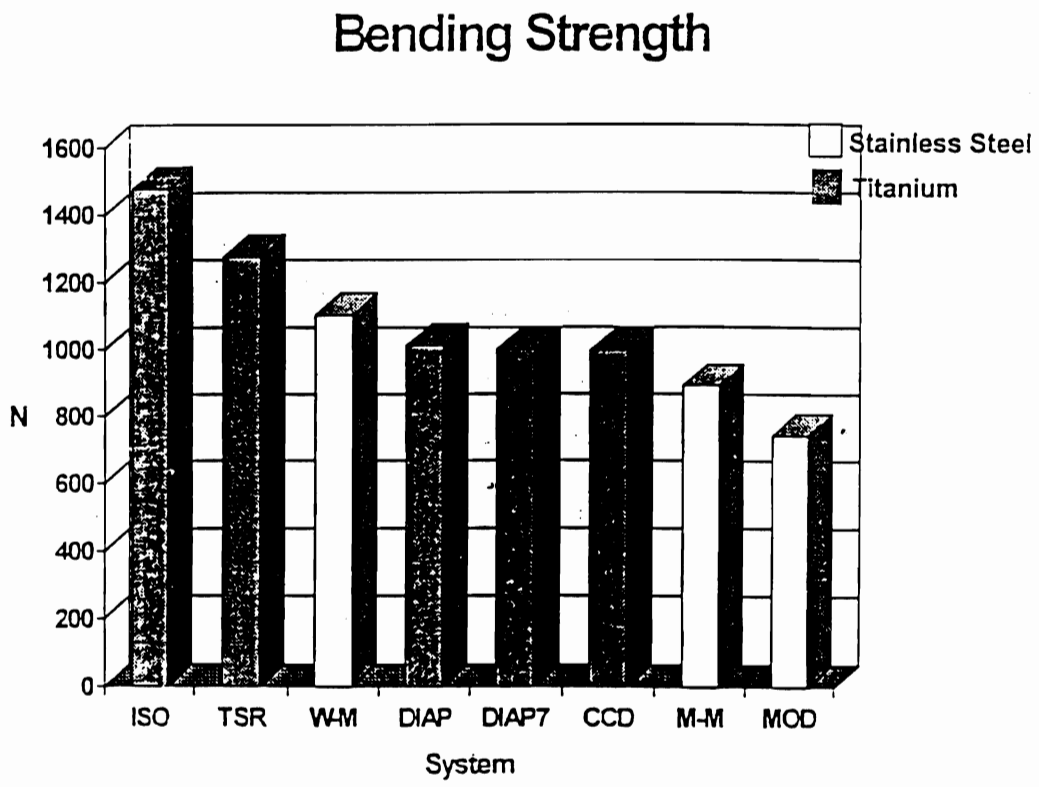
(b) Flexibility

MOD,DIAP,DIAP7 and M-M had high flexibility
CCD,ISOLA,W-M and TSRH had low flexibility



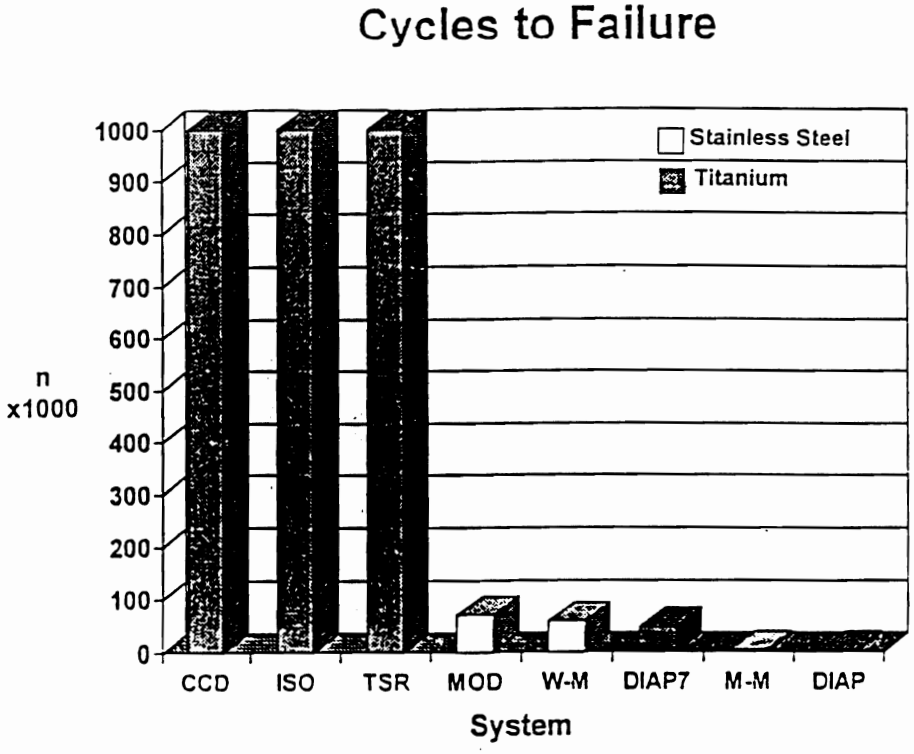
(c) Bending Strength

ISOLA, TSRH and W-M had highest bending strength ranging 1105-1483 N.
DIAP,DIAP7,CCD,M-M and MOD had lower bending strength ranging 741-1013N.



Dynamic results

CCD,ISOLA, TSRH but	allreached cycles	1 million cycles (Standard error)
MOD	69,507	(3002)
WM	51,820	(3616)
DIAP7	46,883	(7573)
M-M	3,985	(190)
DIAP	3,637	(102)



From the study it could be concluded that the titanium-base implant systems performed beter biomechanically in stiffness, bending strength and fatigue characteristics but had less flexibility comparing to stainless steel based implant systems. However, this study composed of construct systems with both no anterior support and with anterior support. The addition of anterior support in the corpectomy model would reduce, according to this study, maximum stress by 80% and these would improve fatigue life of the implant system.

WHY BIOMATERIALS, AS A SPINAL IMPLANT, FAILS

I. General Background

Three groups of metallic alloys are currently available for Orthopaedic implant applications,[3,18] these are stainless steel, titanium alloys and cobalt chromium alloys. The composition of Orthopaedic implant alloys is shown below.

Composition of some orthopaedic implant alloys (wt%)[8]

Element	Cobalt-base alloys ASTM F75	Stainless steel ASTM F138/9A	Titanium alloys Ti-6AI-4V
Co	Balance	-	-
Cr	27-30	17-20	-
Fe	0.75 max	Balance	0.25 max
Mo	5-7	2-4	-
Ni	2.5 max	10-14	-
Ti	-	-	Balance
Al	-	-	5.5-6.5
V	-	-	3.5-4.5
C	0.35-max	0.03 max	0.08 max
Mn	1.0 max	2.0 max	-
P	-	0.03 max	-
S	-	0.03 max	-
Si	1.0 max	0.75 max	-
O	-	-	0.13 m
H	-	-	0.012 max
N	-	-	0.05 max

In recent yeaes Titanium alloy (Ti-6% Al-4%V) has taken over from stainless steel (Type 316L, low C-17/20% Cr-10/14% Ni-2/4%Mo) since the titanium alloy has greater corrosion resistance to body fluids, greater resistance to stress corrosion cracking and has better biocompatibility. Stainless steel(316L) is now generally only used for temporary implants. The cobalt-chromium alloys provide similar properties to stainless steel but have superior pitting resistance and wear properties. A brief comparison of properties of implant alloys in given below.

Comparison of properties of implant alloys and bone

	Cortical bone	Ti-6Al-4V	316L	Co-Cr
Density (gm/cc)		4.51	7.75	8.5
0.1 Proof stress (MNm^{-2})		760-790	300	-
UTS (MNm^{-2})	50-150	825-1,000	560	430-1,050
Young's Modulus E (GNm^{-2})	7-25	105	200	230
% Elongation (ductility)		10	50	-
Kic ($MNm^{-3/2}$)	2-12	80	100	100

Ideally implant materials shoulde have similar stiffness but higher strength compared to bone. It is seen that titanium is less dense and has a much lower elastic modulus than stainless steel or cobalt-chromium alloy and is therefore the most mechanically biocompatible of the three alloys.

II. Failure of a material[18,14]

The service performance of a material depends upon

(a) its inherent mechanical, physical and chemical properties.
(b) the stress system acting up on it.
(c) the operating environment.

The material implant system is considered fail when a component ceases to function, or a component ceases to function in a satisfactory manner or a component functions but is unsafe. Failure can be considered as

(a) early failure	This arisses due to faulty material or manufacturing and or assembly errors that have not been detected by quality systems.
(b) random failure	This caused by chance eg. accidental overload or blocking of lubricant flow.
(c) overload failure	Overloading of a part beyond its safe capacity may cause failure or damage leading to eventually failure under subsequent normal loading.
(d) wearout failure	It occurs when the component reaches the end of its intened life. This is progressive as the part gradually loses its efficiency.

The mechanisms of failure are many and varied hence failure analysis requires knowledge of

(1) ductile and brittle fracture
(2) fatigue and corrosion fatigue
(3) plastic deformation
(4) corrosion and erosion
(5) wear behavior and damage
(6) stress corrosion
(7) hydrogen damage and etc.

The reasons for failure may include one or more of the following

(1) incorrect design
(2) incorrect material selection
(3) faults in processing or fabrication leading to defects and/or incorrect microstructures
(4) faults in assembly and/or commissioning
(5) inadequate quality control, testing and inspection
(6) incorrect use
(7) incorrect maintenance
(8) mechanical and/or chemical and/or thermal or other demages in service.

III. Why pedicle screw fixation system fails[14]

As already mentioned the clinical evaluation of a megareview of 101 articles with almost six thousands patients revealed 7.1% of broken pedicle screws and 0.2% of broken rods. This is the incidence of pedicle screws made from stainless steel. Broken pedicle screw is the main problem concerned in pedicle screw fixation system. We have yet to wait for the figure of failure of pedicle screws made from titanium. However, there was now scanty reports of titanium pedicle screw failure including the author's experience.

If we are to pose questions to someone especially a metal specialist concerning spinal screws, "Why the stainless steel screw in one patient is still fuctioning well while the titanium screw fails in another patient, eventhough it is gerneally accepted that titanium is normally better than stainless steel". You will have these answers in return.

(1) Are pedicle screws used in the same position in spine each patient?
(2) Any details of titanium alloys given
(3) Difference in environments between patients.
(4) Difference in stress levels and stress cyclings between patients.
(5) Are screws free from manufacturing faults?
(6) Are screws tightened up to correct torque on asembly?
(7) Any use of washers?
(8) Are screws left immerrsed in methanol and or chloride solution for cleanin?

Only these answers are made undrstood then we will be able to explain why the pedicle screw fixation ails whether be it made from titanium or stainless steel.

CONLUSION

The ideal pedicle screw system, which should ideally support the spine until fusion and then decay in stiffness, is still not available.

The particular pedicle screw fixation devices, commercially available in the market, should be only used in defined biomechanical situations and licensed according to their performance in both clinical and biomechanical testing trials. Continuing further development in biomaterial properties and designs would probably make possible the perfect and ideal spinal implant systems.

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