

PRELIMINARY STUDY
OF
ARTIFICIAL INTERVERTEBRAL DISC

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by
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ABSTRACT

This study is one of the projects of the artificial joints group conducted by Professor W. R. Newcombe, Department of Mechanical Engineering and Dr. G. R. Viviani, Department of Surgery.

A summary of the literature survey of the lower back which is pertinent to the design of a replacement for the lumbar spine is reported. Motions, force system, and strengths of the lumbar intervertebral joint are obtained from the literatures and calculation.

Advantages of silicone elastomer and titanium as the biomaterials for the artificial disc are presented. An experiment to test the bond between titanium and silicone reveals that the strength provided by only applying primer is insufficient.

Surface structure for prosthetic stabilization and initial fixation is discussed. Proposed design alternatives for artificial discs are presented with the attempts to reduce the number of moulds needed by introducing a prosthesis with a more regular shape.

An important part of this thesis is to indicate the direction in which further work in this area should proceed.

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TEXT

1. INTRODUCTION

Diseases of the lower back are a great source of human suffering, and this is perhaps the most common cause of lost industrial man hours. Posterior herniation, i.e., bulging, rupture, and protrusion, of the disc is the most serious single disability of the lower back. This herniation is produced by degeneration of a disc which loses its ability to withstand the forces of compression, tension, shear, and torsion.

The standard approach to alleviate lower back pain caused by herniated discs has been a simple excision of the disc. Although the results of this approach have generally been satisfactory, many patients have residual aggravating symptoms. Partial resection of the disc may lead to spinal instability with the production of pain. The surgical procedure for relief of recurrent rupture calls for fusing together of the vertebrae above and below the damaged disc. In this procedure, currently, both anterior and posterior or posterolateral fusion are utilized, and it is irreversible. All the degrees of freedom of relative motion are lost after vertebrae are fused. Some overall restriction of spinal motion results, and considerable additional strain is then imposed on adjacent discs.

There have been some attempts in the past to fabricate artificial spinal discs for the replacement of intervertebral discs. Some of the earliest were done by Dr. Hjalmar Reitz of South Africa (1). He has performed several hundred replacements of cervical and lumbar discs using stainless steel balls since 1963. At the lumbar spine, the results have been very satisfactory. He believes the good results are due not so much to any separation of the vertebral bodies produced by the ball, but to the fact that the ball embeds itself into the vertebral body to the extent of ten to twenty percent above and below, and thereby preventing slight forward or backward subluxation with flexion and extension movements, which could be the chief cause of local pain.

More recently, in 1973, Dr. Urbaniak of Duke University (2) has developed a prosthetic device to replace the diseased intervertebral disc. Their preliminary studies have demonstrated that this prosthesis, a silicone rubber central core sandwiched between two reinforced Dacron layers, can maintain spinal stability and function. Its experimental trials in chimpanzees show that the prosthesis allows motion, maintains intervertebral space, and absorbs the compressive stresses placed on the spine. However, there were some important problems of loosening and bone reaction, and these have not been made commercially available or used in humans.

The objective of this project is to produce some alternative designs for an artificial intervertebral disc. For this purpose, the following studies will be performed in this project.

(1) A study to review the real causes of lower back pain, and the possibility of alleviating pain by an artificial device.

(2) A study of the type and range of motion of individual elements in the lower back.

(3) Forces and stress analysis on the various elements of the lower back to obtain knowledge of what loads artificial materials would have to take.

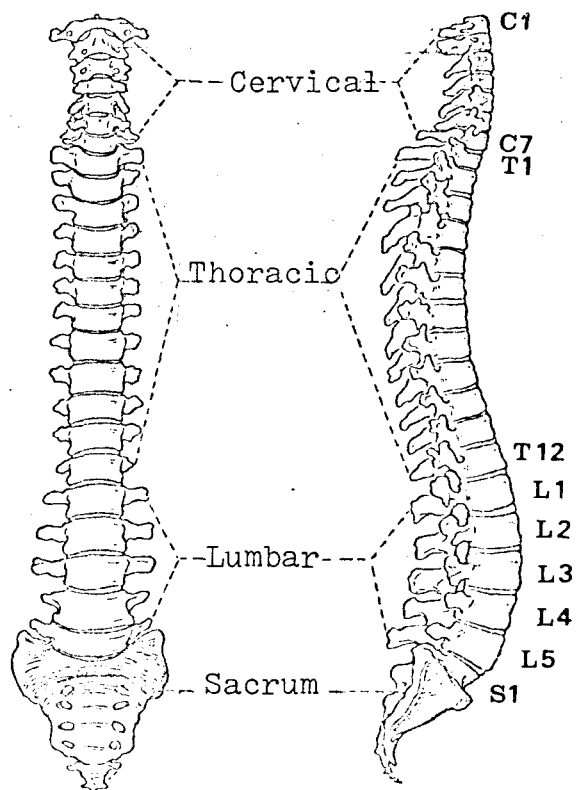
(4) Development of design alternatives for a replacement disc, including the structure of an artificial disc, material, prosthetic stabilization, etc.

2. LITERATURE SURVEY

A study in depth concentrated on the lower back has been carried out with the aim of gaining general knowledge of functional elements of the lower back, cause of pain, conventional treatments, and the feasibility of replacing a disc with an artificial device.

In this chapter, a summary of the study which is pertinent to this project is presented.

Fig. 2-1.
Front and lateral view
of the spine, showing
the four typical curves
(17).



2.1. Basic Anatomy of Lumbar Spine

The vertebral column is formed of a series of 33 vertebrae-- 7 cervical, 12 thoracic, 5 lumbar, 5 sacral, and 4 coccygeal. A lateral view of the spinal column reveals four typical curves-- cervical, thoracic, lumbar, and sacrum curves (Fig. 2-1).

The lumbar vertebrae are more massive and heavier than the other vertebrae, consistent with their primary role of weight bearing. The somewhat kidney shaped bodies are wider in the transverse than in the antero-posterior diameter.

The lumbar spine curve extends from the twelfth thoracic vertebra to the lumbosacral articulation and is convex anterior with the third lumbar vertebra as the transitional position.

A simple method of measuring the lumbar curve is to select from within the lumbar spine an easily recognizable plane of reference, and to measure angular relationships with reference to this plane. Such a plane is that of the intervertebral joint between the third and fourth lumbar vertebrae L3/L4, and this plane is often horizontal.

The typical lumbar curve is shown in Fig. 2-2. Measurements of the upper and lower lumbar angles were made in 182 cadaver spines (6). For the L1/L2--L5/S1 angle of whole curve of the lumbar spine, the lowest recorded angle was 15° , the highest 61° , and the mean 41° . The L1/L2--

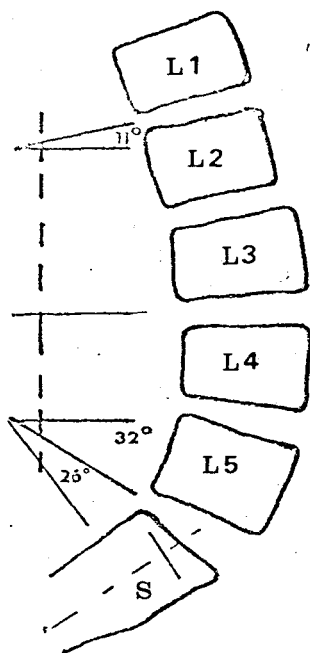


Fig. 2.2.

Typical lumbar curve. The upper and lower lumbar angles based on measurements of cadaver lumbar spine segments. The reference plane for all measurements is the bisector of interspace L3/L4 (3).

L3/L4 angle, Varied from -5° to 26° with a mean of 11° . for the L3/L4--L5/S1 angle, the lowest was 8° and highest 43° , the mean was 32° . The average for the S/L--S angle for a number of 149 spines was found to be 26° .

The bodies of the vertebrae are separated from each other by the intervertebral disc. The disc together with anterior and posterior longitudinal ligaments form the vertebral body articulation. These and other functional elements of the intervertebral joint are shown in Fig. 2-3.

The intervertebral discs contribute approximately one third of the overall length of the lumbar spine. The disc is generally considered to have three components. The

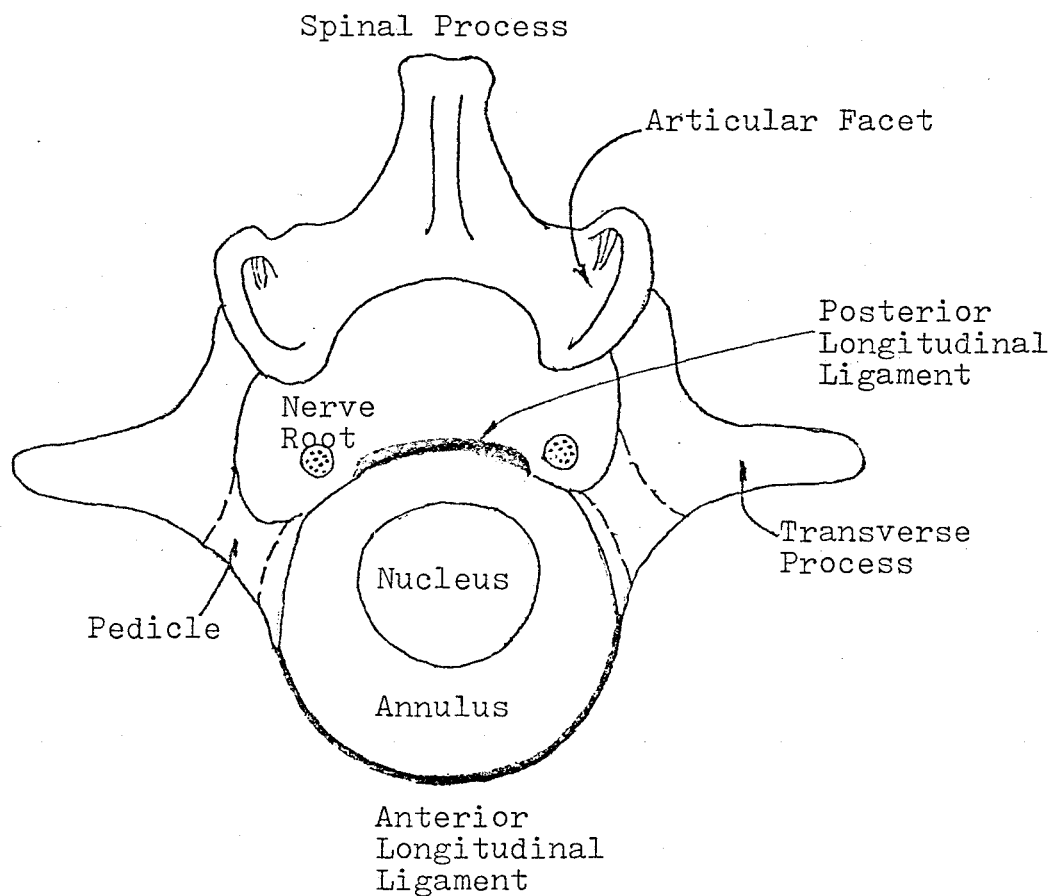


Fig. 2.3.

Vertebral Functional Segments. As view from above it is divided into anterior and posterior segments. The anterior portion is the vertebral body and disc. The posterior portion consists of the ligaments, pedicles, and facets.

nucleus pulposus which occupies 50 to 60 percent of the cross-sectional area of the disc, the annulus fibrosus is the limiting capsule of the nucleus, and the two cartilag-

inous plates, which separate the disc from the vertebrae above and below (3,4,5).

The thickness of the disc is an important factor governing the degree of movement of the intervertebral joint. Thus, it is an important parameter in the design of a replacement for the lumbar disc. As a result of the lumbar curve the average difference between anterior and posterior disc thicknesses will range from 10 percent of the L1/L2 disc to as high 50 percent of the L5/S1 disc.


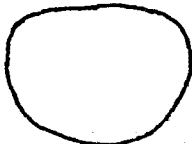
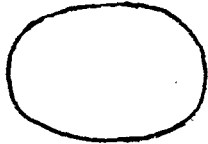
Table 2-1. shows disc thickness data from lateral radiographs of lumbar spines obtained from patients without evidence of disc degeneration (3). These measurement can be regarded as a reference only, as there is considerable variation from individual to individual. Thickness of the L5/S1 disc is not given, but there are many instances where the L5/S1 disc is thicker than the L4/L5 disc, and vice versa.

Table 2-1. Measurements of the thicknesses of the lumbar intervertebral discs (in inch)

Level	Number of Specimens	Range of Posterior Thickness	Average
L1/L2	4	0.25--0.31	0.273
L2/L3	6	0.28--0.44	0.345
L3/L4	6	0.30--0.40	0.324
L4/L5	4	0.35--0.42	0.378

There are three basic shapes of intervertebral discs with posterior outlines flattened, rounded, or with a reentrant angle. The distribution of disc shapes in each level is shown in Table 2-2. These shapes are of importance for the physical strength of the disc, as will be described in the next chapter.

Table 2-2. Outlines and distribution of the lumbar discs shapes.

Level	Number Examined	Disc Shapes		
		Re-entrant	Flat	Round
				
L1/L2	12	83%	17%	0
L2/L3	35	54%	46%	0
L3/L4	99	39%	56%	5%
L4/L5	118	13%	68%	19%
L5/S1	38	5%	37%	58%

2.2. Courses and Conventional Treatments of Disc Diseases

The intervertebral disc is a hydraulic system composed of a fibroelastic cylinder containing a colloidal gel which is constantly exposed to compression, torsion, and shearing stresses. These tissues under repeated stresses over the years are subjected to degeneration from wear and tear. Such degeneration can lead to impaired function and morbidity.

As the disc degenerates, the elastic fibers of the annulus decrease and are replaced by fibrous tissue. A loss of elasticity ensues, and flexibility of movement between two vertebrae is diminished. The intradiscal pressure that normally assists in keeping the vertebrae apart is decreased, and the intervertebral distance decreases.

Narrowing of the intervertebral space because of disc degeneration causes a form of degenerative arthritis termed "Spondylosis". Spondylosis is capable of causing localized lower back pain, or it may irritate the emerging spinal nerve root and cause sciatica (?).

Nevertheless, lumbar disc herniation, i.e., bulging, rupture, or protrusion, is the most single disability from this structure. It produces tremendous pain and economic loss. Herniation of the nuclear material may result from excessive forces, repeated stresses, and prolonged tension on the hydraulic mechanism or the presence of a faulty annulus. But any combination of the above may be involved. Clinically, the patient with a herniated lumbar disc (Fig. 2-4) presents a history of sciatica, the pain most frequently begins as a lower back pain, and eventually progresses and is felt as a pain running down the leg.

It is general information that the most commonly involved levels of disc lesion in the lumbar spine are at

the L5/S1 and the L4/L5 discs. Implication of the L3/L4 disc level is not common, however, there is evidence that lesions at this level are more frequent than generally appreciated. Lesions at the L1/L2 and L2/L3 levels are indeed rare, and are more prone to occur in young adults subjected to violent flexion of the spine (8).

The conservative treatment of the lumbar disc disease is based on correcting the mechanism that irritated the symptoms, and the aims are three fold: relief of pain, increase of the functional capacity of the patient, and slowing the progression of the disease. These treatments can be summarized as: (1) Elimination of gravity by bed rest. (2) Gentle bed exercises to prevent circulatory

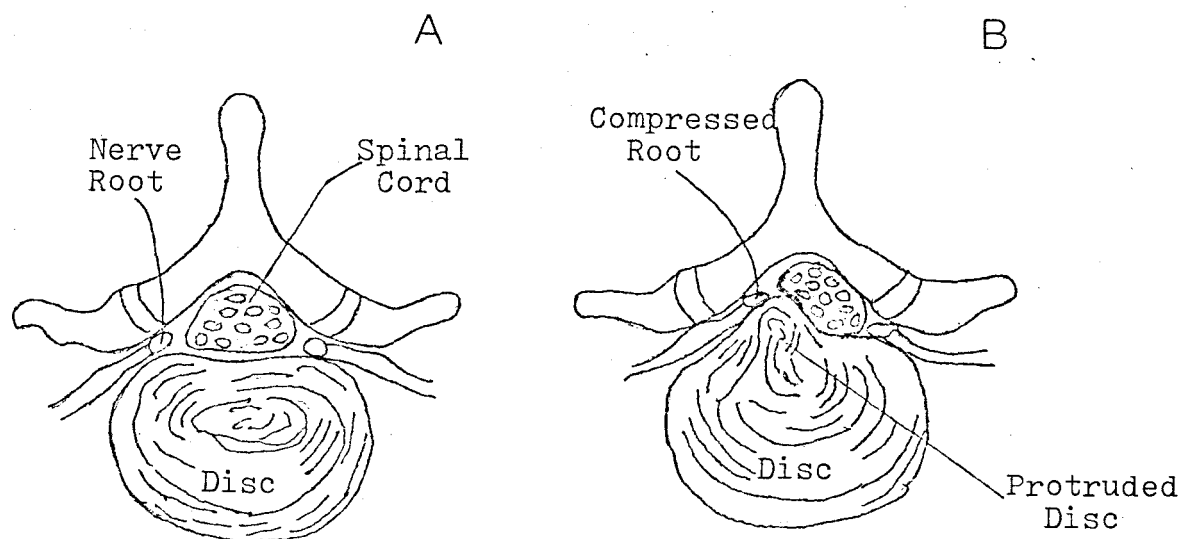


Fig. 2.4. (A) Normal disc.
(B) The distortion produced by a protruded disc.

stasis, atrophy, and pressure point discomfort. (3) Medication to decrease pain, decrease spasm, and tranquilize or sedate the patient. (4) Traction to decrease the lumbar lordosis and decrease muscle spasm (7).

The alternative to conservative treatments is operative treatment. Disc excision is a surgical procedure to take out the protruded disc material or the nucleus of the abnormal disc, because both of these materials may produce severe nerve root compression and cause pain. Excision of one of the herniated disc for the relief of pain is now an established procedure. When simple excision of the herniated disc is unsuccessful in alleviating pain, a fusion is then performed for stabilization of the spine.

In fusion, currently either posterior or anterior fusion is utilized, which eliminated all motions of the fused vertebrae, but this does not necessarily guarantee permanent relief of symptoms. Fusion of one disc space may actually place added burden upon adjacent discs, and although they were initially not the culprits they now become so. Patients after a solid fusion frequently continue to have symptoms similar to those present before surgery.

2.3. Feasibility of Prosthetic Replacement of Disc

Free nerve endings are found in anterior and posterior longitudinal ligaments and facet articular cartilages

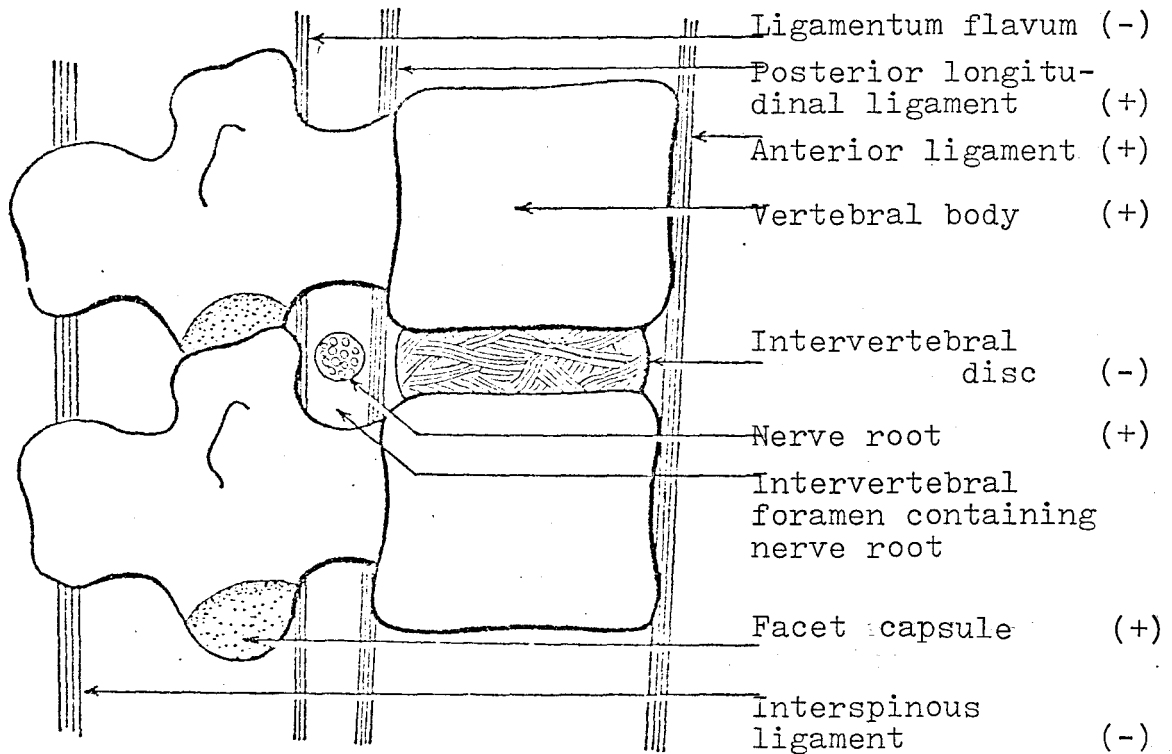


Fig. 2.5.

Pain-sensitive tissues of the function units. The tissues labelled (+) are pain sensory nerve endings that are capable of causing pain when irritated. Tissues labelled (-) are devoid of sensory nerve endings (7).

as shown in Fig. 2.5. Only in the very outermost layer of the annulus fibrosus, directly adjacent to the posterior longitudinal ligament, have nerve endings been found. Hence it is unlikely that disc replacement will alter the structure and function of these sensory elements and cause pain.

Great advances have been made in the development of prosthetic joint replacement of fingers, knees, shoulders,

hips, and elbows which were previously treated with articular fusion or joint resection, and now successfully managed with prosthetic devices. Because of the encouraging results of these replacements, and the shortcomings of current surgical treatments of lower back pain, it is feasible to design a suitable prosthesis such that a more physiologic relief of pain could be achieved (2).

The objectives of the replacement of disc with a lesion by an artificial device will be: (1) To relieve the patient's current pain. (2) To insure the patient of no further recurrence of the syndrome. (3) To provide a stable lumbar spine capable of meeting all of the functional demands that may be required of it.

3. BIOMECHANICAL STUDIES OF LUMBAR SPINE

A study of motion, force system, and strength of individual elements in the lower back has been carried out in order that a knowledge of what kind of movements and loads an artificial device would have to take is obtained.

The information presented here is obtained from the literature and calculations. There has been no experimental approach at this stage.

3.1. Movement of Lumbar spine

3.1.1. General

The spine moves in segments. A motion segment (fig. 3-1) consists of an intervertebral disc, its adjacent vert-

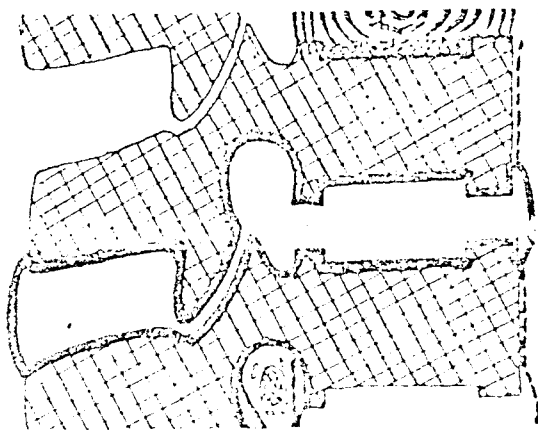


Fig. 3.1.

Motion segment. Consists of intervertebral disc, adjacent vertebrae, facet joints, and ligaments.

ebrae, and all the intervening ligamentous tissues, including the facets joints. All these parts can be alternately rigid or elastic elements (10).

The intervertebral joint permits only very limited movements, but when this slight degree of movement takes place in all of the lumbar spine, the total range of movement is considerable. This considerable degree of flexibility is primary controlled by the intervertebral discs. The amount of flexibility depends on the material properties, the size and shape of the disc, and intervertebral ligaments.

Usually, discs may be considered to act as universal joints, permitting motion in six degree of freedom, three in rotation and three in translation. Because of the anatomy of the joint, certain motions, such as compression, lateral bending, anterior - posterior bending, and torsion, occur most readily.

Flexion and extension in the sagittal plane, lateral bending in the coronal plane, and axial rotation in the transverse plane are considered as principal motions (Fig. 3-2) which will be discussed hereafter.

3.1.2. Flexion and Extension

Flexion-extension and lateral bending movements are represented as tilting motions about the major and minor

axes of the disc, while axial rotation occurs about the long axis of the spine. Tilt or rotation will not occur at an intervertebral joint without some deflection in the disc, or in other ligamentous components, in the neural arch or possibly in the vertebral body itself.

The antero-posterior flexion and extension are considered as the most important motion contributed by the lumbar spine. This is because the relative disc thickness in the lumbar spine is much thicker than those in other areas, and

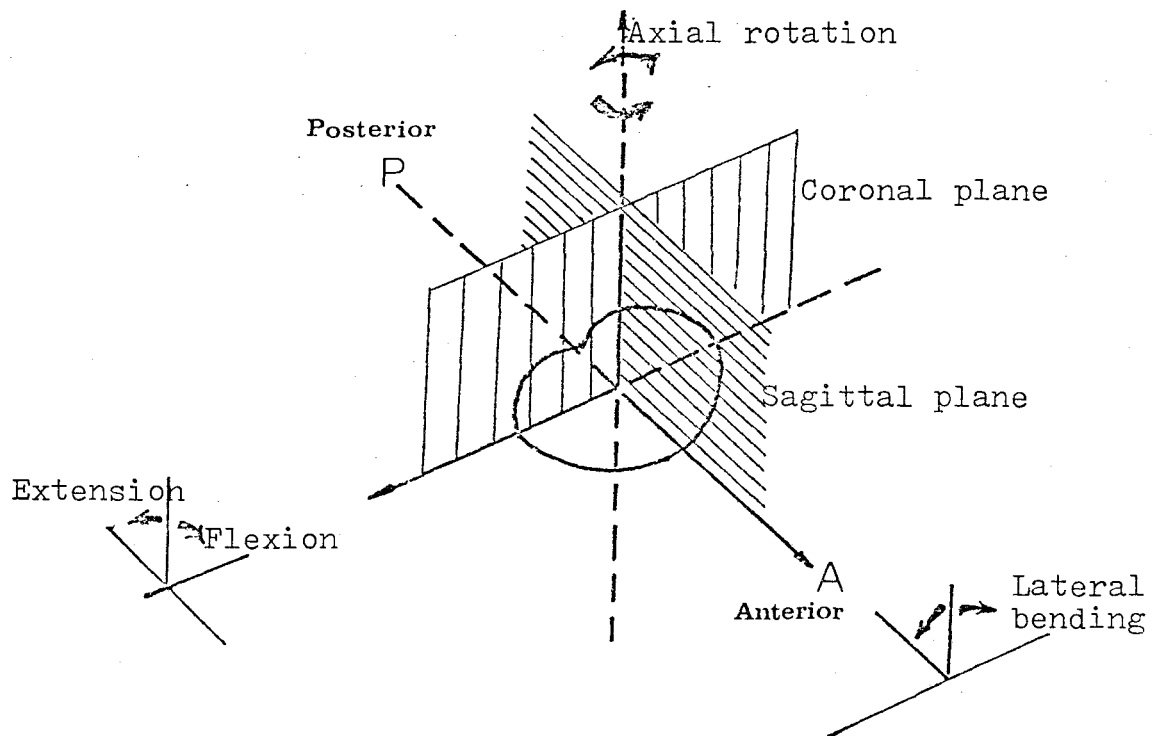


Fig. 3.2.

The principal motions at the intervertebral joint as respect to the vertebral body.

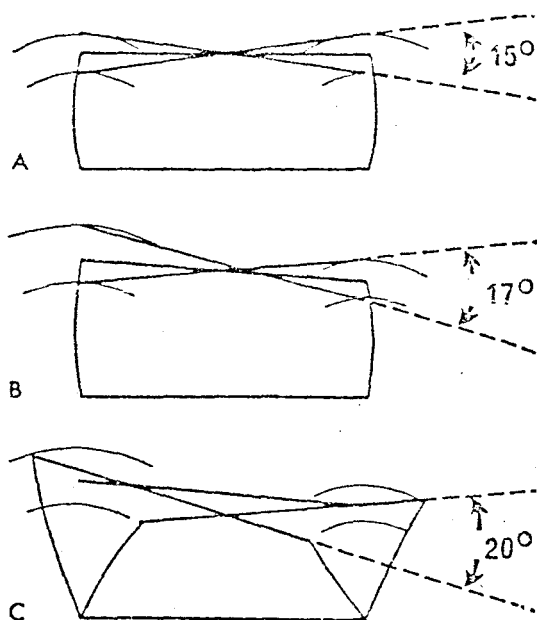


Fig. 3.3.

Geometrical construction showing possible movements of flexion & extension. Assume that the disc may be stretched or compressed 20% of its original height.

- (A) Anterior & posterior height equal (0.5")
- (B) Anterior height: 0.75"
Posterior height: 0.5"
- (C) Same as (B), but one vertebra is allowed to slide forwards or backwards with respect to the next.

we may assume that the disc may be stretched or compressed to the same percentage (strain), since the discs are elastic elements (Fig. 3-3).

A typical lumbar curve shows that the intervertebral discs of L4/L5 and L5/S1 levels are thicker than that of L3/L4, L2/L3, and L1/L2 discs. Moreover, the differences between anterior and posterior thicknesses in the lower lumbar discs are larger than the differences in the upper lumbar discs. With this understanding and the assumption above, we can anticipate that flexion-extension is highest in L4/L5 or L5/S1 level.

In order to unify the measurements of the maximum degree of movement in each level of lumbar intervertebral

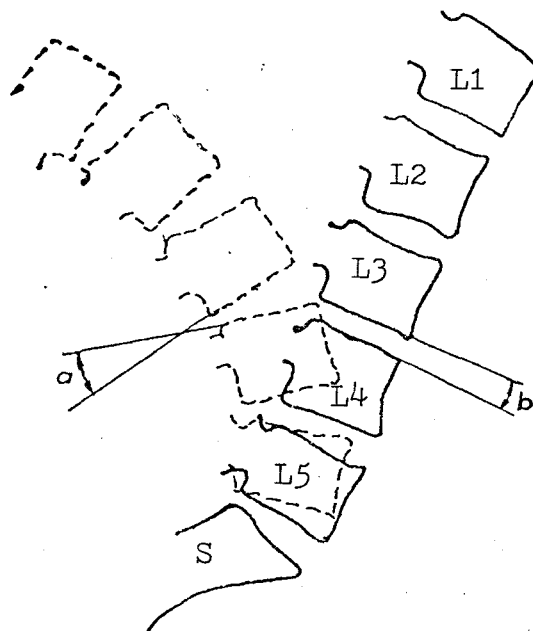


Fig. 3.4.

Outlines of lumbar spine in full flexion and full extension. The difference in degrees between angles 'a' and 'b' is defined as the maximum flexion-extension between L3 and L4.

joint, a definition is given as shown in Fig. 3-4. which shows the maximum flexion-extension in level L3/L4. The same procedure can be applied for the other segments.

Most of the results of measurements presented here came from the experiments carried out by Aho, Vartiainen, and Solo (10). The programme consisted of 48 patients with some internal disease. As for the condition of lumbar spine, they fell into two groups.

Group 1-- Altogether 26 cases. Conventional examination of the lumbar spine revealed nothing pathological. Any symptom and sign were absent, and there was no history of injury to the lumbar spine.

Group 2-- Altogether 22 cases. Each with lumbar symptoms and sign. Even conventional radiographic examination revealed a pathological state of the motional seg-

ents of lumbar spine.

The results of Group 1 and 2 are recalculated to suit the definition above, and are presented in Table 3-1 and Table 3-2 respectively. It was found that the more advanced the morphological changes of the lumbar spine, the more mobility was restricted in the corresponding motional segment.

Another result come from Farfan (3) who presented a typical range of flexion-extension of normal lumbar spine, as shown in Table 3-3. This result is quite comparable with those of Group 1 above. Both of these can be considered as providing typical ranges of maximum flexion-extension of the normal lumbar spine.

Table 3-3. Typical ranges of flexion-extension motion of lumbar intervertebral joint.

Level	Full Range	Extension	Flexion
L1/L2	$7\frac{1}{2}^{\circ}$	$3\frac{1}{4}^{\circ}$	$3\frac{1}{4}^{\circ}$
L2/L3	$7\frac{1}{2}^{\circ}$	$3\frac{1}{4}^{\circ}$	$3\frac{1}{4}^{\circ}$
L3/L4	18°	9°	9°
L4/L5	22°	10°	12°
L5/S1	18°	6°	12°

Table 3-1. Distribution of cases in Group 1 by age, sex symptoms and signs, and segmentary mobility in flexion-extension (modified from ref. 10)

Case No.	Age	Sex	Condition of Lumbar Spine	Segmentary Mobility in Degrees				
				L5/S1	L4/L5	L3/L4	L2/L3	L1/L2
1	17	M	Normal	24	30	22	16	10
2	19	F	"	18	16	16	10	14
3	20	M	"	16	20	14	12	10
4	21	F	"	30	22	14	14	8
5	22	F	"	14	20	26	20	16
6	23	F	"	14	28	22	14	12
7	26	M	"	16	16	14	12	8
8	28	F	"	20	24	18	10	8
9	29	M	"	22	26	16	10	14
10	29	F	"	12	14	12	10	8
11	30	F	"	24	32	16	10	18
12	30	F	"	14	22	26	16	10
13	23	M	"	18	20	20	10	6
14	24	M	"	10	26	18	12	6
15	28	F	"	24	16	14	8	10
16	33	M	"	26	30	18	12	6
17	36	F	"	14	14	16	6	8
18	32	F	"	14	26	28	16	20
19	39	F	"	18	20	12	12	10
20	39	F	"	12	12	16	14	6
21	39	M	"	24	14	12	16	8
22	31	M	"	18	20	12	10	6
23	32	M	"	12	22	16	6	10
24	37	M	"	20	26	30	18	20
25	37	M	"	24	20	14	12	6
26	39	M	"	16	26	16	10	16
Mean	30.5		Mean	17.6	21.6	17.6	12.2	10.6
			Deviation	+5.0	+4.4	+4.2	+2.6	+3.6

Table 3-2. Distribution of cases in Group 2 by age, sex symptoms and signs, and segmentary mobility in flexion-extension (modified from ref. 10)

Case No.	Age	Sex	Symptoms and signs	L5/S1	L4/L5	L3/L4	L2/L3	L1/L2
27	48	M	3 years sensation of stiffness in back	0	0	0	4	8
28	52	M	4 years stiff back	0	0	0	6	4
29	60	M	11 years stiff back	0	0	0	8	6
30	52	M	3 years lumbago	6	10	4	8	2
31	58	M	4 years lumbago	10	2	12	6	4
32	61	F	3 years lumbago	0	4	12	0	8
33	32	F	6 months lumbago	8	8	0	10	8
34	42	F	2 years lumbago	14	26	4	0	10
35	54	M	3 years pain radiating to limbs	20	16	12	4	10
36	56	F	6 years lumbago and 1 year pain radiating to limbs	16	0	8	10	12
37	66	M	12 years lumbago	12	18	6	12	6
38	38	F	1 year pain radiating to limbs	16	8	16	14	18
39	38	F	6 months pain radiating to a limb	4	0	16	14	18
40	48	M	6 months pain radiating to a limb	20	10	18	8	10
41	48	F	2 years lumbago	12	10	8	12	6
42	40	M	3 months lumbago	24	30	12	10	6
43	37	M	3 months lumbago	16	20	14	8	10
44	39	F	7 months lumbago	8	12	14	8	4
45	53	M	1 year lumbago	18	14	16	6	8
46	50	M	6 months lumbago	20	16	18	14	14
47	35	F	3 years lumbago	18	36	34	16	14
48	44	M	1 year lumbago pain radiating to limbs	0	10	12	12	10
Mean	48.3		Mean	11.1	12.2	12.0	8.4	8.9
			Deviation	±6.2	±7.4	±4.8	±3.8	±3.0

3.1.3. Lateral Bending

Of the principal motions of the spine, lateral bending has had the least study. The movement is said to be greatest in the upper lumbar levels, and reduced progressively with each lower level. The angular side-to-side bending in the coronal plane has been measured to be of the order of 12 to 15 degrees (3).

In both flexion-extension and lateral bending of the lumbar spine, the centers of rotation are coincident, and pass close to, or within the nucleus pulposus, somewhat posterior to its midpoint.

It is worthwhile to note, however, that axial rotation of the vertebral bodies must occur if motion in the coronal plane--lateral bending--is to take place. Lucas and Gregersen (11) performed an experiment which supported the concept that axial rotation is an integral motion of the thoracolumbar spine during lateral bending.

3.1.4. Axial Rotation

It was found that the lumbar region of the spine is considerably stiffer in torsion than the thoracic region. The disc at L3/L4 level is six times stiffer than the disc at thoracic 10/11 level. Measurements of maximum axial rotation were made by Lucas and Gregersen (11). Living subjects with inserted pins in thoracolumbar spinous proce-

sses were used, and direct measurements of the angular displacements of the pins from one side to the other side were made.

The average cumulative amount of rotation measured at each vertebra in sitting and standing position is recorded and presented in Fig. 3-5.

For standing position, an average of 74 degrees of rotation occurred between the first and twelfth thoracic vertebrae, 11 degrees of rotation occurred at the thoracolumbar joint, 9 degrees between the first and fifth lumbar vertebrae, and 13 degrees in the lumbosacral joint.

In Fig. 3-5, when the curve for the sitting position is compared with that for the standing position, it may be observed that during sitting there is a marked difference in the amount of rotation at the lumbosacral joint, less difference in the lumbar spine, and essentially none in the thoracic spine. The average amount of rotation at the lumbosacral joint was 3 degrees for the seated maneuver as compared with 13 degrees during standing position.

Although the lumbar spine permits a total rotation of 10 to 20 degrees, the range of rotation in everyday's activity is of small magnitude, in most instances probably less than 5 degrees.

Cossette's group (12) performed an experiment to determine the instantaneous centre of rotation of the

L3/L4 joint. They found that the centres of axial rotation in a normal lumbar region were without exception located anterior to the facet joints, they were near the posterior part of the disc.

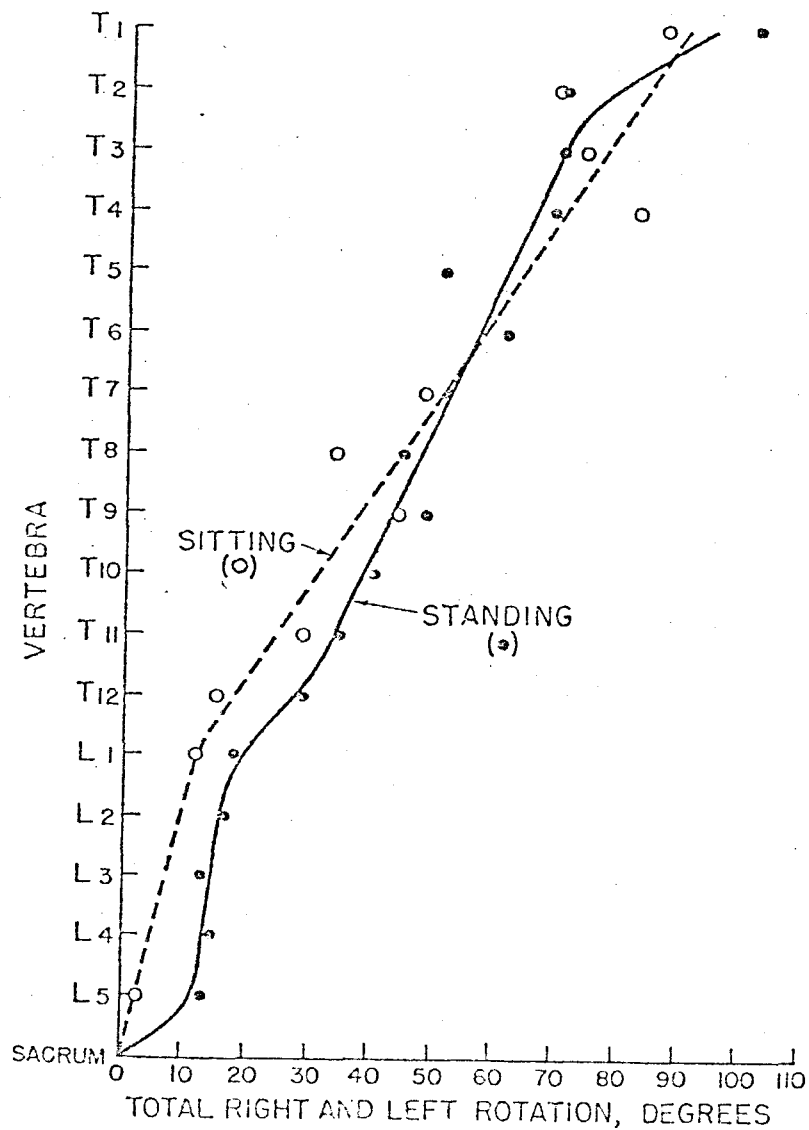


Fig. 3.5.

Maximum total axial rotation of the thoracolumbar spine in the sitting and standing position.

There appeared to be a relation between the location of centre of rotation and direction of rotation. The centre of rotation appeared to move towards the side to which rotation was forced. Because the weakest part of the disc is believed to be the posterior lateral portion of the annulus, we may assume that the centre of rotation is so located as to distribute a safe level of stress to all components of the intervertebral joint.

3.2. Force and Stress Analysis

The purpose of this study is to obtain general information about the forces and resulting stresses existing in the lumbar spine. This analysis together with the knowledge of normal motion of the intervertebral joint, enable us to rearrange disc material in such a manner that the stresses caused in everyday's activity will be insufficient to cause failure.

3.2.1. The Load on Lumbar Discs

The disc has been considered as an elastic construction in which the arrangement of collagen structure was made especially to respond to mechanical forces. The cartilaginous end-plate, the annulus fibrosus, and the nucleus pulposus are the main functional elements. The nucleus pulposus was considered to be a semi-liquid substance with

a stress distributing purpose, the annulus is the major structure which determines the compressive characteristics and strength of the disc (Fig. 3-6).

In this section some measurements about the load that lumbar discs have to carry in different positions of the body are presented (13). A schematic drawing of the method used to measure the pressure in the annulus is shown in Fig. 3-7. The measuring needle is inserted from behind at an angle of 45 degrees to the level of the disc to be tested. Measurements have been performed on L2/L3, L3/L4, and L4/L5 discs, since the L1/L2 and L5/S1 discs are difficult or impossible to measure with this technic.

The external load on the discs was calculated from the disc pressure measurements. Since it was proven experimentally that the pressure in the nucleus is 50 percent higher than the externally applied stress, i.e., a external load of 100 psi will give a pressure of 150 psi inside the disc. The load per unit area of the disc is equal to the measured pressure divided by 1.5.

It has been shown that the load on the disc is somewhat related directly to the body weight above the level measured. The proportion of body weight above different levels of the spine has been calculated and stated as, about 59 percent of the weight is above the L4/L5 disc, 57 percent is above the L3/L4 disc, and 55 percent is above the L2/L3 disc.

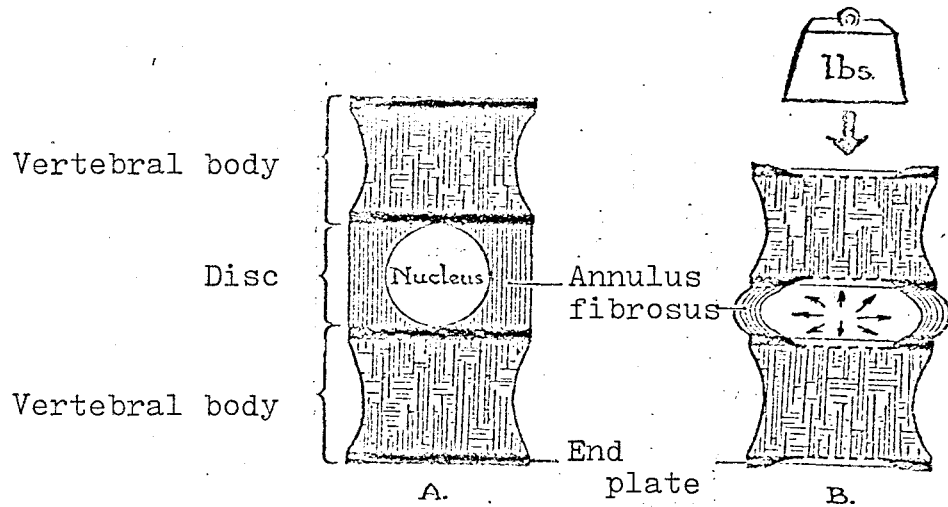


Fig. 3-6.

Normal disc under external loading. Both the nucleus and the annulus act to absorb forces that occur primarily in a vertical axis and redistribute them evenly in all direction.

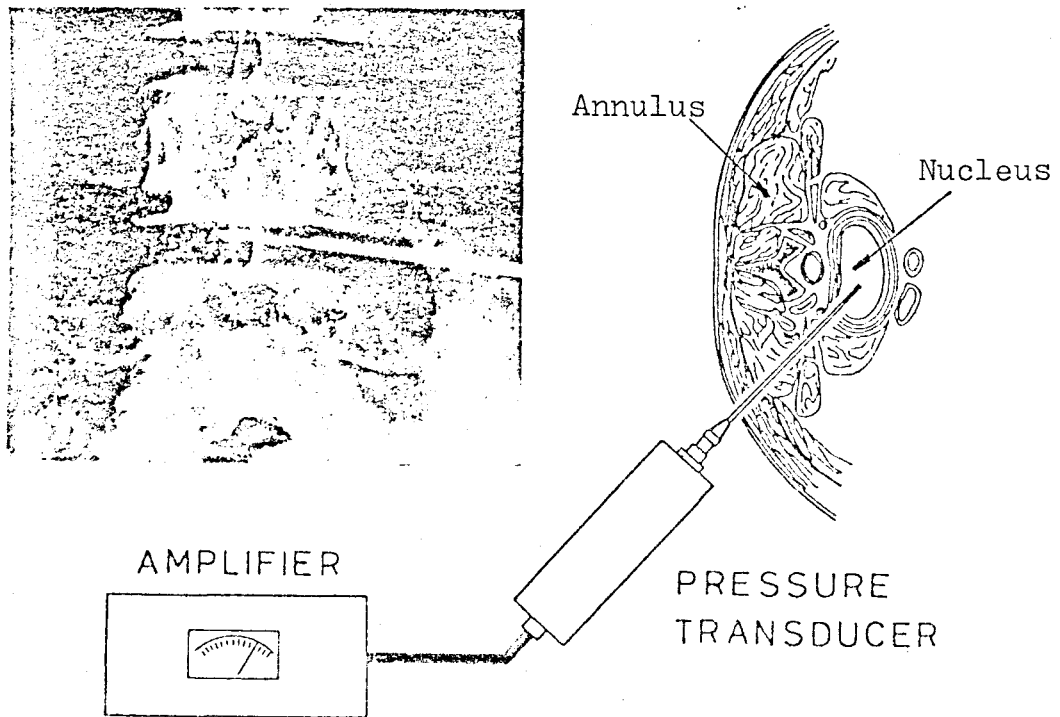


Fig. 3-7.

Schematic drawing of the method used in disc pressure measurement (ref. 13).

The load on the lumbar discs in the sitting position studied was found to vary between 220 and 400 lbs for body weight above the level of the probe between 50 and 120 lbs, thus the load is about 3 times the body weight above the measured level. In the standing position, loads from 175 to 330 lbs have been recorded for body weight above the measured level between 80 and 120 lbs.

The reason why pressure in the standing position is about 30 percent less than that in the sitting position is because the line of gravity falls closer to the nucleus pulposus of the lumbar disc in the standing than in the sitting position.

Measurements were also made in the reclining and forward leaning position. With some approximations, the formulas for loads in different positions were derived, as shown in Table 3-4. The deviation of each single measurement from these formulas is less than 10 percent.

In addition, approximate loads on the lumbar discs in different positions in individuals of varying body weight are listed in Table 3-5. It should be noted that what is called "Weight above the level measured" implies not only the body weight of the subject but also the eventual added loads by the arms.

The results reported here were derived from measurements in normal discs, it is obvious that the load on a

Table 3-4. Approximate formulas for loads (P) on the lumbar discs in different positions.
 Pi = Approximate intrinsic pressure
 W = Weight above the level measured

Position	Approximate Formulas (in pound)	
Upright sitting with arms and back unsupported	$P = P_i + 2.8W$	$P_i = 65$
Upright standing	$P = P_i + 2.1W$	$P_i = 33$
Reclining (tilted on side, lateral decubitus)	$P = P_i + 2.8W/2$	$P_i = 65$
Reclining (relaxed supine)	$P = P_i$	$P_i = 33$
Sitting + forward leaning α degrees	$P = P_i + 2.8W + 3.6W \sin \alpha$	$P_i = 65, \alpha = 10-20^\circ$
Standing + forward leaning α degrees	$P = P_i + 2.1W + 3.6W \sin \alpha$	$P_i = 33; \alpha = 10-20^\circ$

Table 3-5. Approximate loads on the third lumbar disc in different positions in individuals of varying body weight.

Weight of Subject (lbs)	110	132	154	176	198
Position of body	Load on the disc				
Upright sitting, unsupported	242	278	312	348	383
Upright standing	165	191	218	244	270
Reclining (lateral decubitus)	121	139	156	174	194
Reclining (relaxed, supine)	33	33	44	44	55
Sitting + forward 20°	320	370	420	471	522
Sitting + forward 20° and 22 lbs load in each hand	498	548	594	645	698
Standing + forward 20°	242	285	326	368	410
Standing + forward 20° and 22 lbs load in each hand	390	430	473	515	577

degenerated disc in a comparable subject should be the same, even if the internal distribution of stresses is altered.

3.2.2. Stress Analysis

Stress is simply defined as " the internal force acting per unit area on a material as a result of external force". The stresses which arise in structures occur in two categories: (1) Normal stress is directed in a direction perpendicular to the cross-section. (2) Shearing stress is directed parallel to the cross-section.

The aim of this analysis is to determine the relationship between the stresses in the lumbar spine and the externally applied forces and deformation. most of the work which has been done considered only the intervertebral discs on the assumption that the discs are clinically the most critical components of the load bearing system.

One of the major functions of the discs is to support the vertical load such as part of the body weight. It is generally accepted that this generates axial stress in the annulus as well as hydrostatic pressure in the nucleus. The latter, in turn, gives rise to additional radial and tangential stresses in the annulus.

Nachemson (13) performed pressure measurements both in vitro and in vivo in the nucleus pulposus for various

loading conditions. He found that the relation between the pressure (P) applied to the disc and the generated pressure (Pn) in the nucleus may be formulated as:

$$P_n = K \times P$$

Where 'K' is a constant. This constant was found to be independent of disc level, degree of degeneration, age, and geometry. The mean value of 'K' from experiments was 1.5 in a range of 1.2 and 1.8; i.e., the generated pressure inside the nucleus is about 50 percent higher than the applied vertical stress.

With regard to the stresses on the annulus fibrosus, it could be deduced that in a normal disc, due to the relatively high pressure in the nucleus, the vertical load on the annulus (Pa) is only half of the externally applied load. On the other hand, the tangential tensile stress (σ_t) in the narrow dorsal part of the annulus seems to be 4 to 5 times the applied external load per unit of area. Thus we have two formulas for Pa and σ_t in normal disc:

$$P_a = 0.5P = P_n/3$$

$$\sigma_t = 4 P = 2.7P_n$$

Table 3-6 listed the approximate values of vertical and tangential stresses on the posterior part of the annulus fibrosus in individuals weighting 110, 154, and 198 lbs respectively, and assuming different positions of the body.

The vertical stress acting on the annulus fibrosus

Table 3-6. Approximate vertical and tangential stresses on the dorsal part of the annulus fibrosus (in psi)

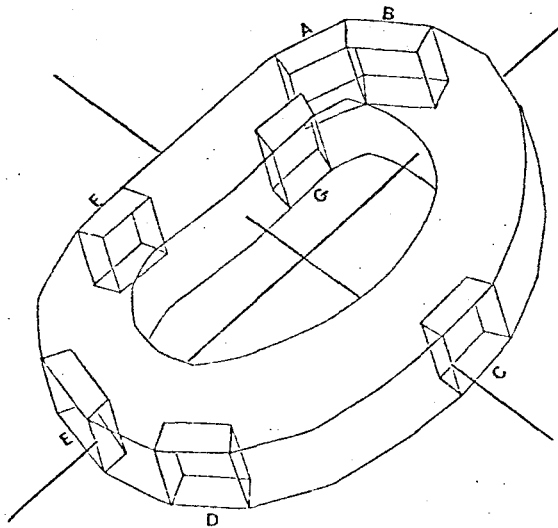
Weight of subject (lbs)	110		154		198	
Surface Area of Disc	2.33 in ²		1.71 in ²		3.10 in ²	
Position of body	Vert- ical	Tange- ntial	Vert- ical	Tange- ntial	Vert- ical	Tange- ntial
Upright sitting, unsupported	57	412	57	454	57	497
Upright standing	43	284	43	312	43	355
Reclining (lateral decubitus)	28	213	28	227	28	241
Reclining (relaxed)	14	57	14	57	14	71
Sitting + forward 20°	71	568	71	624	86	681
Sitting + forward 20° with 22 lbs in each hand	114	852	114	880	114	908
Standing + forward 20°	57	412	57	482	71	525
Standing + forward 20° with 22 lbs in each hand	86	667	86	695	99	738

is relatively low, the highest value recorded is 128 psi. However, the tangential tensile stress in the dorsal part of the annulus is high, the maximum value recorded, in the forward tilting and weight bearing position, being 1035 psi. It is possible that those high stresses play a role in the occurrence of posterior annulus ruptures.

The stresses presented above considered only compre-

Fig. 3-8 Disc used in finite element analysis

Cross-sectional area of disc	: 2.9 in ²
Anterior vertical height	: 0.4 in
Posterior vertical height	: 0.4 in
A-P disc diameter	: 1.56 in
A-P nucleus cavity diameter	: 0.81 in
Major disc diameter	: 2.25 in
Major nucleus cavity diameter	: 1.375 in



ssion of the disc. Actually, there are two other externally applied loads in everyday activity, torsion and bending. It is obvious that all of these loads may occur simultaneously.

Kraus (3) employed finite element analysis to study the stresses due to combined torsion, compression, and bending of the typical intervertebral disc. The disc under consideration is shown in Fig. 3-8, as an assembly of finite elements. For the purposes of analysis, the material behav-

our is assumed to be linear, isotropic, and homogeneous.

The disc under study was subjected to the following deformations: A uniform shortening δ (compression) of the height of disc, a flexion α in the sagittal plane, and a twist (axial rotation) β about the vertical axis. The peak stresses σ are listed along with their locations in Table 3-7.

Table 3-7. Maximum stress and its location in intervertebral disc caused by combined loadings. (in psi)

Case	α Deg.	β Deg.	δ in	Maximum Tensile Stress	Location	Maximum Compres. Stress	Location
1	0.5	3.0	0.015	151	A	221	D
2	2.0	9.0	0.015	550	B	595	E
3	8.5	0.0	0.015	470	F	696	C
4	0.25	1.5	0.015	none		141	D
5	1.0	4.5	0.015	133	G	317	D
6	4.25	0.0	0.015	193	F	390	C

Comparing these cases and Table 3-5, 3-6, 3-7 we may find the stresses increase significantly by adding bending and torsion. All these results are preliminary, however they do involve the exact shape, and they do consider the combined loading problem.

3.3. Strength and Mechanical Properties

Failure occurs when stresses in a material exceed certain limits. These limits can be determined in labora-

tory tests using samples that are of interest. Tensile failure is accompanied by tearing, compressive failure by crushing, and shearing failure by sliding and subsequent cleavage. In this section the tensile, compressive, and torsional strengths of lumbar spine, especially lumbar discs, together with their mechanical properties are presented.

3.3.1. Tensile Strength

Tensile strength tests for two discs from the same lumbar spine were performed, they are L3/L4 and L4/L5 (14). Fig. 3-9 presents a plot of the contours of ultimate tensile strength for two tested discs. The central portions are in general much weaker than the peripheral portions. While the anterior and posterior portions, being fused with and re-enforced by fibers of the anterior and posterior longitudinal ligaments respectively, are stronger. The tensile strength of the annulus ranges from 200 to 700 psi.

Typical tensile strengths of other elements were also tested. Three specimens of the ligamentum flavum from L4/L5 joint were tested, maximum tensile strengths range from 230 to 380 psi. Tensile strength of vertebral body was reported as 120 psi, this value is considerably less than that of ligaments which attach to vertebral body.

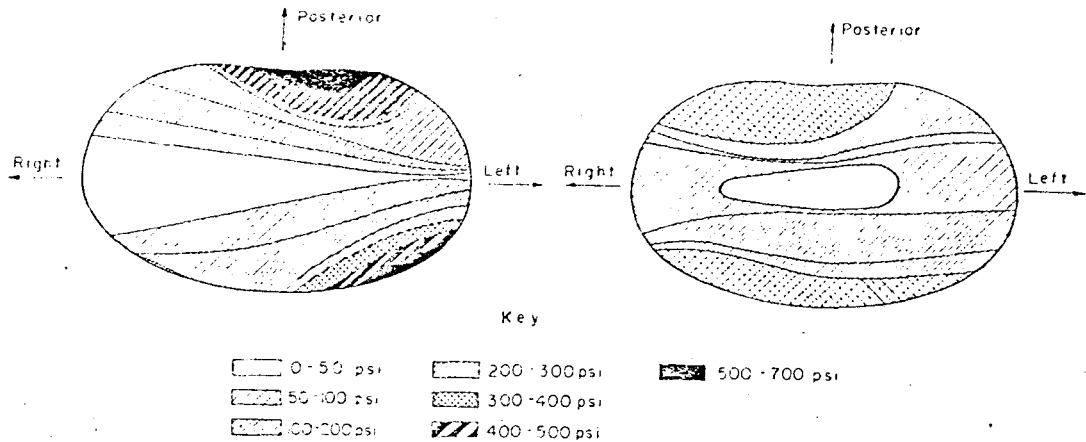


Fig. 3-9. Contours of maximum tensile strength in intervertebral discs (14).

Tensile strengths of anterior and posterior longitudinal ligaments have been measured and found to be approximately 3000 psi (14).

3.3.2. Compressive Strength

Compression tests have been performed on several different vertebra-disc assemblies. The compressive strength consistently range in between 300 to 500 psi in despite the differences of test specimens.

Virgin (15) performed tests on the discs with only thin plates of bone adjoined (Fig. 3-10, A). In his work it was found that discs could support over 330 psi. He found that at maximum loading, the deformation increased and vertical splits could be produced in the annulus, but herinations produced by compression loads were rare.

Brown (14) performed tests with specimens consisting of vertebra-disc-vertebra combination. The specimen was mounted in plaster contained within segments of copper pipe (Fig. 3-10, B). He found failures occurred at stresses between 330--430 psi. These failures were usually accompanied by fractures of the vertebral end-plate but not of the annulus.

Compression strength tests on whole disc with adjacent vertebral body halves were done by Farfan (3). The average load per unit of area at failure is approximately 430 psi which is less than the strength of the vertebral body which was found to have an average strength of 460 psi.

Fig. 3-10 Specimens used in compressive strength tests

- (A) Disc including vertebral end plates
- (B) Disc-vertebra unit with vertebra support
- (C) Disc-vertebra unit

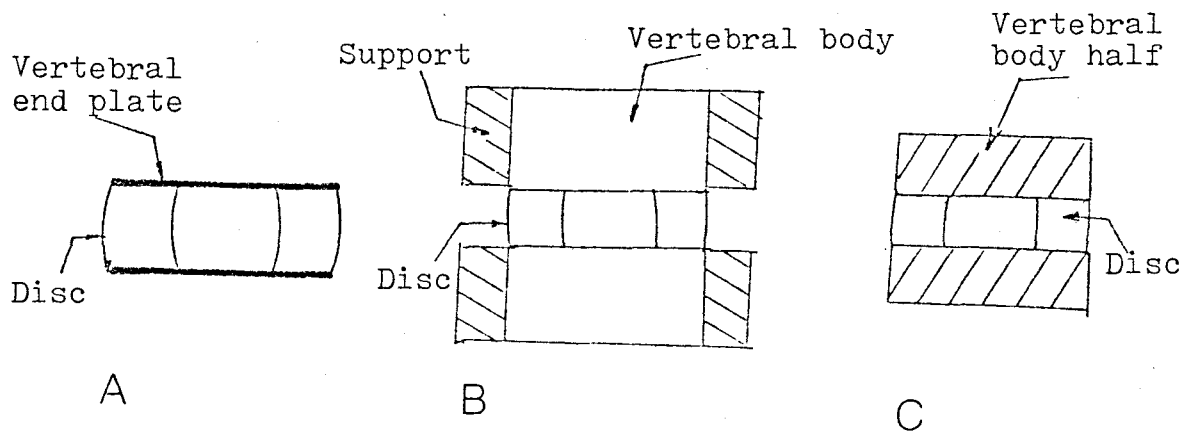
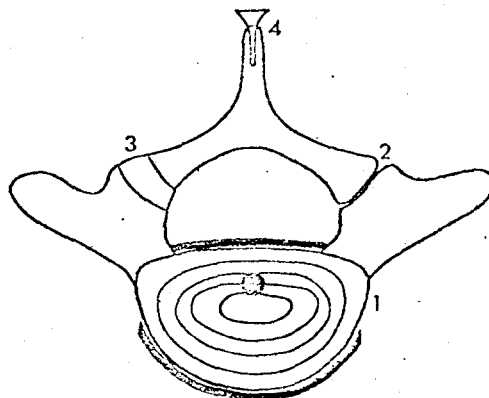


Fig. 3-11.

Members of the joint that resist torsion include:

- (1) The disc and its anterior and posterior ligaments
- (2) The bony facet articulations
- (3) The capsules of the articulation
- (4) The supraspinous and other intervertebral ligaments
- (5) The musculature.



3.3.3. Torsional Strength

The elements which determine the torsional strength of the intervertebral joint include the disc and its anterior and posterior ligaments, bony facet articulations, capsules of the articulation, and supraspinous and other intervertebral ligaments (Fig. 3-11).

The average total torque at failure for an intact whole intervertebral joint with a normal disc was found to be 750 to 900 in-lb. These results are presented in Fig. 3-12. It is also to be noted that the disc, facet articulations, and the interspinous and supraspinous ligaments contribute about the entire torsional strength. The contributions from the ligamentum flavum and intertransverse ligaments are quite small.

The normal disc contributes about 350 in-lb to the torsional strength. The degenerated disc offers much less resistance to torque. The influence of disc shape on this torsional strength is determined by its ovality ratio (major diameter/minor diameter) or its torsional section modulus. From the torsional strength formula, discs with large ovalities are weaker than the same size discs with low ovalities. The discs under this experiment consisting of 21 discs (3) have the results in line with the prediction of the formula.

The induced stress on the disc under torsion was

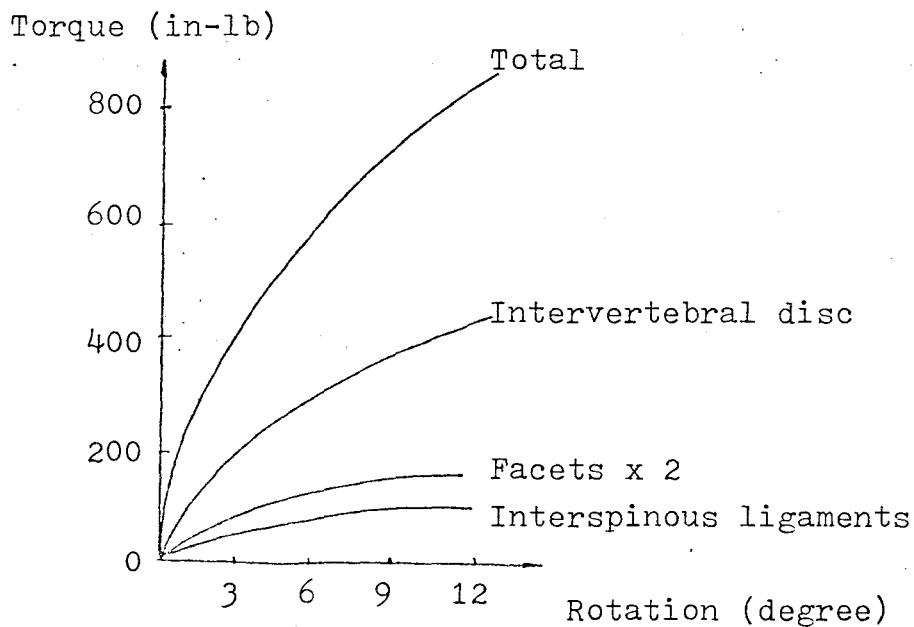


Fig. 3-12. Average values of torsional strength of various components of a normal intervertebral joint (3).

found to have a maximum value range from 200 to 500 psi.

3.3.4. Mechanical Behaviour of the Disc

In a series of experiments of the discs (15), the results showed that the intervertebral discs hold the property of elasticity to a very marked degree. This property depends largely upon the ability of the disc to absorb and lose fluid, it is in fact a viscous elasticity. Moreover, the elastic efficiency of the disc improved with use, and the energy lost during recovery become less.

To determine the stiffness--load per unit length of deformation--of the isolated disc, a representative model of the lumbar spine was constructed by Schultz (16). The stiffnesses for all lumbar intervertebral discs are listed in Table 3-8, these values are mostly consistent with the data obtained from cadavers.

Table 3-8. Stiffnesses of the isolated lumbar intervertebral discs.

Disc Level	Stiffness (lb/in)		
	Axial	Shear	Torsion
L1/L2	8940	5030	6700
L2/L3	8380	4470	6700
L3/L4	8380	4470	6700
L4/L5	7820	3910	6150
L5/S1	6150	3350	5030

Under maximum loading, cracking or splits in the annulus fibrosus appeared. They extended from the top to the bottom of the disc, but were not usually associated with herniations from within the disc. It appears that herniations of the disc material are relatively uncommon phenomena even under heavy stress. They probably occur only in discs where degenerative changes are fairly well advanced. When herniations occurred the tissue expelled through the splits in the annulus fibrosus represented only a small portion of the total contents of the disc.

4. IMPLANTATION MATERIALS FOR ARTIFICIAL DISC

4.1. General Consideration

Biomaterial must be used wisely and with proper regard to their shortcomings in order to meet the basic requirements for the particular site of implantation.

The requirements of a successful implant material are simple yet stringent. It must function for the necessary time to effect the required therapy while simultaneously avoiding such reactions with its host as might lead to damage of the tissue, or to a decrease in the desirable properties of the implant. The implant must also have adequate strength, a good serviceable life, resistance to corrosion and biodegradation, and adequate tissue compatibility.

The choice of implantation material is important to successful repair and replacement. No single material, metal or polymer, meets every necessary characteristic for successful implantation in all of the many regions where implants are used. Solids in pure elemental state do not generally possess the desired combination of properties necessary for a successful implant. Instead, most implants

are made from alloys in the case of metals, and highly polymerized chains in the case of polymers (18).

Prostheses are of standard dimensions, but they are required to fit into irregular spaces. Two methods of prosthetic fixation are possible: (1) The attachment can be of such a configuration that it can jam in the space to be fitted, and surrounding tissues will grow around it and will invade it if it is of suitable structure, or (2) The attachment can be used in conjunction with a grouting agent which hardens in the narrow cavity and mechanically locks the device in position. The first method has been proven very successful and will be discussed in the next chapter.

Generally, for joint replacements the following clinical considerations must be taken (19):

(1) The prosthesis must be sterilizable without a change in its chemical and physical properties.

(2) The properties of the prosthetic materials must not be affected by the tissue fluid and the stresses to which they may be exposed in clinical use.

(3) The prosthesis often has to withstand intermittently applied loads during its lifetime.

(4) The products of wear and/or corrosion of components must not cause an undesirable tissue response close to the implant or in more distant tissues.

(5) Prostheses must be of such dimensions that they

can be implanted in the tissues without causing undue damage to the tissues.

4.2. Silicone Rubber as the Primary Prosthetic Material

4.2.1. General

It is well known that the intervertebral discs are made up of soft tissue and soft materials must be used to replace them. A successful disc prosthesis must allow motion, and absorb the compressive stresses placed on the disc.

Scales (20) defined the properties of an ideal synthetic soft tissue as:

- (1) Not physically modified by soft tissue.
- (2) Chemically inert.
- (3) Not inflammatory or without foreign body reaction.
- (4) Noncarcinogenic.
- (5) Produce no state of allergy or hypersensitivity.
- (6) Capable of resisting mechanical strains.
- (7) Capable of fabrication in the form desired.
- (8) Capable of sterilization.

The advent of medical-grade silicone has made available a material possessing a high degree of biological acceptability as an ideal soft tissue substitute. Of all soft implant materials, the silicones appear to be the most satisfactory because they are chemically inert and cause no

inflammation or foreign body reaction. Toxicological studies conducted for Dow Corning Corp. on medical-grade silicones have revealed no significant tissue reaction from long term implantation (21).

4.2.2. Chemistry of Heat-vulcanized Silicone Rubber

Among medical-grade silicones, only the heat-vulcanizing type offer mechanical properties strong enough for the replacement of the intervertebral disc. In order to be able to bring them into full use, it is necessary to review the chemistry of this material from the original polymer manufacturing through the various stages necessary to obtain that type of rubber.

The silicone rubber used for medical purpose is compounded with polymer, filler and a vulcanizing agent. The filler gives additional strength to the polymer, and the vulcanizing agent serves to change the raw material from a plastic to a true rubber.(22).

Heat-vulcanized silicones have three commonly used grades. They cover the hardness range from soft through medium to hard, and are available under the nomenclature "Clean-grade Elastomers". They are MDX4-4514, MDX4-4515, and MDX4-4516 respectively. The compositions of raw material are listed in Table 4-1 (21).

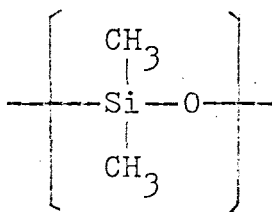
The filler used in these three compounds is very

Table 4-1. Composition of Clean-grade Silicone Elastomers

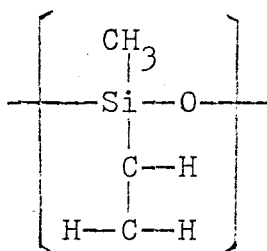
	<u>MDX4-4514</u>	<u>MDX4-4515</u>	<u>MDX4-4516</u>
Polymer	Dimethyl, Methylvinyl, & Methylphenyl	Dimethyl, & Methylvinyl	Dimethyl, & Methylvinyl
Filler	Silica	Silica	Silica
Vulcanizing Agent	0.71% Dichlorobenzoyl Peroxide	0.54% Dichlorobenzoyl Peroxide	0.54% Dichlorobenzoyl Peroxide

pure, finely divided silica to strengthen the polymers, in general the more filler being used, the harder is the resultant rubber.

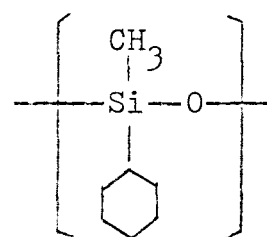
The structures of the three types of polymers being used are:



Dimethyl



Methylvinyl

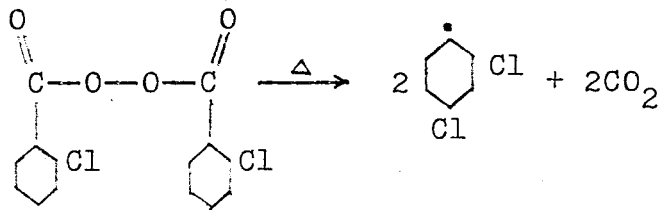


Methylphenyl

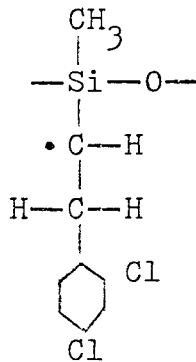
The medium and hard grades are made from a polymer composed primarily of the dimethyl type but with very small amount of methylvinyl siloxy copolymerized with it. This copolymer is used because the methylvinyl portion makes for

a more efficient vulcanization yielding a rubber with better properties.

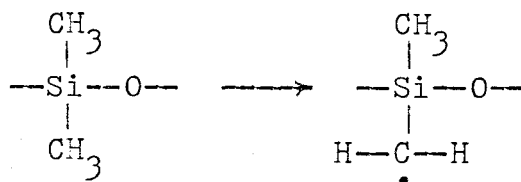
When the plastic mass containing the polymer, vulcanizing agent, and filler is heated, with temperature at 240°F (116°C), the vulcanizing agent breaks down, forming free radicals:



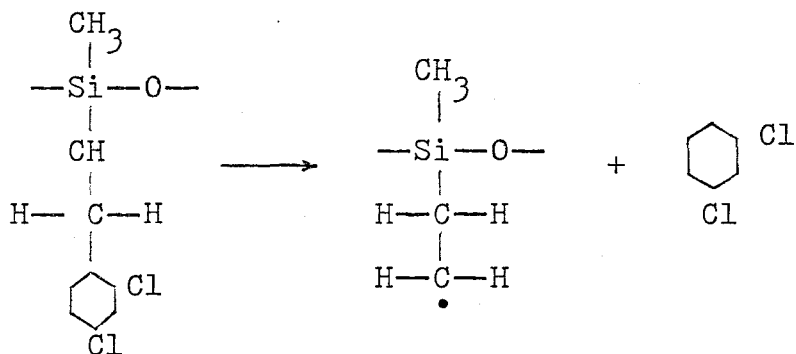
The free radicals will then add on to the vinyl group on the polymer:



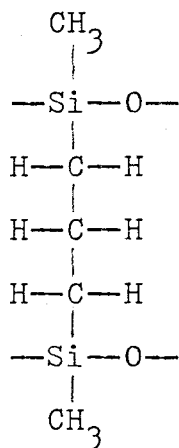
When this contacts a methyl group, it pulls off a hydrogen:



Simultaneously, the dichlorophenyl group is removed from the other polymer chain:



Now, there is an ethyl side group on one polymer chain and methyl on another, both with an unsatisfied valence. They combine and form a cross-link between the two polymer chains:



There are other reactions that take place, such as methyl-methyl cross-links, but the above is thought to be the dominant reaction.

After vulcanization a period of post cure is needed to drive off the vulcanization by-products. A properly vulcanized and cured piece of silicone rubber is composed only of the cross-linked polymer with the silica strengthening agent in it.

The polymer-filler mixtures have the consistency of putty, and filler particles are extremely small and amorphous. We can assume that the molecular distribution of the raw material mixture is homogeneous. The vulcanization change the mixture from a putty like mass to a true-rubber with permanent shape.

Moreover, from the vulcanizing mechanism described above, the cross-linking will happen in both methyl and ethyl, and in random positions in all of the three dimensions. Since the amount of molecular is so large, there is no directivity in which one can distinguish the vulcanized product. It means there is no direction factor affecting its physical properties. This is very important when we consider an implantation material, because the force acting on the disc is multidirectional, and the directions may change at any time. If the material is not isotropic, and weak in one direction, it will fail more easily.

4.2.3. Physical and Biomechanical Properties

Typical properties of Dow-corning clean-grade silicone elastomers are listed in Table 4-2.

Table 4-2. Physical properties of clean-grade silicones

Properties	Soft Grade MDX4-4514	Medium Grade MDX4-4515	Firm Grade MDX4-4516
Specific Gravity	1.12	1.14	1.23
Durometer Hardness (Shore A)	25	50	75
Tensile Strength (psi)	850	1200	1000
Elongation (%)	600	450	300
Die B Tear Strength (lb/in)	70	75	75
Brittle Point (°F)	-175	-100	-100

An important property which is not available is the fatigue limit under various loading conditions which act on the intervertebral disc. Although silicone rubber devices used for finger joint prostheses have been flex-tested for 100 million flexes without breaking (22), yet the value of fatigue limit is not given. In regard to the complicated loading condition on the discs, a great deal more study for the material to withstand dynamic loadings must be completed before accurate design can be accomplished.

Urbaniak, Bright, and Hopkins (2) develop a prosthetic replacement for the intervertebral disc. The design is a silicone centre core embedded by Dacron mesh. The

mechanical properties of this artificial disc are mostly contributed by silicones.

The discs were implanted in chimpanzees. A method was devised to test the biomechanical behaviour of the joints including compression, flexion, extension, lateral bending, and torsion. Two implanted discs that had been in place for 1 month and 10 months, together with an intact intervertebral joint from the same animal were tested. The results are shown in Fig. 4-1 -- Fig. 4-5.

Results for the disc implanted 10 months are similar to the normal disc, the results of the disc implanted 1 month suggested less mature binding. Torsional deflections are similar in all discs since this stress is primarily resisted by posterior elements. These results demonstrate that the discs made of silicone rubber can allow motions similar to the natural disc.

During its almost 20 year history in medical applications, silicone rubber has a proven record of stability and long term performance. Swanson (23) performed some experiments to determine the effect of implantation in the physical properties of silicone rubber. Dog-bone shaped silicone samples were implanted in beagle dogs, at predetermined times, the silicone rubber implants were removed and tested.

After six months of subcutaneous implantation, the

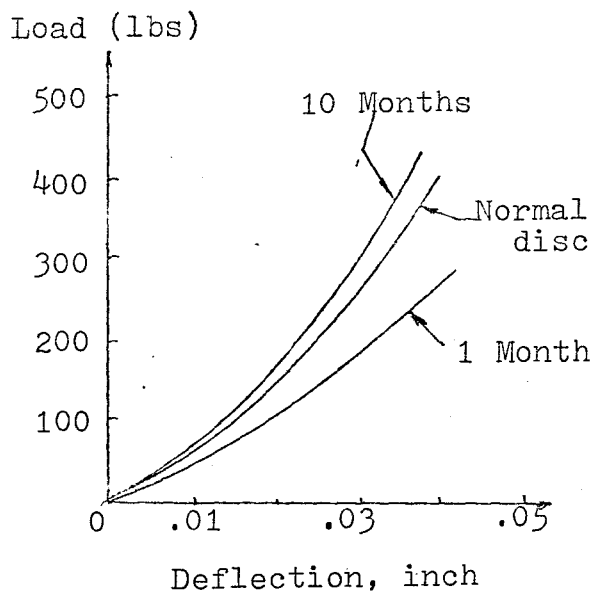


Fig. 4-1. Compression

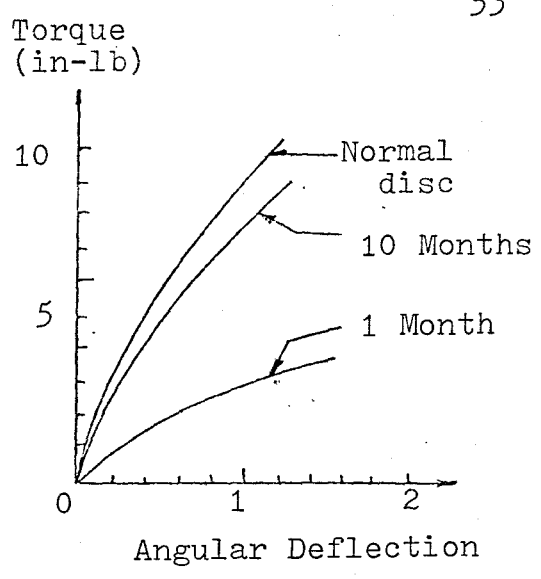


Fig. 4-2. Flexion

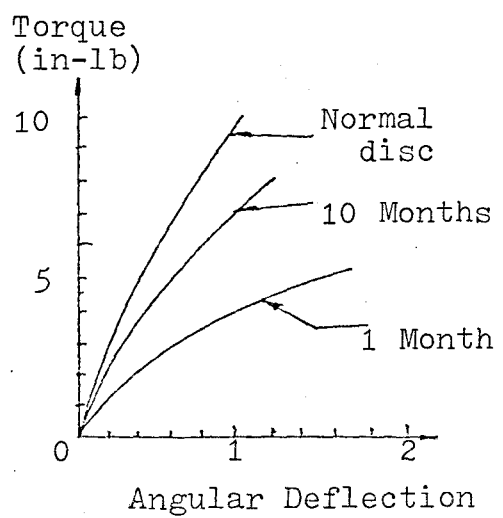


Fig. 4-3. Extension

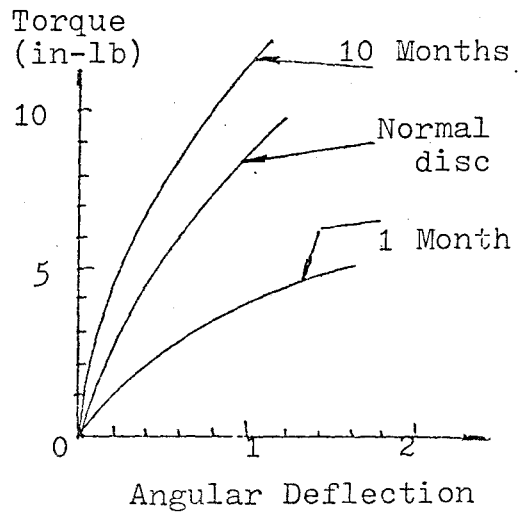


Fig. 4-4. Lateral Bending

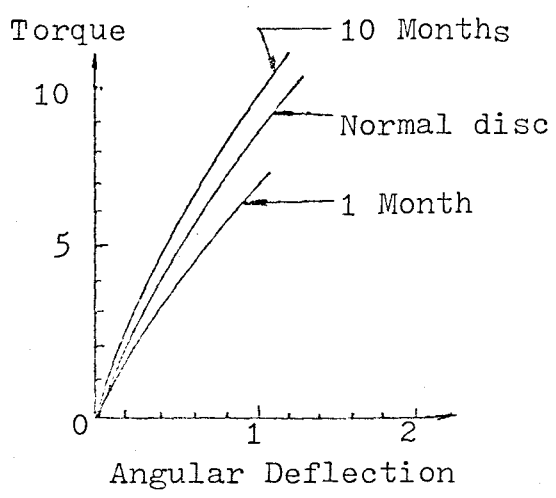


Fig. 4-5. Torsion

physical properties of medical-grade silicone rubber change, tensile strength decreased 7%, ultimate elongation decreased 10 %, and the 200 % modulus increased 8 %. A two year implant study demonstrated a further change in properties. Tensile strength decreased 8 %, elongation decreased 15 %, and 200 % modulus increased 16 %. Similar data is not available for times greater than two years. However, during its almost 20 years history, silicone rubber has a proven record of stability and long term performance.

Table 4-3 lists the physical properties of the samples after being implanted for various times. Each time group consisted of 5 samples.

Table 4-3. Physical properties of medical-grade silicone rubber as a function of implantation time (24)

Time	Tensile Strength (psi)	% Elongation	200 % Modulus (psi)
0 WKS (control)	1388 \pm 33	377 \pm 20	506 \pm 10
4 WKS	1323 \pm 68	359 \pm 3	539 \pm 29
8 WKS	1320 \pm 61	360 \pm 28	510 \pm 23
16 WKS	1352 \pm 65	373 \pm 9	518 \pm 7
24 WKS	1303 \pm 72	359 \pm 13	567 \pm 23
32 WKS	1294 \pm 13	354 \pm 6	559 \pm 21
2 Years	1285 \pm 65	332 \pm 8	602 \pm 19
Control 6 months	1392 \pm 41	392 \pm 12	516 \pm 15

Although these experiments were performed with implants in the subcutaneous environment. It should be pointed out that in an environment like the intervertebral joint, the change in physical properties are unlikely to be so large to alter the performance of the silicone rubber.

4.3. Implantation Materials for Tissue Ingrowth

One of the fundamental problems encountered in the prosthetic replacement of joint is the bonding of the implant to the connective bone for proper fixation. An open pore material into which tissue can grow should provide ideal skeletal fixation. In this section, the materials currently being considered for use in porous prosthetic devices will be evaluated. These materials include, Stainless steel, Titanium, Cobalt-Chromium-Molybdenum alloy (Vitallium), and Ceramics.

4.3.1. Porous Ceramics

Basically, a ceramic material may be thought of as a solid chemical compound consisting of a metallic element in combination with a nonmetallic element, the nonmetallic element usually being oxygen. Ceramic materials are characteristically very inert, abrasion resistant compounds which possess a well documented history as

materials of choice for applications in highly corrosive environments.

Physical properties of ceramic are listed on Table 4-4. For comparison, corresponding data for stainless-steel is also listed. Ceramics are brittle and subject to fracture. To overcome this defect, a product to provide a sufficiently strong porous material was invented by impregnating the porous substrate with an epoxy resin. Cerosium is a ceramic composite of this type being manufactured from alumina, silica, calcium carbonate, and magnesium carbonate impregnated with a liquid aromatic epoxy resin of the diepoxide O type mixed with an hydroxy aliphatic amine hardener. The desired pore size distributions were achieved by controlling the grain size of the calcium carbonate. Cerosium was designed to

Table 4-4. Physical Properties of Ceramics and Stainless steel.

Properties	Ceramic 99.75% Al ₂ O ₃	Stainless Steel
Specific Gravity	3.8	7.8
Hardness (10 ⁶ psi)	3.34	1.16
Compressive Strength (10 ³ psi)	72.5	116
Flexural Strength(10 ³ psi)	7.3	116
Young's Modulus (10 ⁶ psi)	55	29

provide physical properties similar to those of natural bone.

The potential of ceramics as biomaterials stems directly from their clinical inertness and the increased surface area associated with porous ceramics such that the ingrowth tissue will exist deep within the pores and almost completely enclosed by the ceramic material.

Ceramics would appear to offer several theoretical advantages over metals as an implant material. It has lower density, with a specific gravity of 3.8. Furthermore, it can be manufactured with any degree of porosity, thereby affording maximum opportunity for infiltrating tissues to bond firmly with them.

Cylindrical rods of Cerosium and its parent ceramic were implanted into the shaft of the tibiae of dogs (25). Push-out tests were performed to determine the stresses needed to dislodge the implants after various times of implantation. Table 4-5 lists the results, there was no significant improvement noted in the bonding characteristic after 6 months. Hence, the maximum interface strength measured was in the range of 420 to 460 psi. This strength is poor when compared with the strength obtained by porous metallic materials in the same animal tests which will be shown in Chapter 5.

Table 4-5. Results of Push-out Tests for Ceramic and Cerosium Embedded in Cortical Bone (psi).

Time (months)	0	1½	4	6
Ceramic	5	33	99	96
	8	31	99	129
	8	36	120	143
Cerosium	6	43	409	415
	8	53	447	447
	8	58	447	460

* Three specimens at each time period.

The practical applications of ceramic materials appear to be limited by their poor durability. In some experiments (25) it was determined that after prolonged implantation, the mechanical properties of Cerosium which were originally comparable to those of bone, showed a profound deterioration (Table 4-6).

Table 4-6. Results of Mechanical Tests of Ceramic-Epoxy Composite Following Implantation for Six Months (Mean Value from Five Specimens).

Physical Properties	Cerosium		% decrease
	0 Time	6 Months	
Flexural Strength (psi)	11500	6000	48%
Compression Strength (psi)	23200	15600	33%
Abrasion Resistance (Weight loss in gm)	0.201	0.323	60%

The failure of Cerosium to serve as a clinically acceptable replacement material for bone has been subsequently attributed to its pore structure, and to the in vivo degradation of the epoxy resin used to fill the pores of the ceramic resulting in loss of its "ideal" physical properties.

Although Cerosium did not prove to be a suitable replacement material for bone, substantial information has been developed on ceramic. Hench (35) has done extensive work on the surface features of bioceramic and chemistry of the tissue ingrowth mechanism. Ceramic metal composites may one day become a suitable surgical implant material with the progresses in biomaterial research.

4.3.2. Porous Metallic Material

Stainless steel, cobalt-chromium base alloy, and titanium all appear to satisfy the requirements of metals for surgical implants. Because they: (1) show adequate resistance to the corrosive forces of the body environment, (2) induce a tolerable reaction in the tissue, and (3) have the necessary mechanical strength.

Among the metal materials for use in porous prosthesis devices, titanium appears to be very favorable due to its relatively low modulus of elasticity. The

modulus of bone is 2 to 3 x 10⁶ psi and that of Co-Cr alloy is 30 x 10⁶ psi. Severe stress concentrations occur at the bone and implant interface because of this large difference in elastic modulus. Young's modulus for bulk titanium is about five times that of bone. When the titanium porous prosthesis becomes completely ingrown with bone, the elastic modulus of the composite becomes more compatible with bone, approximately 2--3 times that of bone. Therefore, the stresses around the implant can be reduced.

Table 4-5 lists the elastic modulus of titanium, Co-Cr base alloy, and stainless steel together with the estimate bound of elastic modulus of porous metal surface after tissue ingrowth. Other physical properties for these materials are also listed.

Another advantage of titanium is its lower density, 4.5 g/ml, as compared to 7.9 g/ml for steel. In implant, the weight saving means more comfort for the patient, and therefore, reduces patients' consciousness of the implant.

To date, practically every type of implant previously made with stainless steel and Co-Cr base alloy has been successfully made with titanium (27). The unalloyed grades of titanium and the 6Al-4V titanium alloy have received clinical evaluation and found to possess

Table 4-5. Typical properties of metal implant materials.

Properties	Stainless Steel	Co-Cr Base Alloy	Titanium
Ultimate Tensile Strength (10^3 psi)	90--140	95--170	55-130
Fatigue Limit (10^3 psi)	40--44	40--70	25--40
Specific Gravity	7.9	8.3--9.2	4.5
Percent Elongation	9--45	8--55	12--35
Modulus of Elasticity (10^6 psi)	29	29--34	15.1
Estimate Modulus of Elasticity for 50% Bone Composite*	8.3--12.6	8.8--15.3	6.9--8.1

* 50% porosity, assume fully ingrown with bone (26).

acceptable tissue tolerance through clinical usage.

Unalloyed titanium, grades 3 and 4, of ASTM Specification B265-58T have been specified for surgical implants in ASTM Specification F67-74 (part 47). Besides the titanium element, these materials contain small percentages (less than 1%) of nitrogen, carbon, hydrogen, oxygen, and iron.

5. PROSTHESIS STABILIZATION AND RUBBER-METAL BONDING

5.1. Porous Metal Surface for Prosthetic Stabilization

A continuing problem in prosthesis design is the fixation of implants to bone. An open pore material into which bone can grow should theoretically provide excellent skeletal fixation by virtue of the large numbers of fixation points per unit area of interface. Additionally, the modulus of elasticity and damping capacity, both very dependent on the density, can approach values of natural bone and lead to substantial reduction of stresses at the tissue-implant interface.

Three distinct methods have been used with regard to making porous metal prosthetic devices: (1) All-porous material, (2) a surface coating of porous metal on a solid base material, (3) a porous metal segment joined to a solid base material (28). In respect to the prosthesis for disc, in which only very thin metal parts are permitted, we have selected the all porous or porous coating type.

An experiment was carried out by Welsh, Pilliar, and MacNab (25), using a Vitallium (Co-Cr-Mo) substrate coated with Vitallium powders with a depth of 800 micrometers. Two kinds of pore size were used. A coarser product was

obtained by using +325 mesh powder with pore sizes ranging from 50 to 100 micrometers. The other product had pore sizes ranging from 20 to 30 micrometers. The cylindrical implants were implanted into the shafts of the tibiae of dogs. Push-out tests were performed to determine the stress needed to dislodge the implants after several months. The results are listed in Table 5-1.

Table 5-1. Results of push-out tests for specimens of porous coated Vitallium implants (Five specimens at each time period)

Pore Size	20-30 Micrometers		50-100 Micrometers	
	0 Time	4 Months	0 Time	4 Months
Push-out Stresses (psi)	48	840	149	1520
	65	927	163	1660
	74	1056	180	1680
	89	1056	230	1732
	98	1137	277	1775

This result suggests that fixation by ingrowth of tissue is sufficient to be feasible, and the resistance offered to shear stress is to some extent dependent on the pore size. Interfacial shear strength as a function of implantation time and surface condition for Co-Cr-Mo alloy implant was measured (29) and shown in Fig. 5-1. It was determined that pore diameter of 80--120 micrometers is

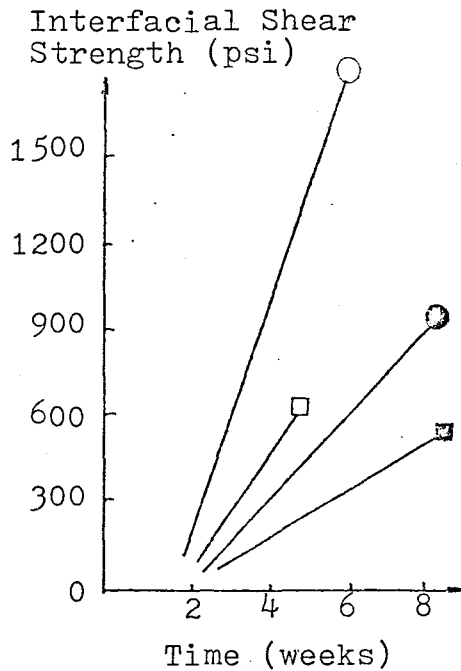


Fig. 5-1.

Interfacial shear strength as a function of time for different surface conditions (29).

- Polished surface
- Sandblasted surface
- Pore size 50-125 micrometers
- Pore size 30-80 micrometers

the most effective. And it could take 6--8 weeks to allow complete tissue ingrowth.

Titanium is regarded as an acceptable surgical implant material, particularly with regard to its excellent compatibility within the human body. Its advantages over stainless steel and Co-Cr base alloy have been described in Section 4-3. Hahn and Palich (30) performed an experiment using wrought titanium implants having porous titanium coatings. These specimens were implanted in sheep femora for periods of 14 to 26 weeks. No adverse affects were noted. Interfacial shear strengths were determined, and ranged from 1790 to 2500 psi, which indicated approximately

a twenty-fold increase over similar tests performed on uncoated control specimens. In this experiment two pore sizes were selected, one of approximately 50 micrometers and the other 75 micrometers. The density of the coating based on the observation of microstructure, appeared to range between 40 and 50 percent of theoretical.

It should be pointed out here, that the performance of the metallic porous implants which have been developed have not been tested in the region of the intervertebral joint. The advantages of this kind of device need further experimental evidence when used as a prosthesis for disc replacement.

5.2. Evaluation of Threaded Surface Implant

Although tissue ingrowth in the porous surface implants seems very satisfactory, it takes quite a long time to get a strong enough bone-implant interface. Moreover, tissue ingrowth will occur in the presence of micromovement, but not of macromovement (31) which occurs in the intervertebral joint region. The importance of this in the design of a porous surface implant is obvious. Some form of mechanical fixation must be used as an initial supplementary fixation, and this must remain rigid for at least 4--6 weeks. Nevertheless, it is much better to design an implant which can allow tissue ingrowth plus mechanical interlocking, so that it can be well attached

to bone.

An implant with fine threads providing numerous channels with a satisfactory diameter for rapid bone ingrowth would achieve satisfactory mechanical fixation. These threads should be sufficiently deep for adequate mechanical interlocking; i.e., such that shear failure would occur through the bone and not at the bone-implant interface.

A threaded surface with optimum shear resistance in any direction of the surface should look somewhat like the one shown in Fig. 5-2 (32). The average width of the tapered channels should be of the order of the optimum bone ingrowth diameter. The tips of the zig-zags should be slightly blunted, to reduce stress concentration. In addition, the depth to pitch ratio for most standard thread design is already such as to give adequate interlocking in a variety of materials and presumably also in bone.

Predecki, Auslaender, Stephan, Mooney, and Stanitski (32) prepared several different types of this kind of

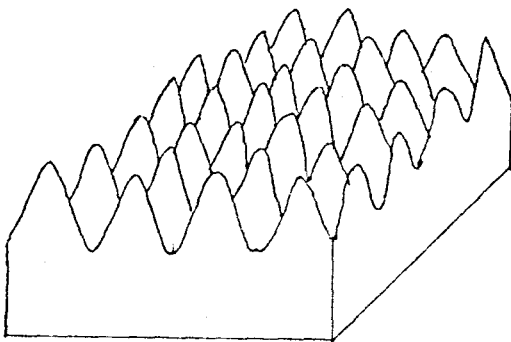


Fig. 5-2.

Schematic illustration of an implant surface with optimum shear resistance in any direction of the surface.

implant, with the type of material and thread fineness, number of threads per inch (tpi), as the main variables. Some of the specimens are listed in Fig. 5-3. They were all cylindrical, approximately $\frac{1}{4}$ " in diameter by $\frac{3}{8}$ " in length. Aluminum oxide and titanium were selected as the primary materials. The actual thread pitch was restricted by the standard threads available. A 28 pitch thread gives a width at half depth of about 400 micrometers, and with 56 tpi a width of 200 micrometers is obtained.

Samples 5 and 6 were prepared by pressing and vacuum sintering 99.92 % titanium powder into 95% dense cylindrical pellets. These were machined with sharp V-thread and lightly surface oxidized in oxygen at 590°C for 35 hr to give one micrometer oxide layer.

These samples were implanted transversely into dog femurs. Four weeks after implantation, the animals were sacrificed, and the samples removed. Metallographic examinations showed that new bone had grown in and completely filled all the threads in all the specimens. Most of the threaded push-out samples showed fracture in lines passing through the new bone from one tip to another. This was particularly so with sharp and deep threads of samples 5 and 6. The results of the push-out tests are summarized in Fig. 5-3.

With regard to the results, all the threaded

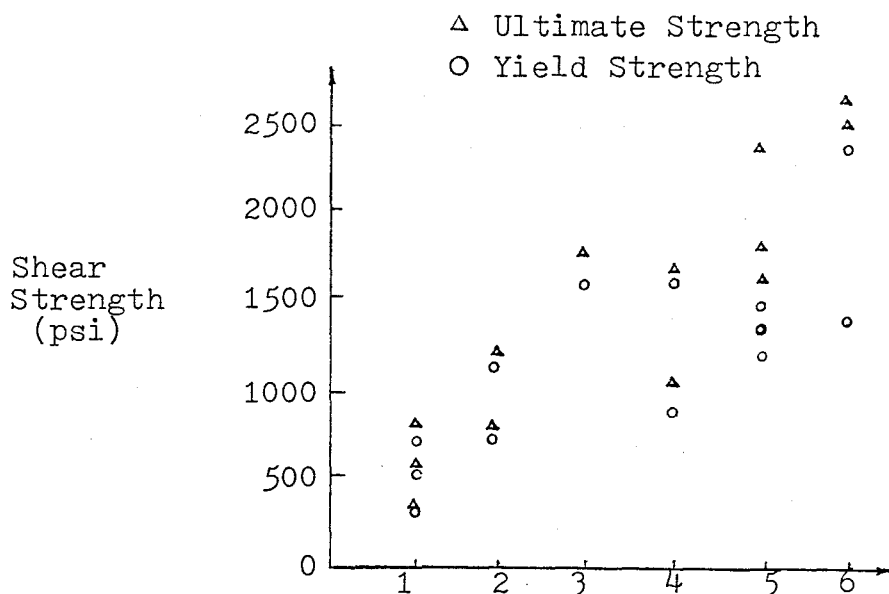


Fig. 5-3. Push-out shear strength for threaded implant after 4 weeks implantation.

- 1--Ti coated with Al_2O_3 , no thread
- 2--Ti coated with Al_2O_3 , 28 tpi
- 3-- Al_2O_3 , 29 tpi
- 4-- Al_2O_3 , 29 tpi, 4 slots
- 5--Ti, 28 tpi, surface oxidized
- 6--Ti, 56 tpi, surface oxidized

samples showed substantially higher shear strengths than unthreaded samples. Samples 5 and 6 with the sharpest and deepest threads had the highest strengths. The best titanium samples had push-out shear strength of 2000--2500 psi, these values are probably as high as can be expected and represent the shear strength of the new bone formed. There appeared to be a slight effect of the number of threads per inch, with the finer threads being

slightly superior. Since the finer threads were not as deep as coarser threads, one might expect the bone within them to be denser and more calcified and therefore are stronger at four weeks.

5.3. Basic Concepts of Rubber-to-Metal Bond

A dual structured prosthesis is now being considered for the disc which consists of a metallic surface layer on a solid substrate, with silicone rubber being considered for the solid substrate at this stage. The bonding strength between metal and rubber is very important in this design.

Practically all of the commercially available rubbers can be bonded to metal by the correct choice of bonding agent. However, proprietary bonding agents are used almost exclusively in modern manufacturing processes for bonding products, and the majority of the commercially available adhesives in use today are complex mixtures of undisclosed composition and are specific in many instances for particular rubbers and substrates. Although it is difficult to realize the nature of bond between the selected materials, it is important to understand the proper procedure and the design criteria so that a good bond strength can be obtained.

The following general procedures apply for all

adhesive system.

The substrate, thoroughly cleaned, and then coated with a thin layer of adhesive, is placed in a mould together with the unvulcanized rubber, and the vulcanization of the rubber and the bonding process are carried out simultaneously. This procedure gives by far the strongest and most consistent bond. Weaker bonds can be obtained by bonding directly to the vulcanized rubber.

There are many features to be taken into consideration when designing a bond unit. Failure to recognize any of these features would result in the premature failure of the unit. The following are the most important aspects (33).

(1) The shape should be kept as simple as possible and the rubber be as uniform in cross section as possible. Sharp difference in cross section would lead to difference in the state of cure.

(2) Sharp edges on the metal part should be avoided. They will tend to cut into the rubber and cause failure.

(3) Generous radius should be put on all corners. Sharp angles in the rubber are usually points of fatigue.

(4) Considerations should be given to what happens to the rubber under load so as to minimize stress concentration.

(5) Tolerances on the metal part should be suffici-

ently close that they will fit snugly into the mould and leave only small clearances for the flow of rubber out of mould. Thus, high moulding pressure can be used and high strength obtained.

The failure of a rubber-to-metal bond may occur either at the interface of rubber/metal or inside the rubber itself. In case of failure in the rubber during tests, the strength of the bond is obviously not measured, but is shown to be greater than the strength of the rubber itself.

5.4. Testing the Adhesion Between Silicone Elastomer and Titanium

It is very important to know the bond strength before proceeding with the prosthesis design, and data on this strength is currently not available. Here, tear strength tests were performed to determine the adhesion values between flat surface titanium and silicone elastomer.

5.4.1. Test Specimen and Method

Heat-vulcanizing silicone elastomer medium grade MDX4-4515 supplied by Medical Product Business, Dow Corning Corp. was used to bond to pure titanium (Grade 3, ASTM Specification B-265). The primer used for the adhesion is Dow Corning 2260 Primer.

To prepare the test specimen, a stainless steel

screen is laminated in silicone elastomer with approximately $1/16$ " thickness of elastomer on each side of the screen. This lamination is bonded to the titanium plate which has the size of 8" square by $1/8$ " thick. The procedures involved in preparing the specimen include:

(1) Two pieces of 8" x 7" x $1/16$ " unvulcanized silicone elastomer were preformed by hand from 0.144 pound of elastomer.

(2) The titanium plate and stainless steel screen (80 mesh, 8" x 12") were thoroughly cleaned by first degreasing with 1.1.1.-Trichloroethene, and wiping with an acetone-soaked cloth, then the surface was allow to dry completely.

(3) The titanium plate and screen were coated with Dow Corning 2260 Primer and 30 minutes were allowed for the solvent to evaporate.

(4) Starting with the primed titanium plate, the first layer of elastomer was pressed against it. Then, the screen was placed over this and a second layer of elastomer was pressed on top of the screen.

(5) This specimen was then put inside a frame with a cavity of $8\frac{1}{16}$ " x $8\frac{1}{16}$ ". A plate was then placed on top of the specimen. 4 clamp rings were used on corners of top plate to keep the cavity in uniform height.

(6) An air circulated oven was preheated to 240°F ,

and the vulcanization and bonding process were carried out for 10 minutes with temperature at $240 \pm 2^{\circ}\text{F}$.

(7) The specimen was removed from the frame, and post cured for 3 hours at $300 \pm 3^{\circ}\text{F}$.

The specimen is shown in Fig. 5-4. After vulcanization and post cure, it was kept at room temperature for 48 hours before testing. To evaluate the adhesion, the lamination was cut into 1 inch wide strips using a .1 inch wide template and a sharp knife which cut through the elastomer, screen, and hard into the metal plate. By doing this, 8 test strips were obtained from the specimen.

To test the adhesion, a sharp knife was used to cut the silicone-screen lamination free from the titanium plate for a distance of 1.5". The strip is then folded back against itself such that the screen protruded beyond the titanium plate for a distance of 1". The adhesion values were measured using the Instron Test Machine by pulling on the plate in one direction and the screen at 180° , as shown in Fig. 5-5.

Normally, the value of the adhesion to introduce failure will be higher than the pull values needed to propagate the deformation. Since the most significant value is that required to introduce failure, when the failure propagated, the strip was cut loose again for a short distance, in order to return the path of failure back to metal-silicone interface.

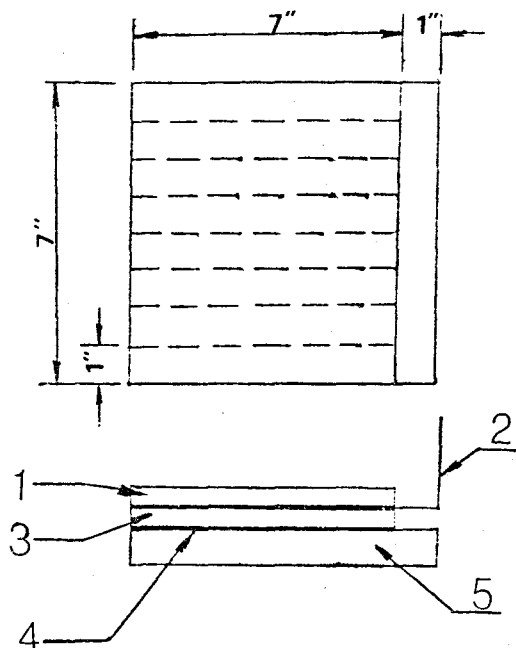


Fig. 5-4.

Specimen for adhesion strength test.

- 1, 3-- Silicone elastomer, 8" x 7" x 1/16".
- 2-- Stainless steel screen, 8" x 12" x 80mesh.
- 4-- Titanium-Silicone interface, applied with Dow Corning 2260 primer.
- 5-- Titanium plate, 8" x 8" x 1/8".

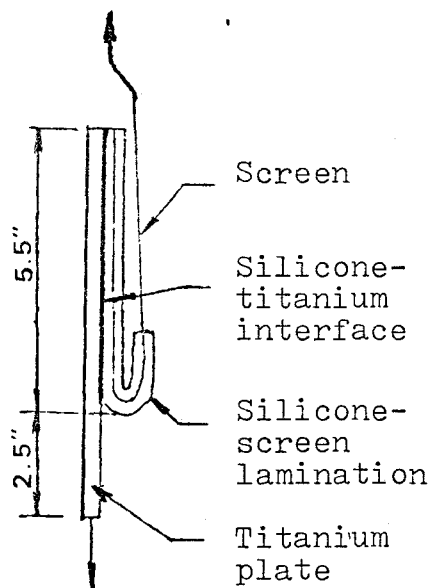


Fig. 5-5.

To test the adhesion strength, pulling on the plate in one direction and the screen at 180°.

5.4.2. Results

There were 8 test strips cut from the specimen. The strips at left and right ends (No. 1 & 8) were used for setting up the testing machine. The results for the other 6 strips were recorded. In this type of testing, the test values are reported as pounds per inch strip.

The results for strips No. 2 to No. 7 were recorded and listed in Table 5-2. When the failure begins to propagate, the strip was cut loose for a distance of about 0.1". A typical load-deformation curve is shown in Fig. 5-6.

Table 5-2. Results of adhesion strength test.

Strip No.	Pull Force to Introduce Failure		Failure Location
	Range (lb/in)	Average (lb/in)	
2	21 -- 23	22	
3	16 -- 19	18	
4	16 -- 26	19	All in the Silicone- Titanium Interface
5	17 -- 23	20	
6	18 -- 22	19	
7	18 -- 27	22	

5.4.3. Discussion

The results from this test show that the load to introduce failure falls in the range of 16 -- 27 lb/in, with an average of 20 lb/in. Without exception all the

Full load : 50 lbs

Cross Head speed: 0.5 in/min

Paper speed : 1 in/min

↓ --Cut loose for a short distance

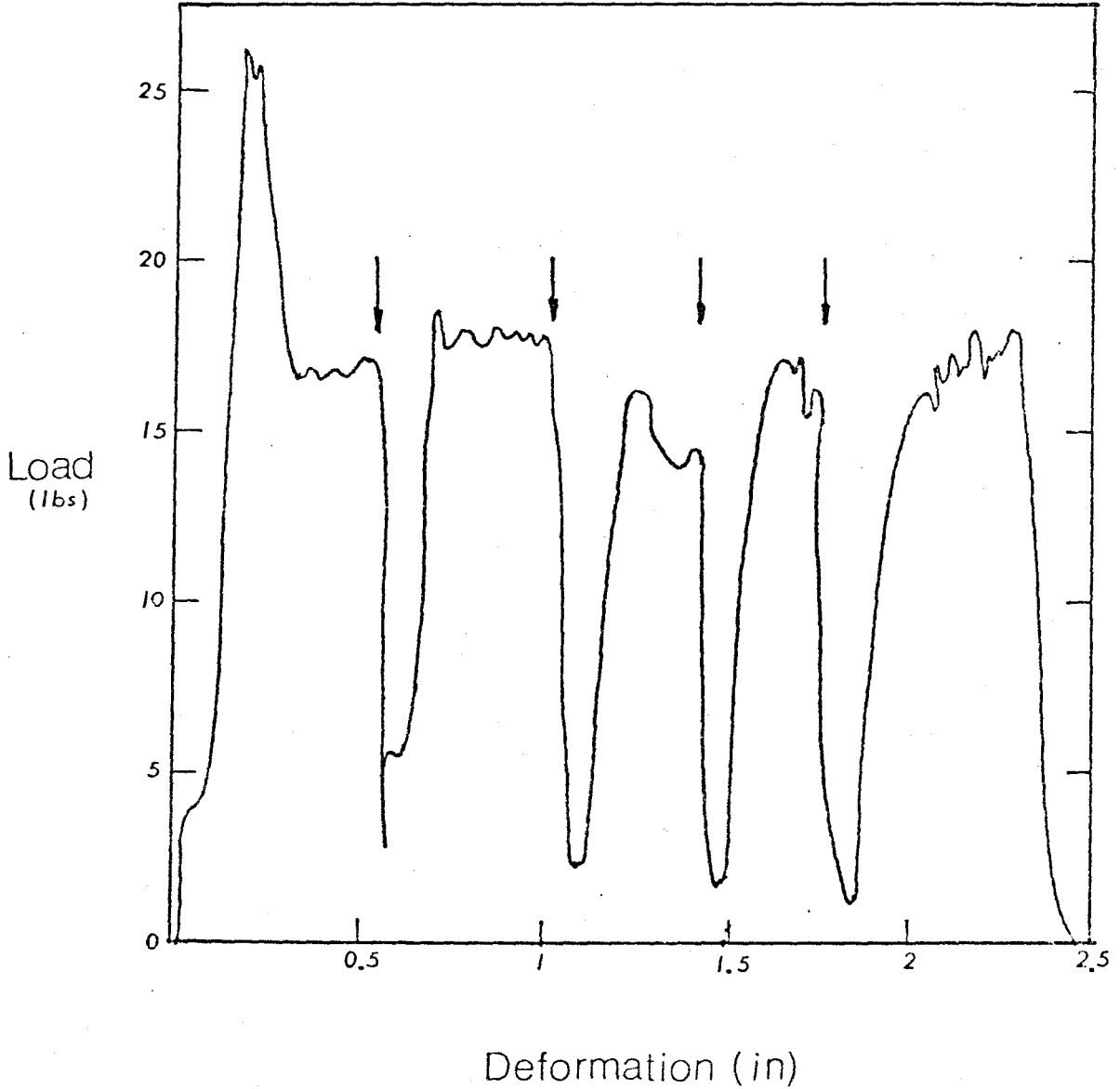


Fig. 5-6. Load-deformation curve for strip No. 4.

failures happen in the interface between titanium plate and silicone elastomer. Under ASTM D624 Die "B" tear strength test, silicone elastomer MDX4-4515 has a tear strength of 75 lb/in. Although the two test methods and specimens are not quite the same, but both of them do represent the loads needed to introduce failure.

The adhesion strength may be increased by improving the bonding condition-- by the following : use a more precise mould, apply high pressure during vulcanization process, prepare more uniform preforms, etc.. However, under all these conditions, the silicone-titanium bond is unlikely to have such a improvement that the failure will transfer from interface into rubber itself.

In order to obtain a bond greater than the strength of the rubber itself, a surface with certain degree of roughness should be developed such that some kind of mechanical interlocking will exist in addition to the adhesion provided by the primer.

6. PROPOSED DESIGN

Although it is difficult, it is surgically feasible to remove the disc with a lesion and insert an artificial disc from either an anterior-lateral or posterior-lateral approach. Some basic proposed designs are presented here based on the above studies. Further laboratory and animal tests have to be completed before accurate design engineering can be accomplished.

6.1. Construction of the Prosthesis

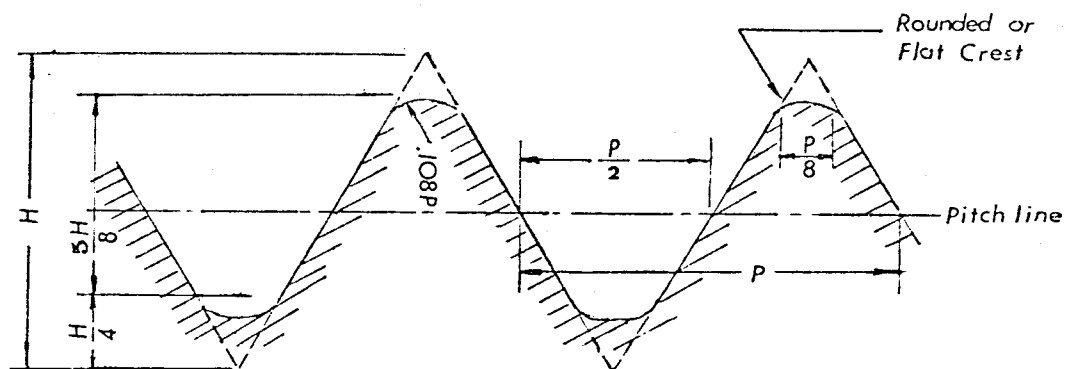
The primary design of the artificial disc is a dual structured prosthesis which consisted of a soft centre part assembled between two metal surfaces. The material for the central portion must have physical properties similar to the natural disc to allow motion, and absorb the stresses placed on the intervertebral joint. As described in Section 4.2, silicone elastomer performed quite satisfactory in this aspect. Other biomedical polymers, i.e., polyether urethane or polyester urethane, which have somewhat similar properties shall also be considered.

The purpose of metal portions is to provide an implant vertebrae interface which can stabilize the implant

by allowing tissue ingrowth. Tissue ingrowth into porous surfaces is being proven to be a very satisfactory method of fixing prosthesis, but some form of initial fixation must be utilized to keep relative motion to a minimum for the initial 4--6 weeks. Mechanical devices such as pins or screws may be used to attach the implant to vertebra, but this will reduce the strength of vertebral body which already has relative low strength compared to other rigid body tissue*. There have been instances of vertebral body fracture. In addition, the design requires to keep the metal portion as thin as possible makes the attachment of the prosthesis difficult. This requirement is necessary to allow sufficient thickness for the elastic element to provide a modulus equivalent to that of the natural disc.

An implant with a fine threaded surface will embed itself into the vertebral bodies above and below, it will provide a form of mechanical interlocking, and can be well attached to the bone. Thus the surface of the metal portion will look some what like Fig. 5-2. The standard screw thread (Fig. 6-1) is assumed to give adequate interlocking at this stage. An implant surface with 28--56 threads per inch (tpi) has been shown to be very satisfac-

* The lumbar vertebra has tensile and compressive strengths of 540 and 770 psi, whereas bones of arm and leg are in the range of 20000 psi.



$$H = 0.866 P$$

Fig. 6-1. Unified and American external screw thread

tory (Section 5-2) when implanted transversely in dog femurs. However, thread fineness for optimum tissue ingrowth and implant fixation needs further laboratory tests. Table 6-1 lists some thread data which is pertinent to the design for thread finenesses from 28 to 72 tpi.

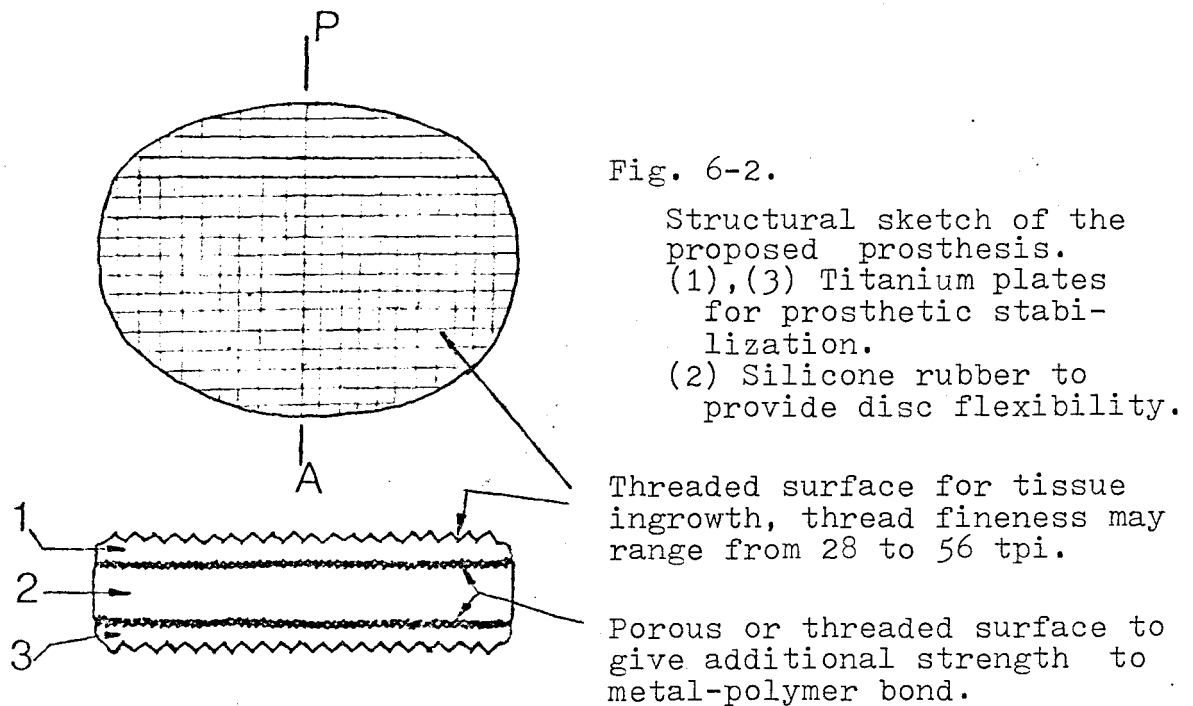
Table 6-1. Thread datas for finenesses from 28 to 72 tpi (in micrometers).

Threads per inch	28	36	44	56	72
Pitch of Thread (P)	907	705	577	453	352
Height of Sharp V-Thread (H)	785	610	500	392	304
Effective Height (5/8H)	490	381	312	245	190

While the outside surfaces of two metal plates of the prosthesis are treated to form satisfactory implant-bone interfaces, the inside surfaces need to be bonded to the polymer central portion. The bonding strength must have a value no less than the polymer under various loadings.

Because an adhesive alone is unable to form a sufficient metal-polymer bond, some kind of mechanical interlocking must be developed. Based on the same phenomena as tissue ingrowth, elastomer penetrated into a porous or threaded surface will obviously provide additional strength to the metal-polymer interface. Sufficient pressure must be applied before and during the vulcanization process. The performance of a porous or threaded surface and its optimum size shall be determined under the simulated loadings which are supposed to act on the intervertebral discs, and if possible all the different loadings shall be acting simultaneously. Fatigue will also be a very important consideration.

In concept, the prosthesis will be made up of two thin metal plates and a polymer central core, and bonded together in a mould during the vulcanization process. The metal parts will be kept as thin as possible to give the prosthesis maximum flexibility. A metal part with a total thickness of 2.5 mm (2500 micrometers) will allow



an outside threaded surface and an inside porous or threaded surface, with up to 28 tpi or up to an 800 micrometers porous coating which has proven to be sufficient. When the disc material is totally removed, there is an average cavity height of 10 mm (Fig. 6-3) which will be the average thickness of the prosthesis. A sketch of the proposed artificial disc structure is shown in Fig. 6-2.

6.2. Proposed Designs for Different Vertebral Levels

Selection of an improper size of the implant is an important factor which will likely contribute to the failure and breakage of a polymer implant. Because the

configuration of lumbar discs are different from one level to the other and from individual to individual, it becomes necessary to fabricate a wide selection of prostheses to fit the disc spaces.

A statistical analysis of lumbar disc lesions in 1000 consecutive cases has been done by Finneson (5). 31 patients had midline lesions with no lateralizing preponderance of symptoms. Of those who had lateralizing symptoms, 540 were left, and 360 were right. The levels affected were as follows:

L5/S1 =516

L4/L5 =218

L5/S1 and L4/L5 =243

L3/L4 =16

L2/L3 =3

L1/L2 =2

T12/L1 =2

99.7% of the lumbar disc disease were found in the L4/L5 and/or L5/S1 level. The lesions found in the upper level are rare.

The lateral view of the lower lumbar spine is shown in Fig. 6-3. The cavities are of irregular shapes after the disc materials have been removed. Because of the difficulty of fabrication and stress concentration caused by irregular cross-section, it is unrealistic to

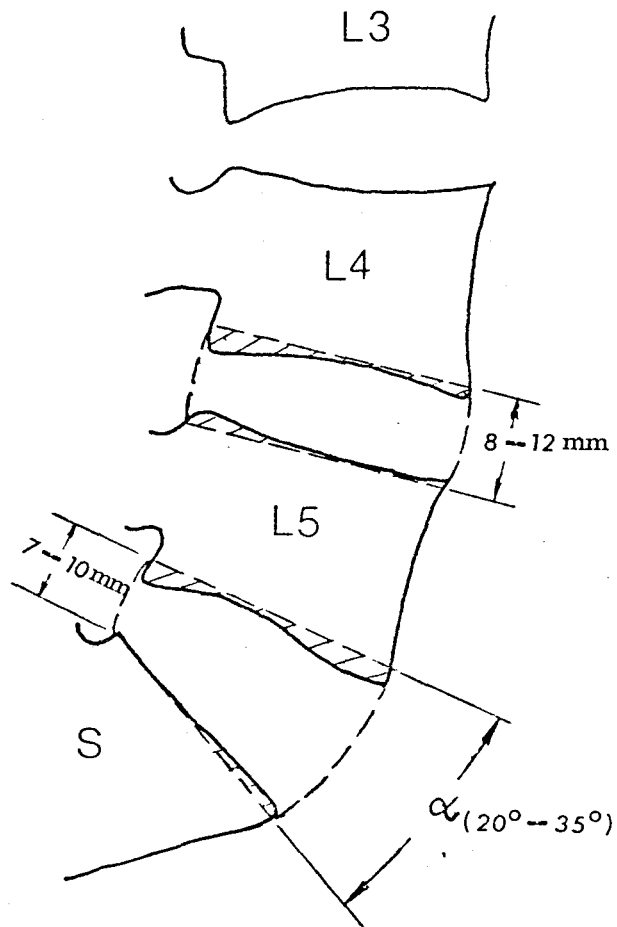



Fig. 6-3.

Lateral view of the lower lumbar spine.

The vertebral bodies above and below the disc are cut so that a simple shape of prosthesis can be fitted.

 Vertebral body which will be removed

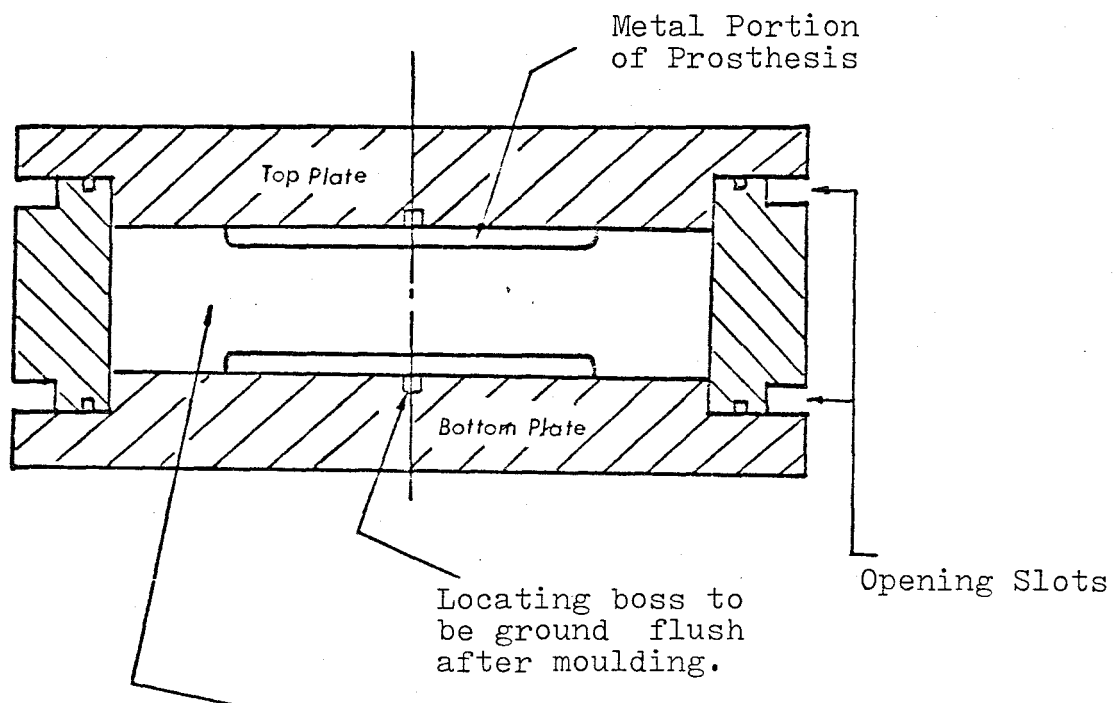
design the prosthesis to fit the particular cavity exactly. It is feasible to cut the vertebral bodies above and below the disc such that a more simple and regular shape of prosthesis can be fitted, as shown in Fig. 6-3. A special cutting tool can be designed that will cut exactly the correct space between the vertebrae, and will be simple and safe to use.

Two designs are proposed here, one for the L4/L5 disc, and another for the L5/S1 disc. Because of the difference in disc shape between L4/L5 and L5/S1 produced by the natural lumbar curve a prosthesis which properly fits the L4/L5 space is generally improper for the L5/S1 space.

In all designs the two metal portions are prepared in accordance with section 6-1. These metal plates are then machined into the desired shape which may have either round, flat, or re-entrant contour. These metal plates are actually smaller than the prosthesis by 2--3 mm, such that the periphery of the implant is free of metal.

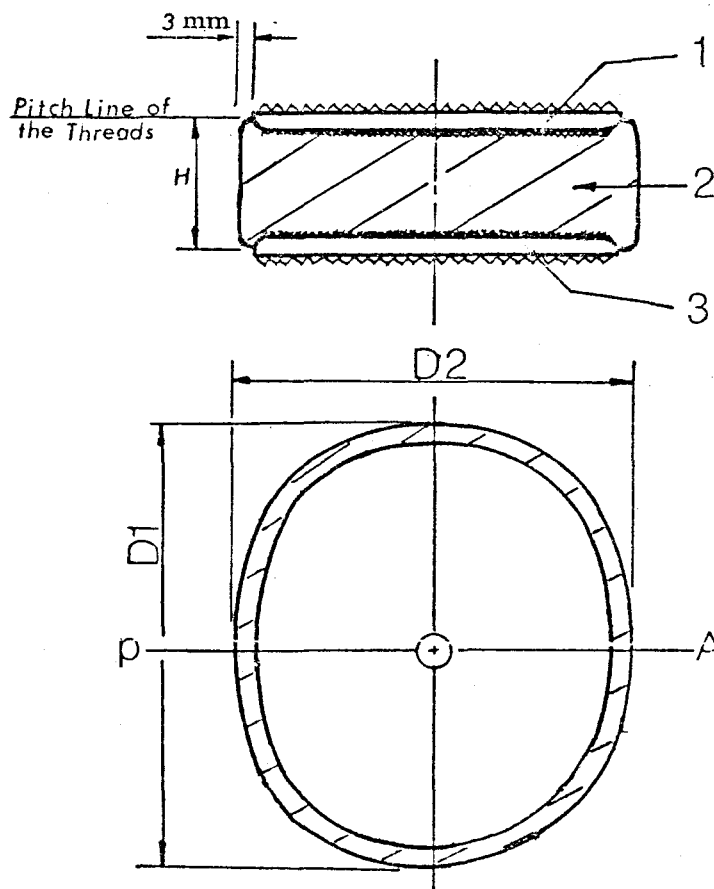
The average posterior height of the L4/L5 disc is about 10 mm, and the difference in height from anterior to posterior in L4/L5 level is about 10%. By removing a small portion of the vertebrae, a parallel space between fourth and fifth vertebrae can be prepared. The proposed design for the L4/L5 disc which is rectangular in lateral view is shown in Fig. 6-5.

The cavity of the mould is cylindrical with diameter larger than the maximum major diameter of the disc obtained from anatomic data. A diameter of 70 mm (2 3/4 in) will be sufficient (Fig. 6-4). The excessive portion of the polymer can be removed very easily by using a sharp knife. Fig. 6-5 show the



Cylindrical mould cavity in a compression-plunger mould. With diameter = 70 mm, and height in the range of 8 to 12 mm.

Fig. 6-4. Compression-plunger mould used to produce artificial prosthesis for the L4/L5 and upper lumbar discs.



Lateral View

$H = 8--12$ mm

Top and Bottom View

$D1 = 50--60$ mm

$D2 = 35--45$ mm

Fig. 6-5. Proposed design of prosthesis for the L4/L5 and upper lumbar discs.

- (1), (3) Metal with surface prepared as shown on Fig. 6-2.
- (2) Silicone elastomer.

finished prosthesis with the outside surfaces of the polymer flush with the pitch line of the thread of outside metal surfaces.

Several moulds, each with different cavity heights, will be needed in order to cover the thickness range of normal L4/L5 discs which vary from 8 mm to 12 mm. It is worthwhile to note that although this prosthesis is designed for the L4/L5 disc, if disc replacement in the upper level is needed, it can also be used following the preparation shown in Fig. 6-3.

Because of the large difference between anterior and posterior thicknesses of L5/S1 disc, the basic design of the prosthesis for the L5/S1 disc has a trapezoid shape in lateral view. The mould cavity is also cylindrical but with tapered surfaces as shown in Fig. 6-6, (A). The mould shall be designed to hold the metal plates in various positions, so that prostheses with different thicknesses can be prepared from the same mould when we change the positions of the metal plates. The polymer is removed as described above, and the finished prosthesis with the angle of tapered surfaces = α is shown in Fig. 6-6, (B), (C). In this design several moulds each with different tapered angle are also needed to cover the range of the angles between the fifth lumbar vertebra and the sacrum which vary from 20° to 35° .

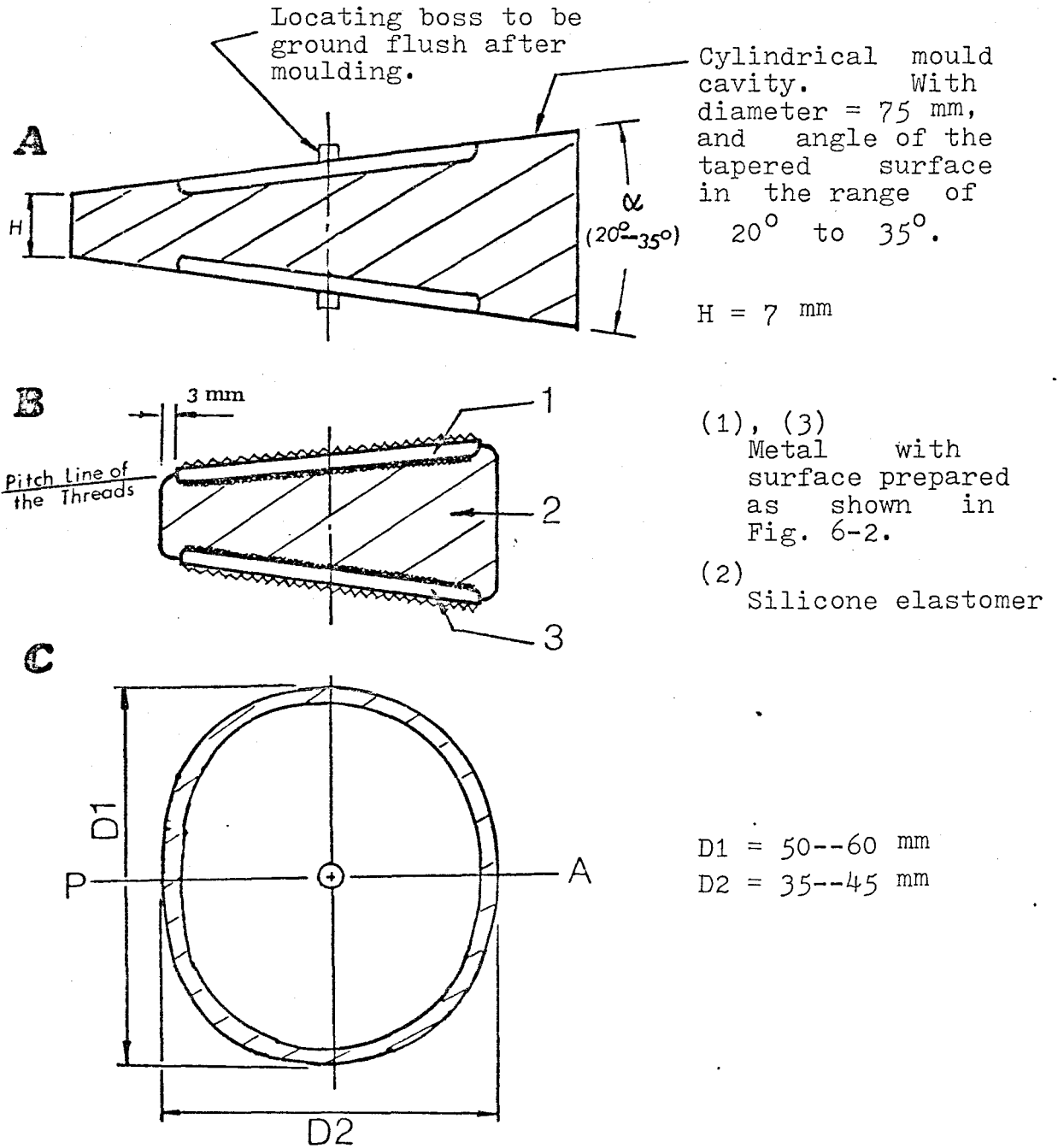


Fig. 6-6. Proposed design of prosthesis for the L5/S1 disc.

(A) The cylindrical mould cavity with tapered surfaces.

(B) Lateral view of the prosthesis, with angle of the tapered surfaces = α .

(C) Top and bottom view of the prosthesis.

6.3. Alternative Designs for Initial Fixation

Initial fixation to keep the prosthesis in position for a minimum of 4--6 weeks to allow sufficient tissue ingrowth is very important in the artificial disc design. Some alternative designs of the implant surface based on the structure described in Section 6-1 are proposed.

The first design is a threaded surface coated with a thin layer (0.3--0.5 mm) of porous titanium. For the 28 tpi surface, the effective thread height is 0.5 mm, as shown in Fig. 6-7, (A). Clinical evaluation is needed to determine whether these threads can provide sufficient fixation, because they can only embed into the bone for a depth of 0.2--0.4 mm.

The second design is shown in Fig. 6-7, (B), which has 4 sharp nails on the metal surface and coated with a 0.6--0.8 mm layer of porous titanium. The height of the nails are 10 times that of the 28 tpi thread. These nails will provide more firm fixation, and if necessary the number of nails can be increased. This alternative design with protrusions on the surface can be placed inside the disc cavity by pulling the vertebral bodies apart for a required distance with a special set of tools.

The third design is an all porous titanium plate with a large protrusion on the surface. As shown in

Fig. 6-7. Alternative designs of metal surface to allow tissue ingrowth and provide initial fixation (all drawings are not in scale).

- (A) Threaded surface with 28 tpi, then coated with 0.3--0.5 mm depth of porous titanium.
- (B) Porous metal surface with 4 sharp nails to provide firm fixation.
- (C) A all porous metal with a large protrusion to fit into the vertebral body.

A

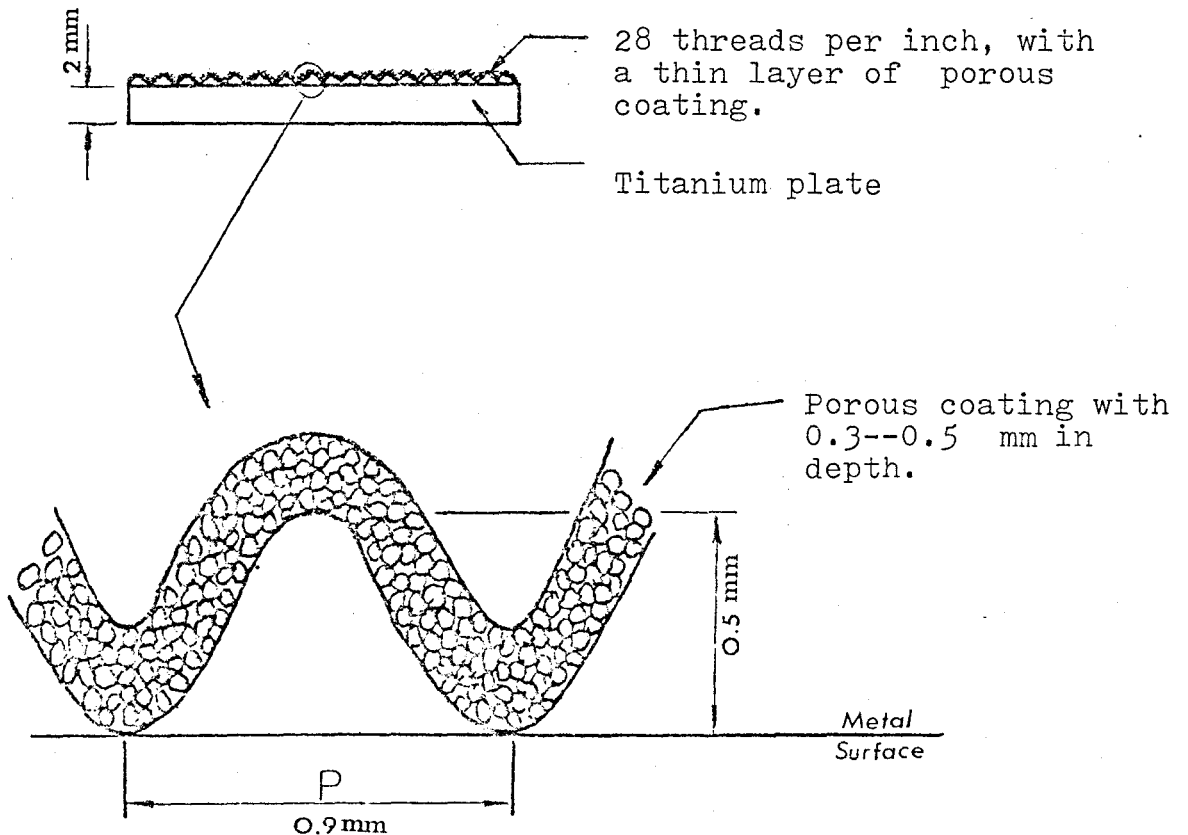


Fig. 6-7

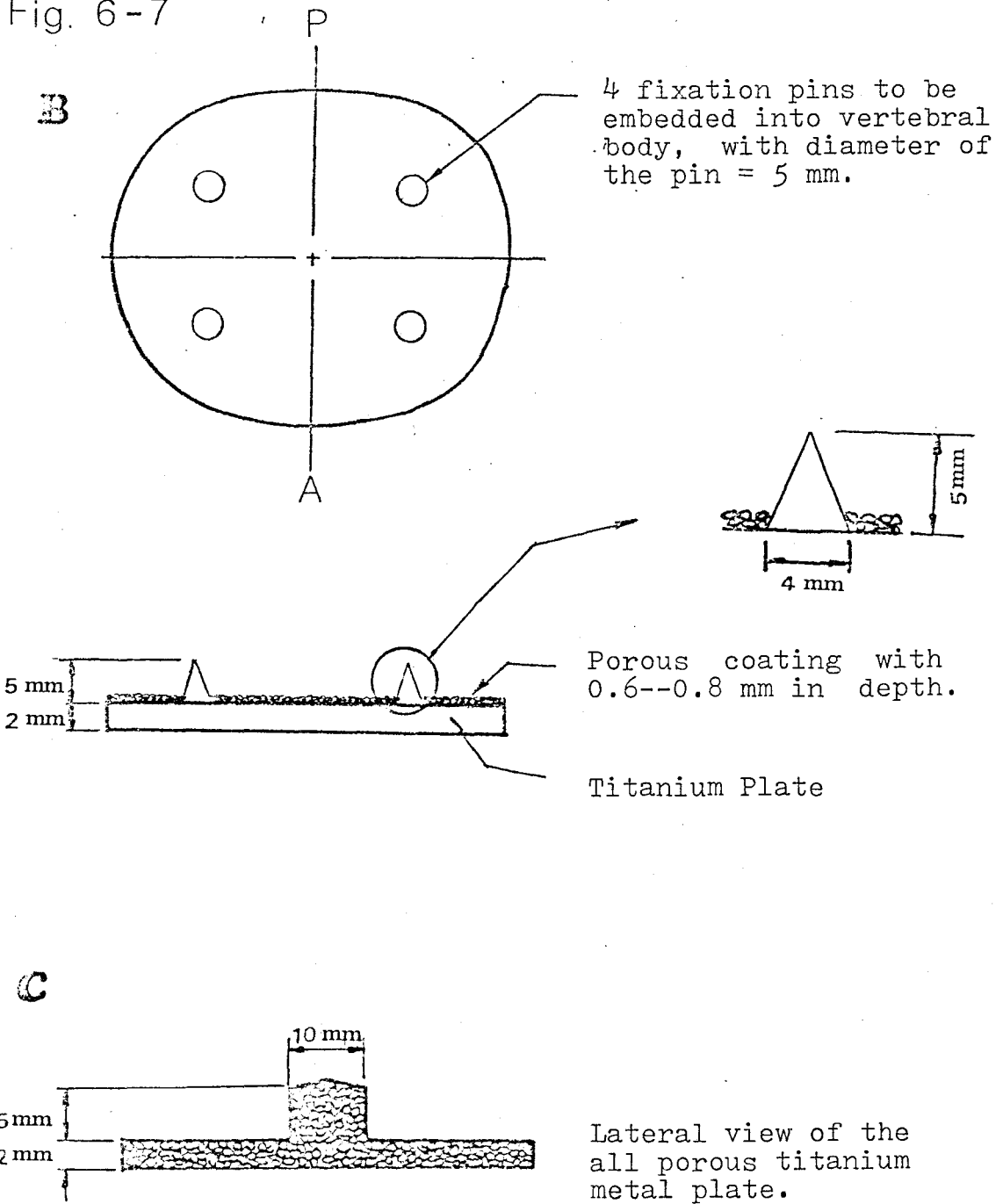


Fig. 6-7, (C). This surface will provide more mechanical interlocking because the intervertebral disc is constantly subjected to compressive loading. However, it is necessary to remove a small portion of vertebral body to form a cavity which can fit the implant, and again a special tool will have to be designed to accomplish this.

7. CONCLUSION

Great success in the developments of artificial joints for many regions of human body in past years has encouraged this study of the replacement of joints or joint portions to alleviate lower back pain. The study has been concentrated on the disc, since from past research and medical practice it is fairly obvious that the intervertebral discs present the most common problems.

Further study on the biomechanical properties of the lumbar spine is necessary to obtain a knowledge of the requirements of artificial materials. This study will also help in understanding other spine disorders, such as scoliosis.

A successful artificial disc must maintain the flexibility of the intervertebral joint and this calls for soft material. The overall axial stiffness should be in the order of 8500 lb/in. The dynamic strength of the elastomer used under various loadings which occur on the disc is yet to be determined. Surgical procedures must be carefully planned and executed and a set of specially designed tools for each specific implant must be provided

to avoid the factors most likely contribute to the failure of the polymer implants, which include: (1) failure to correct subluxation of the joint, (2) failure to properly release contractures, (3) insufficient joint resection, (4) unsatisfactory preparation of the space in which the implant fits, (5) rotation of the implant during the operation process, and (6) selection of an improper size of the implant.

Titanium shows some advantages over stainless steel and Co-Cr base alloys for the metal portion of the artificial disc. The metal portion must be kept as thin as possible, because it is only for the purpose of prosthetic stabilization. The polymer-metal bond strength provided by primer is obviously not strong enough so that porous or threaded surface on the inside surface of the metal is proposed.

A radiographic examination will need to be done before an operation to obtain the shape and height of the disc, and the procedure needed for the preparation of the disc cavity. In the proposed designs, different shapes of prostheses can be produced from the same mould, although about 50% of the polymer is going to be lost. A total of 10 moulds will be sufficient to produce all the prostheses of different shapes for all the levels in lumbar spine. This is not only time-saving, but also economic

because the primary cost of the prosthesis is not the material but the expense for the construction of the mould.

8. SUGGESTIONS FOR FUTURE WORK

Following the outcome of this preliminary study, a great deal of work must be completed before accurate prosthesis design can be accomplished for clinical evaluation.

To ensure the material used can perform similarly to an intact disc, tests to determine the mechanical behaviour of silicone elastomer and other polymers shall be done. These tests will include static load vs deformation, deformation vs time with load held constant (creep), and load vs time with displacement held constant (load-relaxation) etc., and a comparison of the results with those which have been obtained from experiments performed on the intact discs.

Toxicological information of the primer used to bond metal to polymer must be obtained before clinical use to ensure it will be safe and efficacious. By all means, the bonding strength of the metal-polymer interface must be proven stronger than the polymer itself.

The artificial disc obviously must withstand static and dynamic loadings and have factor of safety appropriate to the disc it replaces. To determine

the fatigue strength of the proposed prosthesis, specimens which may have more regular and simple shape shall be built. In addition, equipment shall be set up to simulate the loadings which may act on the intervertebral joint. These loadings which include compression, bending, and torsion will need to be applied simultaneously.

Special tools and jigs are inevitably needed for the operative procedure. Animal tests are also necessary to determine the optimum thread fineness or pore size for tissue ingrowth in the disc area, the effectiveness of initial fixation provided by threaded surface, and the effect of implantation on the animal.

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