MEASUREMENT OF PRESSURE DISTRIBUTION IN THE HUMAN HIP JOINT

by

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Submitted to the Department of Mechanical Engineering on May 22, 1967 in partial fulfillment of the requirement for the degree of Master of Science.

ABSTRACT

It is desired to measure the magnitude and distribution of pressure acting on the load-bearing cartilage surfaces in the human hip joint. The pressure measurement is to be accomplished by replacing the upper portion of the femur in the hip socket by a suitably instrumented prosthesis. Pressure transducers located on the spherical portion of the prosthesis will measure the spatial and temporal pressures acting on the joint surface. A self-contained miniaturized multiple-channel transmitter located inside the hollow sphere of the prosthesis is to be used to transmit the electrical signals produced by the transducers to externally located data recording equipment.

The present study investigates the feasibility of the proposed method of measuring pressure in the human hip joint and presents a design for a suitable pressure transducer.

The results of this study indicate that it is feasible to measure pressure in the hip joint by the proposed method. Integrated circuit technology is sufficiently far advanced to make possible the design and construction of a multiple-channel transmitter dimensionally small enough to be located inside the prosthesis. A spherical diaphragm pressure transducer utilizing a semiconductor strain gage as the mechanical to electrical conversion element is capable of providing adequate sensitivity and linear response.

Thesis Supervisor: Robert W. Mann
Title: Professor of Mechanical Engineering

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Special thanks are also due Mr. R. B. Melton for his assistance in the construction of parts of the test apparatus.

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CHAPTER I

INTRODUCTION

Knowledge of the magnitude and distribution of pressure on the mating surfaces of the human hip joint is of considerable importance to several current research areas. Information on the distribution of pressure would make possible the comparison of the patterns of deterioration of the joint surface with the areas of the surface that are subjected to the greatest pressures, and this information would materially improve the understanding of the pathophysiology of arthritis. The lubricating mechanism of joints is not fully understood, and knowledge of the magnitude of the pressure developed between the sliding surfaces of the hip joint would contribute to a better understanding of joint mechanics. Knowledge of the spatial and temporal pressure distribution in the joint is also of importance in the study of human gait and locomotion, and this information could play a significant role in the design of replacement prostheses. Furthermore, the techniques developed to study the hip joint and the data obtained from such studies could be applied to the investigation of other joints.

The purpose of this investigation is to determine the feasibility of measuring the magnitude and distribution of pressure in the human hip joint and specifically to develop a pressure transducer suitable for use in the hip joint.

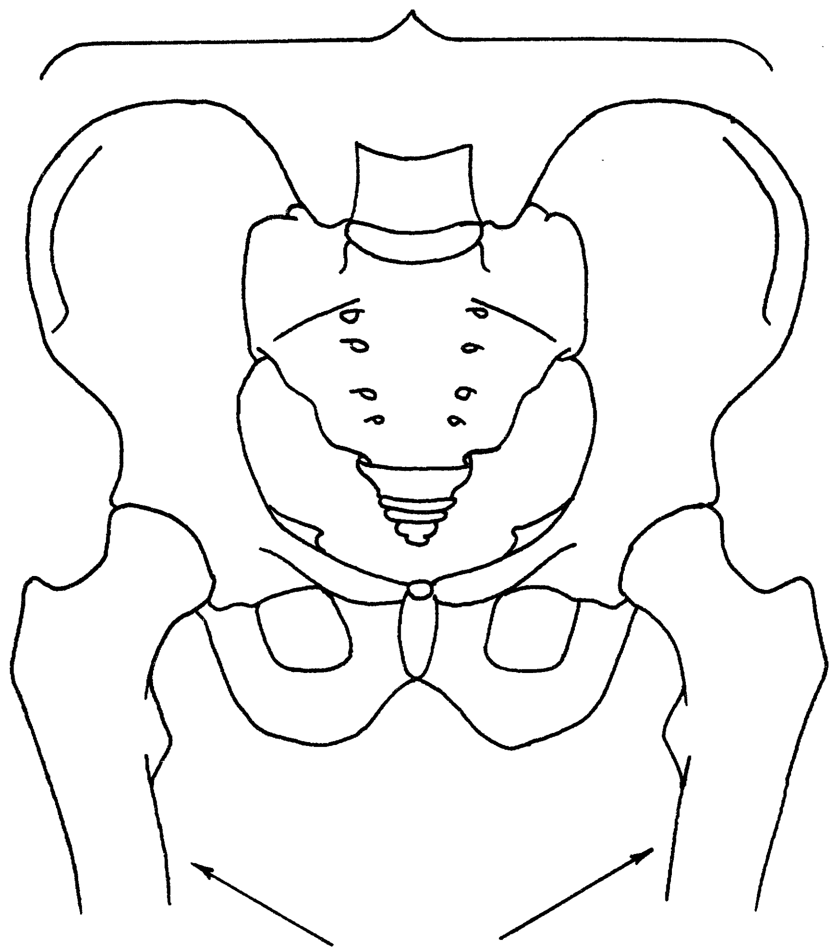
CHAPTER II

THE HIP JOINT

Physiology of the Hip Joint

The two parts of the human skeletal system that comprise the hip joint, the femur and the pelvis, are shown in Figure 1. The joint is a ball-and-socket joint which allows three degrees of freedom of the femur relative to the pelvis. The head of the femur is held in the socket, the acetabulum, by a layer of strong ligaments which run from the rim of the acetabulum to the neck of the femur. These ligaments surround the hip joint and form the joint capsule. The acetabulum exhibits a spherical raised land or plateau that serves as the load-carrying portion of the acetabulum. This horseshoe-shaped area forms an incomplete hemisphere, as can be seen in Figure 2. Both the head of the femur and the acetabulum are covered by cartilage, a firm, elastic material with a smooth surface. The average diameter of the head of the femur in an adult is slightly under two inches. The joint surfaces are bathed in a viscous fluid, the synovial fluid, which provides for the nutrition of the cartilage. The lubricating mechanism of the joint is not fully understood, but one hypothesis is that the cartilage is a porous, sponge-like material filled with synovial fluid, and that the two cartilage surfaces are supported hydrostatically by the fluid in

Pelvis



Femurs

Figure 1. The human skeletal system associated with the hip joint.

[Redrawn from W. Henry Hollinshead, <u>Anatomy for Surgeons: Volume 3</u> (New York: Harper & Brothers, 1958), p. 712.]

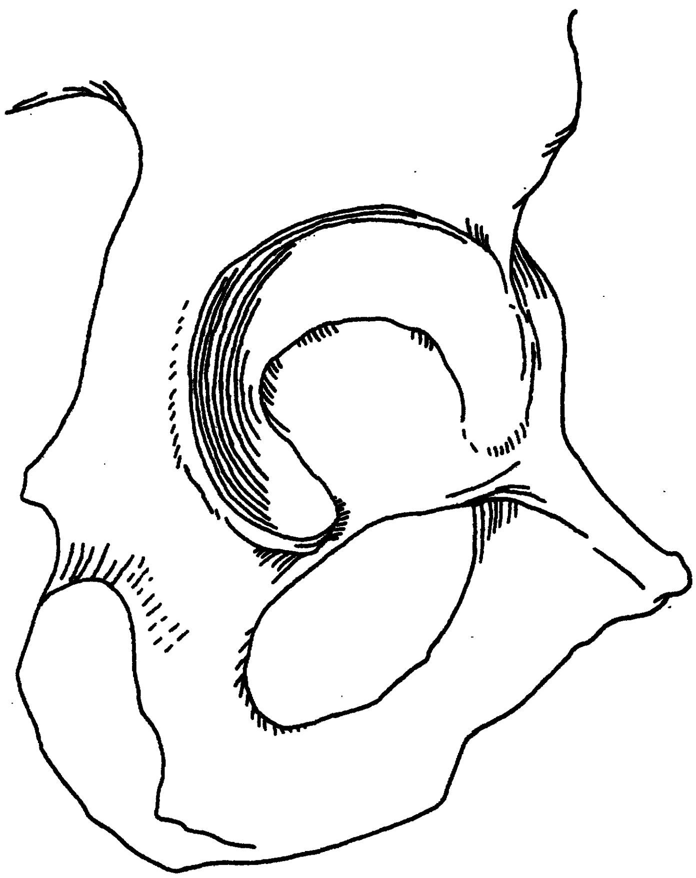


Figure 2. A side view of a portion of the pelvis illustrating the acetabulum. The horseshoe-shaped area is the load-carrying surface.

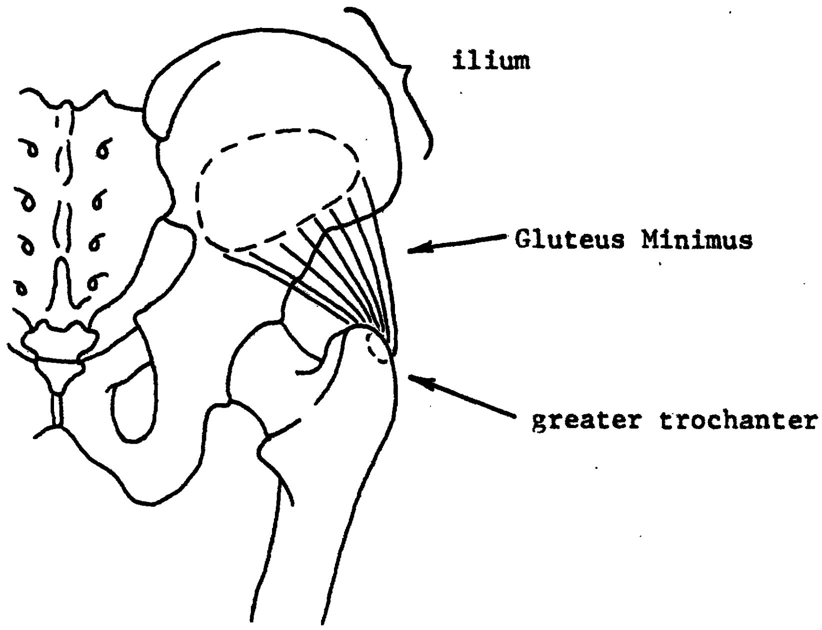
[Redrawn from J.C. Boileau Grant, An Atlas of Anatomy (Baltimore: The Williams & Wilkins Co., 1962), figure 276.]

the cartilage. The joint has very little friction, the coefficient of friction being on the order of 0.01 to 0.02 (1).

There are nineteen muscles associated with the hip joint. These muscles can be grouped into four categories, the flexors, the extensors, the abductors, and the adductors. The flexors and extensors control the forward and backward motion of the leg respectively, while the abductors swing the leg sideways out from the body, and the adductors provide the opposite motion. The abductors are the principal muscles that hold the pelvis level when the body is supported on one leg. The two major abductors are the Gluteus Minimus and the Gluteus Medius. These muscles arise from the ilium, the wing-like portion of the pelvis, and insert into the greater trochanter, the projection on the outer side of the femur. These muscles are shown in Figure 3.

Forces Across the Joint

The forces acting on the hip joint can be quite large. If the body is supported evenly on both legs while standing erect and motionless, the hip muscles serve only to keep the body balanced on the legs, and the load on each hip joint is one-half of the weight of the trunk, head, and arms and is about one-third of the total body weight. However, when the body is supported on one leg, the abductors contract to hold the pelvis level, and the resultant force on the hip joint increases greatly. Figure 4 is a much simplified representation of the forces involved. In a typical hip joint the ratio of "a" to



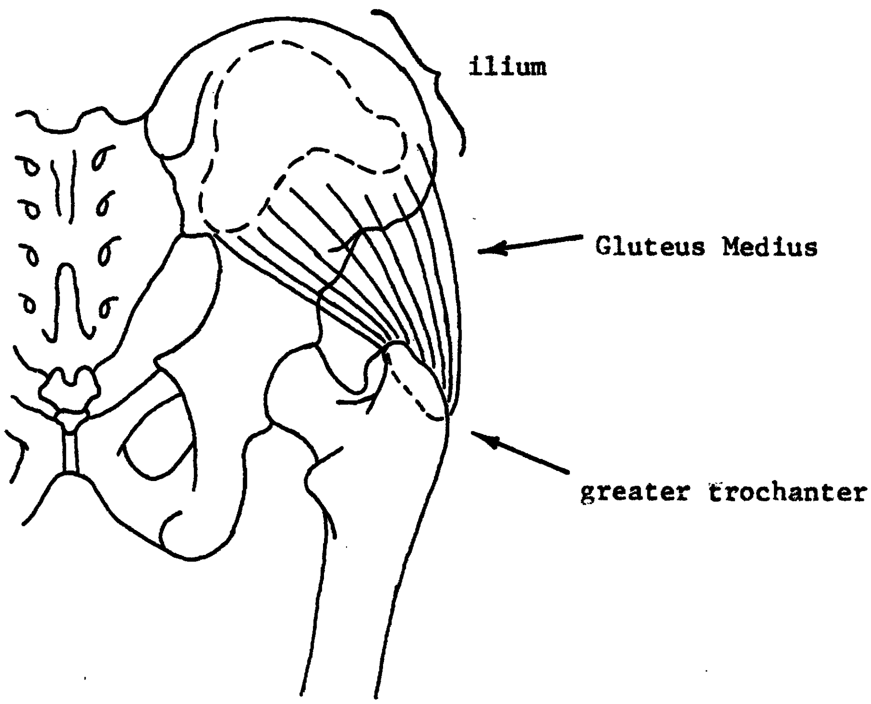
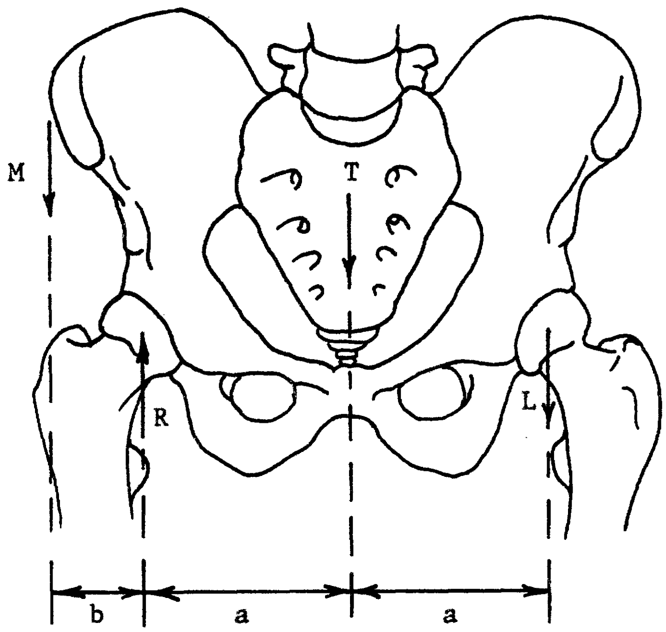


Figure 3. A view from the back illustrating the two major abductor muscles. The dashed lines indicate the areas of muscle attachment.

[Redrawn from W. Henry Hollinshead, <u>Anatomy for Surgeons: Volume 3</u> (New York: Harper & Brothers, 1958), pp. 687-690.]



T = weight of trunk, head, and arms
M = abductor muscle force
L = weight of one leg
R = resultant hip joint force
W_b = total body weight

$$Rb = T(a + b) + L(2a + b)$$

Typically, $T = \frac{2}{3} W_b$ and $L = \frac{1}{6} W_b$

$$R = \frac{2}{3} W_b \left(\frac{a}{b} + 1\right) + \frac{1}{6} W_b \left(\frac{2a}{b} + 1\right)$$

$$= W_b \left(\frac{a}{b} + \frac{5}{6}\right)$$

If $a = 2b$, $R = 2\frac{5}{6} W_b$

Figure 4. A simplified analysis of the forces acting on the pelvis when the body is supported on one leg.

"b" is approximately two, and thus in this case the force acting on the joint is nearly three times the body weight. Analyses of this sort for a person standing motionless on one leg have been made by Inman (2), Blount (3), and Denham (4). Inman calculated the minimum static load on the hip joint for single-leg support to be between 2.4 and 2.6 times the body weight.

The forces acting on the hip joint are higher for walking than for standing on one leg due to dynamic effects. Paul (5) has developed equations relating the forces and moments on the hip joint to the forces developed between the feet and ground while walking and the accelerations of various parts of the body. The forces on the feet were measured by having the test subject walk on a load-measuring platform, and the body accelerations were determined from motion pictures taken simultaneously with the load measurements. The average ratio of peak hip load to body weight for sixteen test subjects was 3.88. For one subject the peak load was computed to be 6.4 times the body weight.

The forces acting on the hip joint were measured directly by Rydell (6) by use of a specially instrumented prosthesis. This prosthesis is a modification of the Moore prosthesis which replaces the neck and head of the femur as shown in Figure 5. The Moore prosthesis is normally used when the head or neck of the femur is damaged and must be replaced, but when the acetabulum is intact. Strain gages mounted in the neck of the modified prosthesis measured bending and torsion, and the gages were connected to

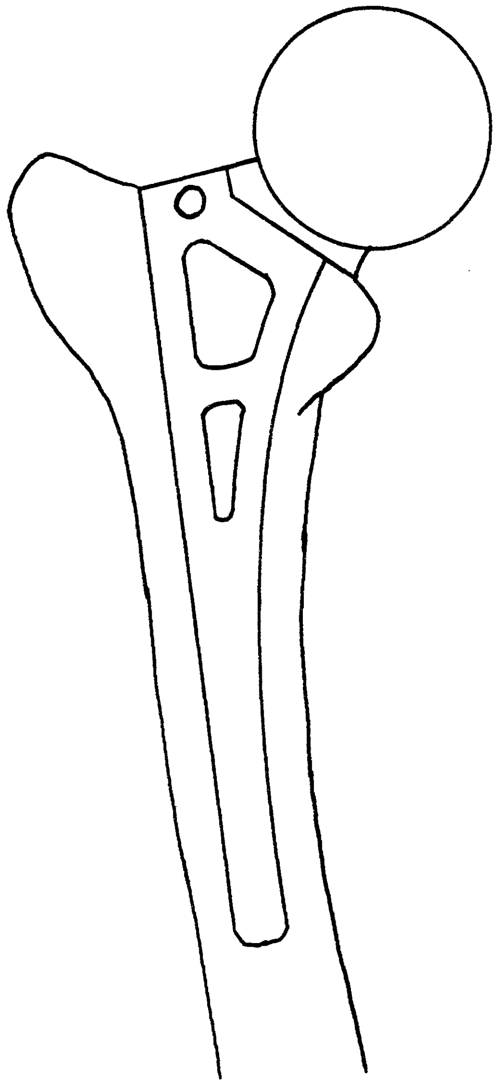


Figure 5. The Moore prosthesis implanted in the femur.

recording instruments by wires brought out through the skin.

Measurements were made on two test subjects in whom the special prosthesis had been implanted. For standing motionless on one leg the ratio of joint force to body weight for one subject was 2.3 and for the other 2.8. These figures are of the same magnitude as the calculations made by Inman. For walking the peak ratio for varying speeds was 1.5 to 1.8 for one subject and 2.95 to 3.27 for the second subject. No meaningful comparison can be made between these data and the figures computed by Paul since only two subjects were tested and the differences in results between the two subjects are quite large. Furthermore, the loads in the prosthetic joint are not necessarily identical to those in a normal joint, since the joint mechanics and the muscle functions are disturbed somewhat in the process of implanting the prosthesis. Measurements were also made in one subject of the forces generated while the subject was running. The ratio of the peak joint force to the body weight in this case was 4.33.

Surgical Reconstructions

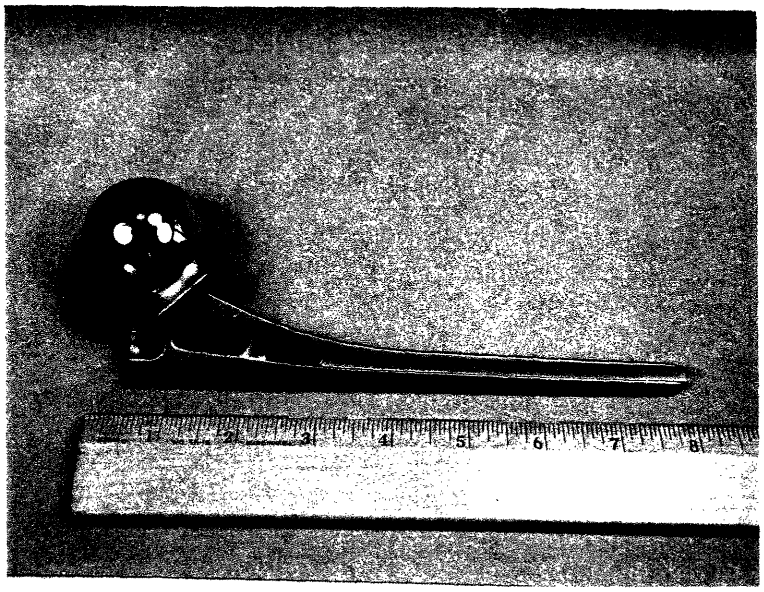
The Moore prosthesis is often used in current medical practice when fracture of the neck of the femur occurs in older people, particularly when healing of the fracture may not take place readily. The prosthesis is also used when the head of the femur has collapsed due to an inadequate blood supply. In all cases, however, the surface of the acetabulum must be undamaged for the prosthesis to be used successfully.

The surgery involved in implanting the prosthesis is not very extensive. A group of small muscles, the short external rotators, are disconnected from the femur, and the joint capsule is opened to allow the femur to be dislocated from the acetabulum. The damaged neck and head of the femur are then removed, and the prosthesis is firmly implanted in the femur by driving the stem into the marrow cavity in the shank of the femur. Finally the femur is replaced in the acetabulum, and the muscles are reattached.

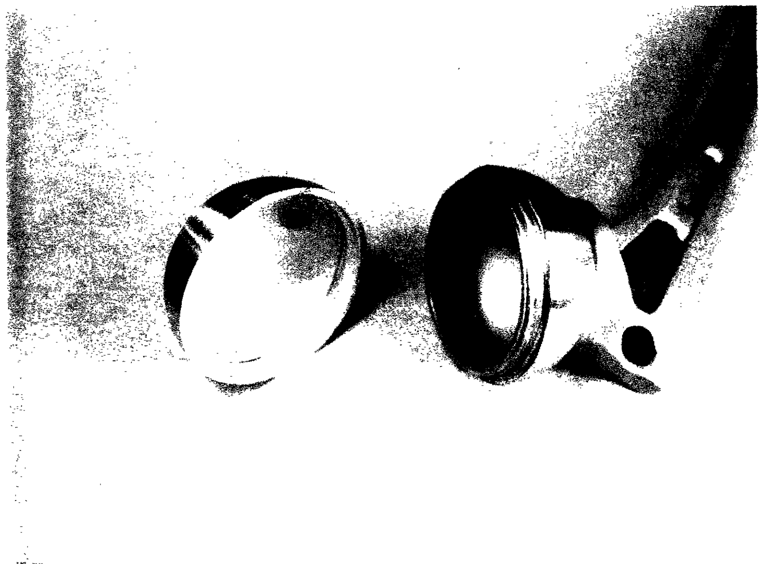
For several days following the operation the leg of the patient is kept in suspension so that no weight is placed on the hip joint. At the end of this period mild exercises are begun, followed gradually by walking on crutches and later a cane. Approximately six months after the operation the patient is usually able to walk unaided in a nearly normal manner.

The Moore Prosthesis

A completed Moore prosthesis and one in the process of construction are shown in Figure 6. The prosthesis is initially cast in two parts in order to make the spherical portion hollow. The hemisphere is fastened to the main portion of the prosthesis by screw threads, and the two parts are permanently joined by welding. The welding process seals the head of the prosthesis and closes the seam so that there is no discontinuity in the surface when the sphere is ground to final size.



(a)



(b)

Figure 6. A typical Moore prosthesis (a). The construction of the sphere of the prosthesis is shown in (b).

The prosthesis is made of Vitallium (7), a cobalt-chromium-molybdenum alloy that has good corrosion resistance and is readily accepted by body tissues. At room temperature the yield strength of Vitallium in tension is 80 ksi and the fatigue strength in reversed bending at one hundred million cycles is 35 to 40 ksi. The alloy has a hardness of about 35 on the Rockwell C scale in the as-cast condition. Becasue of this hardness Vitallium is difficult to machine, and parts are normally made as precision castings and are finished by grinding.

CHAPTER III

THE CURRENT INVESTIGATION

Pressure Measurement

It is proposed to use the Moore prosthesis as a means of introducing suitable pressure transducers into the hip joint. These pressure transducers will be mounted in the hollow sphere of the prosthesis and will provide a continuous measurement of the pressure at a number of points on the surface of the sphere. From these measurements the magnitude and distribution of the pressure acting on the prosthesis can be determined.

The fundamental assumption that the magnitude and distribution of pressure in the prosthetic joint will closely resemble the pressure patterns in the normal joint needs justification. The prosthetic joint is obviously not completely normal, since the cartilage-covered head of the femur has been replaced by a rigid metal sphere.

In a normal hip joint the cartilage surfaces on the head of the femur and the acetabulum are very nearly spherical. Assuming that the surface of the head of the femur is spherical and that it is constant in size implies that it can be replaced by another sphere of identical size without grossly affecting the distribution of the pressure acting on the joint surface. Therefore the pressures as measured in the prosthetic joint should be representative of the pressures in a normal joint. The coefficient of friction may be different in the prosthetic joint, but this should affect only the forces tangential to the surface, not the perpendicular forces.

It is impossible to implant the prosthesis without disturbing to some extent the muscles and connective tissue surrounding the hip joint, and this fact represents a possible source of error that cannot be eliminated. To reduce this source of error the prosthesis must be chosen to preserve the geometry of the hip joint as closely as possible, and every effort must be made to return the muscles and connective tissue to their original positions.

Transducer Design Considerations

Of fundamental concern in modifying and instrumenting the prosthesis is the safety and well-being of the person in whom the prosthesis is to be implanted. The primary function of the prosthesis is to replace a damaged load-carrying portion of the skeletal system, and the modifications to the prosthesis should not reduce its ability to function satisfactorily for the life of the patient. In particular, the prosthesis should not be seriously weakened by the modifications, and the pressure transducer should be chosen so that the surface of the prosthesis remains spherical and presents a smooth, uninterrupted surface to the cartilage in the acetabulum.

The pressure distribution on the surface of the sphere is assumed to be continuous, so that plotting the pressure measured at a number of discrete points and drawing a smooth curve through the data points will result in a reasonably accurate reproduction of the actual pressure distribution. The accuracy of the reproduction is determined by the number of points at which the pressure is measured. Due to the method of attaching the hemisphere to the main part of the prosthesis, the region on the head of the prosthesis on which pressure can be measured is limited to the hemisphere. This should not be a serious drawback, since the data obtained by Rydell indicate that the resultant load on the hip is centered in a small region on the head of the femur.

Since the surface area available for mounting pressure transducers is limited, the size of the transducer must be small enough to allow a reasonable number to be mounted on the hemisphere. Also, it is desirable to have the pressure sensitive area of the transducer as small as possible to more closely approximate measuring the pressure at a point.

The Pressure Transducer

The proposed pressure transducer is illustrated in Figure 7. It consists of a thin, spherical diaphragm formed directly in the wall of the hemisphere with a strain gage glued to the concave side. The diaphragm deflects when a load is placed on the surface, and the strain gage measures the resulting surface strain.*

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* Other transducer designs are considered in Appendix A.

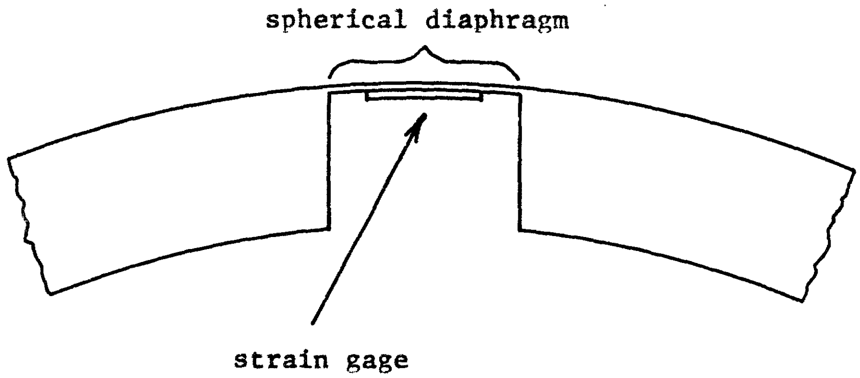

Figure 7. Cross section of the spherical diaphragm pressure transducer.

This type of pressure transducer has a number of advantages. The surface of the sphere remains spherical and unbroken, and there is no possibility of fluid leaking into the sphere. Forming the diaphragm in the wall of the sphere results in a transducer that is of minimum size, and the diaphragm should exhibit very low hysteresis. A strain gage glued to the diaphragm is a simple and reliable method of converting mechanical motion into an electrical signal.

The disadvantages are that a special machining process is necessary to form the diaphragm in the relatively hard Vitallium, and higher sensitivity could be obtained by more elaborate strain measuring devices. Also, there is the possibility of buckling the diaphragm if excessive pressure is applied, since the diaphragm is loaded on the convex side. The diaphragm can be made more resistant to buckling by increasing its thickness, but this results in lower sensitivity.

Construction of the Pressure Transducer

The spherical diaphragm is formed in the hemispherical part of the prosthesis by electric-discharge machining. In this machining process a spark occurring between an electrode and the workpiece melts a small amount of metal at the point on the workpiece where the spark jumps, and this fragment of eroded material is carried away by a fluid bath. The electric-discharge machining process forms a hole whose cross-section is similar to but slightly larger than the electrode. To form a spherical diaphragm of uniform thickness a round copper electrode slightly smaller than the desired diameter with the end machined to the correct radius of curvature is used. Because the electrode is eroded in the same manner as the workpiece, it is necessary to replace the electrode and measure the diaphragm thickness occasionally. The surface produced by electric-discharge machining is a finely pitted surface which is ideal for glue adhesion. Also, the machining process leaves a small fillet at the periphery of the diaphragm which reduces stress concentrations at that point.

The minimum diameter of the diaphragm was determined by the size of the strain gage. The gage used in the pressure transducer is a P-type semiconductor gage with a gage factor of approximately 120. The semiconductor element is a single filament bonded to a rectangular backing which is 0.04 inches wide and 0.12 inches long. By trimming the gage slightly it can be mounted on a 5/32 inch diameter diaphragm. A diaphragm of this diameter constructed on a hemisphere of one inch radius is a very shallow shell, and the gage can be glued securely to the diaphragm even though the surface is spherical. Attaching the gage to the concave surface of the diaphragm is a rather delicate procedure since the surface is approximately one-tenth of an inch below the inner surface of the hemisphere, but if a little care is exercised the procedure is relatively straightforward.

Transducer Design Calculations

The diaphragm thickness is a function of the maximum design pressure, the maximum safe stress in the diaphragm, the diaphragm diameter, and the radius of curvature of the diaphragm. It is difficult to predict the maximum pressure that the transducer might encounter in the hip joint. The peak instantaneous pressure developed on the joint surfaces is determined by the ratio of the peak hip joint load to the body weight, the physical size and geometry of the joint, and the pressure distribution on the cartilage surfaces. It is estimated that for a 160 lb person engaged in a strenuous activity, such as running or jumping, the peak instantaneous pressure will be on the order of 1,000 psi.* The maximum safe stress in the diaphragm was chosen to be the fatigue strength of Vitallium, rather than the yield strength, since the diaphragm may be cycled many millions of times during the lifetime of the person in whom it is implanted. The diameter of the diaphragm is 5/32 inch, and the radius of curvature of the diaphragm is 31/32 inch. Based on these figures the diaphragm thickness is 0.011 inch.†

The buckling pressure of a shallow spherical shell cannot be predicted accurately. The theories which predict buckling pressure are not entirely in agreement with each other, and the theoretical values do not always agree well with experimental results. As a first approximation the maximum design pressure was compared to the theoretical buckling pressure of a complete spherical shell having a wall thickness identical to the diaphragm thickness. On

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* The derivation of this estimate is presented in Appendix B.

† Calculations of diaphragm thickness, buckling pressure, and center-to-center spacing are presented in Appendix C.

this basis the buckling pressure of the diaphragm is roughly five times the maximum design pressure.

It is estimated that twenty pressure transducers distributed uniformly over the available surface of the hemisphere will give a sufficiently accurate reproduction of the pressure distribution. A diaphragm diameter of 5/32 inch will allow twenty diaphragms to be constructed on the hemisphere without appreciably reducing the structural strength of the prosthesis. With this number of diaphragms the center-to-center spacing of adjacent diaphragms is approximately 0.47 inch.

Pressure Transducer Test Results

The hemisphere in which the pressure transducer was constructed was mounted in a pressure chamber in such a manner that the entire hemisphere was subjected to uniform pressure, as shown in Figure 8. Temperature changes proved to be a problem during the tests, so the chamber was filled with glycerin to help stabilize the temperature of the diaphragm and strain gage. The gage was connected in a single-active-arm Wheatstone bridge, and a regulated air supply was used to apply a known pressure to the transducer.

The output of the pressure transducer is shown graphically in Figure 9. The transducer is linear over the entire pressure range and has a sensitivity of 0.004 millivolts/volt/psi. The

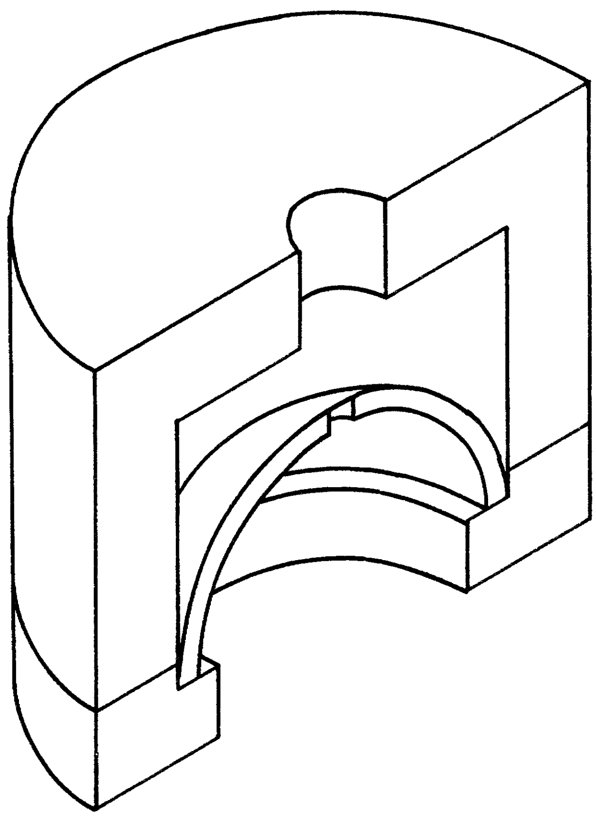

Figure 8. Cross section of the pressure chamber and hemisphere. The transducer is at the top of the hemisphere. Compressed air is supplied through the hole in the top of the chamber.

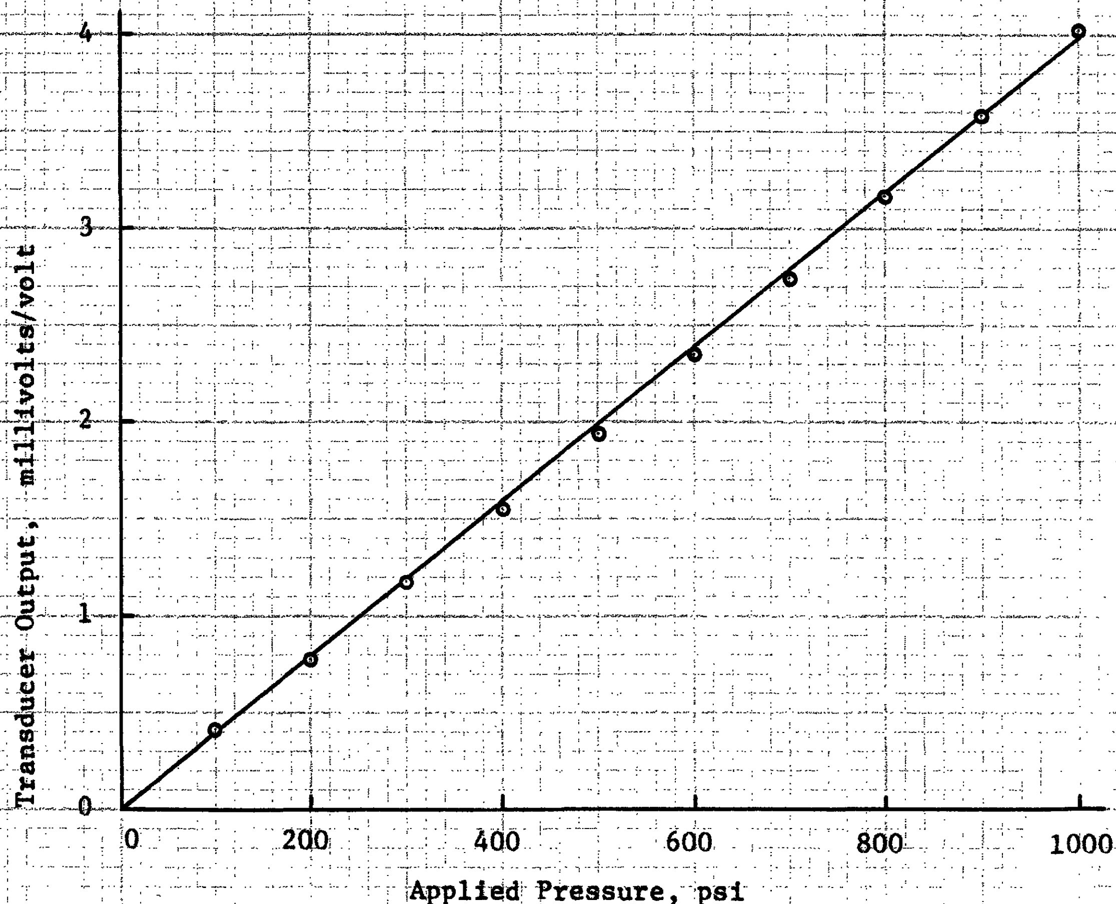

Figure 9. Output of pressure transducer when connected in a single-active-arm Wheatstone bridge.

deviation of the data points from a straight line is apparently due to temperature fluctuations. While the sensitivity of the transducer is not high, it should be sufficient to allow pressures to be measured to the nearest ten psi, which is adequate for the purposes of the proposed investigation.

The measured strain at 1,000 psi is 134 microinches/inch. The figure is considerably less than the theoretical strain, which is approximately 430 microinches/inch.* The difference between the theoretical strain and the measured strain is probably due principally to a displacement of the gage away from the center of the diaphragm. Any such displacement will place the gage in a region of lower strain.

The semiconductor strain gage is quite temperature sensitive, and some form of temperature compensation is necessary even though the temperature fluctuations of the human body are at most only a few degrees. Temperature compensated semiconductor gages employing both a P-type and an N-type element mounted side by side on a single backing are available, but not in a size suitable for use in the pressure transducer. The P-type element has a positive gage factor while the N-type has a negative gage factor, but both elements have the same sensitivity to temperature changes. These two elements can be connected in a bridge circuit in such a manner that the temperature effects cancel. A strain gage of this type when matched with the thermal expansion coefficient of the material on which it is mounted

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* This figure is derived in Appendix C.

has excellent temperature compensation and has an effective gage factor of 250, thereby doubling the output over that of a single element gage. It may be possible to obtain the temperature compensated gages in a size suitable for mounting on a 5/32 inch diameter diaphragm. If not, mounting a dummy gage on an unstrained section of Vitallium inside the sphere of the prosthesis should give satisfactory temperature compensation, since the temperature changes in the body occur very slowly.

CHAPTER IV

TELEMETRY

Data Transmission System

A telemetry system will be used to transmit the signals generated by the pressure transducers to suitable recording equipment. The transmitter and its power source will be completely self-contained and will be implanted in the body of the test subject so that no wires need be brought out through the skin. The telemetry system eliminates the possibility of infection when the skin is broken to allow the passage of wires and thus allows pressure measurements to be made at any time without endangering the test subject.

Transmitter Location

The hollow head of the prosthesis is a very desirable location for the transmitter. The prosthesis provides a ready-made hermetically sealed chamber, and all the circuitry involving low-level signals would be very effectively shielded from external interference. In addition, only the antenna wire and the wires to the separately located power source would leave the prosthesis, thereby simplifying the problem of sealing the prosthesis.

Transmitter Design

The design of the transmitter is governed directly by the number of input channels required. It is relatively simple to build a single channel transmitter, and when only two or three channels are required it is sometimes possible to provide a separate transmitter for each channel. With larger numbers of input channels this method becomes impractical from both a size and a power standpoint. For up to six or eight channels a frequency multiplexing system, which requires only one transmitter, is often used. Each input signal modulates a separate subcarrier, and the subcarriers are then combined to form a complex signal which modulates the carrier of the transmitter.

For the twenty input channels required for the pressure-measuring prosthesis, the most satisfactory method of data transmission is time multiplexing--sequentially sampling the output of each pressure transducer. Time multiplexing is accomplished by using the electronic equivalent of a multiple pole switch, or commutator, between the input channels and the transmitter. Electronic gates, operated sequentially by a ring counter, connect each input in turn to a single transmitter. The output of the transmitter is a series of pulses or bits of data, each pulse corresponding to a particular input. A synchronizing pulse is transmitted each time the input channels are scanned in order to determine to which pressure transducer a given pulse corresponds. The principal limitation of time multiplexing is the frequency response of the system. If the input signals have high frequency components, the scanning rate may need to be very high to get a satisfactory reproduction of the input signals.

The most common method of modulating the transmitter is frequency modulation, principally because of the simplicity of the electronic circuitry. The resulting system is called PAM/FM--pulse amplitude modulation/frequency modulation. The input to the transmitter is a series of pulses, the amplitude of each pulse corresponding to the magnitude of the pressure measured by a given transducer. The pulses are then used to frequency modulate the transmitter.

Figure 10 is a block diagram of the proposed transmitter. The electronic gates require a fairly high level signal in order to operate satisfactorily, so one or more stages of amplification may be necessary to boost the signals from the pressure transducers to the required level.

Transmitter Power Sources

There are two principal methods of powering the transmitter--batteries and magnetic induction coils. Batteries are a convenient source of energy, but they provide only a limited amount of operating time due to their rather low energy storage density. The battery power supply would be placed in a readily accessible location so that the battery pack could be removed or replaced with a minimum of surgery. A magnetically operated on-off switch in the battery leads could be used to turn on or off the transmitter.

Powering the transmitter by magnetic induction coils utilizes what is essentially a simple transformer. The secondary winding of

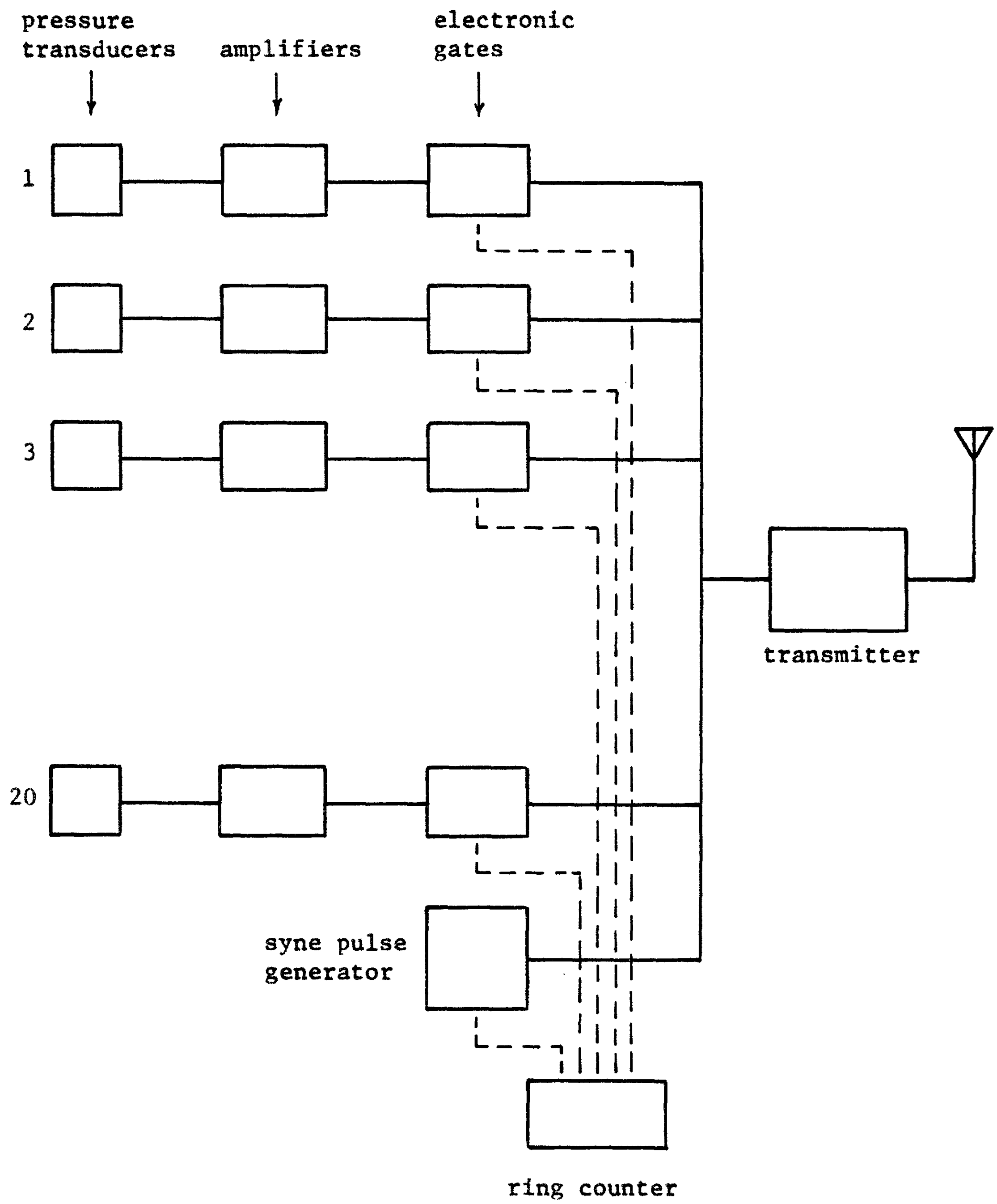


Figure 10. Block diagram of transmitter and input circuitry. The dashed lines indicate ring courter trigger circuits.

the transformer is placed under the skin, and the primary winding is taped in place on the surface of the skin directly opposite the secondary winding. An alternating current in the primary coil induces a corresponding current in the secondary which can then be rectified and filtered to provide a source of DC power. The operating life of the transmitter is unlimited with this form of power source, but this method is more complicated than a simple battery circuit.

Transmitter Feasibility

Dr. Wen Ko (8) of the Case Institute of Technology, an authority in the field of microelectronic circuits and biotelemetry, has stated that it is possible to build a twenty-channel transmitter small enough to be mounted inside the Moore prosthesis. Dr. Ko estimates that approximately 100 milliwatts would be required to power such a transmitter, and that a battery supply measuring one inch square by one-fourth inch thick would provide 50 hours of operating time. If the transmitter were powered by magnetic induction coils, the secondary coil would be one inch in diameter.

Data Receiving and Recording

An FM receiver will convert the transmitted signal to a series of pulses of varying amplitude which can then be recorded on suitable equipment. The frequency response of the recording equipment is a major consideration, since the rate at which data are acquired is quite high. For a scanning rate of 40 times per second, 800 bits of data are transmitted each second, and a large amount of data can be accumulated in a very short time. Also, since the data are received in a form which is not readily interpreted, the recording equipment should convert the data into a more easily handled form.

Recording the data on magnetic tape for direct processing by a computer is the most efficient method of handling the data. The computer can be programmed to plot pressure profiles and to determine the location and magnitude of the peak pressures. The computer can also determine the resultant load on the hip joint by integrating the pressure distribution over the surface of the joint.

A continuous indication of the performance of the telemetry system can be obtained by coupling the output of the receiver to the vertical input of an oscilloscope and using the synchronizing pulse to trigger the horizontal sweep. The resulting trace is an instantaneous plot of the pressures in the hip joint.

It is desirable to correlate the activities of the test subject with the pressure measurements, and one method of accomplishing this is to have the person perform on a load-measuring walkway. The times at which heel-strike and toe-off occur could then be readily determined. An even more informative method would be to take motion pictures simultaneously with the pressure measurements.

So far no attempt has been made to analyze the data recording and processing techniques in any detail. The specific design of the recording equipment will depend upon both the type of signal generated by the transmitter and the desired method of handling the data.

CHAPTER V

RECOMMENDATIONS FOR FURTHER STUDY

Mechanical Testing and Design

Several additional tests should be performed on the spherical diaphragm pressure transducer before it is used in an implanted prosthesis. The transducer should be subjected to a fatigue test with the pressure alternating between zero and 1,000 psi to determine the fatigue characteristics of the diaphragm. This test would also determine the long-term operational characteristics of the pressure transducer. Another factor that should be investigated is the buckling pressure of the diaphragm. The most satisfactory method of determining the actual buckling pressure is to test a few diaphragms to failure or to a pressure well above any pressure that might conceivably be developed in the hip joint. In addition, some method should be devised to load the hemisphere in a nonuniform manner to determine the sensitivity of the transducers to deformation of the hemisphere as a whole.

There are at least two additional mechanical design problems of some importance associated with the construction of the prosthesis. One problem is the development of a welding technique to join the hemisphere to the main portion of the prosthesis without damaging the strain gages or the transmitter by excessive heating. The second problem is that of sealing the sphere at the point where wires are brought out through the wall of the sphere. Some form of glass or ceramic seal would be desirable to provide a permanent hermetic seal between the prosthesis and the external wires.

Telemetry

No attempt has been made to study the telemetry aspects of the proposed investigation in detail, and only a brief sketch of the basic problems is presented here. A considerable amount of effort will be required in the design and construction of the telemetry equipment. At present the technology is sufficiently far advanced to make the construction of a miniature twenty-channel transmitter feasible, but no transmitter with this number of input channels has ever been constructed. Data recording techniques must be devised, and the computer analysis of the data must be worked out. In addition, methods of correlating the data with the activities of the test subject must be developed.

CHAPTER VI

CONCLUSIONS

It would seem that it is feasible to measure the instantaneous magnitude and distribution of the pressure on the cartilage surfaces in the human hip joint. It is not possible to foresee all the problems that will be encountered when the proposed pressure-measuring prosthesis and the associated equipment are constructed, but the two major considerations fundamental to the success of the project, the design of a suitable pressure transducer and the feasibility of building an implantable transmitter, have been satisfactorily resolved. The spherical diaphragm pressure transducer is capable of measuring the pressure in the hip joint with acceptable accuracy, and integrated circuit technology is sufficiently far advanced to make possible the design and construction of a miniature twenty-channel transmitter.

APPENDIX A

OTHER PRESSURE TRANSDUCER CONCEPTS

Three other pressure transducer designs were conceived, as well as another scheme of producing an output from the spherical diaphragm transducer. Instead of measuring the surface strain of the spherical diaphragm, the deflection of the center of the diaphragm cauld be measured by an unbonded strain gage or a similarly gaged mechanical linkage, as shown in Figure A1. Measuring the deflection of the diaphragm would give a higher output than a bonded gage which measures the surface strain, but the bonded gage is simpler and much more rugged.

One method proposed to measure pressure would utilize a thin flexible metallic shell supported by radial posts as shown in Figure A2. A load applied to the shell would cause the posts to compress, and the change in length of each of the posts would be measured by a bonded strain gage.

A serious difficulty associated with this method of measuring pressure is that the deflection of the shell at one point is influenced by loads applied at all points on the surface of the shell. By making only a finite number of deflection measurements it is imposssible to determine the pressure distribution.

A second pressure measuring method is to cover the surface of the sphere with an elastic membrane and measure the change in

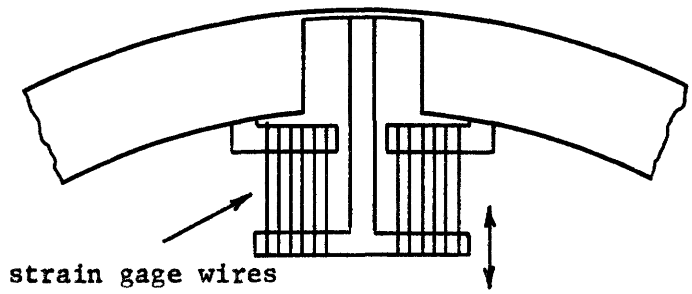


Figure A1. A device to measure diaphragm deflection.

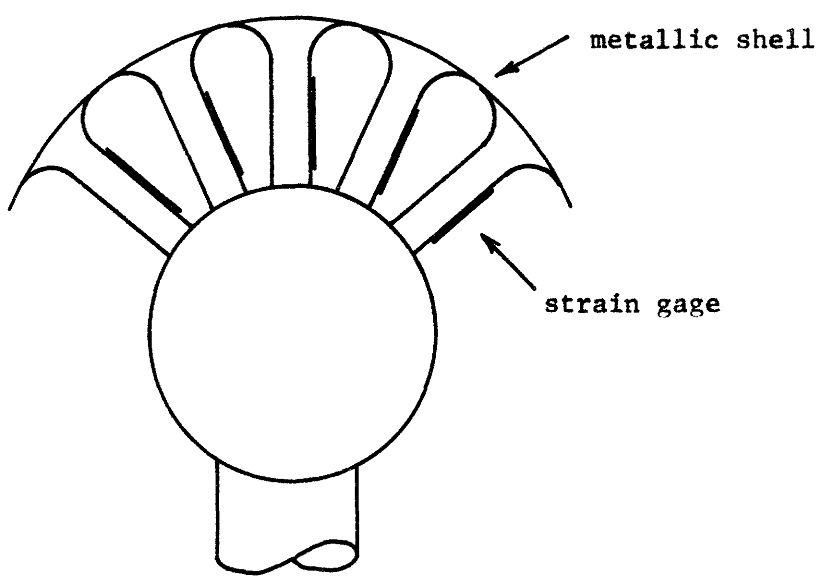


Figure A2. Radial post pressure sensing device.

thickness of the membrane at various points by capacitive means. A metallic film deposited on the outer surface of the membrane would serve as one side of a set of capacitors, and insulated metallic discs mounted on the surface of the sphere under the membrane would be the fixed plates of the capacitors. Figure A3 illustrates the proposed construction.

A number of difficult design problems are posed by this method. The membrane material would have to be inert and unaffected by fluids in the joint and would necessarily have to have excellent elastic properties. Finding an adhesive to bond the membrane to the sphere and developing a method of depositing a metallic film on the membrane would require a considerable amount of investigation. In addition, static loads are difficult to measure satisfactorily by capacitive means.

A third method of pressure measurement might be feasible if it were known that a thin layer of synovial fluid separated the cartilage surfaces in the joint. The pressure in the synovial fluid at various points on the surface could then be measured. A tiny hole drilled through the surface of the sphere leading to a conventional pressure transducer mounted inside the sphere, as shown in Figure A4, would transmit the fluid pressure to the transducer.

Since it is doubtful that the cartilage surfaces are separated by a fluid layer, attempting to measure fluid pressures is a rather uncertain method. In addition, the holes in the surface of the sphere could present a physiological hazard.

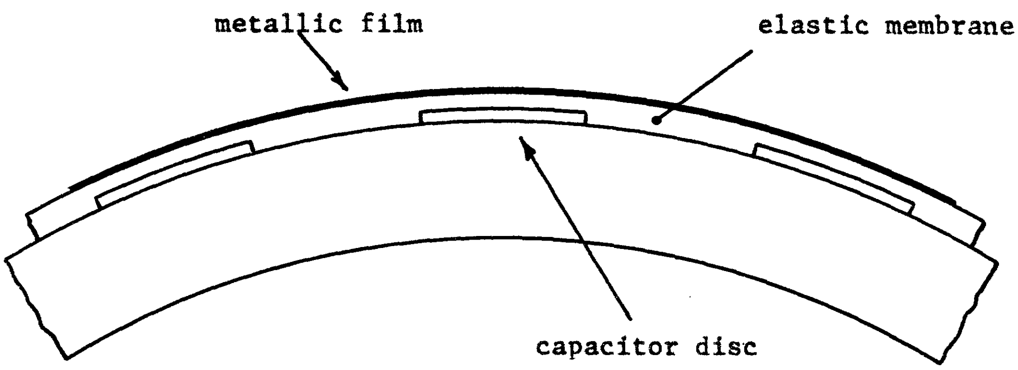


Figure A3. Pressure measurement by capacitive means .

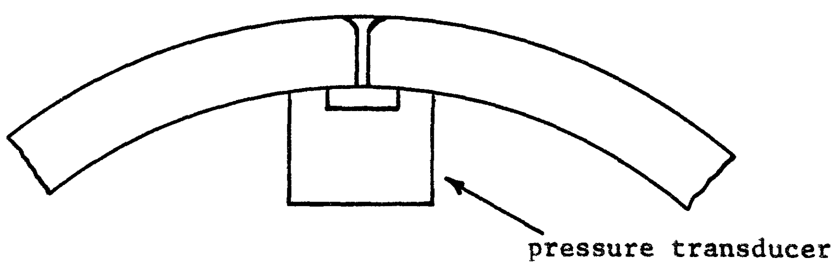


Figure A4. Direct measurement of fluid pressure.

APPENDIX B

ESTIMATE OF MAXIMUM HIP JOINT PRESSURE

The peak instantaneous pressure in the hip joint is a function of several factors: the peak load on the joint, which in turn depends upon the body weight and the ratio of the peak hip joint load to body weight; the size of the surface area on which the load is carried; and the pressure distribution on the load-carrying surface.

The pressure distribution is the most difficult factor to determine, since although the load-carrying surface is spherical, the outline of the surface is quite irregular. Also, the manner in which the cartilage surfaces distribute the load is not known.

The extracellular matrix of cartilage is known to consist of fibrous protein and a structureless ground substance permeated by synovial fluid. It is hypothesized that when cartilage is placed under load a portion of the load is supported by the fluid bound in the matrix. The fluid gradually seeps to regions of lower pressure and eventually is squeezed out of the cartilage on surfaces which are not loaded.

Zarek and Edwards (9) have postulated that the pressure distribution between two stationary spherical joint-cartilage surfaces, such as the hip joint, is sinusoidal when the area of contact is small. For a circular contact area the pressure is a maximum at the center and zero at the circumference. The authors have not attempted to determine the pressure distribution when the contact area is a large proportion of a hemisphere.

If the pressure distribution is assumed to be sinusoidal when the contact area is nearly a full hemisphere, and if it is also assumed that the load-carrying surface in the acetabulum can be approximated by a segment of a hemisphere, then the peak pressure in the joint can be determined if the total load on the hip joint is known. The second assumption is admittedly only a first approximation, but it allows a rough estimate of the peak pressure to be made fairly readily.

The approximate situation is shown in Figure B1. The angle ϕ_1 is approximately 70 degrees, and for this angle the formula relating the peak pressure p_o to the applied load W for a sphere of radius R is

$$p_o = \frac{2W}{\pi R^2} \quad .$$

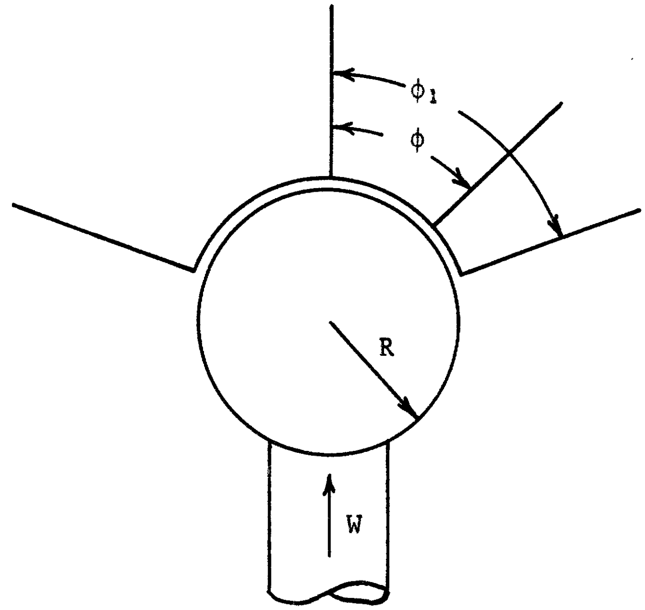
Paul has calculated the ratio of the peak joint load to body weight to be an average of 3.88 for normal walking, and for one person the ratio was 6.4. Rydell measured the load on the hip joint of a woman of age fifty-six while the woman was running and found the peak ratio to be 4.33. The scarcity of data makes it difficult to estimate what the ratio might be for activities in which the impact loading is high, such as running or jumping.

Extrapolating from the available data, the ratio of the peak instantaneous load on the hip joint to the body weight is estimated to be ten. The equation relating peak joint pressure p_o to body weight W_b is then

$$p_o = \frac{20\ W_b}{\pi R^2} \quad .$$

The peak pressure for a person weighing 160 lb is slightly greater than 1,000 psi. For a body weight other than 160 lb the peak pressure will vary proportionately.

This figure of 1,000 psi may be in error by a considerable margin, but it is impossible to obtain a figure of significantly greater accuracy, simply because of the uncertainty in the basic assumptions that must be made in any analysis of this sort. The only way to obtain accurate, reliable data is to actually measure the pressure in the human hip joint.



$$p = p_o \cos\left(\frac{\pi}{2}\,\frac{\phi}{\phi_1}\right)$$

$$W = \int_0^{\phi_1}\int_0^{2\pi} p_o \cos\left(\frac{\pi}{2}\,\frac{\phi}{\phi_1}\right) \cos\phi\, R^2 \sin\phi\, d\theta\; d\phi$$

$$= \pi p_o R^2 \left[- \frac{\cos (m - n)\phi}{2(m - n)} - \frac{\cos (m + n)\phi}{2\,(m + n)} \right]_0^{\phi_1}$$

where $m = 2$, $n = \dfrac{\pi}{2\phi_1}$.

For $\phi_1 = 70°$, $W = \dfrac{\pi p_o R^2}{2}$.

Figure B1. Approximate analysis of peak hip joint pressure.

APPENDIX C

SPHERICAL DIAPHRAGM DESIGN CALCULATIONS

Diaphragm Thickness

The thickness of the diaphragm was determined on the basis of the maximum allowable stress in the diaphragm. The fatigue strength of Vitallium, rather than the yield strength, was chosen as the limiting stress, since the diaphragm may have to withstand many millions of cycles during the lifetime of the patient. Using the fatigue strength as the maximum design stress results in a large safety factor, since the diaphragm will be subjected to the maximum design pressure only occasionally.

The diaphragm thickness is a function of four parameters: the maximum stress, the maximum design pressure, the diaphragm diameter, and the radius of curvature of the diaphragm. The maximum stress, chosen as the fatigue strength of Vitallium, is 40 ksi. The maximum design pressure was previously estimated to be 1,000 psi. The diaphragm diameter, based on the size of the strain gage, is 5/32 inch, and the radius of curvature of the particular diaphragm tested is 31/32 inch.

No simple formulas exist relating the diaphragm thickness to the four parameters. An analysis has been made by Berman (10) of the stresses developed in a shallow dome for various loading conditions with the results presented graphically in dimensionless form. Although the analysis was intended for use in calculating the stresses in spherical domes in buildings, the analysis is valid for shallow spherical shells of any scale. A trial-and-error solution for the diaphragm thickness subject to the four design parameters gave a diaphragm thickness of 0.011 inch, to the nearest thousandth. For this thickness the peak stress is approximately 37 ksi. This is a radial compressive stress, and it occurs at the edge of the diaphragm on the concave surface.

Diaphragm Buckling Pressure

It is difficult to predict with any degree of certainty the pressure at which the diaphragm will buckle. Several theories exist for predicting buckling of spherical diaphragms, but the predictions are not self-consistent, nor do they agree very well with experimental results (11).

For a first approximation the maximum design pressure was compared with the theoretical buckling pressure of a complete sphere, the formula for which is

$$q_o = \frac{2E}{[3(1 - \nu^2)]^{1/2}} \left(\frac{t}{R}\right)^2$$

where q_o = buckling pressure

E = Young's modulus

ν = Poisson's ratio

t = wall thickness

R = radius.

For Vitallium, E is 36 million psi and ν is approximately 0.3. The theoretical buckling pressure for a sphere 1-15/16 inch in diameter with a wall thickness of 0.011 inch is 5,640 psi.

The ratio of 1,000 psi to 5,640 psi is 0.177, so if the buckling pressure of the diaphragm is approximately the same as that of a complete sphere, the maximum design pressure is roughly 20 per cent of the buckling pressure. This would seem to be a safe margin, but owing to imperfections in the metal and inaccuracies in predicting the buckling pressure of the diaphragm, the actual buckling pressure may be considerably lower than the theoretical value. The most satisfactory method of determining how closely 1,000 psi approaches the buckling pressure of the diaphragm is to test a few diaphragms to failure or to a pressure well above any pressure that might conceivably be developed in the hip joint.

Reduction in Strength of Prosthesis

Two methods were used to get a qualitative estimate of the reduction in strength of the instrumented prosthesis. First, a comparison was made of the volume of metal removed and the original volume of the spherical shell. Second, the surface area available for each diaphragm was computed to determine the approximate center-to-center spacing of the diaphragms. The threads on the hemispherical section of the prosthesis occupy about 25 per cent of the surface of the hemisphere, so that 75 per cent of the hemisphere can be instrumented.

The volume occupied by 75 per cent of a 1-15/16 inch diameter hemisphere with a 0.10 inch wall thickness is 0.398 cubic inches, and the volume of metal removed to form twenty diaphragms is 0.0383 cubic inches. The ratio of the metal removed to the initial volume of metal is 9.6 per cent.

The surface area of 75 per cent of the hemisphere is 4.42 square inches, and dividing this among twenty diaphragms gives 0.221 square inches of surface area for each diaphragm. If the hemispherical surface is marked off into curvilinear squares each of 0.221 square inches in area the length of a side of each "square" is 0.47 inch. This figure is also the center-to-center spacing of adjacent diaphragms if the diaphragms are uniformly distributed. Subtracting the diameter of a diaphragm from the center-to-center spacing gives 0.31 inches as the distance of closest approach of two diaphragms.

From this rather indirect analysis it would seem that the amount and location of the metal removed to form the diaphragms should not seriously degrade the load-carrying capacity of the prosthesis. However, the instrumented prosthesis should be thoroughly tested to determine its structural integrity before implanting it in a person.

Theoretical Measured Surface Strain

In the central region of the diaphragm in the surface on which the strain gage is mounted the bending stress predominates over the membrane stress to give a tensile stress in the radial direction. The average strain as measured by the strain gage was calculated by integrating the strain along a diameter from the center out to one-half the gage length and dividing by one-half the gage length. Graphical integration of the data in Berman's analysis resulted in an average strain of approximately 430 microinches/inch for an applied pressure of 1,000 psi.

The actual strain as measured by the gage is lower than this value for several reasons. First, it is difficult to get the gage element centered on a diameter. Any displacement longitudinally along the diameter or laterally from the diameter will place the gage in a region of lower strain. Second, the fillet at the periphery of the diaphragm reduces slightly the effective diameter of the diaphragm. This smaller diaphragm results in lower stresses and smaller strains. Third, there may be some lost motion in the strain gage adhesive, and also the gage may tend to stiffen the diaphragm.

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