DETECTION OF LOOSENING OF ARTIFICIAL HIP COMPONENTS IN VITRO

by

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ABSTRACT

This thesis describes the development of a new diagnostic method to detect loosening of the components of the artificial hip implants. The initial in vitro results are presented.

A sweep oscillator generates a low frequency signal over the range 100Hz to 5KHz. The low frequency input drives a modified speaker which produces a force input to the tested component. The resulting acceleration is measured by an accelerometer transducer. The output signal is amplified and then fast fourier transformed. The frequency response is displayed on a storage oscilloscope.

The frequency responses of the stem, a tightly implanted bone-stem complex a loosely inserted bone-stem complex and finally a partially loose bone-stem complex were obtained. The effect of varying excitation input placement was found for three positions. Soft tissue and joint fluid were simulated to determine their effect on the frequency response.

The waveforms showed that the loosely inserted bone-stem complex could be differentiated from the tightly inserted bone-stem complex as could the partially loose bone-stem complex.

The clinical development of this method is considered in light of the above results.

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Finally I acknowledge with thanks my indebtedness to Professor George W. Pratt, Jr., whose support, involvement and enthusiasm motivated this thesis and whose friendship I appreciate.

Introduction

With the widespread popularity of the total hip replacement operation, the growing incidence of loosening of the components is a matter of great concern. Last year in the United States alone over 75,000 total hip operations[1] were performed with over 5% of these destined to suffer from loosening of one or more component[2]. The ability to accurately assess the state of adhesion of the prosthesis would provide considerable improvement in clinical management of the total hip patient.

This thesis will describe the development of a mechanical testing method to monitor loosening of the prosthesis system. The initial in vitro results are presented.

The technique is based upon the different degrees of coupling existing between a loose femoral component and a tightly implanted component or stem within the femur. The degree of coupling can be obtained by making use of the differing resonant frequencies of the bone and of the femoral component. The bone resonance is located at approximately 1KHz while the femoral component's main resonant frequency is 2KHz. Depending upon the coupling between the bone and femoral component the resonance of the femoral component or stem can be measured. The better the coupling the greater the excitation of the stem at its resonant frequency.

Anatomy of Hip-Joint

The normal hip-joint is a ball-and-socket joint, formed by the reception of the head of the femur into the cup-shaped cavity of the acetabulum. The articulating surfaces are covered with cartilage, that on the head being thicker at the center than that at the circumference[3]. The structure of the hip-joint is illustrated in figure 1-1. The anatomy of the os innominatum which contains the acetabulum and the femur is shown in figure 1-2.

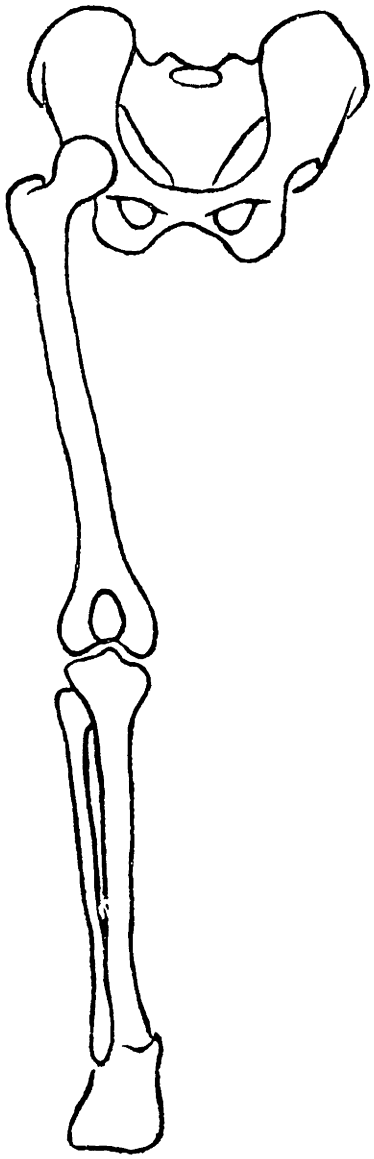
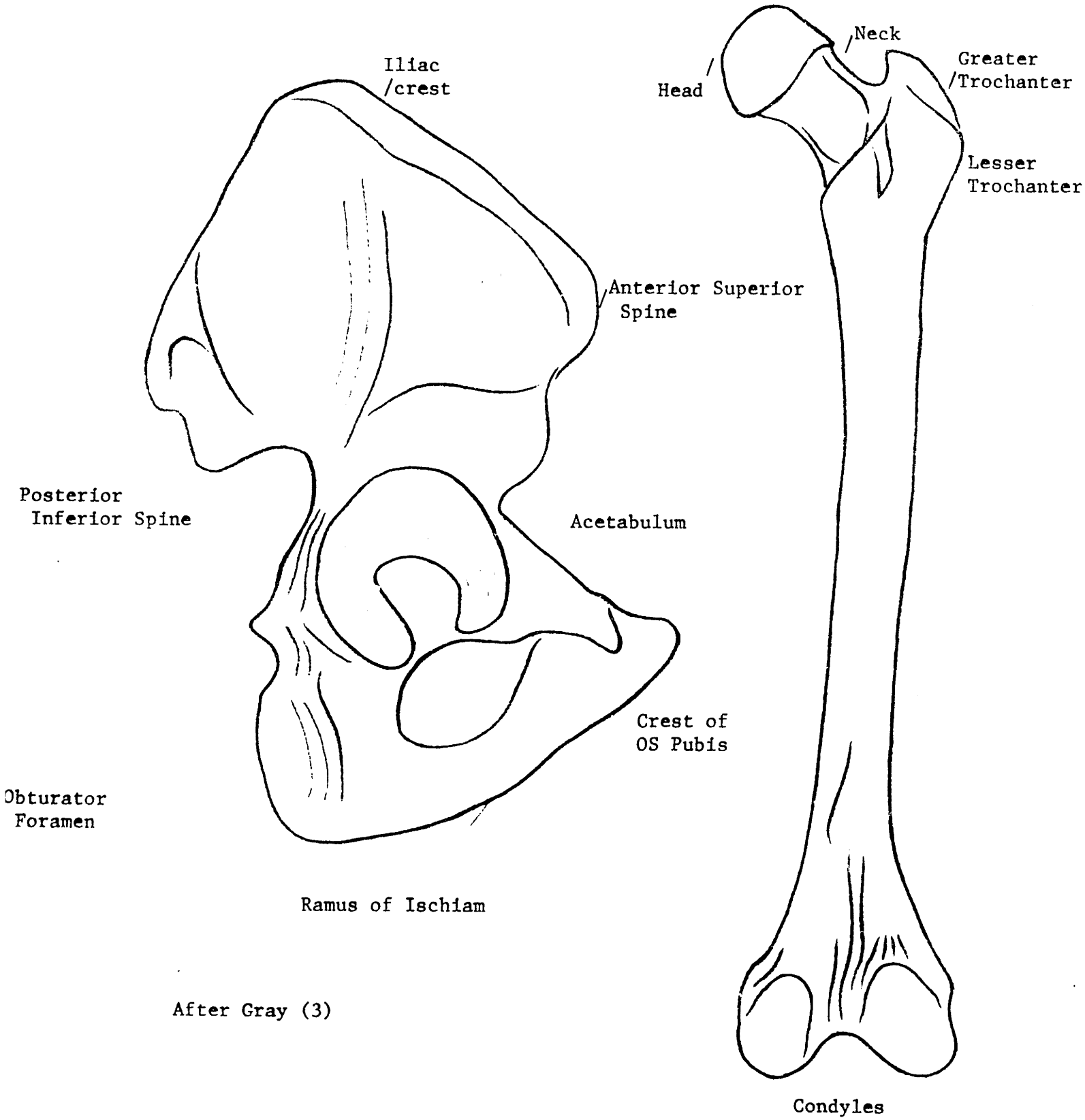


Figure 1-1 Structure of the Hip-Joint



After Gray (3)

Figure 1-2 Anatomy of the Os Innominatum and the Femur

The hip-joint is surrounded by ligaments to maintain functional shape which attach to both the greater and lesser trochanters of the femur from the os innominata[3].

In the total hip replacement, the acetabulum is replaced with a socket while the head of the femur is replaced by a intramedullary femoral stem. There are over 100 different types of implants varying not only in design but also in method of attachment and material composition[4,5], see figure 1-3. This study focuses on the metal-to-plastic prosthetic implant. In this version of the total hip, the acetabular component is made of high density polyethylene. The cup articulates with the stem or femoral component. The stem is composed of a cast or forged chromium-cobalt molybdenum alloy. Both components are fixed to bone by means of methylmethacrylate, a polymer cement. The metal-to-plastic total hip has found more favour than its metal-to-metal counterpart because of the lessened need for accurate fitting and lowered incidence of loosening[6].

Since loosening of the prosthesis is the underlying driving force for this study it is necessary to review the causes of loosening along with the present means of detection.

Loosening of the Prosthesis

There are several interfaces at which loosening of the prosthesis can occur. These are

Bone-Cement-Prosthesis-Prosthesis-Cement-Bone.

However loosening always occurs at the weakest link in the chain, the bone-cement interface. This is true both for the femoral component and the acetabular cup[4]. The bone-cement interface is the source of loosening because of tissue reactions which occur at this junction between living and inert matter. Several

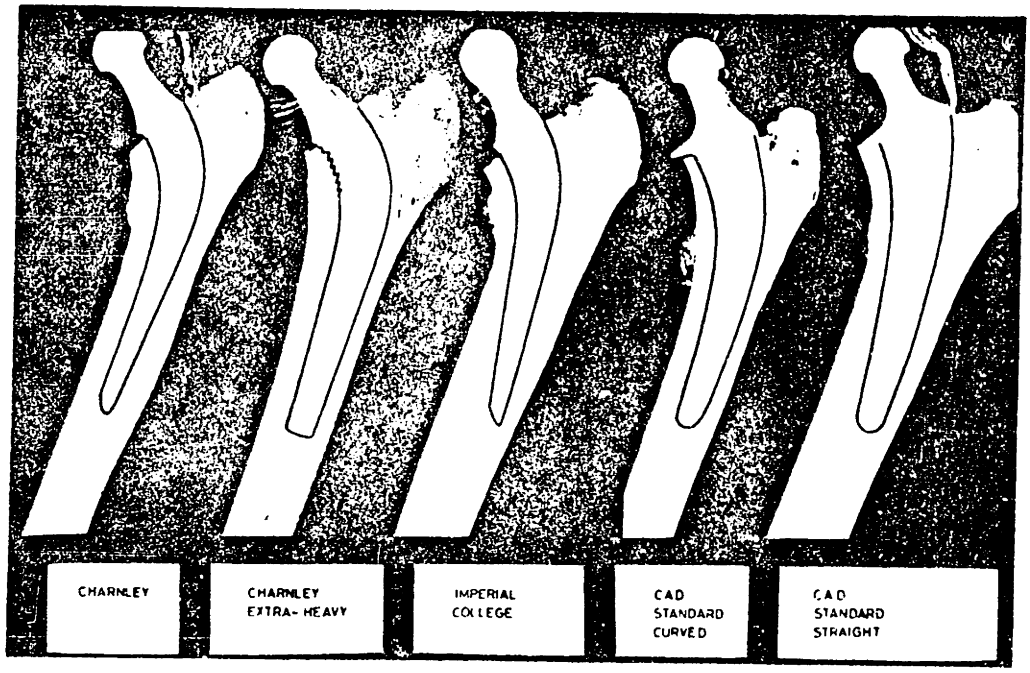


Figure 1-3a Five Commonly Used Stem Configurations (after B. Weightman)

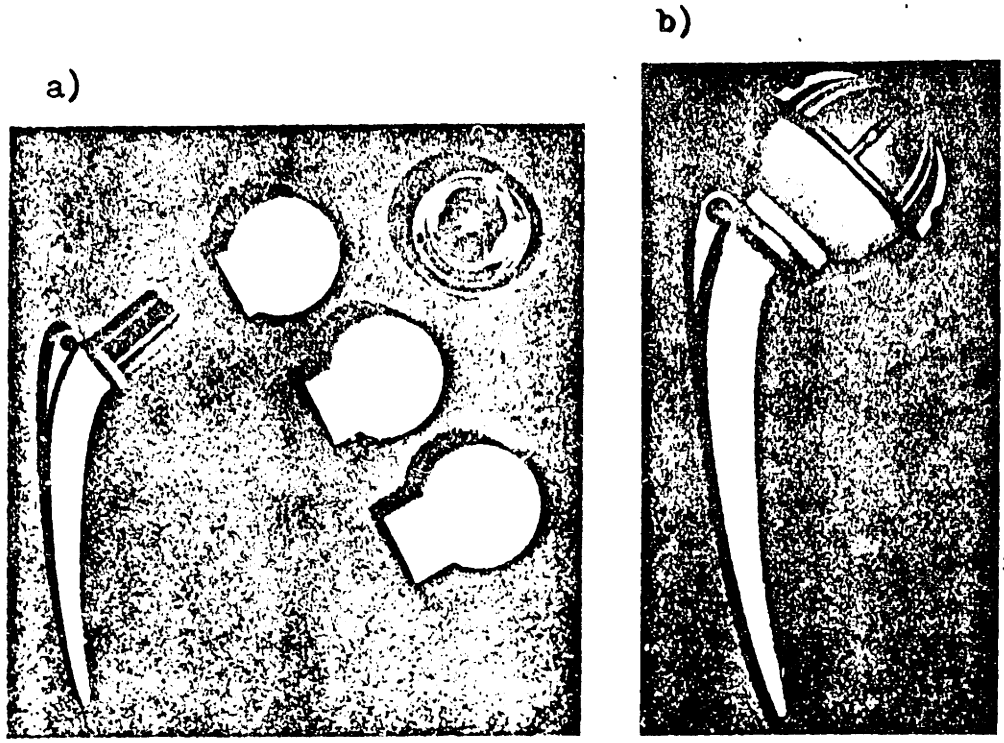


Figure 1-3b The Trunnion Bearing Total Hip Prothesis

a) The 3 components: Femoral component and cup made of chromium cobalt alloy, the heads with different neck lengths made of polyester

b) The assembled prothesis, the head rotating on the trunnion

(after B.G. Weber & G. Stuhmer)

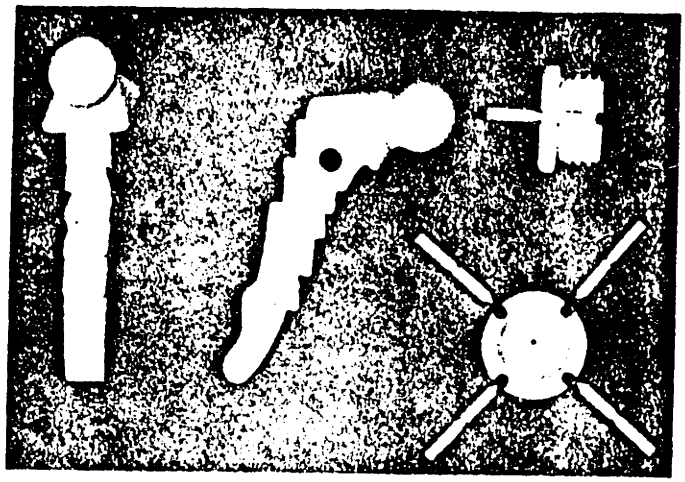


Figure 1-3c New Stem Design for Better Load Transmission along the Whole Stem Area
(after P. Griss, G. Heimke, and G. Jentschura)

characteristics of the operation itself precipitate increased reaction at this site which will be examined later.[2,4,6]

The causes of loosening can be listed and categorized as in table 1.

TABLE I

Causes of Loosening

1. faulty implantation
2. trauma
3. infection
4. reaction to implant materials

Except for trauma, the other determinants of loosening give rise to a gradual loss of adhesion. It is this chronic development that may permit alternative therapy once loosening has begun.

Following the implantation of the prosthesis the healing process can be divided into three phases: 1) the initial phase- immediately following implantation to about three weeks, 2) the reparative phase three weeks to two years, 3) stabilization - beginning 1-2 years after the operation.

In the initial phase the fixation of the prosthesis is the greatest, progressively decaying throughout the following stages. There is no mobility between the cement and bone. Upon histological examination there is a zone of dead bone and marrow tissue extending approximately 1/2cm out[6]. This necrosed tissue is due to the reaming, from the heat produced during polymerization and from the toxic effect of non-polymerized monomer. Occasionally there is death of other areas of cancellous bone and cortical bone due to occlusion of vascular supply by the operative procedure.[6]

The formation of the cement is an in sita polymerization. Powdered pre-polymerized methylmethacrylate containing benzoyl peroxide (activator) is mixed with liquid monomer containing the initiator dimethylparatoluidine. This induces polymerization which is exothermic and autocatalytic. The completion time is several minutes. During this period temperatures may

reach as high at 100°C. Between 2 and 5% of the pre-polymerized methyl-methacrylate is not polymerized remaining as small (-80μm diameter) spheres.[6]

The reparative phase begins the normal repair process to tissue death. Here is progressive invasion of the dead bone by vascular granulation tissue. Scavenger cells move in to remove the dead bone while marrow and connective tissue cells form new bone and fibrous tissue. The cement is separated from living tissue by a membranous acellular layer which is usually thin and delicate. An additional layer of collagenized fibrous tissue up to 1mm thick may be present. The repair process eventually replaces all dead tissue by living bone and soft tissue.

In the stabilized phase the granulation tissue that had invaded the marrow spaces during the repair process is replaced by normal haemopoietic and fatty marrow. The dead bone and woven repair bone are also replaced by healthy lamellar trabecular bone. However surrounding the cement still remains the thin membrane which may be only a few microns thick.

In loosening of the bond between bone and cement there is an altered histological structure. Indeed it is possible to subdivide the pathology of loosening into early (<2 years) and late (>2 years) loosenings.

Within loosenings of less than 2 years increased removal and remodelling of bone is found. This is probably due to larger than normal areas of necrosed tissue present. Dead bone is more prone to fatigue failure than living bone. Therefore if there is more necrosed tissue than normal due perhaps to vascular injury during the operation there is a much greater probability of fatigue failure in the dead bone leading to loosening. Bone death at other stages gives rise to similar occurences.[6]

In late loosening tears are present in the implant bed. Haemorrhages and fibrinous exudates are found in the surrounding connective tissues along with bone resoption. Bone resorption is much more marked near the

articulating surfaces, which since the shaft of the component is still firmly implanted may lead to fracture of the prosthesis. Once loosening has started it is usually progressive.

In late loosening there are several causes which could give rise to the loss of fixation: 1) sepsis, 2) reaction to implant wear and corrosion especially in metal-sensitive patients, and 3) fatigue failure. Infection is relatively intractable at this level in the bone and once begun usually remains. Anti-microbial cements may overcome this to some extent.

Particulate material is produced as a result of wear on the articulating surfaces. The degree of wear varies with the type of implant. Metal-to-metal implants have a much greater rate of wear. In response to the wear particles produced, the articulating surfaces are surrounded by macrophages and giant multinucleate cells. The number of these cells depends upon the rate of wear.[6] In a sucessful implant a state of equilibrium exists between the amount of foreign material produced and the number of macrophages and giant multinucleate cells. If the rate of wear is too great the macrophages and giant cells proliferate and eventually lead to granulation tissue resorption and loosening. This reaction is exaggerated in metal-sensitive patients. The breakdown of granulation tissue is rapid and widespread in these patients. Figures 1-4 and 1-5 illustrate this process of loosening due to wear. The following section will look at detection of the loose prosthesis.

Detection of the Loose Prosthesis

Detection of the loose prosthesis can be done at present by a variety of means. The diagnosis of a loose prosthesis is the complete instability which precludes load-bearing. Occassionally relative motion can be felt or heard through a stethoscope. The clinical signs are listed in table 2.[4]

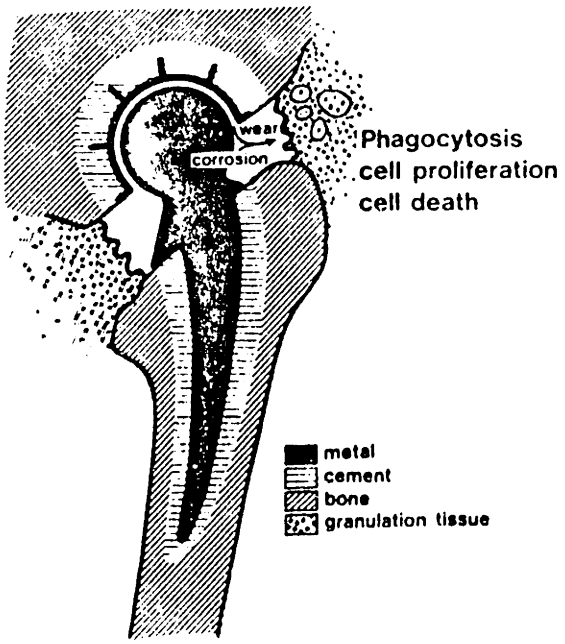


Figure 1-4 Diagram Illustrating Proliferation of Macrophages and Giant Cells in Articular Tissues in Response to Products of Wear and Corrosion (after B. Vernon-Roberts & M.A.R. Freeman)

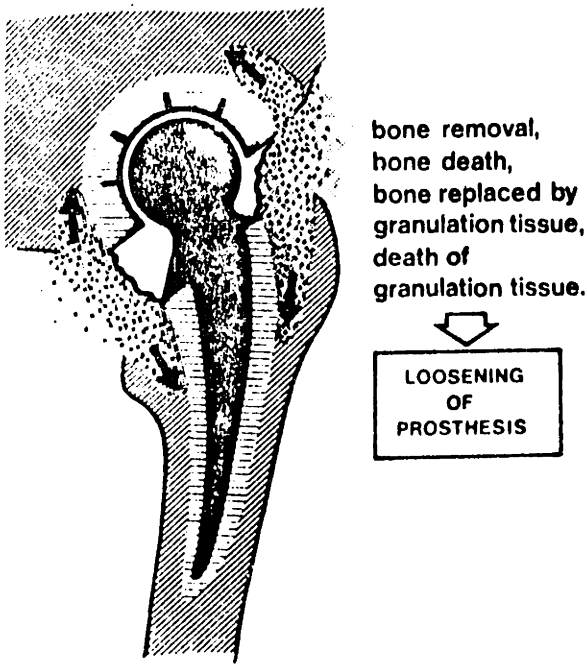


Figure 1-5 Diagram Illustrating How Loosening of Prosthesis Arises from the Extension of Articular Granulation Tissue into the Bone and from the Removal of Bone around the Cement Which Bonds the Prosthesis in Position

TABLE 2

Signs of Loss of Fixation

X-ray	Extended zone around prosthesis
X-ray image intensifier	Mobility between bone and prosthesis
Arthrography during traction	Radiopaque fluid between cement and bone.
Scintigraphy	"Hot" zones around the joint

Each of these diagnostic tests are useful if the loosening is quite severe but not very good if the loosening is not fully advanced.

This study proposes using mechanical testing as a new means of predicting loosening of the prosthesis. Characterizable signals have been obtained to distinguish in vitro, the well-fixated or "tight" femoral component and both completely and partially loose components. Hopefully this method will provide an earlier detection of loss of adhesion leading to a better understanding of the development of loosening and its clinical management.

System Development

There are two main approaches to the investigation of component loosening. The first involves using the present artificial hip implant components and through some means identifying the cohesion of the cement to the bone. This is the preferable method since no other additional components are introduced into the body, maintaining the stress relations of the present system. A particular advantage of this modality is the ability to use it on all those with presently implanted hips.

The second approach consists of modifying the implant in some way so as to better enable loosening to be detected. This would entail inserting into the total hip components whatever instrumentation necessary for this to be accomplished. Thus those already implanted would not be able to use this technique. The ability to insert components without altering the lifetime of the prosthesis may not be very easy, particularly in the acetabular cup where the small size and composition make this appear difficult. Of course the size of the necessary instrumentation would determine their successful insertion to a very large extent.

Both of the above approaches can be further subdivided into various investigative modes. Some of the methods considered are shown in figs.2-1 and 2-2. Figure 2-1 charts the avenues of research for the unaltered components. These areas will be discussed more fully below. Figure 2-2 presents the second approach of modifying the components.

Because of the very substantial advantages of not altering the components, it was decided to concentrate on this approach. One mode, acoustic measurement, was focussed on in particular since in appeared best suited for detection of loosening, and the necessary equipment was easily obtained.

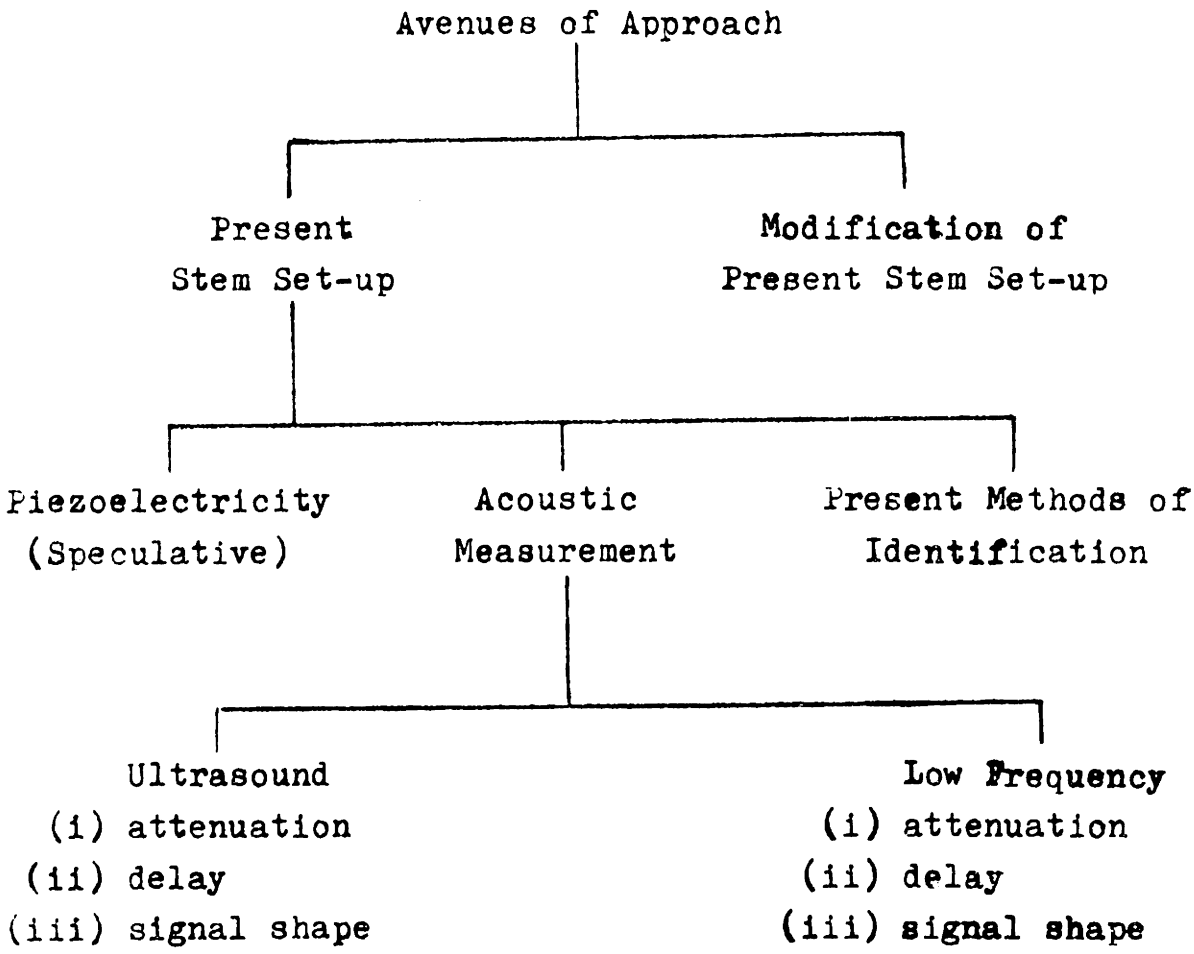


Figure 2-1 One Approach to the Investigation of Prothesis Loosening --- with Unaltered Components

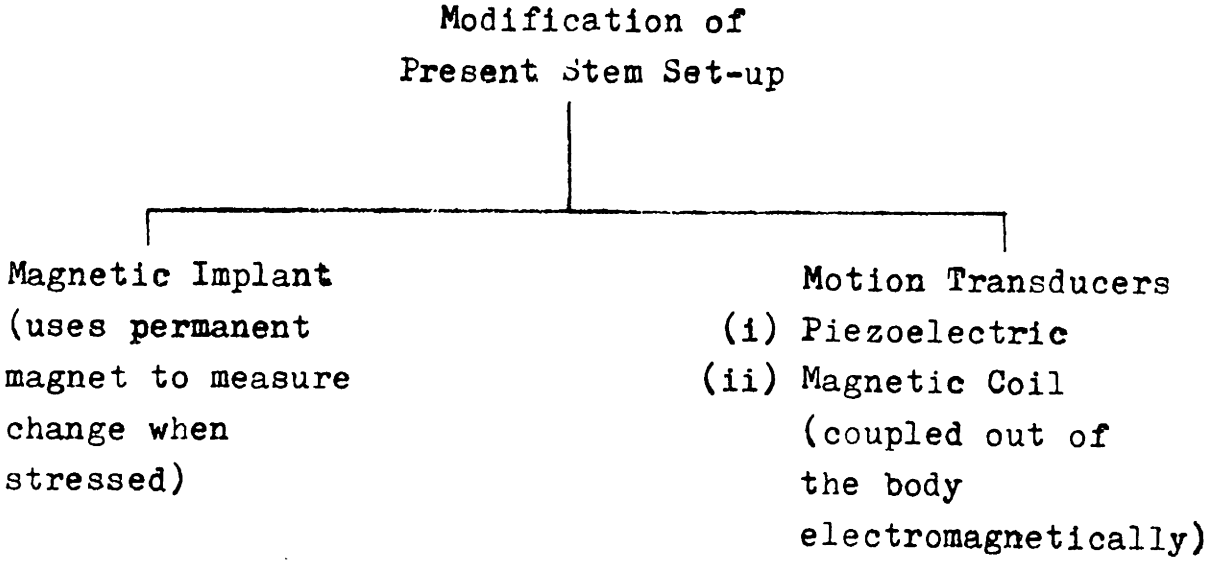


Figure 2-2 Alternate Approach to the Investigation of Prothesis Loosening --- with Modified Components

Throughout the development of the testing system it was assumed that an alteration in coupling would affect the physical characteristics of the implant-bone structure, which would be amenable to conventional analysis.

Analysis of mechanical integrity of bones in fractures repair has long been studied by acoastic means.[7,8,9,10] In 1932 Lippman published a paper on the sound of union and non-union using a percussion hammer and stethoscope.[8] Recently work has been done on mechanical resonance tests to determine bone continuity.[9,10]

In our initial work both high frequency (500KHZ) and audio frequency (300-10KHZ) testing was performed. The first experiment attempted was the measurement of the impulse response of the hip-joint. This was done by repeatedly striking the anterior-superior iliac spine with a reflex hammer. The force generated was monitored by means of a piezoelectric transducer. The input force signal was approximately a pulse 100usec in duration. The response of the system was received both at the greater trochanter and at the medial femoral condyle with a simple microphone. The response was averaged over several "impulses" and then fouvier transformed to obtain the frequency spectrum. This was a poor technique because of the lack of reproducibility of the input force; its amplitude, frequency content and exact area of contact. Additional problems associated with surrounding environmental noise picked up by the microphone hindered analysis. However, the greatest problem was the variability in soft tissue depth and composition. The effect of soft tissue on wave-propagation and vibration tests has been studied by Saha and Eakes.[11] They found that soft tissue decreases the vibrational modes at higher frequencies. Thus the more soft tissue at both the force input and the pickup the greater the decrease in response amplitude and frequency content.

This effect is illustrated in Figure 2-3 where some of their work is reproduced. In this figure the impulse response of an excised whole, dry embalmed human femur was found, dependent upon the amount of soft tissue simulated. The damping effect of the soft tissue is clearly evident. At this point emphasis on the low frequency range was discontinued and transferred instead to high frequency ultrasound (500KHZ). It was hoped by this to provide less variability due to placement, constant input amplitude and frequency content.

Since ultrasound (500KhZ) is not significantly attentuated by soft tissue[7] it was hoped to avoid the problems of soft tissue at least in altering the signal input. The equipment used a pulsed Panametrics Doppler unit that allowed both transmission through the inplant-bone system and reflection off the various media interfaces. With ultrasound it was hoped to detect more of the microscopic changes that occur prior to and upon loosening.

However at a frequency of 500KHZ analysis of the received signal proved too difficult. Sound propagation in air and soft tissue is longitudinal or compressional where the particle motion is in the direction of energy propagation. In bone sound can also propagate as a transverse or shear wave where the energy propagates normal to particle motion. Finally Rayleigh surface waves may also be propagated in bone.[7] These three modes of sound have different propagation velocities with the compression wave having a velocity approximately twice that of the shear and Rayleigh waves. With these differing modes and internal reflections the resulting waveform is extremely complex. Therefore this approach was abandoned and attention returned once more to low frequency analysis.

Many investigators have measured the resonance frequencies of human

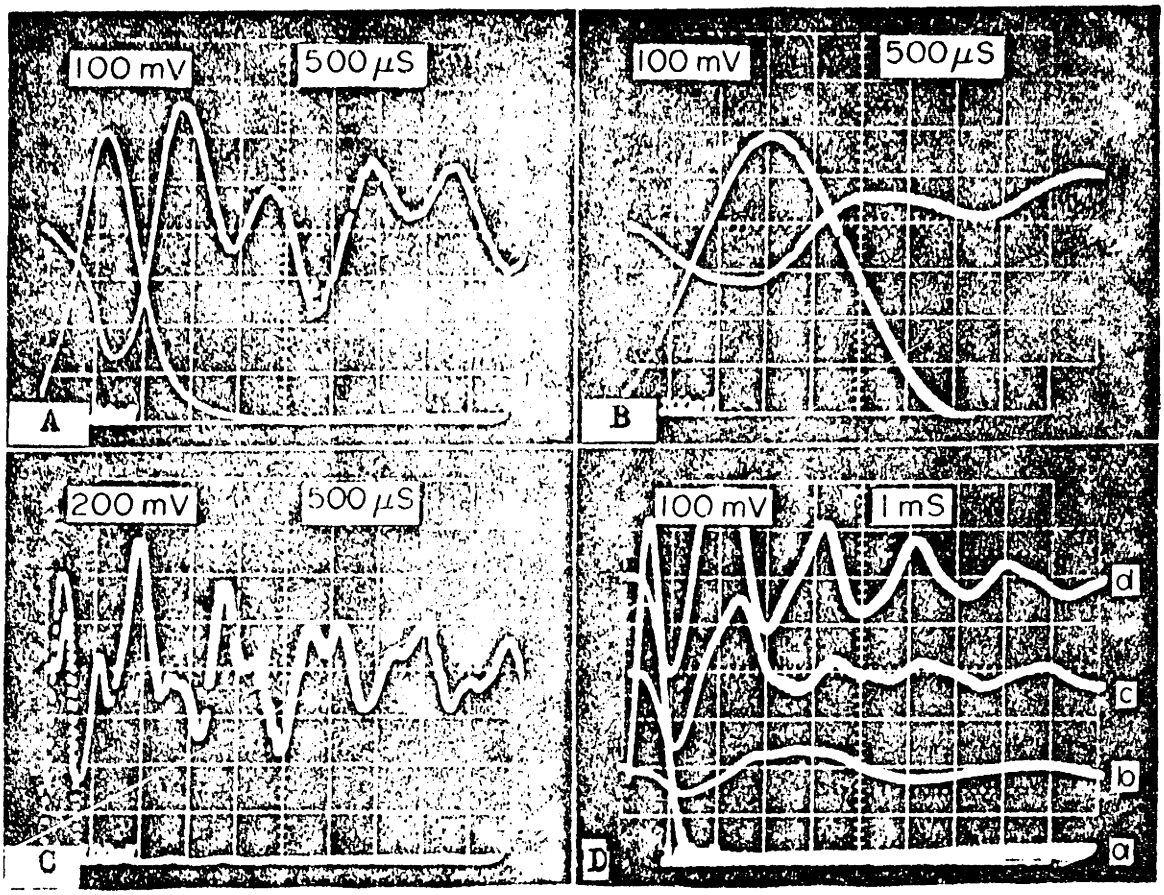


Figure 2-3 **Effect of Soft Tissue on the Impulse Response of Excised Human Bone**

(A) One layer H rubber between hammer and bone. Scale: Top, acceleration, 10g/div. Bottom, impulse force, 2 lb/biv.

(B) Three layers S rubber between hammer and bone. Scale: Top, acceleration, 10g/div. Bottom, impulse force, 2 lb/div.

(C) Hammer impacted directly on bone. Scale: Top, acceleration, 20g/div. Bottom, impulse force, 2 lb/div.

For figures (A) through (C), accelerometer was fixed to the bone; horizontal scale, 500 sec per division.

(D) Curves: (a)(bottom)Impact force, 2 lb/div. (b)(c)(d)Acceleration, 10g/div. (b): Four layers of rubber between accelerometer and bone. (c): Two layers. (d): One layer.

(After Soha and Lakes)

long bones both in vitro and in vivo for assessment of bone strength.[9,10,12,13] For example Jurist has correlated the frequency of the ulna times the length of bone with the osteoporotic state of the bone. The usual method of determining the resonant frequency is to apply a constant amplitude swept - sinusoidal force by means of an electromechanical shaker in the range of 30-1000HZ. The resulting acceleration is measured by an accelerometer located on the bone. Several models describing the response have been proposed to predict the resonant frequency as a function of longitudinal elastic wave propagation velocity, length of bone, cross-sectional boundary conditions and modes of vibration.

In our project instead of returning to the measurement of impulse response we decided to use the available information on resonant frequencies and its determination to characterize the implant-bone system and its components.

Independent of our research a group of doctors in Lille, France have constructed a very similar testing procedure.[14] Using a frequency range of 40HZ - 20KHZ they input the force through a Danis probe on the anterior superior iliac spine. The output was recorded from the diaphysis of the femur by an accelerometer. The amplitude of the output signal was recorded as a function of frequency. In this testing procedure the signal is transmitted across the joint. In vitro work was not presented.

Similarities and differences between their work and ours will be examined in the Discussion section.

Instrumentation and Method

The frequency responses of the in vitro components were obtained by the following technique. A Hewlett Packard 501 sweep oscillator provided a constant amplitude swept-sine wave over the range of 100HZ - 5KHZ with

a sweep rate of 20 seconds. The signal is then amplified and impedance matched by a Scot 299 audio amplifier. The output of the amplifier drives and eight ohm 5 1/2" speaker. The speaker is modified so as to provide a force output by the addition of a one-holed rubber stopper, glued to a steel washer mounted on the speaker diaphraghm. A steel hypodermic needle was inserted into the rubber stopper. This provided greater force per unit area, easy replacement and adequate strength for the vibrating input. The setup schematic is given in figure 2-4.

The output was obtained by a vibration transducer Texas Instruments Guitar Transducer. The transducer was attached to the tested component by means of the contract adhesive provided with the transducer. The transducer's operating frequency is similar to the range of excitation. The output signal was then amplified and bandpassed over the range 300HZ-10KHZ by a Princeton Applied Research Pre-Amp. The lower cut off removed the low frequency vibration inherent in the system. The amplified signal was then input to a Princeton Applied Research fourier transform machine model #4512. The spectrum was computed continuously at the sampling rate and displayed on a Tektronix 5103N storage scope. Since the fourier machine samples at a constant rate while the sweep oscillator is an exponential sweep one must be careful not to sweep at a too great rate so as not to lose resolution. As the oscillator sweeps over the frequency range the storage scope records the changing spectral distribution. The cumulative effect is to display the response of the system as a function of frequency. The display is then recorded off the scope by a Tektronix polaroid scope camera. During testing the electronics were maintained in a standard configuration listed in Table 2-1 to reduce extraneous variability and allow easier comparison.

The physical apparatus used to suspend the components during testing

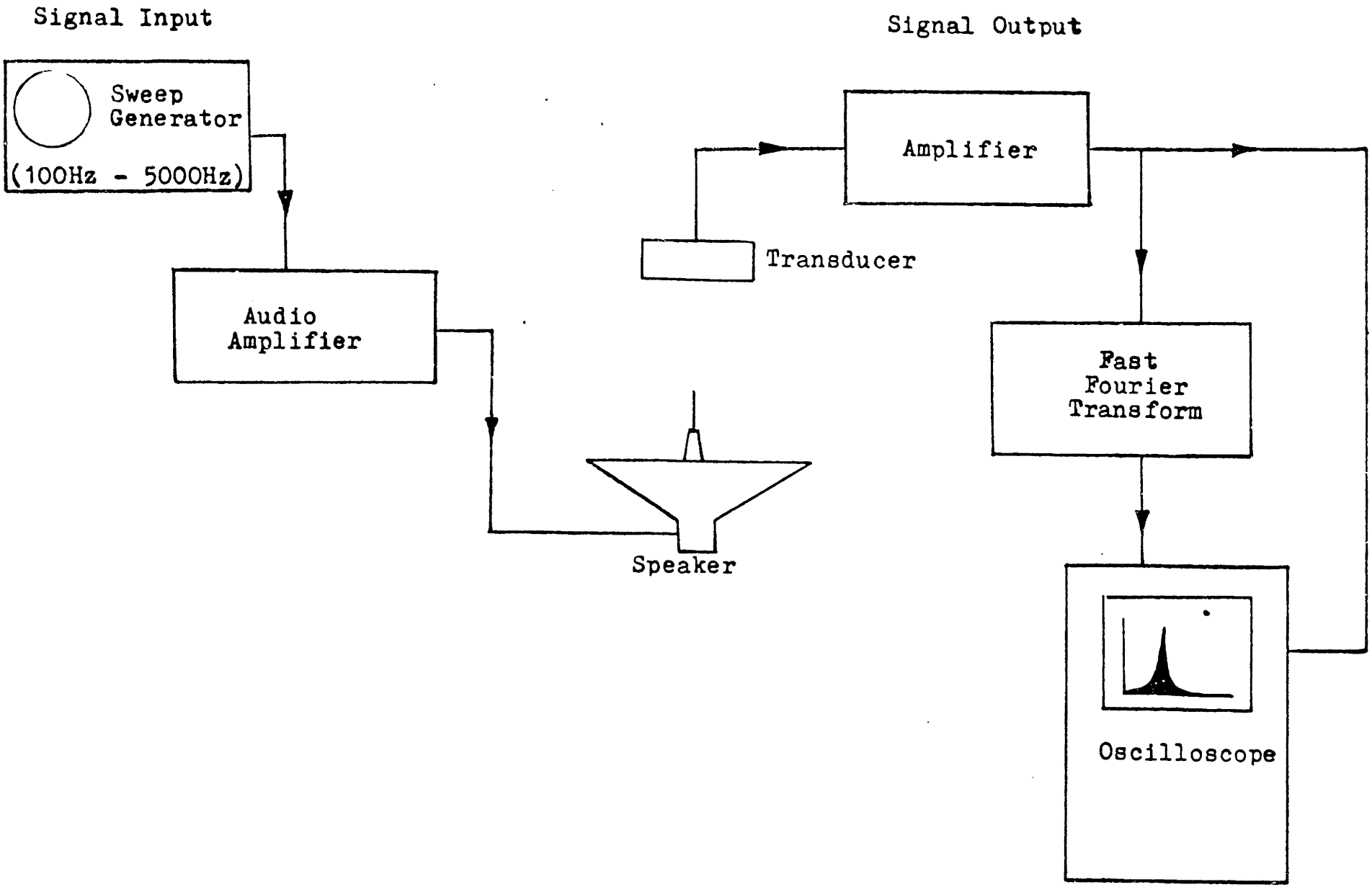


Figure 2-4 Schematic Diagram of Electronics Set-Up

is shown in figure 2-5. The speaker was supported by a lab bench while the height of the tested component was adjusted by moving the support bar up and down. The tested component was placed so that it rested on the vibrating needle causing appreciable bending.

With this apparatus the following components of the implant-bone system were tested; the femoral stem and ocetabular cup, the tightly implanted stem-cement-bone, and the femur without cement but hollowed out. No acetabulum was tested, nor were any acetabulum-cement-cup systems.

The bones and implants used in this experiment were kindly provided by Dr. Robert Poss of the Robert Bent Brigham Hospital. The prostheses were Austin-Moore devices manufactured by Zimmer Inc. The three femurs used in the study were of two types. The femurs in the tightly implanted stem and the totally loose non-cemented stem were partial excised human femurs. They extended in length from the greater trochanter to mid-diaphysis. The partially loose cemented stem was implanted in a whole excised human femur.

Experiments were performed using the above apparatus to determine the affect of transducer placement and excitation position along the bone or stem. The affect of soft tissue was simulated by wrapping a one inch strip of one eighth rubber around the femur. The excitation was then placed on the rubber to drive the bone-stem system. Since this was an in vitro experiment there was generally no fluid between the loose stem and bone. The action of the joint fluid was simulated by using a water-filled plastic bag.

The next section lists the results obtained to the above described experiments.

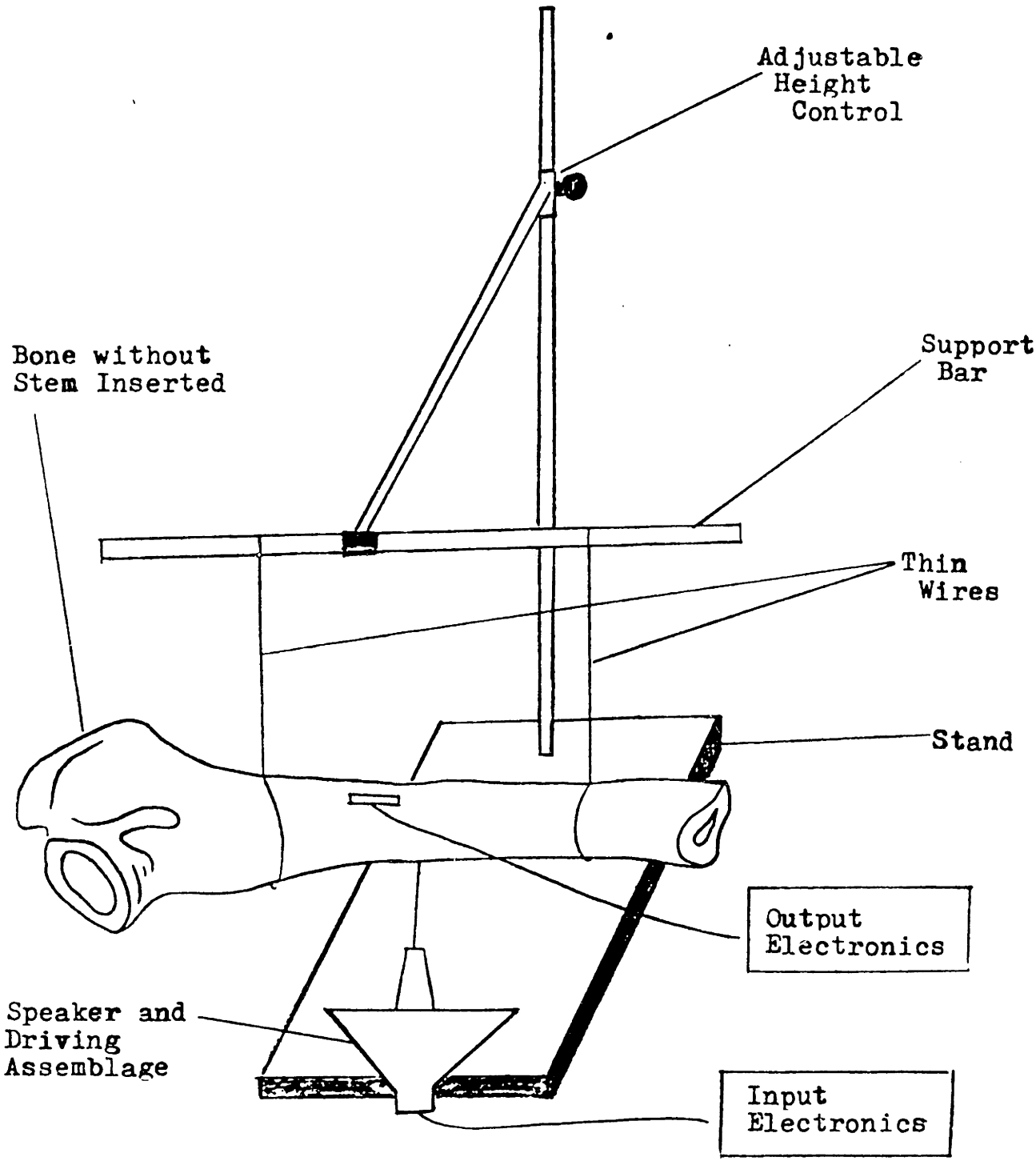


Figure 2-5 Experimental Apparatus

Results

Before examining the specific details of the results obtained, a word should be said about the recording method. As mentioned previously, the frequency response was photographed from the oscilloscope display using a Tektronix polaroid scope camera. The frequency range was constant throughout the experimentation at 0-5000HZ. Each division (1cm) of the oscilloscope graticule therefore corresponds to an increment of 500HZ. The frequencies of the major peaks were obtained by making use of the cursor provided in the fourier transform machine. This allowed resolution to within 10HZ. The frequency of the smaller peaks can be estimated by using the graticule.

Variation of Driving Speaker Position

This subsection will present the frequency responses obtained by varying the excitation position and transducer placement for each component of the femoral implant system.

This first set of experiments varied excitation position while keeping the transducer attachment site constant. There were three excitation positions for each of the different situations; the stem alone, the bone without stem, the bone with stem inserted and the tightly implanted stem-bone complex. The tested positions and transducer sites are illustrated in figure 3-1. Due to the complicated structure of these components the same degree of coupling of the needle onto the component may not have been achieved at all sites. Typical response curves for the stem alone and the bone without a stem inserted are shown in figure 3-2.

For the stem, the position of the major resonance peak was independent of excitation placement being constant at 2.01KHZ. The amplitude of the response varied in the different positions. The lowest response was obtained when the stem was driven on its smooth spherical surface. This is probably evidence of the poor coupling mentioned earlier.

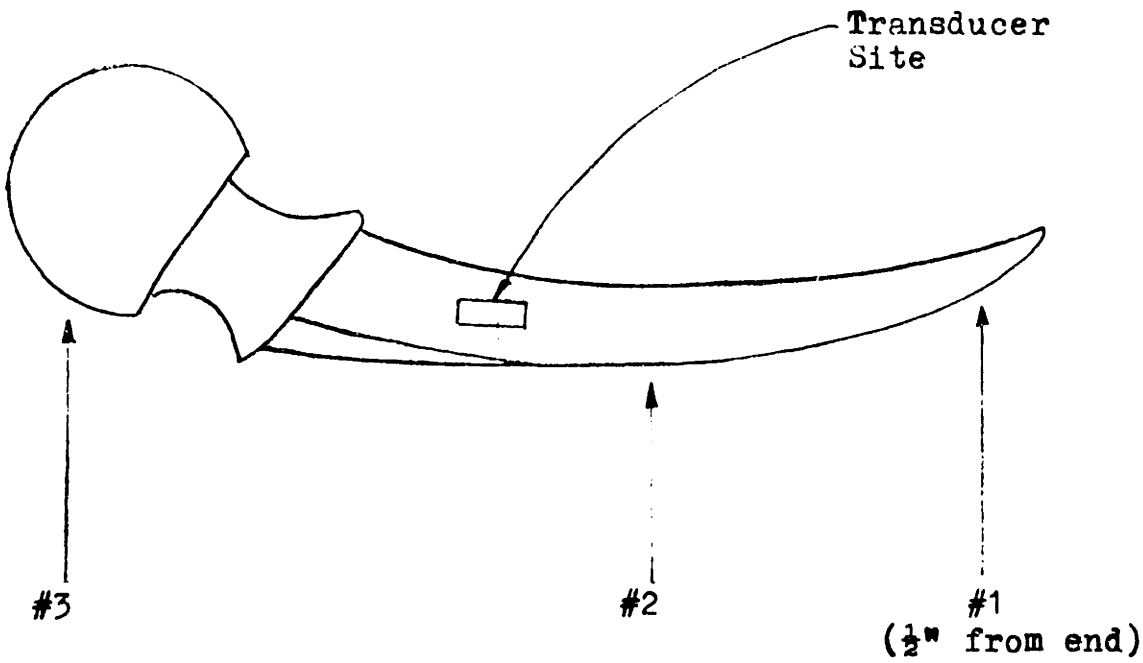


Figure 3-1a **Excitation Positions on Stem**

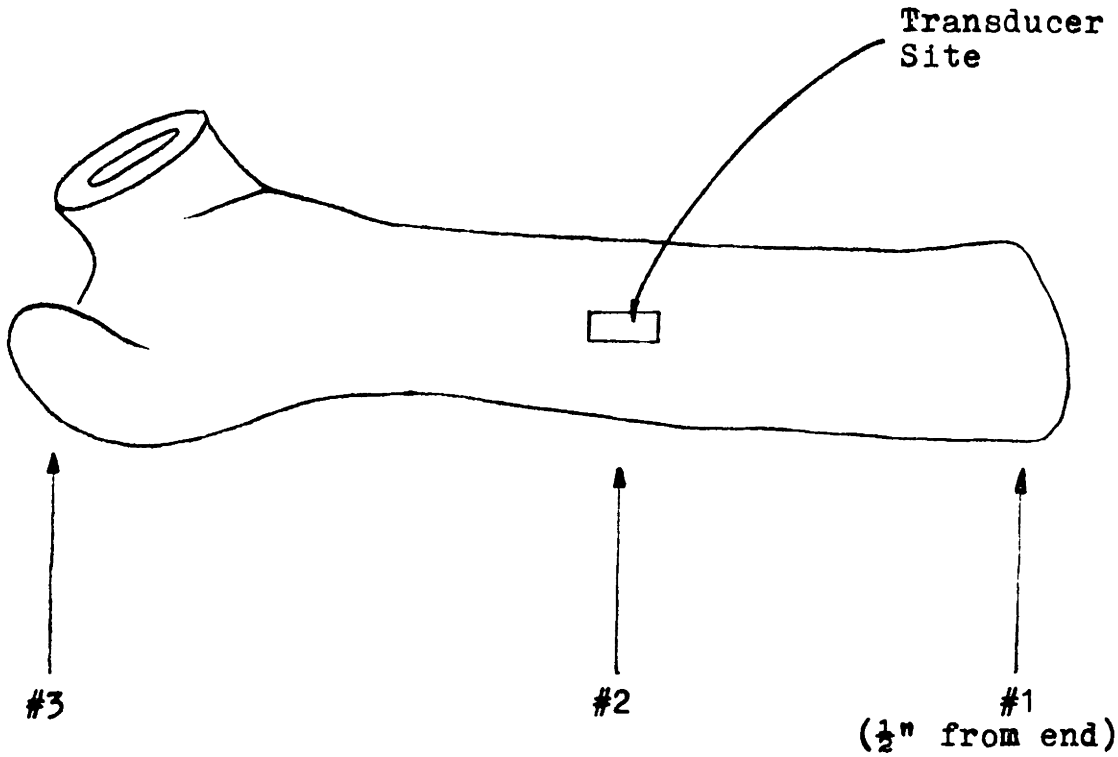


Figure 3-1b **Excitation Positions on Bone**

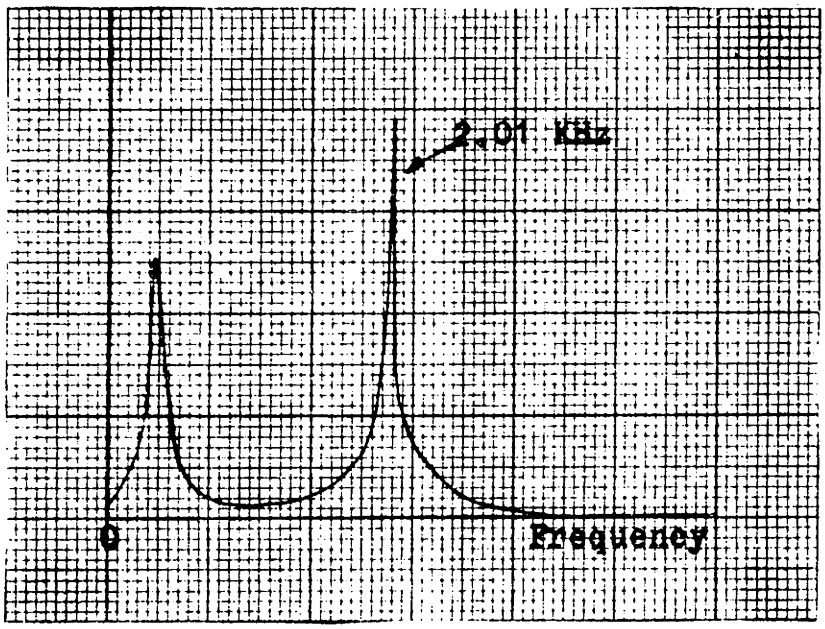
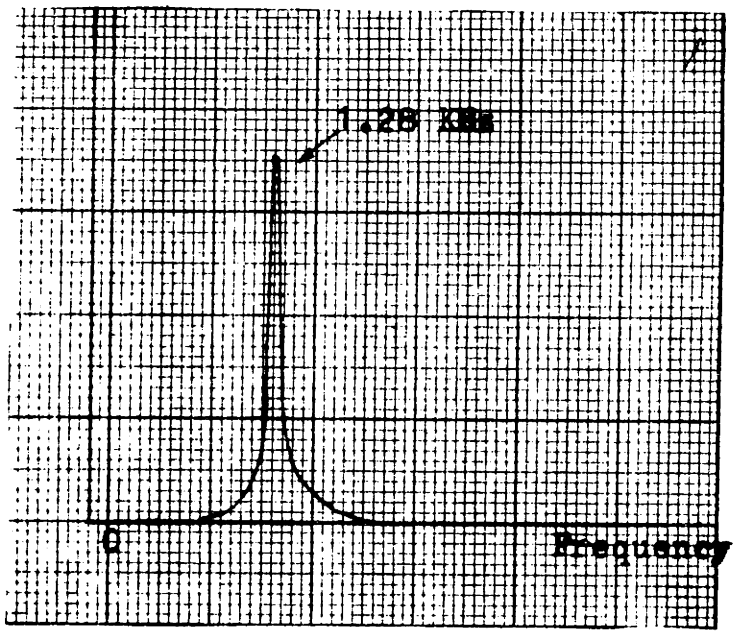


Figure 3-2a

Response Spectrum of Stem Alone

Figure 3-2b

Response Spectrum of Bone Alone



The bone without an inserted stem showed a sharp resonance at 1.28KHZ. Again the response was independent of driving position.

When the stem was inserted into the bone with hand pressure the response differed from those described previously. This result is shown in figure 3-3. The peak at 1.28KHZ is still the greatest in amplitude but now an asymmetrical damping is seen toward the higher frequencies. The skewness of the curve may be slightly position dependent. Notice that no significant resonance at 2.01KHZ or in the surrounding region is seen. The position of the major peak did not vary with different excitation positions.

The response of the tightly implanted complex is seen also in figure 3-3 when the driver was at position 2. Two major peaks are seen above 1KHZ. The lower of the two is at 1.18KHZ while the higher one is a 2.18KHZ. This frequency curve is very different from that of the loosely inserted stem. The sharpness of the resonances for these two peaks is such that the amplitude for the region around 1.5KHZ approaches baseline. This is not the case for the loosely inserted stem under any of the tested conditions. The response of the tightly implanted stem does vary with position. In excitation position 2 the amplitude of the bone resonance to the stem resonance is approximately 2:1. At the end farthest from the stem this is increased to 5:1. At the end over the stem on the greater trochanter the amplitude of the stem response is reduced still further to a new ratio of 6:1. The relative amplitudes are shifted but the peaks are at the same frequencies.

Transducer position was varied but due to the relatively large size of the transducer (1/4" x 1" x 1/8") and the convoluted shape of the bones and stem only a limited number of positions could be tried. The frequency peaks obtained were independent of transducer placement at those locations attempted.

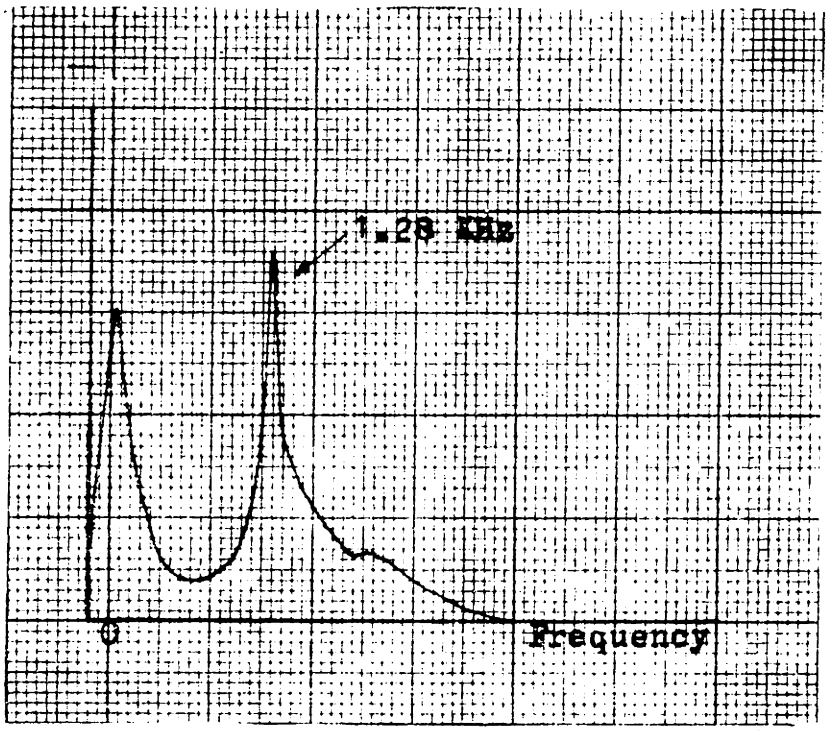
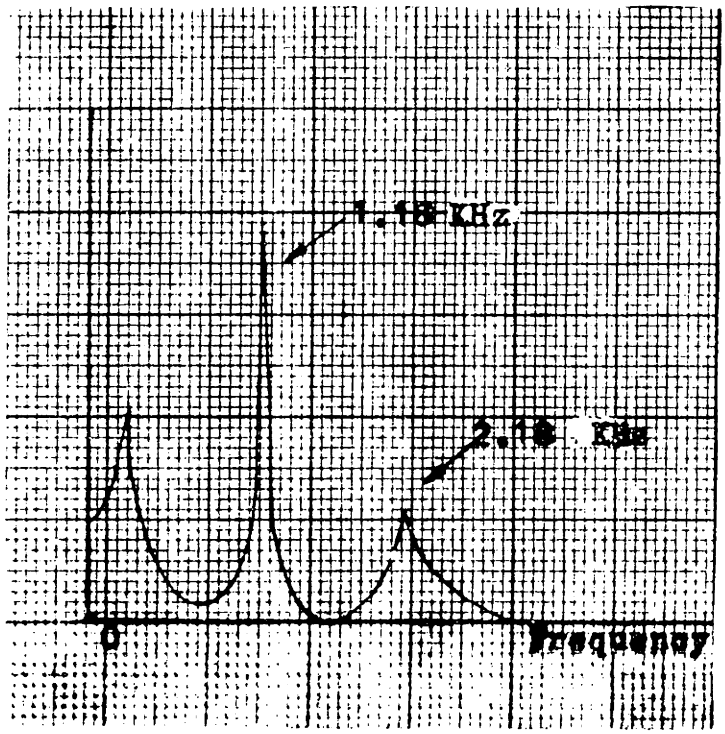


Figure 3-3a

Response Spectrum of
Loosely Implanted
Complex --- Bone Driven

Figure 3-3b

Response Spectrum of
Tightly Implanted
Complex --- Bone Driven



Next the response to exciting the stem with the transducers on the bone was determined. The results for both the loosely inserted and the tightly implanted stems are shown in figure3-4. In the loosely inserted stem a second peak appears at 1.90KHZ. This is not a sharply defined peak at one frequency but rather a plateau over 150HZ in width. (1.82KHZ-1.97KHZ). Again note the relatively high amplitude of the mid-region, circa 1500HZ, of the loosely inserted stem compared to the tightly implanted stem. No new peak appeared in the tightly implanted stem response when it was driven on the spherical surface of the stem. The frequencies of the major peaks are 1.20KHZ and 2.17KHZ, approximately the same as before. The transducer position was maintained.

Simulation of Soft Tissue

The action of the soft tissue was simulated as stated previously by wrapping and gluing a one eighth inch thick, one inch wide strip of rubber around the tightly implanted stem bone complex. The driver was then placed under the rubber, but the needle was not driven through to the bone as illustrated in figure3-5. The curve obtained both at standard gain and at increased gain (~8X) is shown if figure 3-6. Stem response is not seen at either gain setting. To verify that this indeed was a change due to the rubber, the deiver was moved off the rubber and placed back on the bone keeping the rubber strip in place and transduce position constant. The response returned to that normally seen for the tightly-implanted stem with excitation on the bone. The rubber then effectively dampens the stem response by filtering and/or attenuating the input signal.

Simulation of Joint Fluid

Water was placed between the loosely inserted stem and bone to determine whether there is enhanced coupling when fluid surrounds the loose stem.

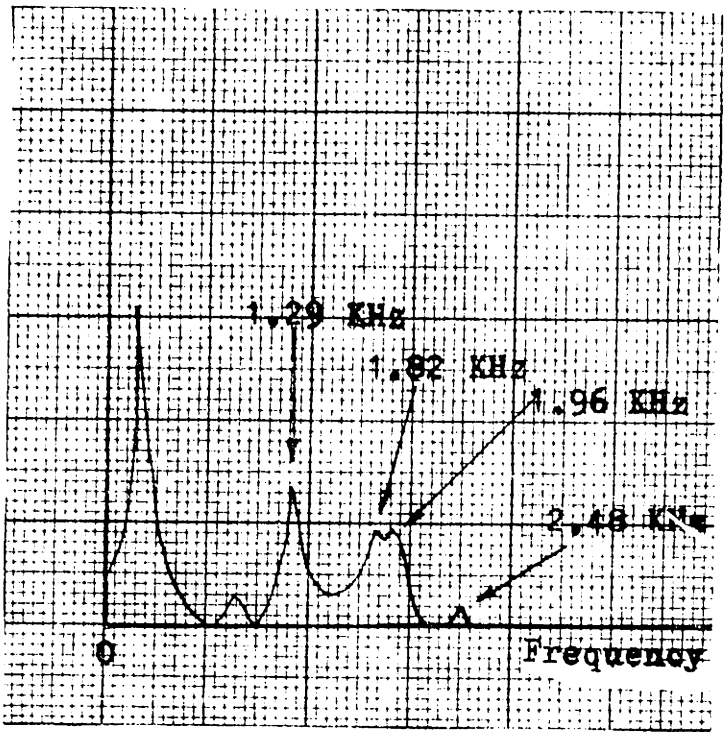
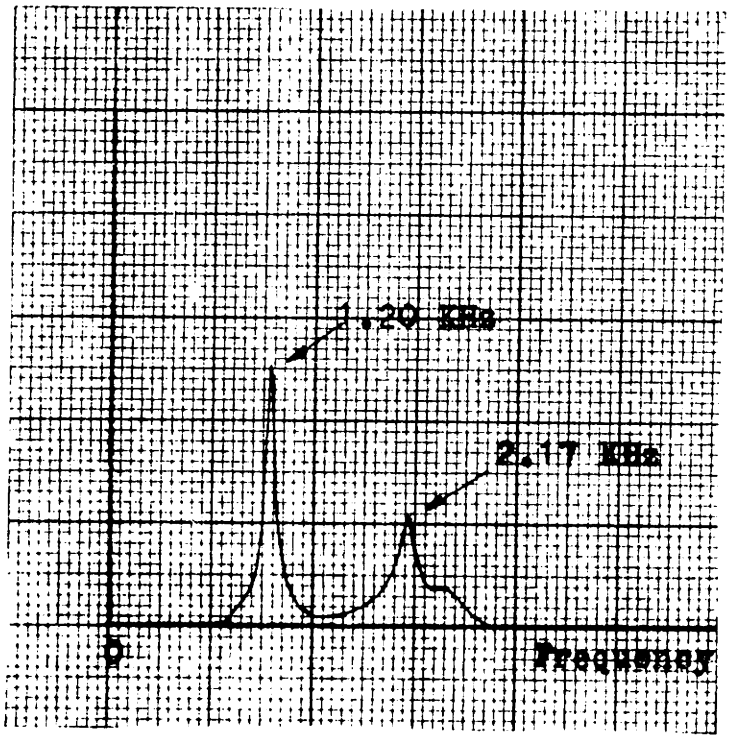


Figure 3-4a

Response Spectrum of
Loosely Implanted
Complex --- Stem Driven

Figure 3-4b

Response Spectrum of
Tightly Implanted
Complex --- Stem Driven



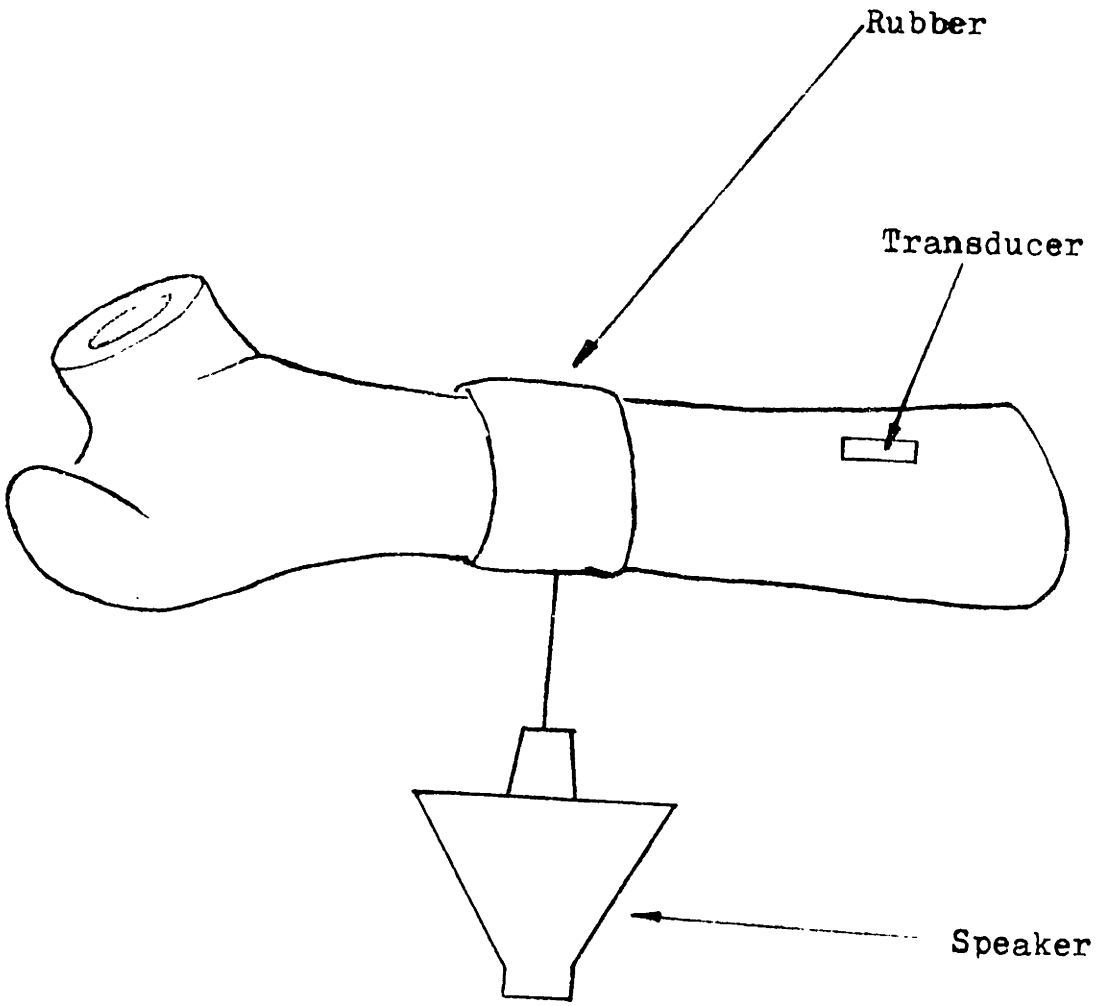


Figure 3-5 Simulation of Soft Tissue Experiment

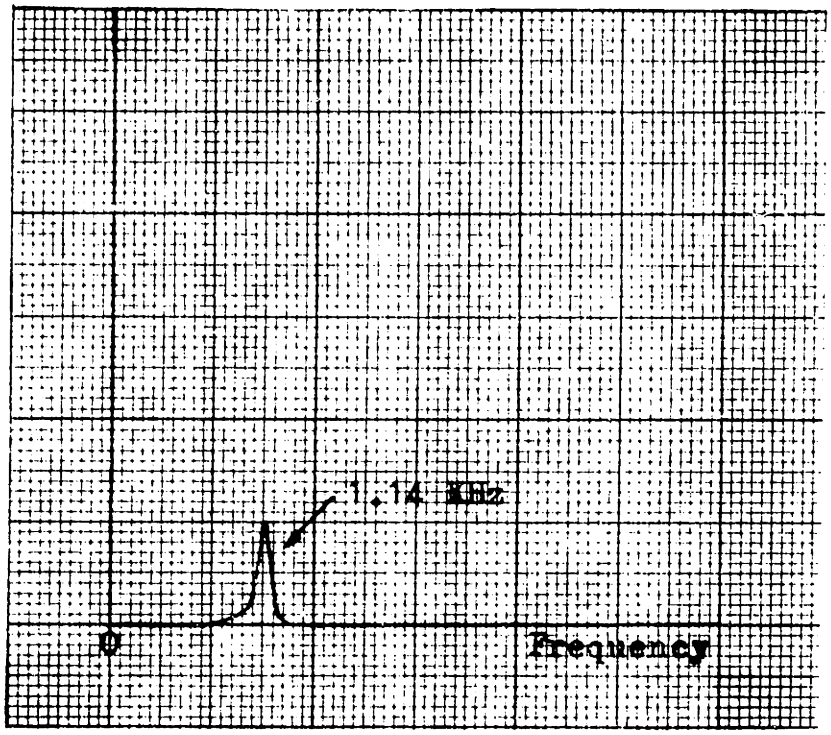


Figure 3-6a

Response Spectrum Showing Effect of Simulated Soft Tissue on Tightly Implanted Complex (Standard Gain)

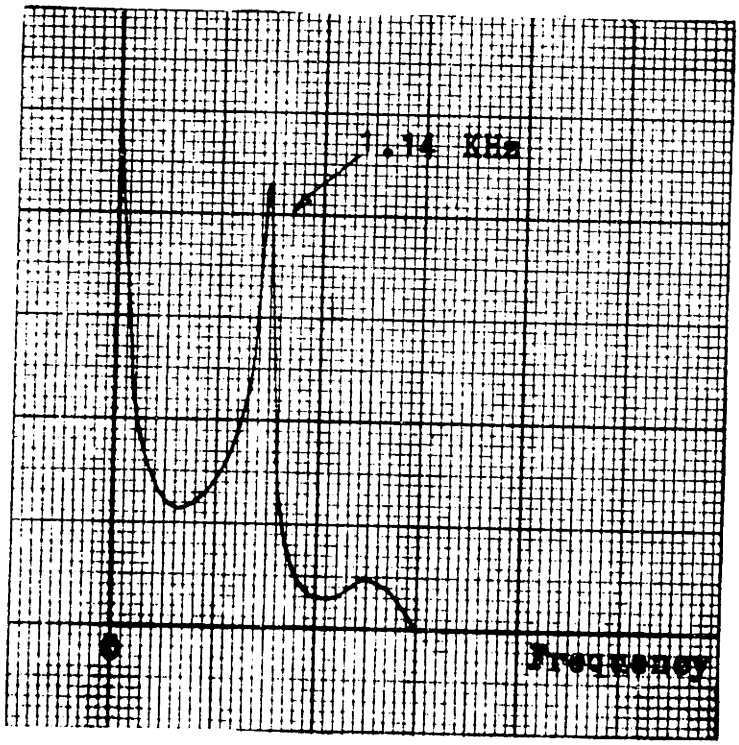


Figure 3-6b

Response Spectrum Showing Effect of Simulated Soft Tissue on Tightly Implanted Complex (8X Gain)

The transducer was placed on the diaphysis above the attachment of the plastic bag. The system was driven on the bone near the transducer. The response is shown in figure 3-7. The fluid surrounded not only the stem in the bone but also the head of the stem external to the bone. In figure 3-7 there is no visible improvement in stem resonance as no peak appeared around 2KHZ. A new peak was introduced at approximately 1.5KHZ which was broad in resonance. The sharp bone resonance has either been shifted downward or has disappeared completely.

A partially loose implant defined as hand tight (but radiologically loose or without cement at some point along the shaft) was tested. The implanted stem was in a whole femur so the results cannot be directly compared to that of the previous cases. Its response with both transducer and driver on the proximal diaphysis is shown in figure 3-8. Five very sharp resonances are seen occurring at .83HZ, .99KHZ, 1.16KHZ, 1.74KHZ and 1.96KHZ. Clearly this response is quite distinguishable from either the totally loose or tightly implanted prosthesis. The reason for the five peaks in this response is not known

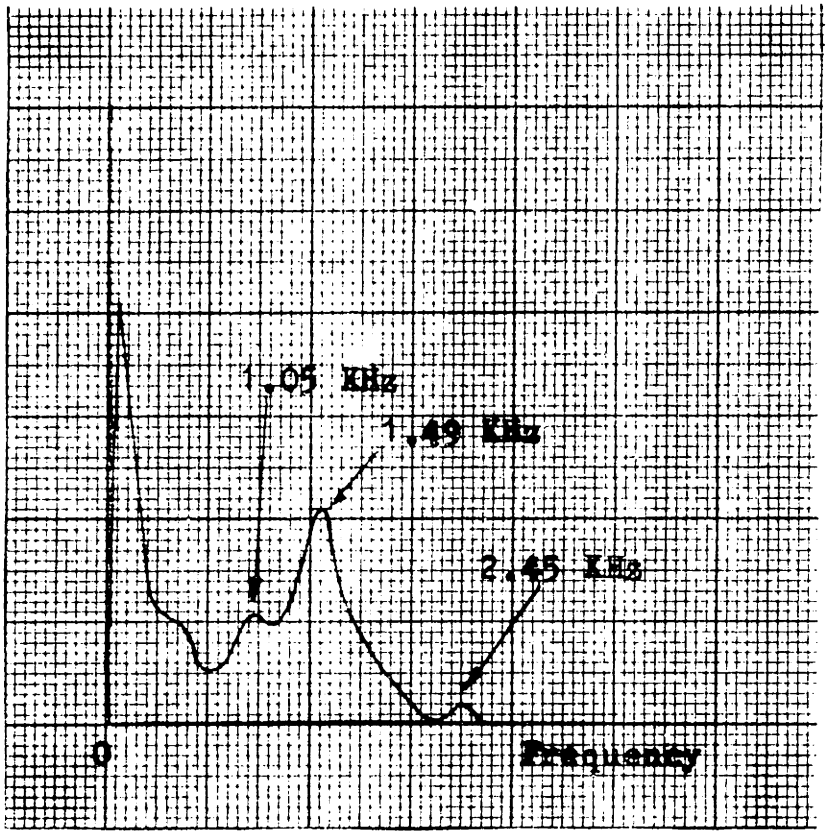


Figure 3-7 Response Spectrum of Simulated Fluid-Joint System

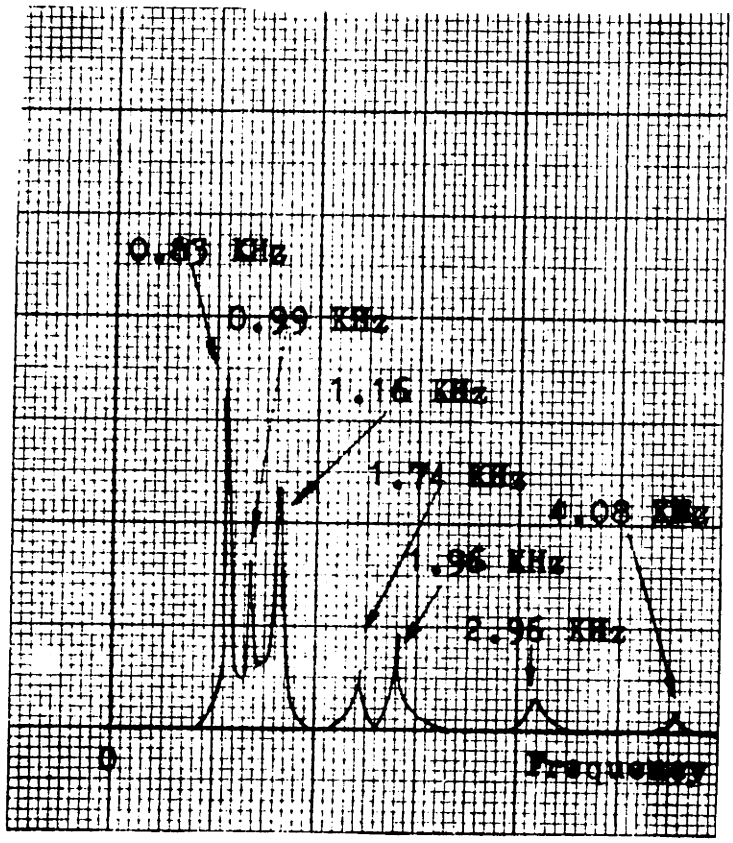


Figure 3-8 Response Spectrum of Partially Loose Implant Complex

Discussion

The results of the preceding section clearly show the easy distinguishability of the frequency responses obtained under differing states of adhesion in vitro by the frequency peaks obtained. However the existence of a frequency peak in the region of 2KHz is not the only change that occurs with tight adhesion of the stem. There is a frequency shift as well as seen by comparing the free stem response to the second peak of the tightly implanted stem. (2.01KHz versus 2.18KHz) The reasons for the direction and magnitude of the frequency shift are not known. A concomitant shift downward of the lower frequency peak also exists, however the magnitude of the two shifts are not equal. Naturally the question arises whether further characterization of the system will allow more accurate estimation of loosening.

The cases studied in this thesis were the simplest possible. From these gross models, only qualitative statements can be made so far. This is due both to the complicated structures involved and the lack of a suitable physical interpretation of coupling. Perhaps if the structures were much simpler a mathematical model might be derived that would help interpret the results and their dependence upon coupling. No easy approach has been found as yet. Therefore the technique remains an empirical one. Only with more data from refined experimentation may it be possible to accurately assess the phenomena.

As outlined previously a team of researchers headed by J. Decloux in Lille, France have reported on the development of a similar testing procedure. Their system known as Coxonar also uses a swept-sine wave input (40Hz - 20KHz) and an accelerometer as the output transducer.

The signal was input on the anterior diaphysis of the femur above the level of the knee joint. The output was recorded off the anterior-superior

iliac spine.

Decloux has done a clinical study of 78 total hip patients. The patients studied had had bilateral total hip replacements with one-sided loosening. This effectively allowed them to have a control for each loose prosthesis.

The results they obtained showed a good correlation with clinical loosening of the cup. (29 cases out of 31 confirmed clinically or during surgery) However loosening of the stem was not diagnosed with any certitude (10 cases out of 20). The waveforms were reproducible for each patient. Typical responses for both the tightly implanted prosthesis and loosening implants are reproduced in figure 4-1.

A tightly implanted prosthesis waveform started at 40Hz and increased in amplitude until 1200Hz. From this peak the amplitude decreased sharply returning to baseline in the range of 4000Hz. In the case of a clinically evident or surgically verified loosening the waveform has an altered response. There are now two major peaks the upper one at 1000Hz and the lower which starts around 120Hz and extends to 270Hz. The origin of these peaks is not known, however the acetabular cup has a free resonance around 250Hz.

Direct comparison of Coxonar results with those of this study are difficult since the exact characterization of the Coxonar system is not known. The difference between an in vitro and in vivo study is extremely hard to predict in this case. Superficially the results seem contradictory. Upon loosening of the cup two peaks are seen while for loosening of the stem only one is seen. However recalling the frequency shifts seen with tight adhesion we can hypothesize what is occurring. For the free stem the peak was at 2.01 KHz. Upon tight adhesion the peak was shifted upward. The bone frequency was shifted downward (1.28KHz to 1.18KHz). Assuming similar shift direction

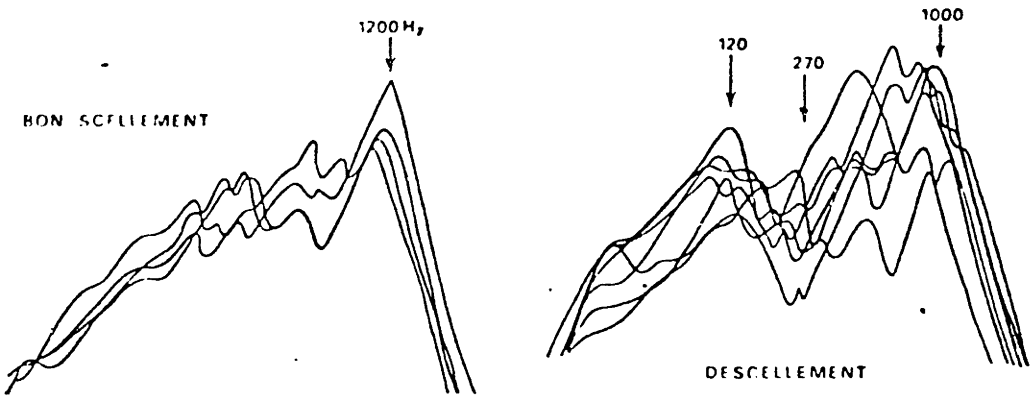


FIG. 5. — A gauche : *superposition de 4 courbes de prothèses bien scellées.*
A droite : de 7 courbes de prothèses descellées.

Figure 4-1: Response Spectra of Human Hip-Joint Prothesis System in Coxonar Experiment

a) Super position of 4 responses of tightly implanted prostheses.
b) Super position of 7 responses of loose prostheses.

for upper (bone?) and lower (cup?) peaks we see that upon loosening the higher peak should decrease from 1200KHz which it does. Secondly a new peak has appeared. If the lower frequency peak was below 40Hz in the tightly implanted case it would not appear on the response until loosening appeared. This is conjecture of course at this point because the origins of the peaks are not known.

The work of Decloux raises the important question of why no response was obtained above 1200Hz. The extremely linear decrease in amplitude once the higher peak has been reached is very difficult to explain. Perhaps this filtering is due to transmission across the joint. The joint fluid may filter the higher frequency signal components although this doesn't seem too likely from the crude fluid simulation performed here. Another possibility may be that the input through the soft tissue attenuates the higher frequencies. This is seen in the simulation performed here if placing the needle on the rubber pad is a valid model. However in Decloux's work specific mention is made of placing the needle directly on the bone. Additional work is clearly required to settle the questions raised here.

Future Studies and Conclusion

The most immediate future work is the development of an in vivo system. With an in vivo system development will be more directly attuned to patient needs. In designing the in vivo study many difficulties and questions are bound to arise. Some of the primary considerations are

1) Is the present system sensitive enough to detect the in vivo loosening of the cup and stem?

2) Do the in vitro results correspond to the in vivo results?

3) How dependent is the response to position of input excitation and output transducer point?

4) What is the effect of soft tissue?

5) If the system is sensitive enough to detect loosening, at what stage is loosening discerned?

The future clinical uses may be as periodic checks; where the response waveform is compared with responses obtained post-operatively. The basic assumptions behind this use are that the initial insertion is tight and that any change reflects loosening. A second use would be at the operating table to verify that the stem and cup had been inserted correctly. s would require that a loose prosthesis could be differentiated directly from an tightly implanted one.

In this study a new diagnostic method for detection of prosthetic loosening has been advanced. The in vitro work so far has proved encouraging but future study will be required to accurately assess the clinical significance of this method.

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