IN VIVO LOADING ON KNEE JOINT REPLACEMENT

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The Biomechanics Laboratory of Case Western Reserve University has had considerable experience in the techniques of radio telemetry of in vivo load data. Our work on the total knee replacement has been greatly influenced by our previous experience with instrumented hip nails. For several years we have been conducting a study of in vivo loads imposed on hip nails used to treat various disorders of the proximal femur. Nails containing telemetry instrumentation have been inserted in five patients. These patients have been monitored for periods of 6 months. This is sufficient time to follow the course of recovery from the various operative procedures. During this 6-month period, the devices were monitored while the patients were performing various activities necessary for daily living. In addition, the nails were checked while the nursing staff cared for the patients. Finally, when the patients were ambulatory, nail loads were noted during all critical phases of early ambulation, and periodically during the later recovery period. Particular care was taken to record early transient activity such as climbing out of bed for the first time, getting into a wheelchair for the first time, or using a walker.

The instrumented hip nail was designed and constructed at Case Western Reserve University. The nail is a two-piece design (Fig. 1). The main body, made of 316L surgical grade stainless steel, contains all structural elements necessary to provide the strength and rigidity needed to perform its biomechanical function. In addition, the main body contains two cavities, one of which accepts the strain gage instrumentation and batteries, while the other houses the electronic circuits. The second piece of the nail is a cover plate which is used to mechanically seal all electronic components from the external environment.

a Now at the Veterans Administration Hospital, 10701 East Boulevard, Cleveland, Ohio 44106. Presented the paper at the conference.
In addition to the primary mechanical seal provided by the cover plate, two secondary sealing systems are utilized. Under the primary mechanical seal a coat of biological grade silicone rubber is used to separate all the metal surfaces from the third seal which is a low chloride epoxy. Thus, all electronic components are encased in epoxy resin which is in turn covered with medical grade silastic which is in itself completely surrounded by the 316L stainless steel. There are no wires or other electronic devices extending from the nail. Only tissue interfaces the stainless steel. Several of the nails utilized in patient studies have been recovered after periods of implantation from 5 to 9 months. These nails were sectioned and examined for possible fluid contamination of the electronic compartment. No evidence of fluid contamination was found beyond the primary seal.

The electronic circuits consist of two channels of signal generators whose output is a sinusoidal wave in the audio frequency (3,000 and 10,000 Hz). These a.c. signals are modulated in each of the strain gage circuits. The modulated signals are then mixed and sent into an FM transmitter. The AM-FM signals are received by an ordinary FM broadcast receiver where the FM signals are demodulated. The AM signals are
then separated by narrow band pass filters, and the individual signals are amplitude demodulated.

The designs of total knee joint replacements are now well into their third generation. The earliest of these designs are typified by the fixed hinge type of device which required two long stems or skeletal attachments into the femur and tibia. The second generation of devices utilized a sliding joint concept in which one of the halves of the joint replacement was strictly a metal component while the contacting surface was manufactured of high density polyethylene. Third generation designs are now being evaluated and include various combinations of the previously mentioned two design concepts.

Several different design techniques have been utilized in constructing the sliding joint type of total knee prosthesis. Some of these designs have incorporated separate condylar replacement components for the distal femoral portion. The type of design which we have chosen to instrument is of this duo-condylar nature. The reason for this choice is that instrumentation of the type of device which has both lateral and medial condyles cast in the same integral section would allow only the total load borne by both condyles to be monitored. It is possible that some information could be obtained as to loading distribution. Instrumentation of separate condyles, however, allows us to monitor separately the load in each of the condyles and this would give rise to a more accurate and useful measurement of the actual loads that are imposed on each condyle of the knee joint replacement. The loads recorded for the separate condylar prosthesis would of course be entirely applicable in designing a prosthetic device with attached femoral condyles. There is no reason to suspect that the load pattern would be different in response to the design of the prosthesis itself.

Each of the femoral condyle replacements has been constructed according to the design shown in Figure 2. The actual contact surfaces of these prostheses are very similar in nature to those of the available commercial types. The basic difference between the two structures lies in the fact that the body of the prosthesis is instrumented with strain gage telemetry devices. Mechanical construction of the devices is such that all loads must pass through the instrumented central portion before the load is ultimately distributed to the methylnmethacrylate and then to the bony portion of the femur. Our instrumentation allows up to five channels of loading information to be monitored simultaneously. These five channels will allow the determination of surface loads on the prosthesis and will allow the investigation of some of the frictional phenomena associated with artificial joint motion. The design of the prosthesis is such that standard high density polyethylene tibial components may be used in conjunction with the instrumented femoral portion. At the present time we have a completely manufactured and
instrumented prototype which was built of aluminum to allow evaluation of the mechanical design as well as the telemetry components (Fig. 3). This prototype prosthesis performed satisfactorily in all respects. We therefore started production on 12 unicompartmental knee prostheses at Case Western Reserve University.

**FIGURE 2**.—Design of femoral condyle replacement, a. inner portion and b. shroud.
The electronic circuitry is shown in circuit diagram form (Fig. 4). The circuit consists of five parallel signal generators each operating at a different audio frequency. The outputs of these five signal generators power five independent strain gage bridges each with two active arms and two dummy arms. The audio frequency sine wave is amplitude...
modulated as it passes through each bridge. The lowest frequency chosen will be approximately 3,500 Hz. This allows adequate signal resolution down to approximately 300 Hz. All other channels will have resolution capabilities of above 500 Hz. This is deemed more than sufficient for the type of data that are to be recorded. The output signal from the individual bridges are then summed in an operational amplifier. This summed signal is then fed through a transformer circuit into an FM transmitter. The transmitter, a model K-6, is supplied by the Biomechanics Laboratory at Case Western Reserve University, Wen-Hsiung Ko, Ph.D., Director. By varying the geometry of the coil, in the circuitry of the transmitter, an appropriate FM frequency can be chosen. A single battery pack is used to power all electronic instrumentation. The circuit may be turned on and off remotely by means of a magnetically actuated reed switch. As outlined on the diagram in Figure 4, the circuitry consists physically of three flat packs and their associated electronic components, one battery pack, one magnetic reed switch, and one transformer. Three signal generators and all necessary electronic components are assembled about one flat pack while the remaining two signal generators and the summing amplifiers are assembled on a separate flat pack. The K-6 FM transmitter and the necessary power supply and input circuitry are assembled onto a third flat pack. The actual configuration will incorporate eight batteries. Since there is more than the necessary minimum internal volume in currently produced femoral prostheses, no packing problems were encountered within the prototype using the necessary batteries. The necessary monitoring instrumentation has been designed and assembled in the Biomechanics Laboratory, so that at the present time we are ready to monitor the first patient who will receive the instrumented prosthesis.

In order to monitor the telemeterized signal from the total knee prosthesis, a single commercial FM receiver is employed. The FM transmitter in the prosthesis is tuned to operate approximately at the 89m Hz frequency range. The FM demodulated signal from the tuner is fed directly into a two-channel audio tape recorder. It must be remembered that the demodulated FM signal is within the audio range. The audio tape recorder is used only in studying the patient in the operating room and in the immediate postsurgical period. After a period of approximately 3 or 4 days, the patient is capable of being brought into the Gait Laboratory and data storage is then accomplished using a standard 14-channel instrumentation tape recorder. This is the same tape recorder that is currently employed to store the output signals from the force plate and EMG receivers, and comprises an integral portion of the instrumentation of the Gait Laboratory.

Both the FM receiver and the tape system are calibrated with a gain factor prior to each run. This is accomplished by monitoring an AM-FM
signal with the AM wave carrying a modulated square wave signal of known amplitude. The gain of the system is also adjusted by allowing the patient to remain at rest and by comparing the relative amplitudes with the signals of all channels. In each experimental procedure there is one channel when the relaxed patient is in a position which is most likely to be unloaded. For example, with the knee in 90 deg. of flexion and the thigh portion supported just behind the knee, the joint would not be subjected to an axial load. In each case, this signal gives a reference level which allows the internal calibration of the amplitude modulation circuit.

With the amplitudinal modulated signal stored on tape, demodulation may be accomplished at a later convenient time or it may be accomplished simultaneously with testing for immediate evaluation of testing procedures. In either case the mixed AM signals from the five channels are fed through a bank of five band pass filters. This effectively separates the frequencies which are then amplitude demodulated. These signals may now be recorded on a strip chart recorder.