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Non-invasive diagnosis and prophylaxis in orthopaedics

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In this paper some ten years of work in bioengineering is described. The central theme is non-invasive diagnosis and prophylaxis. This theme is exemplified in several interrelated sections of work which are described. The work is categorized into: modest beginnings, hip and knee vibration papers, deep venous thrombosis and cavitation in human joints. The philosophy is straightforward—to benefit patients by making harmless measurement.

1 INTRODUCTION

It has been said that medicine advances by revolutions. The nineteenth century saw several, including hygiene, asepsis and anaesthesia. The first part of the twentieth century saw the introduction of chemotherapy, beginning with aspirin and leading to antibiotics, analgesics, tranquillizers and hypotensive drugs. Now we are in the midst of another revolution, in which medicine is being transformed by the application of ideas and techniques derived from physics and engineering.

Since the discoveries of X-rays and radioactivity, physicists and engineers have been at the leading edge of modern medicine, particularly since World War II. Nuclear medicine evolved from instruments and methods devised by wartime engineers, and radiotherapy called on techniques originally used in radar. The role of ionizing radiation in medical physics is still significant but it no longer dominates the subject. Physicists and engineers are now to be found as members of clinical teams in many medical departments and research centres in virtually every speciality. In this setting they become *bioengineers*, trying to understand the physical principles governing biological effects, initially through the design and use of instrumentation to record these effects.

The orthopaedic surgeon is one who depends as much as any clinician on the services of the physicist and engineer. The very fact that orthopaedic surgery involves an engineering infrastructure—the skeleton—means that it has always been involved with mechanical engineering and physical science.

The name 'orthopaedic' was first used in 1741 by André, a professor of medicine in Paris, who derived it from the Greek: *orthos* meaning *straight* and *paedios* meaning *a child*. For centuries, doctors knew that growing bones were malleable and that, if a deformed bone could be splinted, it could be made straight. This is especially true in childhood diseases: hence the term *straight child*. The later discovery of hygiene, asepsis and anaesthesia, mentioned above, had a profound effect on bone and joint surgery.

The recent huge success of human joint replacement, by metal and high-density plastic, was a British invention, perfected by Sir John Charnley (1911–1982), and it was the spirit of his multi-disciplinary approach that resulted in such a miraculous cure for many millions of

people world-wide (1). Orthopaedic surgery has been able to advance in recent years as a result of the application of basic scientific principles to the art of surgery by means of team-work between scientist and doctor.

2 MODEST BEGINNINGS

The Chair of Orthopaedic Surgery at Queen's University was founded in 1978. Robert Irvin Wilson MBE was appointed to the Chair, which he occupied until 1982. It was during this time that the department began to germinate, among the experiences and problems of the doctors and patients.

The early work of the department was presented to The Ulster Biomedical Engineering Society in 1982. Ulster has quite a short, but active history of bioengineering work and this Engineering Society has grown up from small beginnings to a Society of over 100 members. The Society now holds a residential scientific weekend each spring and several other meetings throughout the year (2, 3).

Initially Professor Wilson redirected a young consultant (RABM) to spend one year thinking about where orthopaedic research should go and to develop a research strategy for the embryo department. Following an extensive programme of discussions with senior orthopaedic academics and visits to active research units in Europe and the United States a number of key priorities became clear. Orthopaedic surgery required non-invasive measurement systems to achieve accurate diagnoses, to learn the natural history of disease and, through this, to plan interventions and measure their effects and, as a final vision, to understand the pathophysiology and attempt prevention. It was also clear that the answer to wholesale joint replacement was a direct assault on the aetiology of osteoarthritis from a number of viewpoints, in an attempt to develop methods of prevention.

In the course of that early experience it was obvious that joints emitted vibrations that had clinical relevance. No one had succeeded in capturing this information for analysis and it seemed a good place to start. Early work with microphones was superseded by the discovery that *accelerometers* could be used to capture these signals.

Ten years ago we described a method that used an accelerometer to detect human joint vibration from the

patella (4). The method has had several name changes, but will be referred to herein as *vibration arthrometry*. When the technique was first applied to the knee, a transducer was simply attached over the centre of the kneecap with adhesive tape and the output recorded as the patient moved the knee back and forth (see Fig. 1). With this initial system three basic types of vibration were recorded: *tremor*, felt to be caused by the muscular control system, *clicks* and *crepitus*. Initially, no explanation of the causes of clicks or crepitus was given. Spectrum analysis was indicated as a possible method to apply to joint vibrations. A computer program was described for the transfer of data between a Bruel and Kjaer spectrum analyser and an Apple II micro-computer. Analysis methods for the Apple were exponential fit to the decaying peaks of a transient and integration of the acceleration waveform to produce, on hardcopy, in approximately 15 minutes, a velocity and displacement signal. The maximum acceleration, velocity and displacement were 6 m/s^2 , 20 m/s and 0.1 mm respectively, but a statistical sample was not given.

A computer was then introduced during the recording phase to provide an animation of the leg moving, to guide the limb motion while knee vibrations were recorded (5). The programs were illustrated using *struc-tograms* as an alternative to traditional flowcharts. The paper described the (then) new technique and the analysis methods used in the system, including exponential fitting and integration. It was suggested that it may be possible to precisely determine the source of the vibration using the results from three simultaneous detectors, but this idea was not followed up until some time later.

Development of a non-invasive method of neonatal screening for congenital dislocation of the hip (6) described the first use of vibration detection to diagnose hip dislocation, again by attachment of three accelerometers to the body—in this case around the neonatal pelvis—as the hips were tested. It was suggested that the frequency content of the vibration was an indicator of dislocation. If a vibration of 30–40 Hz was produced during hip testing then a clunk of a dislocated hip was suspected, while higher frequency vibration, of about 140 Hz, was thought to be normal. Several output traces from computer programs were presented and

helped to illustrate the proposed differences between normal and abnormal hips.

The accelerometer system for vibration recording from human joints was introduced for the first time to the medical world in Manchester in 1982 (7). The accelerometer could be used to detect locomotor sound and crepitus, and analogue recording and analysis could possibly be improved by the use of modern digital methods. It was clear that much work was needed before a useful vibration system could be produced.

This early work formed the scientific basis for the study of vibration at Musgrave Park Hospital over subsequent years. The instrumentation and methods of digital analysis are described elsewhere (8) and will be mentioned only briefly here.

Initially a small number of patients were examined, each with a different condition: a normal knee with a patellar click, a patient with a painful knee, a sporting injury, the researcher's own knees and babies with hip dislocation. Programmes were used firstly: to control limb movement during testing, to analyse transient and continuous joint vibrations, to capture four channels of vibration signals, to map the vibration by angle and to handle the vibration data on a minicomputer (see Fig. 2). It was this computer programming and these few clinical cases which proved the case for further investigations of vibration arthrometry.

In the early stages of vibration arthrometry, unwanted background noise served to confound the recording process. It was for this reason that noise sources were investigated by producing artefact signals on purpose and examining the vibration in both the time and frequency domains. Artefact signals were very characteristic and could easily be distinguished from true vibrations (9). The only remaining problem with artefacts was due to the accelerometer cable being part of the capacitance system and causing spurious signals if the cable was accidentally struck. Since that time several new accelerometers have become available. The latest types have one stage of preamplification in-built within the transducer housing. This has virtually eliminated cable impact artefact.

General methods of signal processing for these vibrations have been described (10). Three types of vibration were referred to: *tremor*, *crepitus* and transients includ-



Fig. 1 Early investigations of knee vibration were carried out using a miniature accelerometer taped over the patella and an oscilloscope to view the vibration waveforms



Fig. 2 A system was devised to analyse any human joint vibration consisting of reel-to-reel tape, spectrum analyser, oscilloscope, Apple computer and hard-copy devices

ing 'clicks' and 'clunks'. Continuous vibration from the first two categories were analysed using root-mean square calculation and average and peak acceleration and, from these, form factor and crest factor were calculated. Although these methods were given, no results using these techniques were included, but a computer chart of a typical patient was given, which was used to indicate joint angles at which the crepitus signal was seen.

One significant and more recent article of a general nature described several applications and demonstrated the diagnostic potential of vibration arthrometry throughout orthopaedics (11). This paper gave specific examples of vibrations and their meaning, although population statistics were not presented. In the area of testing for hip dislocation, one type of hip vibration—the 'clunk'—was said to be caused by the dislocation and reduction of the femoral head sliding in the acetabulum. The 'click', a higher frequency event, was said to be due to a rapid reduction in pressure, resulting in the breakage of the thin layer adhesion between the articulating surfaces. The same paper refers to knee vibration—giving examples of both physiological patello-femoral crepitus and meniscal vibration arthrometry. Interesting mechanisms of production of each knee signal were provided and will be dealt with below.

Vibration arthrometry is a useful method to assist in the examination of various human joints, but particularly in early detection of congenital dislocation of the hip (see Section 3), in diagnosis of knee injury (see Sections 4 and 5) and in cavitation of human joints (Section 7). Quotations of various authors, who have tried to put into words the sounds and vibrations heard and felt during joint testing, show that human language is evidently limited in this respect (12). Accelerometers have been used to record joint vibrations in a hip dysplasia pilot study of 300 neonates, and these vibrations contain different frequencies, corresponding to what was felt at birth and on the outcome. Accelerometers have also been used to record knee joint vibrations in a study of 250 cases, and these vibrations were recorded at different amplitudes around the knee and at different joint angles, depending on the outcome (12). The kneecap or patella click is referred to as a normal finding and may be produced as the area of contact crosses the transverse ridge on the underside of the patella.

The continuous vibration, produced as the patella 'sticks' and 'slips' during slow motion, has also been introduced, and this will also be referred to later (Section 5). It indicated how possible damage can be initiated by cavitation: a phenomenon that was examined using vibration arthrometry. At the time of writing there are clear signs that such negative pressure activity within human joints could be of considerable significance in the early stages of osteoarthritis (13, 14).

3 HIP VIBRATION PAPERS

The use of accelerometers to detect neonatal hip vibration during screening for congenital dislocation of the hip (CDH) (15) has already been alluded to above. The fundamental problem is that, when CDH presents later than about three months of age, it is a difficult condition to treat, necessitating traction and major bony

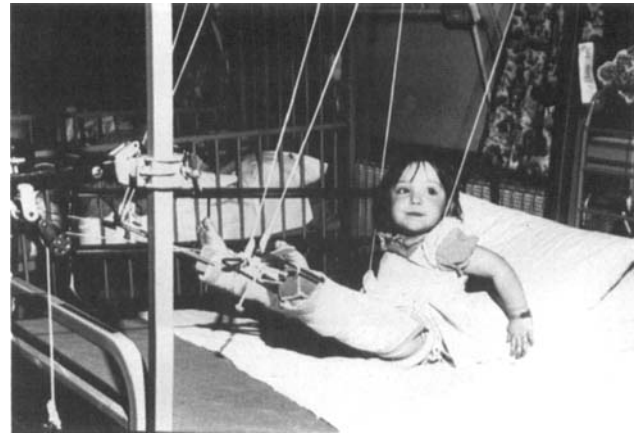


Fig. 3 Late treatment for hip dislocation. If not diagnosed sufficiently early congenital dislocation of the hip is a disease that necessitates prolonged traction and repeated surgical intervention

operations (see Fig. 3). In general, the condition is easier to treat successfully when detected in the first days of life. To achieve the early diagnosis, several tests have been devised (16, 17), and the new technique allows these tests to be automated in terms of detection and interpretation (15, 18). Two groups of children were examined and had hip vibrations recorded. Thirty babies with clicks had high-frequency vibration (mean frequency 169 Hz) while those with unstable hips had low frequencies (mean 12.5 Hz). This indicated that innocuous clicks often heard and/or felt during hip testing could be differentiated from the pathological clunk vibration.

Initially, four groups of children were studied: normals, clicks, unstable at birth and cases with late presentation of CDH. One comment at the time was that the human factor was still present in execution of the test, if an accurate test was required. Indeed, a trained examiner is still required to perform the testing correctly—if the results of the screener are to be relied on.

The analogue system of recording vibrations in CDH, with its separate recording and analysis stages, was a useful one for initial work and provided flexibility. However, it became clear that, for large-scale projects, some more convenient and portable system would have advantages, particularly for less computer-literate users.

One of the first attempts to reduce the system complexity involved a modified Apple microcomputer, which was programmed, mainly in 6502 assembly language, to digitally record hip vibrations during testing (19, 20). The computer could then act as both a vibration datalogger and subsequently as an analyser using abbreviated Fourier analysis methods. Engineering details describe hardware and the three phases of the software: capture, display and analysis (20). The system has come to be known as the Belfast CDH screener (see Fig. 4), and it allowed larger trials to be drawn up.

The initial trial of the CDH system was carried out on selected children referred to a research clinic (21, 22). The study involved selected groups totalling 306 selected neonates, referred for vibration arthrometry. The largest subset ($N = 217$) were already diagnosed with 'clicky' hips. On testing, a total of over 600 vibration episodes were captured for analysis. To be certain of the

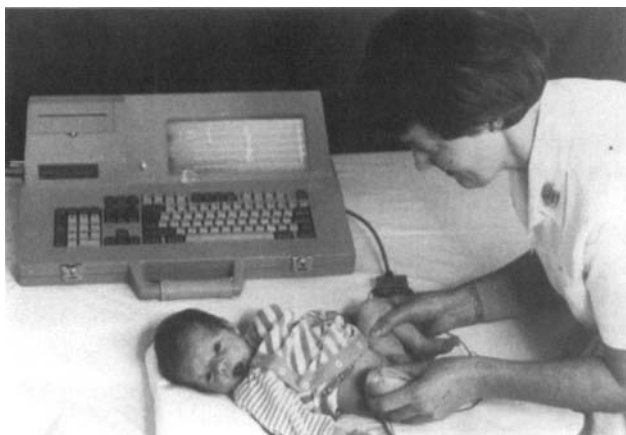


Fig. 4 Vibration arthrometry can be used in early detection of congenital dislocation of the hip by recording vibrations produced during manipulation of the hip. The nurse is operating the Belfast hip screener

clinical outcome the children underwent a long follow-up with several attendances over a four year period. Several went on to require treatment for CDH; these were examined retrospectively and it was clear that the unstable hips were signalled at birth by low-frequency, high-amplitude vibration emissions. The study included a group of normal, clinically silent hips, which also produced some vibration during testing, though, on analysis these were entirely different vibrations. Using vibration arthrometry it was possible to predict or classify vibration detected from new hips with unknown pathology. The result of testing this classification system suggested a sensitivity of 75 per cent, a specificity of 99 per cent, a positive predictive value of 86 per cent and a negative predictive value of 99 per cent. The probability of the findings occurring by chance were very low ($P < 0.005$). The importance of both time- and frequency-domain measurements was emphasized, though individual parameters (for example, amplitude of vibration) were not sufficient, in their own right, to distinguish normal from abnormal. The technique of vibration arthrometry was proposed to not only facilitate CDH screening but also assist with careful monitoring of clicky hips.

A large-scale trial of vibration arthrometry for CDH screening was carried out on a group of 3000 unselected cases during the period from December 1984 to December 1985 with follow-up from 1988 to 1990. The aim of this larger study was to further evaluate the potential of vibration arthrometry in early detection of CDH. Since significant hardware development took place during the trial, not all vibrations were recorded in the same fashion. The initial 500 cases were recorded on analogue reel-to-reel tape and these were reported first, together with 18 unstable-at-birth cases. This was a report of vibration arthrometry being assessed on a representative group of neonates chosen at random from five major maternity hospitals. Of the 3000 neonates, 18 unstable-at-birth cases were detected, and 15 of these produced diagnostic hip vibrations. It is not clear how many of these 18 would have stabilized spontaneously, as all were regarded as suspicious and each was treated in nappy splint or double nappy. The earlier findings were confirmed, that is unstable hips produced vibration of lower frequency and higher amplitude than did

normal hips, though some changes to the discriminant function were found when the results were statistically analysed. Further analysis of these 3000 cases will be carried out to obtain further evidence that vibration arthrometry is a useful population screening method for CDH.

Another clinical study of CDH was carried out on an unselected group of 300 neonates examined in maternity wards. This focused on the ability to manually detect hip vibration. The aim here was to find the sensitivity of manual palpation to neonatal hip vibrations using the objective detection system, based on vibration arthrometry. Almost half produced hip vibration during testing. This random study of babies further showed the value of vibration arthrometry in early detection of CDH, as very few hip vibrations (7 per cent) were found by routine medical officer examination. An experienced examiner—the research nurse—recorded 86 per cent of the total number of vibrations recorded using the method of vibration arthrometry. This again showed the importance of careful screening for CDH.

In a climate of cost efficiency, the more widespread implementation of vibration arthrometry using the Belfast hip screener warranted an economic appraisal. To carry this out, 12 patients who had recently received hip replacement surgery as a result of late diagnosis of CDH were reviewed and all their costs were identified. At this stage these people could be thought of as end-stage CDH and of having had the complete treatment. Benefits of screening would be further increased as no estimates were included for the pain and suffering endured by the patients or for loss of income. The full appraisal includes both epidemiology and option analysis (23). It was found that screening using the Belfast hip screener would be successful if it is able to raise the detection of CDH at birth from 50 per cent, at present, to 63 per cent, with additional screening using ten teams of nurses examining every neonate in Northern Ireland. The costing exercise helped to show that the 'high-tech' Belfast hip screener was not mere 'diagnostic overkill' but made economic sense in a hard-pressed health service. Even though no financial estimates were included for the patient's loss of earnings through hospitalization and/or failure to find suitable work, the use of an extended screening service, based on vibration arthrometry, would be financially justified if it increased the detection rate by just 13 per cent.

The use of vibration arthrometry in CDH depends on the mathematical methods of discrimination, that is the ability to distinguish normal from abnormal. Decision mathematics was used to compare linear versus non-linear discriminant methods, showing only marginal improvement when the non-linear kernel density method was used (24).

The theory of vibration arthrometry can be illustrated with particular examples from neonatal hip signals. The two statistical methods used to discriminate normal from abnormal were outlined: one linear, the other non-linear. The linear discrimination was performed using the ubiquitous statistical package SPSS^x to calculate the equation of a line dividing normal and abnormal, while the alternative was based on drawing a *kernel* or 'core' around each case and then calculating the sum of all kernels in order to define the geometry of the dividing line between normal and abnormal joint

vibration (24, 25). The more simple linear approach actually gave acceptable results for implementation in the portable hip screener.

Another application of mathematics in CDH (26) outlined a new approach to the assessment of the human form or morphology. In this method a plane photograph was taken of the neonatal head, viewed axially, and the symmetry of the outline was assessed geometrically. It may be that such measurement could help in identification of children in whom abnormal forces have been acting, pre- or peri-natally. The same forces that cause plageocephaly (head moulding) may also contribute to CDH (which might also be thought of as hip 'moulding'). To test the correspondence of CDH and plageocephaly a measurement foil has been devised to define a unique point at head centre. The line between this point and the nose defined one axis while a second axis was set up at right angles to this. This permitted measurements of four quadrants:

$$\begin{bmatrix} 4, 1 \\ 3, 2 \end{bmatrix}$$

Normal shape was defined when equality of the left and right front quadrant together with equality of the left and right rear quadrant is present ($1 = 4$; $2 = 3$). At the time of writing, a series of seven normal babies, four with clinical plageocephaly and fifteen who underwent clinical treatment for CDH have been photographed using a standardized camera rig, and the quadrant measurements made. If this geometrical method can be shown to measure plageocephaly then an extended group of CDH cases will be examined in the future to establish the link between plageocephaly and CDH.

In order that the benefits of CDH screening could be made widely available, it was necessary to develop commercial methods and a marketing strategy was devised in an attempt to achieve an early diagnosis for neonatal hip dislocation beyond Musgrave Park Hospital to other hospitals world-wide. Otherwise the findings would never be applied outside the research unit.

One of the biggest problems in paediatric orthopaedics has been addressed: CDH. Without doubt,

vibration arthrometry is not the complete solution to all the problems of CDH; however, there is evidence that important new information has become available using the technique, which has gained international recognition, and economic analysis has shown that it may be implemented at little or no cost to the world's health services.

4 TRANSIENT KNEE VIBRATION SIGNALS

Physicians have been interested in vibrations emitted from the human body—both normal and abnormal—for centuries. Knee vibrations have been of particular interest to the authors. The main reason is that the diagnosis of knee injury and disease is such an enormous problem. Currently (May 1991) over six hundred cases are waiting for diagnostic arthroscopy in Northern Ireland alone and, on average, each person waits for twelve months before being seen. Thus, any method that might have the potential to reduce the need for diagnostic arthroscopy is worthy of considerable attention.

For vibration arthrometry of the knee, the initial attachment was of three accelerometers: one taped over each femoral condyle and one over the patella. The same recording and analysis system was used as that described for CDH (15). In an examination of patients with a torn cartilage, transient vibrations were recorded from all three accelerometers during flexion and extension of the knee (see Fig. 5) and some theory was examined to find how the source of the transient vibration could be found (27, 28). The three accelerometers detected vibration of different amplitude at different times. The arrival time consideration was neglected as, at most, only a $100 \mu\text{s}$ delay could be expected. Detection of such a delay was beyond the resolution of vibration arthrometry mainly due to the low frequency of these naturally occurring vibrations (average peak frequency 100 Hz). An alternative method, using relative sizes of the impulses, was preferred which assumed a uniform wave propagation method. For each pair of transducers a circle of possible source points was defined and so the source point could be estimated by finding where these circles overlapped.

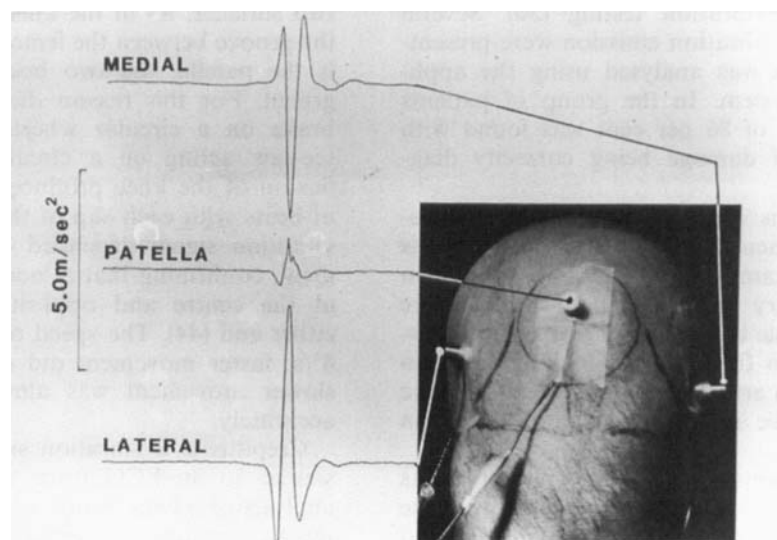


Fig. 5 Cartilage damage in the menisci was manifested by transient vibrations recording during flexion and extension of the joint, using three accelerometers

Like any bioengineering project, the real value of vibration work only became apparent in clinical hands (29). We presented early results using the above system at the International meeting of Societe Internationale de Recherche en Orthopedie et Traumatologie in 1984. The first substantial works involving the method applied to the knee joint were translated for *Zeitschrift fur Orthopadie* (30). 'Moderne tendenzen' gave a full historical perspective followed by a detailed comparison of microphones with accelerometers for human joint vibration recording. The essential problem with microphones is that they are designed to record air-borne sound of audible frequency whereas the accelerometer detects structural vibrations down to 0 Hz. This gives the latter properties which make it useful in orthopaedic vibration measurement. Some details were given of a potentiometer-based goniometer used to record joint angle. This has since been superseded by a novel strain gauge goniometer (31) which allows a continuously changing centre of rotation more in line with the physiological movement of the knee joint.

A second German paper, 'Vibrationsarthrographie' (32), gave examples of vibrations from a normal knee, a patella 'click' and a tear of the lateral meniscus. These were contrasted with vibration emitted from a damaged medial meniscus and from a sub-clinical medial plica. It was noted to be particularly interesting to record knee vibrations before and after an operation, as this allowed subjective alleviation of symptoms to be objectively measured by a reduction in the vibration level recorded (33).

The use of vibration arthrometry in assessment of knee injury has been fully described (34, 35). The angle of the joint was shown to be one of the important variables to measure using the goniometer simultaneously with the accelerometers for joint vibration. Lesions that occurred at the back of the joint tended to produce vibration at greater angles of flexion, while damage in the middle of the joint gave vibration at the midpoint of the swing.

A direct correlation of the vibration produced by various pathologies was given by setting vibration signals adjacent to arthroscopy views, photographed during surgery, after vibration testing (36). Several examples of knee joint vibration emission were presented and each vibration was analysed using the applicant's measurement system. In the group of patients examined an accuracy of 86 per cent was found with both site and type of damage being correctly diagnosed.*

In general, vibrations could be detected from traumatic damage to the meniscus. This kind of damage is frequently found, for example, in professional sportsmen and women. The injury may be caused by a severe twisting movement while balancing on one leg—in football, for instance, when the player is making ready to kick the ball. Vibration arthrometry may therefore have crucial importance in the application of biomechanics in sport (37).

All the instrumentation for these early measurements was based on analogue recording (4). However, the analysis of these meniscal vibrations was slow and laborious, and a digital capture and analysis technique

was developed (38), consisting of customized hardware and software. The menu-driven computer software package was written mainly in the Pascal language, except for the speed-dependent sampling routine, written in 6502 assembly language. This led the way for a commercial development based on IBM-PC architecture.

One aspect of the recording process which was found to be central was the speed at which the limb was flexed and extended (39). A group of 24 subjects with clinical evidence of meniscal damage were examined at three speeds of movement: 30, 45 and 90°/s. Increasing cycle speed had a clear positive effect on vibration level recorded from a damaged knee—though frequency of the vibration did not suffer the same effect. This variation showed the importance of simultaneous measurement of knee angle (to obtain angular velocity). In order that consistent recordings of meniscal vibration could be made under load a special exercise device was developed. The accelerometers are attached around the knee and the subject exercises the joint while vibrations are recorded continually. Transient vibrations that are emitted may then be detected and a diagnosis made. Further development is under way with the aim of producing a commercial product to assist in the diagnosis of internal knee injury.

5 CONTINUOUS KNEE VIBRATION SIGNALS

Many sub-clinical and normal human joint vibrations may be detected using vibration arthrometry. A further example from the knee, discovered by one of the authors (8), is *crepitus*, recorded from all normal patellae as the knee is very slowly flexed or extended (see Fig. 6) (40). The crepitus vibration may be explained using a physical model of a brake acting on a circular wheel (41). As the wheel is slowly turned with a brake applied, the two bodies initially adhere until the applied force exceeds the frictional force between them—when 'slip' occurs and a momentary vibration may be detected. Some of the parameters of the crepitus vibration (amplitude, beat-to-beat frequency, inherent frequency) may reflect the mechanical properties of the two surfaces. As in the knee joint, where the 'wheel' is the groove between the femoral condyles and the 'brake' is the patella, the two bodies are not perfectly congruent. For this reason the model consisted of a flat brake on a circular wheel, which then acted like a see-saw acting on a circular fulcrum (42, 43). Slow flexion of the knee produces a quasi-continuous series of beats with each slip of the patella. The phase of the vibration signal depended on the position of attachment, confirming that a 'node', or fulcrum, was present at the centre and opposite movements occurred at either end (44). The speed of joint movement used was 4°/s; faster movement did not produce crepitus while slower movement was almost impossible to achieve accurately.

Crepitus is a vibration signal that consists of beats, similar to an ECG trace, and suffers from the same analysis problems. Some problems in finding a characteristic frequency to describe the signal have already been outlined (45). Two digital signal processing phenomena, which are seen when a series of transients are analysed, were studied: *sidelobes* and *sidebands*. Because

* G. F. McCoy obtained the Sir Robert Jones Gold medal for an essay based on this work.

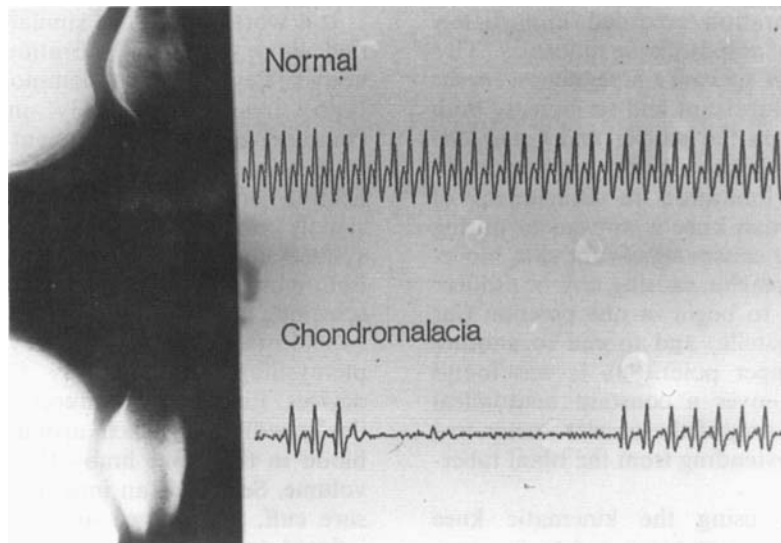


Fig. 6 When the normal knee was flexed at low speed a continuous vibration was detected from the patella and diseased cartilage generated irregular beats of vibration

of these effects, great care must be taken when frequency analysis is performed. In fact, the repetition frequency of the beats has a profound effect on the spectrum (46). Merely using the peak frequency can be unreliable and it is suggested that a weighted-mean calculation is used to obtain a satisfactory characteristic frequency.

Later, the cogwheel and brake model was related to the patellofemoral joint more convincingly (47). Patellar vibration was examined in six volunteers using three accelerometers on the patella and a high-resolution angular transducer. This enabled the movement of the patella to be mapped as it 'stick-slipped' in the troclear groove of the femur. During the 'stick' phase the patella and femur act as cogwheels in contact and move in opposing senses, while during the 'slip' phase they move in the same sense (48).

The relevance of these vibrations of the patella began to be elucidated later (49). The effect of loading human cartilage is to increase the friction by creep deformation. Large increases in the amplitude of crepitus after loading were given as evidence that vibration recorded was actually measuring cartilage properties: both deformation and friction under load. It remains an expectation of the authors that crepitus measurement will be of value in such diseases as chondromalacia patellae (50) and, indeed, patellofemoral arthritis.

Vibration arthrometry of the knee includes transient vibration recording, in meniscal damage, and continuous vibration recording of physiological patellofemoral crepitus, in normal and abnormal subjects (51). Arthrometry shows how the patella moves during crepitus and how the cartilage is affected by isometric load. This represents the first non-invasive objective measure of the state of articular cartilage (52, 53).

The unwanted effect of gross joint movement on joint vibration has been noted (39). To control knee movement at the very slow rate required to produce physiological patellofemoral crepitus, a special mechanical control system was devised. There are considerable difficulties in driving a multi-axial joint (the knee) through a series of uni-axial bearings. The solution, which has

been termed the *kinematic knee machine* (see Fig. 7), was built up from the reinforced frame of an examination couch, with an angled back support and a rotating gutter into which the lower limb is fixed (see Fig. 7). Preliminary results using the device showed that normal individuals produced crepitus continuously from 20–90 degrees of flexion (54–56). It was also found that the magnitude of the acceleration increased after isometric loading. The displacement during crepitus was estimated to reach 0.06 mm (57).

The vibration recorded from the patella when the normal knee is passively moved by the machine consists of a series of beats, which often appear to make up a continuous vibration. Each beat is thought to coincide with a sudden slipping of the patella back to equilibrium—having been pulled away from an equilibrium point because of static friction between the patella and femur. Such a movement clearly depends on the surface quality; smoother cartilage surfaces could be expected to experience lower frictional forces. During the application of load, by asking the subject to strain against a restraining force, some effect took place

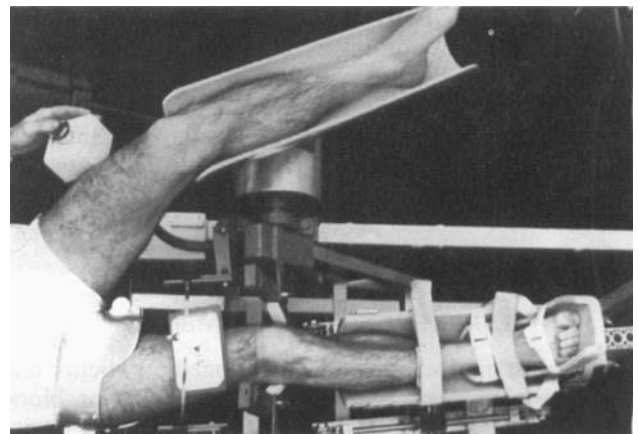


Fig. 7 To generate regular beats of vibration from the patella, a motorized multi-axis cradle was built, to slowly flex and extend the knee passively under computer control

causing the crepitus vibration recorded immediately afterwards to increase in amplitude significantly. This applied force was thought to cause a reduction in the amount of synovial fluid lubricant and so increase both the frictional force between the patella and femur and the vibrational amplitude during slow flexion/extension.

The most important limitation in attachment of accelerometers to the human knee is movement during flexion and extension that causes significant skin movement with respect to the patella, causing any transducer to move likewise, that is to begin in one position (for example, lower pole of patella) and to end in another position (for example, upper pole) (58). It was found that accurate recording—over a constant anatomical point—was possible, but only if the accelerometer was attached via a lever arm extending from the tibial tuberosity.

In a clinical survey, using the kinematic knee machine, ten painful knees were compared to ten controls and it was possible to define the normal waveform seen when patellar crepitus was recorded (59). Each beat of the vibration arises from a single 'slip' of the patella and, under controlled movement, the beats form a quasi-continuous vibration. For the survey, vibration was digitally recorded from each patella as the knee was moved at 2°/s. Each person suffering from knee pain produced crepitus, giving irregular frequency spectra, while normal crepitus produced very regular harmonics throughout the arc of movement. The regular harmonics in a three-dimensional plot of the frequency spectra in a range from 2 to 152 Hz plotted versus amplitude, versus knee angle (59), appear as continuous ridges, whereas the painful knee produced an irregular 'terrain' in the three-dimensional plot. Also, an analytical investigation described several new time-domain measurements of crepitus which allowed further discrimination between normal and abnormal knees. These differences were shown to be due to differences in physical properties—both friction and compliance—between normal and abnormal cartilage.

With careful passive movement of the knee, the crepitus waves can be produced at almost any angle of flexion. The variation in vibration amplitude from 0 m/s² at the extremities (full flexion and full extension) to 2 m/s² at 70° flexion is an important characteristic and the pattern is remarkably consistent (60).

This work has addressed the measurement of human articular cartilage non-invasively. This has very important implications in assessment of any treatment for osteoarthritis—the major orthopaedic disease in the world at this time. Any new or existing treatment of disease in the patellofemoral joint may now be assessed by non-invasive measurement using vibration arthrometry.

6 DEEP VENOUS THROMBOSIS

The biggest mortal risk that orthopaedic patients face today is from deep vein thrombosis (DVT), or blood clots. These can form during, or soon after, major orthopaedic surgery. The detection of these clots is very difficult clinically and non-invasive measurement systems have been devised to detect DVT, based on plethysmography, or volume measurement.

It is worth noting the similarities between this project and those based on vibration arthrometry described above. Beyond their common non-invasive aspects, both areas are heavily involved with portable, computer-based, measurement systems. Both plethysmography and vibration arthrometry involve the amplification of 'biosignals' and the acquisition of these signals with analogue-to-digital converters. Both systems require the display of these signals and then both assist in a clinical setting and provide population screening for orthopaedic problems.

Screening a patient for DVT using the method of plethysmography involves the attachment of two devices. Firstly, a transducer (various types have been developed) is attached around the main reservoir of blood in the lower limb—the calf muscle—to measure volume. Secondly, an inflatable cuff, like a blood pressure cuff, is arranged around the patient's thigh and inflated to a pressure of 50 mmHg, allowing arterial filling while preventing venous return (see Fig. 8). With cuff inflation and deflation come volume changes which are powerful indicators of any problem in the deep veins. Other workers (61) have used impedance measurement to assess changes in blood content. They used the fact that a lower blood volume would produce a higher electrical resistance in the limb and rapid changes in blood volume produce rapid changes in electrical resistance. Such rapid changes are evidence of a clot-free limb. To assess this method, a large study of 800 patients was carried out using impedance plethysmography (62–65). The impedance method of detecting DVT indicated a slow venous outflow from the limb in 21 members of the group. These positive cases were subject to the standard contrast radiograph investigation (venography) and 12 were confirmed to possess a DVT while five more had smaller calf thrombi. Unfortunately, as venography involves painful injection of aggravating dye, it was not possible to subject all patients to it, unless there was some other clinical sign *a priori*. However, all positive venograms indicating a proximal DVT were positive using plethysmography—a most encouraging finding.

During the above trial of impedance measurement various clinical factors were recorded in 800 cases to establish whether some mathematical combination of



Fig. 8 A system devised for early detection of deep vein thrombosis consisted of a computer, small pump, thigh cuff and strain gauge

factors, together with plethysmography findings, might predict those patients likely to develop a clot, as well as being able to detect clots already in existence (66, 67). Details such as age, height-weight ratio, blood pressure, varicose veins, heart disease etc. and operative details such as type of anaesthesia, site of operation, post-operative conditions etc. were carefully noted. These findings, together with the impedance measurements (described previously), were analysed in an attempt to predict whether a clot was likely. A scoring system included venous outflow, venous capacitance (both from plethysmography), mobility and age in a given combination. It is hoped that this score could be used to detect the at-risk patient, allowing pharmacological prevention to be instigated.

In the clinical setting, several other physiological processes were found to affect the measured impedance, obviously reducing the efficacy of impedance plethysmography. For example, skin resistance effects, due to sweat etc., or even minor movement of the limb produced large artefacts, and so other methods were investigated.

Firstly, two new types of transducer were used to detect changes in limb volume (68). The volume plethysmography was one attempt to assess blood volume changes using a wide electroelastic band. Unfortunately this subsequently proved too slow in response time. When the inflatable cuff is released the normal system empties (to the prefilling state) in less than 2.5 s. The presence of a clot in the deep veins slows the emptying, and the time for the veins to empty is then greater than 5 s (69).

In screening for DVT, both the height of the trace (venous capacitance) and the rate of decay of the trace after cuff release (venous outflow) contribute to the discrimination between normal and abnormal. Further work on the detector has resulted in the adoption of a commercially available strain gauge permitting convenient recording of calf muscle circumference (and hence an estimate of volume changes can be made).

It was straightforward to derive an expression for change in volume of the leg (70) and so the authors devised a strain gauge measurement system to achieve it. To test a patient, the lower limb is raised slightly (25 cm) using a foot support and two devices are attached to the leg—an inflatable cuff and a 1 mm diameter strain gauge. The natural (unextended) length of the strain gauge was 280 mm and its extension was limited to 50 mm.

The cuff is then inflated as described previously, and measurements from the strain gauge are taken continuously at a sampling rate of 25 Hz, until a plateau is reached when the limb is full (71). At this point the cuff pressure is swiftly released and calf measurement sampling increased to 250 Hz. This allows accurate assessment of venous capacitance and venous outflow.

A trial of 99 at-risk patients showed high values for the sensitivity of the method. Each patient had strain gauge plethysmography and also contrast venography performed. The venogram results were used to define clinical groups: (a) normal and (b) positive DVT. Then the discriminating ability of strain gauge results were tested and the sensitivity, specificity and predictive value of a negative test were found to be 100, 89 and 100 per cent respectively.

Concurrently, the strain gauge system was developed as a portable DVT screener for commercial exploitation.* The new device was essentially a repackaged IBM-compatible computer with custom software and additional interface hardware including flat screen display, mini-pump, mini-printer, strain gauge interface etc., all enclosed in a specially designed case which includes compartments for thigh cuff, strain gauge etc. (see Fig. 9).

Deep vein thrombosis is not solely an orthopaedic problem. Therefore the Belfast DVT screener is likely to find application wherever major surgery is performed. For example, colorectal and gynaecological surgery, and even following childbirth, when the risk of DVT is increased. Like the development of the Belfast CDH screener, the central aim of the commercial development was to apply the techniques of plethysmography as a screening service to benefit patients who may be at risk from DVT, whether at Musgrave Park Hospital or at any other hospital world-wide. While the screener has been operated by research nurses, it can easily be used by any medic or paramedic. Ideally, in service, screening for DVT is carried out by dedicated nurses whose only role would be early detection of DVT. This would mean the standard of the test would be high and independent of other issues in the hospital ward. Furthermore, the costs and benefits of screening would be more clearly identifiable.

We have been interested in examining how research findings might be economically applied in bioengineering (23, 72). To obtain an estimate of possible savings to be made by implementing DVT screening a small case-control study was carried out to compare inpatient costs 'with' and 'without' DVT. Due to increased hospitalization and extra diagnostic tests, each patient who developed a DVT cost the health service an average of £700 more (1988-9 prices). Given an incidence of 26 per cent, an extra amount of £181 per admitted patient is required for this complication. Therefore DVT screening or any preventative measure can be thought of as cost effective if such measures cost no more than this amount.

Deep vein thrombosis is a particular problem during, and after, major orthopaedic surgery since the venous



Fig. 9 The preproduction prototype of the 'clot-spotter'—a screener for deep vein thrombosis—shown attached to a subject undergoing examination

* The authors gained the 1990 Northern Ireland Information Technology Award for the Belfast DVT screener.

flowrate from the limb is reduced and may be static while the patient is heavily anaesthetized. One bioengineering solution is to artificially maintain blood flow by allowing the calf veins to act as a pump using electrical muscle stimulation. We have designed a self-contained calf stimulator which may be used in the operating room as a prophylaxis against deep vein thrombosis. A 70–100 V pulse of 10 ms duration is applied to the calf at five second intervals, each pulse producing a significant surge of blood in the popliteal vein. Research showed that such electrical stimulation of calf muscle prevented stasis and thus acted as a DVT prophylaxis (73, 74). Like the DVT screener and the Belfast hip screener, the calf stimulator has been prepared for commercial marketing and a production prototype is currently on the market.

Musgrave Park Hospital is one of the largest orthopaedic hospitals in Europe and DVT is recognized as an important risk postoperatively. The best alternative method to compare with the DVT screener is venography, though this is invasive, involves the use of irritating dye and is often painful. Venography may be performed only once, some days after surgery. However, the complication of DVT can be significantly reduced using the DVT screener. A few days after an operation, patients are tested using the strain gauge system. The screener has been shown to be simple to operate and painless for the patient, permitting regular, repeated monitoring.

The biggest risk that orthopaedic patients face, namely DVT, has been addressed. Initial attempts to devise early warning of clot formation has resulted in a commercial prototype and the risk of such clots forming during surgery has been reduced by use of the Belfast calf stimulator.

7 CAVITATION

In this section the earlier subject of vibration arthrometry will be returned to—this time applied to the hand—and then an examination of finger joint cracking sounds is made. This work led to the subsequent development of high-energy ultrasound as a model for osteoarthritis. The use of ultrasound in bone testing is included.

The previous description of human joint vibrations (Sections 1 to 5) centred on hip and knee movements. However, the technique is not limited to these joints. Experiments have been performed where accelerometers were used to record naturally occurring vibrations from the hand (75). A single accelerometer was used to detect finger clicks and crepitus. Characteristic waveforms were recorded from 'cavitation' clicks, from trigger fingers and from deQuervain's tenosynovitis. The potential of vibration arthrometry of the hand was clear from this Liverpool–Belfast collaboration (76).

In an attempt to better control the production of these finger 'clicks' and perform a more scientific evaluation, a motorized system was devised to permit controlled distraction of the metacarpophalangeal joint and simultaneous recording of any vibrations emitted in the process. The vibrations were amplified, recorded and analysed as before, using frequency-modulated analogue tape. A custom-built device was used to pull the finger and record the applied load and extension (77). When load and extension was plotted against time, both vari-

ables increased as the experiment proceeded and, if the joint 'cracked' during the procedure, a sharp drop in load was detected. However, no simultaneous change in extension was noted. Eight experiments were carried out, including a long (50 s) distraction, diurnal variation, high/low temperature effects, high/low distraction speeds, time since previous distraction, variation with atmospheric pressure and an X-ray study during finger cracking. These gave important new insights into joint cracking, which may no longer be regarded as a completely innocuous phenomenon, as the energy imparted by the crack may be sufficient to cause irreversible damage to human articular cartilage—particularly if repeated (78).

Such finger cracking has been linked to the phenomenon of *cavitation*, a term used to describe bubble activity in fluid systems. The authors have described what happens when a synovial joint is distracted: the pressure in the synovial fluid drops. When the pressure drops to the vapour pressure of the fluid, it evaporates spontaneously. X-rays of metacarpophalangeal joints taken after a cracking sound was heard show a bubble of vapour, thus creating a link between cavitation and joint cracking.

One straightforward method of producing cavitation in a fluid is to pass high-frequency sound waves through the fluid, from an ultrasonic horn for example. This method has been used to examine the effect of cavitation on bovine articular cartilage (79). Specimens of cartilage were subjected to ultrasonic cavitation for various times, and the effect observed (see Figs 10 and 11). Photomicrographs of the cartilage surface after cavitation for 0, 1, 2, 10 and 20 minutes were made. The overriding evidence from these showed that these conditions produced craters similar to well-documented defects that were observed in human samples removed from the theatre during total hip replacement for osteoarthritis. Thus the ultrasonic method could serve as a convenient model for osteoarthritis in other work (for example, treatment trials). Two mechanisms were suggested that could contribute to the effect *in vivo*: macro- and microcavitation. Both effects may be produced by low pressures set up during normal activities of daily living and so contribute to degeneration of articular cartilage. Microcavitation in particular can occur during normal and strenuous activity, causing repetitive damage to the cartilage surface. This opens the door to well-known degenerative paths towards osteoarthritis.

Further work was carried out, using the ultrasonic method, on human post-mortem specimens, with detailed, computer image analysis of the photomicrographs of cartilage after cavitation. This extension of the work showed, as might be expected, that adult cartilage was found to be more susceptible to cavitation damage than the infant sample. Also, a similarity between the effects on adult and bovine specimens effects was found: bovine articular cartilage may therefore be substituted for human tissue in future experiments of this nature (80, 81).

Studies have shown that low-pressure activity within human joints causes cavitation. The effects of cavitation may be studied *in vitro* using an ultrasonic field adjacent to the joint bearing surface. The surface characteristics are similar in some respects to those seen in osteoarthritis. Thus cavitation could be of considerable

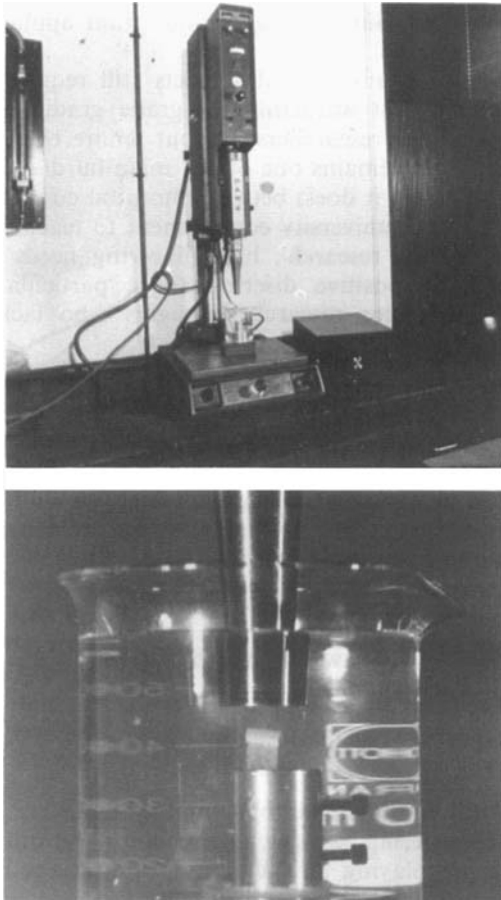


Fig. 10 To investigate the effect of cavitation on human cartilage tiny samples were subjected to cavitation produced, in saline, by high-intensity ultrasound

significance at some stage, yet to be established, in the natural history of osteoarthritis.

Ultrasonic waves are simply high-frequency acoustic vibrations which, at lower energies, generally do not produce cavitation in fluid media. Indeed, low-amplitude ultrasound permeates human tissues in a completely non-invasive fashion. The minor heating effect of the vibration has been used in physiotherapy to

relieve symptoms of aches and pains. Also, the linear transmission and reflection of ultrasound is used routinely to obtain many useful images of the softer human tissues. Recent advances yield even more accurate images of the developing embryo in utero and even ovulation can be observed using an ultrasound beam. With such imaging possibilities the likelihood exists to detect orthopaedic disease earlier than ever before.

It is much less common to use ultrasound to examine hard tissues. One idea is to test human bones by timing the passage of ultrasonic waves through them. Such a method is described (82) in which the speed of ultrasound across a healing fracture was measured in an animal model. A standard fracture was created in the tibia and the speed of ultrasound across the fracture was measured at two frequencies, on several occasions, as the fracture healed. Mechanical testing yielded load at failure, stiffness and elastic modulus, which were compared to ultrasonic velocity. The experimental results were indefinite: the best correlation was between elastic modulus and 1 MHz ultrasonic velocity, yielding a correlation coefficient of 0.63. This was felt to indicate that ultrasonic velocity could not accurately reflect the mechanical properties of bone; the correlation between ultrasound velocity and fracture strength in any clinical situation would be expected to be even lower.

The investigations of the metacarpophalangeal joint 'cracks' have uncovered new knowledge relating joint distraction to low-pressure cavitation and a possible new damage mechanism resulting from macro- and microcavitation in human joints. This may lead to a new understanding of the mechanical origins of joint deterioration of osteoarthritis. Ultrasonic vibration has been introduced as a convenient method of generating cavitation, and experiments have shown how this mechanism yields similar damage patterns to those seen in osteoarthritis. Ultrasonic vibration has also been used in the assessment of fracture healing, while poor correlation was found between fracture strength and ultrasound velocity. Significant changes in ultrasound transmission times were recorded as the natural repair proceeded.

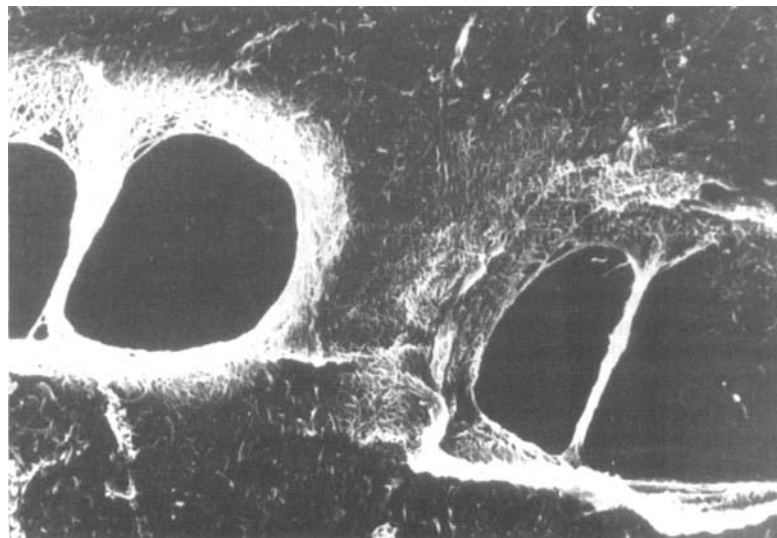


Fig. 11 Cavitation effects adjacent to articular cartilage cause cratering of the surface similar to that seen in osteoarthritis

8 DISCUSSION

Advances in technology in the past 10–20 years have brought about a close relationship between medicine and engineering. Part of this has been the close association of orthopaedics with the basic sciences. Orthopaedic bioengineering is an example of professionals in distinct disciplines applying their skills to problems that require an interdisciplinary approach.

The application of technology in orthopaedic surgery is the outcome of a revolution in medical practice arising from a growing realization that a range of disciplines outside surgery can offer assistance to benefit its practice. Three areas of technology in particular that are set to further enhance orthopaedic patient care are: digital radiology, vibration arthrometry and strain gauge plethysmography (83).

Orthopaedics has made stunning advances in the past few decades and there is no sign that the pace of progression is slowing down. New technology has led to the emergence of new techniques for caring for those suffering from diseases of the locomotor system. There have been major advances in recording vibrations from normal and abnormal joints, in detection of potentially fatal deep vein thrombosis, in analysis of biosignals and in various other bioengineering topics.

The preceding sections have reviewed recent progress and present problems which have been tackled in these areas of orthopaedics and bioengineering and efforts to benefit patients by making non-invasive measurement. Obviously research that is useful locally should be applicable world-wide. However, laboratory-manufactured equipment is not suitable for dissemination and it requires a commercial approach to transfer technology from bench to the mass end user. The department has such a system in place. The joint university/business company Advanced Medical Technology Limited has successfully transferred vision into commercial reality by a series of developments and is in the process of adding to the successful commercialization of their DVT screener and calf stimulator to provide a stable of products manufactured in Northern Ireland. The knowledge gained from 'green-fielding' these products is invaluable and represents an investment in time and effort from both university and company personnel.

Work has been presented covering a number of areas in the application of science and engineering to orthopaedic surgery. The continuation of the work will rely on support from research councils, major charities and government departments.

As scientific opportunities grow faster than ever, competition for money is now fierce, within and between specialities, and between individuals, research groups and institutions. For every research grant winner there are now several losers. Government now seems much more interested in accountability for the money spent by the research councils than in scientific merit. However, the emphasis in government policy on research with particular application (and on industrial exploitability) tends to support very applied research, such as medical research and bioengineering. Nevertheless, the new problems of 'unfunded alphas' and 'approved but not funded' categories created by The Medical Research Council (and others) has led to over

40 per cent of 'outstandingly good' grant applications being rejected (84).

Even successfully funded projects still require good management, but attracting top-grade graduates and retaining senior researchers without tenure of employment certainly remains one of our main hurdles for the 1990s. Lying (as it does) between 'hospital commitment to service' and 'university commitment to teaching and single-discipline research', bioengineering needs to be identified for positive discrimination, particularly to support its senior research managers who lack permanent posts.

9 CONCLUSION

Engraved in stone on the National Archives Building in Washington is one of those mottos that architects used to attach to public buildings:

What is past is prologue. (85)

One tourist, who saw this motto, apparently asked the taxi driver what it meant:

'It means, . . . ' said the driver,
' . . . you ain't seen nothin' yet.'

The world is moving into a multi-disciplinary era in which engineering, physics, mathematics and other disciplines are playing an increasingly important role in the practice of medicine and surgery. Orthopaedics has led the way, having woven these other specialities into its very fabric. Bioengineering has become an important part of the modern practice of orthopaedics. Given appropriate resources, the future will bring further acceleration in this trend. Continuation of research programmes in orthopaedic bioengineering would greatly enhance the quality and duration of a patient's life—adding both 'years to life' and 'life to years'.

Patients will enjoy an extended lifestyle of higher quality of life as a result of earlier diagnosis of disease processes and more effective prophylaxis. It is now recognized that past emphasis on life-and-death medicine is no longer a cost effective approach for all medical research. In heart disease, stroke and cancer research, huge expenditure has not resulted in any significant increase in life expectancy. Orthopaedic surgery is more to do with the quality of life and more modest investment results in a dramatic improvement in the quality of life. Crippling and maiming disorders will be minimized, returning millions of people to active, productive lives. Their productivity tomorrow will pay society for today's investment in research and development in orthopaedic bioengineering.

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'brains, annoyingly enough, are attached to stomachs'.

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