Acoustic monitoring
of
prosthetic heart valves

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for the degree of Doctor of Philosophy

by

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Acoustic monitoring of prosthetic heart valves

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Abstract

The aim of the work presented in this thesis was to examine the possibility of detecting structural changes to an implanted prosthetic heart valve by spectral analysis of the sounds produced by the valve.

On closure, mechanical heart valves produce a distinct sound as the occluder strikes the metal frame of the valve. Any change in the mechanical state of the valve will produce changes in the modes of vibration of the entire structure, causing the spectrum of the closing sounds to change.

Initial recordings were made in a large tank of water providing ideal valve actuation and recording conditions. Results showed that all valves produce a stable averaged spectrum, and that each valve has a unique averaged spectrum. A digital filtering technique was developed whereby a baseline spectrum recorded from each valve is used for comparison with all subsequently recorded spectra from that valve. Using this technique, averaged spectra from individual valves were found to be highly reproducible. However, a minor structural alteration to a valve (added mass, or strut fracture) caused significant spectral changes, readily detected by digital filtering.

To investigate the effect of a finite recording volume, recordings were made in a tank with dimensions approximating those of a human thorax. Standing waves generated by reverberations were clearly visible in the results. Structural changes to a valve were still detectable.

Recordings were also made from prosthetic valves implanted in patients. To reduce sound distortion at the thoracic surface, recordings were made with the patient submerged in water. Results showed that reproducible averaged spectra could be obtained from implanted valves provided recording conditions were kept constant.

The technique has not yet been developed to the point where it can be applied clinically. Nevertheless the technique shows promise as a method of screening patients at risk.
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Valvular heart disease and heart valve replacement

1.1 Valvular heart disease

A staggering proportion of the world's population suffers from cardiac problems. Indeed in 1979, over one third of all deaths in the United States were caused by some kind of heart disease [1]. The term "heart disease" can relate to any part of the heart, but any or all of the valves situated within the heart are a common source of cardiac problems.

Valvular heart disease can be either congenital or acquired, but most common valve defects are generally acquired. For many years nearly all acquired valvular heart disease was attributed to rheumatic heart disease occurring as a result of rheumatic fever. Acute rheumatic fever is mainly a childhood disease which was very common until the middle of the century. In 1927 up to 15% of children under the age of 15 years had suffered an attack of rheumatic fever [2]. The relationship between chronic rheumatic valve disease and previous attacks of acute rheumatic fever is well established. Bland [3] followed 1000 cases of patients who had had an attack of acute rheumatic fever as a child. After 20 years he found that 30% had died of valve disease, 44% had abnormal heart sounds, while only 18% were apparently normal.

In the last 30 years however factors such as improved housing conditions, reduced overcrowding, and the widespread use of penicillin have been responsible for the decline of rheumatic fever in the western world [4]. Nevertheless, patients with rheumatic heart disease still represent a significant proportion of valvular heart disease patients, particularly in the older age groups.
There are two fundamental classes of valvular abnormality, \textit{stenosis} and \textit{incompetence}. Stenosis is a narrowing of the valve orifice causing obstruction to forward blood flow. Incompetence is failure of the valve to close tightly allowing regurgitation of flow. Valvular incompetence may develop acutely or chronically; valvular stenosis takes years to develop. In general, severe calcification of the valve is associated with stenosis \cite{5}, whereas an incompetent valve may show no signs of calcification. A combination of stenosis and incompetence at one or more of the valves is possible.

Abnormalities in function can occur in all four cardiac valves, although the valves of the left heart (the aortic and mitral valves) are more often involved. The mitral valve is in its closed position throughout left ventricular systole, and during this time is exposed to the highest pressures of the cardiac cycle (see Appendix A). Any abnormality, be it congenital or acquired which increases still further the haemodynamic stress put on the valve can accelerate the degeneration of the valve leading to its dysfunction.

The efficiency of the heart depends on the proper function of its valves, and their malfunction will result in a reduced cardiac output and an increased volume and pressure in the filling chambers. To a certain degree the muscle can compensate to maintain the overall performance of the heart, despite malfunctioning valves. However this can eventually cause hypertrophy, dilatation and damage to the heart muscles.

\section*{1.2 Cardiac valve surgery}

Over the past 50 years the clinical approach to valvular heart disease has changed dramatically with the evolution of open heart surgery. With this surgical development
came the opportunity for surgeons to observe diseased valves directly. It quickly became obvious that while primary repair of the patient's own valve is sometimes possible, significant valvular heart disease can be managed effectively only by surgical removal and replacement of the diseased valve. Valve replacement has become the major form of surgical treatment for valvular heart disease.

The history of heart valve replacement extends back 40 years. The first implantation of an artificial heart valve was performed in 1953 by Hufnagel [6] in the USA. Since then work by others such as Starr, Carpentier, Ionescu, and Bjork has led to the development of many prostheses. There are now over forty different prosthetic heart valves commercially available [7].

The development of prosthetic cardiac valves has been a major contribution to the management of patients with valvular heart disease, and replacement of malfunctioning valves has become a routine procedure. In 1990 it was estimated that approximately 100,000 replacement operations are carried out world-wide each year [8], with 5000 of these operations occurring in the United Kingdom [9].

The success of valve replacement surgery is undoubted. The mortality rate during and shortly following surgery is quoted as between 5 and 10% [10,11]. The five-year survival rate for those patients discharged from hospital after aortic valve replacement was reported by Copeland as 77% [11]. This is in contrast to 38% and 48% five-year survival rates without valve surgery reported elsewhere [10,12]. Results tend to be better in patients operated on early in the course of their disease. If operation is delayed to the point that myocardial degeneration has occurred, the long-term result is poor.

Substitute heart valves can be divided essentially into two groups: (a)
mechanical, and (b) bioprosthetic. Mechanical valves are constructed entirely of man-
made materials; on the other hand bioprostheses contain elements made from
chemically-treated animal tissue. Additionally, a very small fraction of implanted
heart valves are homografts obtained from suitable donors and treated with antibiotics
prior to implantation. In 1986, 54% of all artificial heart valves implanted in Britain
were mechanical; in 1987 the figure was 63% [9].

1.3 Problems associated with prosthetic heart valves

While valve replacement surgery has certainly improved the outlook for patients with
valvular heart disease, this treatment is not without its own problems. Mechanical
malfunction, obstruction to flow and thrombus formation can occur with prostheses.
Throughout the development of prosthetic heart valves the major problem has been
the need to provide reasonable physiological valve function whilst taking into con­
sideration the problems of implantability, haemodynamics, thromboembolism, and
durability [13]. These four aspects will be considered here in turn.

1.3.1 Implantability

The valve prosthesis must be implanted securely. There must be a high degree of
compatibility so that the prosthesis is readily acceptable to its surrounding host tis­
ues. Direct suture of the solid material of a mechanical prosthesis is not satisfactory;
there must be a porous attaching surface. Wherever non-porous materials are in direct
contact with host tissues, a blood clot can be propagated at the interface [14]. A
porous fabric sewing ring was introduced in 1960 by Harken [15] and Starr &
Edwards [16], and all valves today are implanted today using a modification of these
first sewing rings. The fabric of the sewing ring is compatible with the host tissues, and encourages the in-growth of fibrous tissue. This allows the implanted valve to become well-encapsulated in healthy scar tissue, and a good tissue to prosthesis linkage is achieved.

1.3.2 Thrombosis

Blood clots or thrombi form on non-porous foreign surfaces such as an implanted mechanical heart valve. Davila [17] managed to eliminate thrombus formation in an experimental valve in which all valve elements in contact with the host tissues were porous, and which on implantation was totally encapsulated by the surrounding scar tissues. Unfortunately this valve was plagued by other problems.

Thromboembolism occurs when thrombi in the blood stream block the flow of blood through the vessel. The problem of thromboembolism is a major one, and it has meant that all mechanical heart valve patients must undergo regular anticoagulation therapy. Unfortunately, the anticoagulating drugs (usually sodium warfarin) can themselves cause serious problems, notably haemorrhage [18], and these problems are emphasised when patients cannot or do not take their medications reliably.

Thromboembolism is virtually a non-existent problem when bioprosthetic valves or homografts are implanted, since the thrombus-forming interface occurring with mechanical valves is non-existent.

1.3.3 Haemodynamics

A prosthetic heart valve must act to allow unidirectional blood flow, and within the limits of the physiological flow range it should produce minimal opening resistance
and flow impedance, cause minimal blood turbulence, and should close with negli-
gible regurgitation. Blood turbulence can cause haemolysis of the red blood cells, as
can contact with foreign surfaces. Thus some degree of haemolysis can be expected
with mechanical valve prostheses, but not with bioprostheses.

1.3.4 Durability

The ideal heart valve prosthesis should be capable of performing adequately for the
lifetime of the patient. A valve is required to perform in the region of 40 million
cycles per year, and it is not surprising that the valve’s lifetime may be limited by the
process of fatigue, caused by stresses of the physiological environment. A high degree
of quality control is needed during the complex procedures which occur during the
manufacture of a heart valve. Despite this, it is almost inevitable that there will be
some failures.

Tissue valves do not in general break with catastrophic results, but rather there is
a gradual breakdown of the valve, giving the surgeon ample time for re-operation and
replacement. On the other hand, mechanical valves, which contain metal frames and
pyroilitic carbon occluders, can fail as a result of fracture of either the frame or the
occluder. Failure is usually sudden and fatal.

1.4 Mechanical valves

This section takes a closer look at the three main types of mechanical prosthetic heart
valve currently in use, (namely caged ball, tilting disc, and bileaflet valve), and con-
siders each with respect to the problems discussed above. Figure 1.1 illustrates a typi-
cal valve from each of the three groups.
Some typical prosthetic heart valves: (a) caged ball valve, (b) tilting disc valve, (c) bileaflet valve. Each valve is viewed in both its open and closed position.
1.4.1 Caged ball

A typical caged ball valve consists of a circular valve ring to which is attached a cage (see figure 1.1(a)). Inside the cage is a spherical occluder which moves from a closed position seated in the valve ring to an open position restrained by the cage. The ring and cage are typically made of an alloy known as Stellite, and the occluder made of Silastic. The ring is covered by a fabric sewing ring for attaching the valve in the annulus.

The original prosthetic heart valve implanted by Hufnagel in 1953 was of caged ball design, and modifications of this design are still widely used today. The Starr-Edwards valve is the most widely known valve of this sort; other caged ball valves include the Smeloff-Cutter and the Braunwald-Cutter valves.

Thromboembolism

Anticoagulation achieved by the use of warfarin is highly effective in reducing the risk of thromboembolism. Unfortunately the risk is not entirely eliminated.

Haemodynamics

Flow obstruction is an intrinsic feature of the caged ball valve design. When the valve is open, the ball occluder remains centrally in the pathway of the flowing blood, causing substantial turbulence of the blood. This can lead to haemolysis.

Furthermore care must be taken when choosing the size of valve. In patients with small aortic roots, if the valve is too large, this can result in nearly total outflow obstruction by the ball, whose diameter is only minimally less than that of the aortic root itself [19].

On the whole however, haemodynamic performance of these valves is adequate.
Durability.

The main problem with the original caged ball valves was ball variance. The silicone rubber ball was prone to absorb plasma lipids with resultant swelling. This swelling reduced the mobility of the ball, and sometimes caused complete impaction of the ball within the cage [20]. This problem has been overcome by alteration of the technique used for curing the silicone rubber [21], and ball variance has almost entirely disappeared. Durability of ball valves nowadays is excellent.

1.4.2 Tilting disc

A typical tilting disc valve consists of a circular orifice ring and inlet and outlet struts made of Stellite, which guide the motion of a free-floating pyrolitic carbon disc. The struts define the opening angle of the disc and prevent it from being lost into the blood stream. When the valve is closed the disc fits inside the orifice ring, and on opening it tilts to approximately 60°. A fabric sewing ring surrounds the orifice ring. A typical tilting disc valve is shown in figure 1.1(b).

The concept of a tilting disc valve arose in an attempt to avoid the central obstruction caused by the ball in a caged ball valve. The design gained popularity, and now the most widely known tilting disc valves include the Bjork-Shiley, the Lillehei-Kaster, the Omniscience and the Monostrut.

Thromboembolism

Thrombi do not tend to form on the moving parts of the valve. The disc is unattached to the valve frame and is therefore free to rotate. This constant motion helps to reduce the build-up of thrombus on the valve. In addition, it has been reported that the use of
pyrolitic carbon reduces the risk of thrombogenesis [22]. However as with all mechanical valves, thromboembolism remains a substantial risk, greatly reduced by anticoagulation.

**Haemodynamics**

Incorrect positioning of the valve can cause problems. On opening, the disc should not come into contact with surrounding tissues, and thus a compromise must sometimes be made by the surgeon between orientation of the valve to minimise the risk of disc/tissue interference, and orientation to produce optimal haemodynamic performance of the valve. Valve size must also be chosen carefully, since use of an oversized valve will mean that the valve is tilted out of the plane of the orifice into which it is sewn, distorting its presentation to the axis of blood flow. Antunes [23] reported occluder dysfunction with a tilted prosthesis.

In general however, haemodynamics of the tilting disc valve design are excellent, and this is one of the major advantages of the tilting disc valve over other mechanical valves.

**Durability.**

There have been no reports of pyrolitic carbon disc degeneration to date. Free rotation of the disc allows even distribution of the stresses on the disc and thus helps to eliminate disc wear. However, structural failures have occurred on several occasions, the most widely publicised of which have been those of Bjork-Shiley convexo-concave disc valves when the outlet strut of the valve has fractured allowing the disc to escape [24,25]. These failures have led to the withdrawal of this valve from the market.
1.4.3 Bileaflet

The most common bileaflet valve is the St. Jude Medical valve, first used clinically in 1977. The valve, made entirely from pyrolitic carbon, has two leaflets which rotate on a fulcrum by means of a protrusion on the end of each leaflet fitting into a recess on the inner surface of the orifice ring (figure 1.1(c)). In the closed position the leaflets meet oriented at an angle of about 35° to the plane of the disc, and they open to approximately 85°.

**Thromboembolism**

As with all mechanical valves, long-term anticoagulation is required.

**Haemodynamics**

The two leaflets open to about 85° such that they are almost parallel to the blood stream. Thus they offer minimum resistance to the blood flow. However the 85° opening angle makes this valve susceptible to tilt dysfunction, and care must be taken to ensure that the valve is not tilted when implanted. An oblique tilt of 5° (which is not visibly obvious) will result in one of the leaflets opening past the axis of flow. This will cause asynchronous closure of the leaflets and upset the haemodynamic performance of the valve [26].

**Durability.**

On the whole, durability of bileaflet valves is good. However failures have been reported on several occasions. Examples of failure of bileaflet valves include leaflet fracture of the Edwards-Duromedics valve [27], and escape of a leaflet from the St. Jude Medical valve [28].
1.5 Bioprosthetic valves

By the early 1960s the value of heart valve replacement surgery was well established. However, problems with the mechanical valves, in particular the need for anticoagulation, prompted the search for alternatives. Homografts were the natural choice, but due to a lack of supply, they could never become an adequate alternative. And so studies on non-human animal valves were begun.

The aortic valves of humans and many domestic animals are remarkably similar in structure. Dog and goat valves are too small for adult use, but valves from cows, pigs and sheep are suitable. The first animal valve to be implanted into a human was a porcine aortic valve in 1965 [29]. However the first heterografts tended to deteriorate due to inflammatory reactions. This led to the development by Carpentier [30] of a method of glutaraldehyde treatment of the valves before implantation. The heterograft was now in the strict sense a bioprosthesis.

The advantages of heterografts over mechanical valves soon became obvious; they do not cause haemolysis, are relatively non-thrombogenic, and do not require anticoagulation. The main disadvantage of bioprostheses is durability. The glutaraldehyde treatment greatly improved durability, but still bioprosthetic valves have a finite lifetime with a 10-year failure rate of between 20 and 40% [31,32]. Fortunately, tissue valve failure tends to be non-catastrophic so that re-operation can be planned carefully and accomplished effectively.
1.6 Summary

Mechanical valves have the advantage of durability, but life-long anticoagulation is required with its associated problems. Haemodynamic function is good with the tilting disc and bileaflet valves, and adequate with the caged ball design. Implantability is no longer a major problem since the development of porous sewing rings, which give an excellent valve-to-tissue linkage. Biological valves on the other hand have the general advantage of not requiring permanent anticoagulation, but the disadvantage of limited durability.

It is impossible to draw any conclusions about which valve is the ‘best’ available. There have been many reports on the long-term survival rates for patients with various types of valve. However statistical records of survival after replacement have not proved to be a good basis for comparison between valves. The differences between patient populations (age, cardiac state), operating hospital and surgeon can all influence the rates and obscure any differences between valve type. No particular valve has emerged as superior, and each has its own advantages and disadvantages. Patient variables have a very strong influence and should be taken into account by the surgeon when selecting which particular valve to implant. For example, a bioprosthetic valve should be recommended for patients with contraindications to anticoagulants or who for social or mental reasons are unable to take anticoagulants reliably, or for women planning pregnancy.

Clearly, great progress has been made over the last four decades in the development of prosthetic heart valves. However during this time, important lessons have been learnt, and experience has revealed the problems which can occur with the use of
artificial valves. No one valve currently available meets each of the requirements outlined above ideally, and as new materials and new technologies are developed, the search for the 'ideal' heart valve substitute continues.
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Evaluation and monitoring of prosthetic heart valves

2.1 Failure of prosthetic heart valves

There can be no doubt that the lives of many people have been prolonged and the quality of their lives improved by valve replacement surgery. However patients with artificial valves continue to face a substantial risk of serious complications both during surgery and afterwards. Despite efforts to improve prosthetic valves in design and materials for better clinical results, complications such as thromboembolism, haemolysis and mechanical malfunction still occur. The prognosis for mechanical malfunction in particular is poor, and significant malfunction will require replacement of the prosthesis at the earliest opportunity.

Acute failure of a mechanical heart valve is rare. However failures do occur. The most widely publicised of these has been failure of the Bjork-Shiley convexo-concave tilting disc valve, due to fracture of its outlet strut [25,33]. The occurrence of a complete fracture requires immediate valve replacement surgery, and two out of three such fractures have been fatal. Since these failures, the designs of these valves have been altered, and the original designs are no longer in production. However, the original valves have been implanted in many thousand patients.

It has been suggested that patients with makes of valves known to fail should be given the opportunity of re-operation and replacement of the prosthesis. However, this course of action has usually been suggested by those who do not fully understand the problem. Elective re-operation is not to be recommended, since there is an inherent associated mortality and morbidity [34]. Repeat valve operations can be difficult;
complications can occur, for example, in excising the dysfunctional valve in the presence of severe scar tissue and calcification.

The case-fatality rate has to be balanced against the possibility that acute valve failure may not occur, and against the chances of survival after a re-operation. Statistics are not readily available. However the risk of acute failure of a mechanical heart valve is probably less than the risk of re-operation and re-replacement. Recent figures for perioperative mortality for all valve replacement operations vary between 5 and 10% [9,10,35], and these figures will be higher for valve re-operations. Unfortunately, the risk increases when an emergency operation is necessary [36,37]. The fatality from emergency operation as a result of strut fracture of a mitral valve has been reported as 50% [38].

The assessment of a patient with a prosthetic heart valve at regular intervals is therefore vital, since it is important for the clinician to be able to make an informed decision as to the timing of re-replacement. This is necessary to avoid subjecting the patient to the risks of untimely surgery. On the other hand, once mechanical failure of a valve occurs, re-operation is required within hours. Survival at re-operation will be strongly influenced by the mode of failure; a slow degeneration allows time for planned surgery, sudden catastrophe does not. At present there is no available method for diagnosis of impending failure of mechanical valves. Since the lives of many thousands of patients are in jeopardy because of the unknown longevity of prosthetic valves, an accurate in vivo assessment of the mechanical state of the heart valve is required.
2.2 Noninvasive techniques for the evaluation of mechanical cardiac valve prostheses

At present it is impossible to establish with certainty the need for replacement of a prosthetic valve. However, in a patient with a prosthetic valve, any changes in clinical status for example faintness, diaphoresis, haemolysis, angina, shortness of breath, or cardiac failure, should be carefully considered by the clinician as this may be a sign of an impending prosthetic valve failure.

Several noninvasive methods are used at present in an attempt to detect malfunction of a prosthetic heart valve [39]. They include (a) auscultation [40,41], (b) phonocardiography [42] usually combined with (c) echocardiography [43,44], (d) Doppler ultrasound [45,46], and (e) cinefluoroscopy [47,48]. These tests are usually carried out in conjunction with one another in order to optimise evaluation of the functional state of the prosthetic heart valve.

2.2.1 Auscultation

Cardiac auscultation involves simply listening to the patient's heart using a stethoscope. The development of more sophisticated diagnostic techniques such as those discussed below has tended to overshadow the value of this simple clinical test. Yet Mintz [49] has suggested that careful auscultation may be more sensitive than echocardiography, phonocardiography or cinefluoroscopy in detecting a malfunctioning prosthetic heart valve. Valve stenosis or incompetence causes the blood to pass through the valve in a turbulent jet. This can be heard as a murmur. Unfortunately significant valvular dysfunction usually occurs without audible changes.
2.2.2 Phonocardiography

The phonocardiogram is a complex signal produced by deterministic events such as the opening and closing of the heart valves, and by random phenomena such as blood-flow turbulence. Acoustic vibrations caused by sudden variations in intracardiac pressures are transmitted through the cardiac structures and the chest wall, and these are detected at the chest surface.

Analysis of phonocardiographic time intervals and valve opening and closing sounds can provide supportive evidence of valve malfunction. For example, variations in the A2/mitral valve opening interval (see Appendix A) can be indicative of valve obstruction due to poppet or leaflet problems causing the valve to "stick" [50], although this may also be indicative of left ventricular dysfunction [49,51].

Background noise and the dependence of the phonocardiogram on recording site make abnormalities very difficult to detect. Furthermore, there is a large patient-to-patient variation in phonocardiographic recordings, as well as variations due to haemodynamic status, and it is not possible to predict reliably the state of the valve using phonocardiography.

2.2.3 Echocardiography

Phonocardiography is often combined with echocardiography in order to relate the auscultatory events to actual valve motion. Echocardiography involves the direction of short bursts of ultrasound through the chest wall and the detection and analysis of the returning echoes. At the interface between two structures or tissues of different acoustic impedance (for example, velocity of sound in fat is 1450ms⁻¹, and in muscle is 1585ms⁻¹), there occurs partial reflection of a sound wave. The incident beams of
ultrasound are therefore deflected, absorbed or reflected to various degrees by the tissue structures in and around the heart, and the returning echoes can provide an image of the position and motion of the various cardiac structures.

Echocardiographic examination can be used to evaluate the opening and closing motion of the movable parts of a prosthetic valve, its functional capacity as a replacement for a native cardiac valve, and the stability of the prosthesis within the heart. Echocardiography can also provide information on the response of the heart to haemodynamic alteration induced by the prosthesis.

The metallic elements of prosthetic heart valves are highly echogenic, and multiple reverberating echoes occur causing bright echoes on a two-dimensional echocardiogram [52]. For this reason it is very difficult to identify reliably the presence of small masses such as thrombi or vegetations caused by bacterial endocarditis. It may be possible to detect these in more advanced stages, although in one study, echocardiography correctly diagnosed malfunction in only 6 out of 23 patients having either a large pedunculated vegetation or valve dehiscence (rupture of the sutures that anchor the sewing ring to the annulus of the excised valve) [53]. Excessive reverberations can also distract from the clarity of disc or ball motion.

Furthermore, the appearance of the echocardiogram depends highly on the direction of the ultrasonic beam relative to the orientation of the prosthesis after surgical implantation. Adequate visualisation of the valve on echocardiography may be difficult.
2.2.4 Doppler ultrasound

Doppler echocardiography uses Doppler techniques to identify the pattern and velocity of blood flow across the prosthesis. These flow patterns will be affected by the type of prosthesis, the rhythm, and the haemodynamic status of the patient. When combined with echocardiography, accurate localisation of the intracardiac region is permitted, and real-time flow imaging coded in colour is obtained. Haemodynamic information, transprosthetic flow velocities, extrapolation of the effective orifice areas, and estimates of transprosthetic pressure gradients are possible. However, Doppler echocardiography is of no use in mechanical or structural evaluation of the valve.

2.2.5 Cinefluoroscopy

Cinefluoroscopy involves examination by creation of a moving picture using X-ray techniques.

Cinefluoroscopy is useful for evaluating disc or poppet motion. It can therefore be used to detect, for example, dehiscence of the prosthetic valve. This is observed as exaggerated motion of the prosthetic valve [47]. Cinefluoroscopy is generally disappointing in detecting thrombus, unless the thrombi are large enough to interfere with the motion of the valve. Failure of a tilting disc valve to open fully for example, may indicate thrombotic obstruction. In addition, cinefluoroscopy is only useful when the poppet is radio-opaque, and like echocardiography the results are highly dependent on the relative orientation of the valve.
2.3 Summary

The main use for all of these tests is the detection of haemodynamic dysfunction of the valve. Haemodynamic function is not however altered by minor mechanical malfunctions, and thus these tests are not in general capable of detecting mechanical dysfunction of the valve, except perhaps one of a greatly advanced nature. Guit [54] and Khalil [55] were both able to identify the fracture of the outlet strut of a Bjork-Shiley valve using X-ray techniques; in both reports, the strut had fractured completely and the disc had escaped. On the other hand, it has not been possible to achieve accurate diagnosis of malfunctions at an early stage; a single leg outlet strut fracture was not detected by Shahi [56] using the same techniques.

Clearly none of the techniques currently available have proved effective for early diagnosis of prosthetic valve malfunction. The development of a noninvasive technique for evaluation of the structural integrity of prosthetic heart valves remains a major problem awaiting solution.
Chapter 3

Spectral analysis for valve evaluation

3.1 Nondestructive testing for structural integrity

3.2 Attempts at valve evaluation using spectral analysis techniques

3.3 Problems encountered by previous studies

3.3.1 The use of a pulse duplicator for acoustic studies

3.3.2 "Near field" recording

3.3.3 Sound reverberation within a finite volume

3.3.4 Frequency range of interest
Spectral analysis for valve evaluation

3.1 Nondestructive testing for structural integrity

In modern industry, the function of certain objects and machines is readily examined using nondestructive testing techniques. In these tests, indications are sought of changes in the mechanical integrity of the test object, brought about by the presence of faults, for example subsurface stress cracks in aircraft structures [57] or railway wagon wheels [58]. The aim of the test is to detect the fault before it has a significant effect on the overall performance of the test object. The oldest method of nondestructive testing is probably impact response analysis whereby the object under test is struck by some kind of hammer and its response analysed for any indications of quality variation. A simple example of the application of impact testing is the tapping of fine china to detect flaws. Here quality assessment is done casually by ear to a satisfactory degree. However for more critical objects a detailed frequency analysis of the acoustic emissions is required.

One of the first reported uses of impact testing as a method of assessing mechanical integrity was by McCutcheon in 1954 [59] who tested crankshafts for cracks, and found differences in the frequency spectrum when cracks were present.

Using the same principles, attempts have been made to examine the mechanical integrity of prosthetic heart valves. In this case, the valve does not need to be struck by a hammer, since on closure, prosthetic heart valves produce a distinct click as the occluder strikes the frame of the valve. In most cases the sound of an implanted valve closing can be heard in a quiet room at a distance of a few metres from the patient.
The sounds are produced by impulsive forces exerted when the mechanical structures in the valve collide (e.g. the disc hits the struts, or the ball strikes the cage) as the valve closes. Changes in the mechanical properties of one or more structures in the valve (for example, a fractured strut, or the build-up of thrombus on part of the valve) will alter the sound produced on closure, since the modes of vibration of the valve will change. Analysis of the frequency spectrum of the closing sound of the prosthesis may therefore enable a malfunctioning valve to be detected.

3.2 Attempts at valve evaluation using spectral analysis techniques

Interest in the frequency content of heart sounds developed in the 1950s. As early as 1954 McKusick [60] adapted the technique of sound spectrograms used in voice analysis to heart sounds. He suggested that the technique could enhance the understanding of heart sound production and aid in the diagnosis of cardiac disease. The same technique was used by Winer in 1965 [61] to study specifically the closing sounds of prosthetic heart valves. The contour spectrogram was a plot of intensity of sound plotted by contour lines, with frequency on the vertical axis and time on the horizontal axis. A sound containing relatively high frequency components with significant energy density could be seen as a peak in the spectrogram occurring at the time at which the particular sound happened.

The contour spectrogram was used clinically by Hylen [62] in an attempt to detect ball variance due to lipid absorption in a Starr-Edwards prosthesis, but with little success. He found difficulty in standardising the recording equipment, and also he noted that the position and pressure of the microphone which was placed over the chest was critical to the frequency response.
A similar lack of success was found by other authors using this technique [63], although they all emphasised the attractive potential of sound analysis in terms of its noninvasive nature and ease of use and its potential superiority over phonocardiography and echocardiography. Studies by Adolph [64] and Sakai [65] suggested that useful diagnostic information could be obtained from the frequency spectra of natural heart valves. Their results were obtained by sweeping the heart sound signals with bandpass filters having a bandwidth of 20Hz, and they were not very accurate.

Measurement of the contour spectrogram was time-consuming but a few years later Kagawa [66] reported the use of a real-time sound spectro-analyser which could analyse signals electronically, and speed up the technique considerably. Soon after this, digital computers became available, and the development of the fast Fourier transform (FFT) algorithm for spectral analysis enabled power density spectra to be calculated quickly and accurately, with high frequency resolution [67].

Since then a large number of investigators [68-70] have studied the frequency content of the closing sounds of prosthetic heart valves but with limited success.

3.3 Problems encountered by previous studies

It would appear from these previous attempts to use spectral analysis techniques to monitor prosthetic heart valves, that the technique has limited use. It is the opinion of the author however that the lack of success of these previous studies can be traced back to technical problems caused by the recording and analysis techniques, rather than to any insensitivity in the acoustic response of the valve to changes in its mechanical state.

The majority of previous studies have been performed on valves implanted in
patients. Necessarily therefore the precise condition of the valve and heart were unknown. Contributions to the valve sounds from the physiology of the heart and surrounding anatomy could not be identified and as a result the actual sound of the valve remained unknown.

On the other hand, in vitro studies allow investigation of such factors as valve orientation and condition, pulse rate, and force of closure. The valve can be mounted in a controlled fashion and valve closure is initiated under precisely defined conditions. The information gained from these studies can then be used to enhance the understanding of recordings made from valves implanted in patients. Furthermore, the effect of various structural changes to a valve similar to those which may occur with implanted valves can be investigated.

Studies performed previously on valves in vitro have however been largely unsuccessful, possible reasons for which will now be addressed. Problems specific to recordings from valves implanted in patients will be addressed later in the thesis.

3.3.1 The use of a pulse duplicator for acoustic studies

The majority of previous in vitro studies have been carried out using one form or another of pulse duplicator [71-73]. The action of the pulse duplicator is to mimic the activity of the heart and circulatory system. A typical pulse duplicator is illustrated in figure 3.1. The prosthetic valve is fixed in the duplicator in the equivalent of either an aortic or a mitral position, and a hydraulic piston pumps fluid through the system in a pulsatile fashion causing the valve to open and close.

Use of a pulse duplicator allows the flow conditions to be closely controlled.
Figure 3.1
A typical pulse duplicator acting as a model heart.
Unfortunately other problems are introduced. These problems arise from noise, vibrations and resonances within the system [74]. Pulse duplicators are generally constructed out of rigid materials, commonly acrylic plastics. The impulsive force generated when the occluder in a prosthetic valve closes can be substantial. If the valve is rigidly mounted, as is often the case in a pulse duplicator, this impulsive force is transferred to the structure of the duplicator setting this also into vibration. The recording microphone then detects sound, not only from the valve, but also from the vibrating structures surrounding the valve. The resulting convoluted sound signal is virtually impossible to interpret.

3.3.2 "Near field" recording

The immediate vicinity of a sound source is known as the near sound field. In this region the particle velocity is not necessarily in the direction of propagation of the wavefront, and the sound pressure may vary appreciably at short intervals along the direction of propagation. Simple relationships between sound intensity and other physical parameters such as pressure and particle displacement do not hold. This has the consequence that small changes in the relative position of the sound source and the recording microphone cause frequency dependent changes in the amplitude of the recorded sound.

The extent of the near field at any given frequency is difficult to define, but can be approximated to one wavelength of the sound at that frequency. Thus for acoustic valve recordings made in a pulse duplicator, the microphone or hydrophone used to detect the closing sound of the valve must be placed within its near sound field, as a consequence of the small size of the duplicator. In one pulse duplicator study [72], the
acoustic transducer was placed at a distance of only 2cm from the valve, which is within the near field for sounds up to approximately 75kHz. The consequent frequency dependent signal distortion would have been significant.

3.3.3 Sound reverberation within a finite volume
For any sound source in a finite volume, sound waves propagate away from the source until they encounter the boundaries of the volume, where they are partly absorbed and transmitted, and partly reflected. The reflected sound creates a reverberant sound field. In a small volume such as that of a pulse duplicator there are multiple reflections, and the reverberant sound field interferes with the near sound field of the sound source (i.e. the valve). This creates a complex sound field whose amplitude is highly position dependent. Any sound recorded within the pulse duplicator will be significantly distorted.

3.3.4 Frequency range of interest
The majority of previous studies have concentrated on low frequencies in the 0 to 1 kHz range. However, the sounds produced by mechanical prosthetic heart valves have been found contain high frequency components of up to at least 25 kHz [70]. The normal mode frequency range of the various components of a prosthetic heart valve should be confirmed before valve recordings are made.
Chapter 4

Methods - *in vitro* experimental design and equipment

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Methods - in vitro experimental design and equipment

4.1 In vitro experimental design

The disadvantages of using a pulse duplicator for in vitro acoustic studies of prosthetic heart valves have been discussed in detail in the previous chapter. However they can be summarised as follows:

- Noise and vibrations are generated by the duplicator, which are detected by the microphone. These vibrations are transmitted to the valve due to the rigid mounting of the valve, and in turn, the impulsive force of the valve occluder on the valve ring as it closes is transmitted directly to the duplicator structure. These problems cause convolutions within the acoustic signal.

- The small volume of the duplicator forces the microphone or hydrophone to be placed within the near sound field of the valve at frequencies of interest.

- The finite size of the duplicator causes reverberations of sound within its volume.

To overcome these problems associated with the use of duplicators, the in vitro experiments in this thesis were designed as follows.
4.2 Experimental equipment for valve actuation

4.2.1 Pneumatic actuator

The *in vitro* experiments in this thesis use a pneumatic actuator to operate the valve. The valve is driven up and down through a volume of water, and this movement through the water initiates closure and re-opening of the valve. This method of actuation is therefore unlike methods used by previous investigators, who have mainly used pulse duplicators for valve actuation. In a pulse duplicator the valve itself remains stationary, and the fluid is pumped in a pulsatile fashion through the valve to cause it to open and close.

A pulse duplicator therefore mimics more closely the operation of a valve implanted within the body. However, as discussed in chapter 3, the design of a pulse duplicator is such that any valve sound recordings made within the duplicator are highly distorted, and of no use in evaluating the mechanical state of the valve.

Figure 4.1 illustrates the pneumatic actuator used for opening and closing the valves. The driving element of the actuator was a pneumatic cylinder (Compair Maxam; 32mm bore, 100mm stroke, thrust at 2 bar = 160 Newtons). The cylinder was driven by compressed air from a commercial air compressor (flow rate 95 l/min at 750 kPa). The compressed air at 750 kPa was filtered and the pressure reduced to 2 bar (200 kPa) using a filter pressure regulating valve (Compair Maxam G3/8). The flow of air to the cylinder was controlled by a solenoid-solenoid valve (Compair Maxam G3/8), and two flow control valves (Compair Maxam G3/8) regulated the flow of exhaust air from the cylinder as the piston moved up or down. The solenoid-solenoid valve was controlled electronically using a Neurolog NL 300 Pulse Generator and two Neurolog NL 403 Delay-Width modules. The Pulse Generator controlled the
Figure 4.1
Schematic diagram of the pneumatic actuator.
overall cycle time (5 seconds) and the Delay-Width modules controlled the flow of air to either side of the piston. By adjusting the driving air pressure, the interval between the opening and closing of the solenoid-solenoid valve and the two flow control valves, the thrust stroke, speed and the acceleration of the piston could be very precisely controlled. The resulting movement of the piston rod (to which the valve holder rod was attached) was investigated experimentally (see section 6.1 of chapter 6) and was found to be vibration free.

4.2.2 Valve mounting and actuator rod

To avoid the problems caused by rigid mounting of the valve, the valve, with its sewing ring removed, was held by a light elastic band mounting, which was attached to the three legs of a wooden tripod (see figure 4.2). The valve occluder was unimpeded by this arrangement and could move freely within the valve ring.

The tripod valve holder was fixed to a wooden actuator rod. The actuator rod was made of hardwood (Ramin) whose natural frequency range lies well below the sound frequencies generated by the valve. This ensured that any sounds generated by vibration of the rod would lie in a frequency range well below the sound frequencies generated by the valve. The valve was therefore mechanically isolated from the actuator.

The upper end of the rod was attached with a bayonet fitting to a length of 1" diameter aluminium tube which attached at its other end to the piston rod by a second bayonet fitting. This allowed the actuator rod to be removed from the cylinder and subsequently replaced in precisely the same relative position. A PTFE "finger", projecting from the side of the actuator rod and sliding in a smooth vertical channel, prevented the actuator rod from rotating about its axis as the piston moved up and down.
Figure 4.2

Actuator rod and tripod valve holder, with a tilting disc valve held in the elastic valve mounting.
The actuator rod lies in a vertical plane, and therefore the valve could be mounted such that it was either open or closed due to gravity. By varying the upward and downward acceleration of the actuator rod, the opening and closing of the valve could be controlled.

4.3 Experimental equipment - recording environment

4.3.1 Large tank

The measurements were made in a large tank of water of dimensions 270cm x 240cm x 120cm. The reason for using such a large water volume was to minimise echoes and reverberations of sound within the tank. The tank was foam-lined in an attempt to relieve the problem further. Another advantage of using a large volume of water was that the recording transducer could be placed outside the near sound field of the valve for all except low frequencies.

The actuator rod and pneumatic cylinder were mounted in a vertical plane on a rigid gantry above the tank of water. The valve attached to the actuator rod was sited at the centre of the tank, and only the wooden section of the actuator rod was below the surface of the water. This was to ensure that any vibration from the pneumatic actuator which were transferred to the aluminium section of the actuator rod did not disturb the water in the tank.

4.3.2 Model thorax

The finite volume of a human thorax will significantly alter the nature of the sound field generated by the closing of a prosthetic valve. In order to investigate the effect
of a finite volume on the valve recordings, a series of experiments was performed in a small tank of water roughly approximating the size of a human thorax. The actuating and recording equipment were the same as those used for the experiments in the large tank, apart from a few minor changes. These changes were all a consequence of the difference in dimensions between the two tanks, and they are described in detail in chapter 8.
Chapter 5

Methods - instrumentation; data storage and analysis

5.1 Transducer
5.1.1 Required frequency range for data acquisition
5.1.2 Choice of transducer
5.1.3 Position of hydrophone

5.2 Signal conditioning

5.3 Data storage
5.3.1 Analogue storage of data on magnetic tape
5.3.2 Signal conversion and digital storage of data
5.3.3 Summary of data storage

5.4 Data analysis - equipment
5.4.1 Hewlett-Packard 310 computer

5.5 Data analysis - methods
5.5.1 FFT analysis
5.5.2 Spectral averaging
5.5.3 Digital filtering for spectral comparison
5.5.4 Significance test for spectral equivalence

5.6 Data analysis - other equipment
5.6.1 B & K Type 2032 signal analyser
The term *instrumentation* can be defined as the use of transducers and associated signal processing devices to obtain information about a physical process for the purpose of collecting data about that process.

Before choosing suitable instrumentation and analysis techniques for the valve sound measurements, careful considerations had to be made, in order that the chosen instrumentation should give the best possible results. A wide variety of systems are available for the measurement of acoustic noise, although they all consist basically of a transducer, an analysis section, and an output and/or storage section.

### 5.1 Transducer

The primary element in data collection is the instrumentation transducer. A transducer is a device which translates a measure of a physical phenomenon (in this case, sound) into an analogue (electrical) signal with a calibrated relationship between the input and output quantities.

The transducer is a potential source of error during data acquisition, and the choice of transducer is therefore critical. The transducer should be able to operate satisfactorily in the environment in which it will be used. In this study, therefore, it must be capable of detecting signals underwater, since this is the environment chosen for the experiments. In addition, the transducer must meet the technical constraints such as frequency response, dynamic range, directivity and stability required for meaningful measurements.
5.1.1 Required frequency range for data acquisition

The frequency response of the transducer should ideally be linear over the frequency range of interest. It was important therefore at the start of the project to investigate the extent of this frequency range. As discussed in chapter 3, many previous studies on acoustic emissions from mechanical heart valves have concentrated on low frequencies in the 0 to 1 kHz range. However, it would seem likely due to the nature of the materials used in the construction of a mechanical valve, that higher frequencies will be present in the acoustic signals produced on valve closure.

In order to confirm the frequency range of interest, a simple experiment was performed in which the acoustic emissions from a typical mechanical heart valve were recorded and the associated frequency spectrum obtained.

The valve, a tilting disc valve with its sewing ring removed, was suspended by threads in a horizontal plane such that it was closed under gravity. A B & K Type 4134 microphone was positioned 5cm from the valve and its output connected directly to the input of a B & K Type 2032 signal analyser.

The valve disc was opened manually and allowed to fall shut. The sound created on closure was detected by the microphone and an average frequency spectrum over 20 closures calculated directly by the signal analyser. The resulting spectrum is illustrated in figure 5.1. A number of peaks are clearly visible in the frequency spectrum at frequencies up to 25kHz.

As a result of these observations, it was clear that a meaningful study of the acoustic signals from prosthetic heart valves must cover the entire frequency range up to at least 25kHz.
Figure 5.1

Frequency spectrum from closure of a tilting disc valve, showing spectral peaks up to 25kHz.
5.1.2 Choice of transducer

The transducer which was chosen to meet the requirements of this study was a Bruel & Kjaer (B & K) Type 8103 hydrophone, illustrated in figure 5.2. This is an underwater piezoelectric transducer, with a flat frequency response according to the manufacturer's calibration, over the required frequency range up to 25kHz. In addition it has a large dynamic range, excellent omnidirectional characteristics up to 100kHz (shown in figure 5.3), and a high sensitivity relative to its small size.

5.1.3 Position of hydrophone

In chapter 3, the problems caused by recording acoustic signals from within the near field of a sound source were discussed. The near field extends in the region of approximately one wavelength of sound. In water where the speed of sound is 1500ms⁻¹, a sound of frequency 1kHz has a wavelength of 1.5m. Therefore in order to ensure that there is no distortion of sound at this wavelength, the sound would have to be recorded at a distance of at least 1.5m. However at this distance the signal-to-noise ratio becomes unacceptable (signal-to-noise ratio approximately 2:1). In addition, the finite size of the large tank makes recording at this distance impractical.

A compromise therefore had to be reached whereby the hydrophone was positioned at a distance which maintained an adequate signal-to-noise ratio without producing significant signal distortion at low frequencies due to near field effects. It was decided to position the hydrophone in the large tank at a distance of 30cm from the valve. At this distance the noise is small compared to the signal size, although it is realised that a small amount of signal distortion may occur at frequencies below 5kHz.

The hydrophone was positioned either 30cm directly below the valve, or 30cm horizontally to the side of the valve. It was mounted in a PVC holder (see figure 5.2)
Figure 5.2

The B&K Type 8103 underwater hydrophone in its specially designed holder.
Figure 5.3

Directivity characteristics of the B&K Type 8103 underwater hydrophone.
attached to a right-angled hollow aluminium tube through which the cable of the hydrophone was passed. The horizontal support arm was approximately 60cm long, and of a diameter such that it should not disturb the sound field surrounding the hydrophone. The vertical section of the mounting pole was attached to the rigid boards covering the tank via a foam block, the purpose of which was to eliminate the possibility of vibrations being transmitted down the aluminium rod to the hydrophone.

5.2 Signal conditioning

The acoustic signal detected by the hydrophone must be conditioned before it can be of any use. This involves amplification and filtering.

The high-impedance output signals from the hydrophone were input to a signal-conditioning amplifier, a B & K Type 2635. This is a portable battery-powered low-noise charge amplifier, which is designed specifically for use with piezoelectric transducers such as the Type 8103 hydrophone.

After passing through the amplifier, the signals were high-pass filtered at 1kHz using a "home-made" 4th order Butterworth filter. The filter characteristics are measured in section 6.3 of chapter 6, and the low frequency drop caused by the filter can be seen in figure 6.6. This particular type of filter was used since it gives a maximally flat frequency pass-band. The purpose of this filter was to remove any low-frequency rumble which might occur in the vicinity of the experiments.
5.3 Data storage

5.3.1 Analogue storage of data on magnetic tape

A significant part of the research for this thesis was concerned with the development of a suitable method of signal analysis of the data. At the onset of the project it was clear that the precise method of analysis would only become defined as work progressed. Thus to allow as much freedom as possible to adapt and change the analysis operations of the data, on-line analogue recording and storage, and subsequent off-line digitisation and analysis was chosen as the most suitable method of processing the data.

In most experiments a magnetic tape recorder was used as a data storage system. This has the advantage of being able to store large quantities of data and to reproduce them in electrical form. Signals are stored in analogue form which prevents errors caused by digitisation from being introduced before data storage. The main disadvantage of this method of storage is that individual heart valve closure signals are not easily retrievable.

The tape recorder used was a Racal Store 4D Instrumentation Recorder. The Racal has four recording channels and two available recording modes - direct recording (DR) for a frequency range up to 75kHz at a tape speed of 15 ips, and frequency modulation (FM) providing a signal bandwidth from dc to 5kHz at the same tape speed. The recording tape used was Ampex Grand Master 456 Audio tape.
5.3.2 Signal conversion and digital storage of data

The signal from the transducer is analogue - in other words, it is continuously varying and can take any value. The analogue data must be converted to digital format before it can be passed to the analysis section. This process is performed by an analogue-to-digital converter (A/D converter), which converts the analogue signals into a sequence of digital values at equal time intervals. Appendix B1 contains a more detailed description of the digitisation procedure.

One of the problems associated with digitisation is aliasing, whereby the high-frequency components of the time function can be interpreted as low frequencies if the digitisation rate is too low (see Appendix B1). The consequent digitised data is worthless. In order to prevent aliasing from occurring, the frequency range of the signal is limited before digitisation by a low-pass filter. The analogue signals stored on magnetic tape were therefore passed through a low-pass filter with corner frequency 20kHz before digitisation.

Digitisation was performed using a Nicolet 310 digital oscilloscope. This is a dual-channel, 12-bit resolution digital oscilloscope with floppy disc storage and pre-trigger facility. The pre-trigger is an important facility for acquisition of heart valve acoustic signals. These signals are transient signals of finite duration, and it is necessary for correct analysis that the data-window length to be chosen so that it extends over the entire signal. Selection of a data-window too close to the beginning and end of a transient time signal can produce spurious peaks in the spectrum.

The highest frequency of interest contained within a valve closing signal is 25kHz (see section 5.1.1). The minimum sampling frequency for the analysis is twice this value, i.e. 50kHz. This gives a time interval for sampling of 1/(50kHz) or 20μs. The Nicolet was therefore set to digitise at 20μs. Each signal sampled by the Nicolet
automatically consists of 4000 data points, so giving a total time trace of 80ms. However, a typical acoustic signal produced by a closing prosthetic heart valve has a duration of less than 20ms (see for example figure 7.1). Therefore on analysis, only the first 1024 points were used to give a total time signal of 20.48ms. Data acquisition was triggered by the rising pulse of the valve signal, with the pre-trigger facility used to collect 2ms of data prior to this point.

5.3.3 Summary of data storage

The instrumentation used is summarised in figure 5.4. The stars on the figure indicate the stages at which data storage was possible. Data could be stored in either analogue or digital format at three stages.

- Signals could be stored initially in analogue form on magnetic tape.
- The Nicolet 310 digital oscilloscope has a dual 3½" floppy disc drive and this facility allowed signals to be captured, digitised, and stored in digital format. Signals are stored automatically into a numbered waveform file, which allows easy retrieval for future analysis.
- The Nicolet 310 was interfaced directly with a Hewlett Packard 310 computer via an RS-232 connection. Using HP Basic software, the digitised signals could be read directly into the computer and stored on the computer's hard disk or on floppy disc.

---

1 1024 data points were used since the Ariel DSP-300 functions used by the computer to compute the FFTs are based on the number of digitised points being a power of 2.
Figure 5.4

Schematic diagram of the instrumentation used for recording and analysing the valve signals. Stars indicate stages at which the data may be stored.
5.4 Data analysis - equipment

5.4.1 Hewlett-Packard 310 computer

Analysis of the digitised signals was performed on the HP computer. The methods of analysis are based on Fourier analysis techniques detailed in Appendix B. Physically, the Fourier transform represents the distribution of signal strength with frequency. Specifically, analysis was by Fast Fourier Transform (FFT) which is a highly efficient computer algorithm for performing Fourier transformations on digital signals.

The HP computer contains an Ariel DSP-300 board which is a digital signal coprocessor designed specifically for use with the HP310 computer. This board can perform a wide range of signal processing tasks at high speed. For example, a 1024 point FFT takes only 3.39ms. DSP-300 operations are performed on arrays of data, responding to HP Basic commands.

5.5 Data analysis - methods

This section contains a description of the methods of analysis used to analyse the experimental data. A more complete mathematical treatment of the methods is given in Appendix B, and computer programs written specifically for this analysis are given in Appendix E.

Once the time domain signals had been digitised and read into the HP computer, analysis was by the following techniques.

- FFT analysis to obtain the frequency spectrum of each individual valve closure signal.
- Spectral averaging to obtain the averaged spectrum over a number of valve closures.
- Digital filtering for comparison of two spectra.
- Significance test for the equivalence of two spectra.

5.5.1 FFT analysis

FFT analysis of transient signals is straightforward provided the entire signal fits into the chosen time window, and the signal has effectively died away to zero by the end of the record. This eliminates any discontinuity at the ends of the signals, which could cause problems with the FFT process.

Since the record length has been chosen in section 5.3.2 to include the entire valve closure signal, there are no discontinuities at the ends of the signals. Thus there is no need to apply a special window function to the data (Appendix B4). A rectangular window function can be used, giving equal weighting to all parts of the signal.

The highest frequency of interest in the signals has been chosen as 25kHz, leading to a sampling rate of 50kHz. Each valve closure signal input to the computer contains 1024 points at 20μs, giving a total signal length, T, of 20.48ms. Thus the frequency resolution of the analysis is \(1/T\) or approximately 50Hz.

A computer program (Appendix E1) was written to input digitised time signals from the Nicolet, and carry out the FFT analysis. A frequency spectrum of any individual heart valve sound could be obtained in this way, and the data stored on the computer in the frequency domain as well as in the time domain.
5.5.2 Spectral averaging

Program E1 given in Appendix E has the ability to calculate the frequency spectrum of any number of individual valve closure signals, and then to obtain an average frequency spectrum of all of the individual spectra.

5.5.3 Digital filtering for spectral comparison

The aim of the thesis is to investigate the possibility of detection of a mechanical change to a prosthetic heart valve by looking for changes in its acoustic spectrum. With this in mind, it was necessary to develop a sensitive technique for comparison of two spectra.

A digital filtering technique was developed for this purpose. Using this technique, a previously recorded "baseline" spectrum, \( A \), is used as a digital filter for a subsequently recorded spectrum, \( B \). In mathematical terms, the filter acts by dividing the second spectrum by the first, \( B/A \). The filter output is taken as the logarithm of this result, i.e. \( \log(B/A) \). If the two spectra are equivalent, then \( B = A \), and \( \log(B/A) = 0 \). In other words, the filter output is zero for equivalent spectra. If on the other hand the spectrum has changed, then \( B \neq A \), \( \log(B/A) \neq 0 \), and the filter records a non-zero output.

The computer program written for digital filtering is given in Appendix E2.

5.5.4 Significance test for spectral equivalence

In all real systems there will occur a degree of noise. Therefore even two spectra which are equivalent (within the limits of the noise) will not produce a filter output which is exactly equal to zero at all frequencies. In order to quantify the filter output mathematically and test whether the two spectra are equivalent within the limits of
noise, a statistical test for spectral equivalence described by Bendat [75] is used. This test is described more fully in Appendix D.

The test statistic Bendat used in his test is

$$y^2 = \frac{N}{4} \sum_{i=1}^{N} \left[ \log \left( \frac{R(f_i)}{A(f_i)} \right) \right]^2.$$

Examination of the expression for $y^2$ shows that the term in the square bracket is equivalent to the digital filter output. Thus the value of $y^2$ is representative of the magnitude of the digital filter output. Bendat has indirectly used the same method of digital filtering for comparison of two spectra.

The test can be used over any restricted frequency range. In this thesis, the frequency spectra being compared are divided into four equal frequency bands (0-6.25, 6.25-12.5, 12.5-18.75, 18.75-25kHz) and the chi-squared value calculated for each of the four bands. This allows spectral differences over a restricted spectral range to be detected more easily.

5.6 Data analysis - other equipment

5.6.1 B & K Type 2032 signal analyser

A B & K Type 2032 signal analyser was used as an alternative way of analysing the data. The 2032 is a fully self-contained two-channel signal analysis system with direct input for electrical signals. It can measure and display time domain functions, frequency domain functions (by FFT analysis), and many other functions such as frequency response and cepstrum analysis. (These functions are defined in Appendices B6 and C1 respectively). Analysis parameters such as window length and weighting function are user-selectable, and spectral averaging is possible. There is also a pre-trigger facility.
Unfortunately there are two major disadvantages with the use of the 2032 for this work. Firstly, although the 2032 can perform spectral averaging and store the most recently recorded spectrum, it has no long-term storage facility for data, which must therefore be stored in analogue form on magnetic tape. This makes easy retrieval of data impossible. Secondly, the 2032 has no method for comparison of two spectra, and it is not possible to compute the filter output used in the digital filtering technique described in section 5.5.3.
Chapter 6

Calibration and validation of experimental equipment

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Calibration and validation of experimental equipment

6.1 Validation of the reliability of the actuating equipment

In this section, a simple experiment to validate the reliability of the pneumatic actuation system is described, in order to show that the motion of the pneumatic actuator rod is repeatable on every stroke.

A B&K Type 4370 accelerometer was attached to the valve actuator rod. An accelerometer is an electromechanical transducer that generates an electrical output when subjected to mechanical movement or vibration. The magnitude of the electrical signal is directly proportional to the acceleration of the movement.

A valve was mounted in the elastic valve holder. The acoustic signal from the closing heart valve, detected in the tank by the hydrophone, was amplified and input to one channel of the B&K Type 2032 signal analyser. The electrical response of the accelerometer was passed through a B&K Type 2635 amplifier, and input to the second channel of the analyser.

The accelerometer trace was observed to be relatively smooth (see figure 6.1(a)) and highly repeatable (the time position of the peak was 16.97 ± 0.05ms, and its amplitude varied by less than 2%). This trace shows the acceleration of the rod and not its constant velocity. Constant motion of the rod continues beyond the extent of the illustrated trace, the consequent deceleration phase is not shown. The time at which the impulse caused by the closing valve occurred is indicated on the trace by an arrow. The valve has closed during the constant velocity phase of the rod motion. It can be seen that the valve closing impulse has not been detected by the accelerometer. The valve has been effectively isolated from the actuator rod by its elastic mounting.
Figure 6.1(a)

Output from accelerometer attached to the actuator rod. The time at which valve closure occurred is indicated on the figure. The accelerometer trace is unaffected by the closure of the valve.
Figure 6.1(b)

Histogram of the time interval between initiation of the pneumatic actuator stroke, and acoustic pulse produced by valve closure.
Furthermore the time interval between the trigger for the pneumatic actuator and the acoustic signal from the valve (indicating valve closure) was measured and found to be highly reproducible, with a value of 37.49 ± 0.20ms. Figure 6.1(b) shows a histogram indicating the variation of this time interval. This closing interval is confirmed later in the thesis by a photographic sequence of the closing valve (figure 8.14 of chapter 8).

This simple experiment aimed to give some indication of the reliability of stroke of the pneumatic actuator and to show that the actuator rod does not vibrate during actuation. Ideally, a more complete study of this method of actuation of the valve would have included a measure of the flow characteristics and pressure gradient across the valve. However, no suitable instrumentation was available to perform these measurements.

6.2 Calibration of the large tank

6.2.1 Frequency response of the large tank

Frequency response functions are often used to describe the properties of a physical system because of the simplicity with which they can be used to express its response. The frequency response function represents the ratio of output to input in the frequency domain. A more detailed mathematical treatment is given in Appendix B6.

The response characteristics of the tank were investigated to ensure that no spurious peaks appear in its frequency response which could be misinterpreted in valve spectra recorded in the tank. These peaks would be associated with resonances caused by the normal modes of the tank. Ideally the frequency response of the tank should be flat across the frequency range of interest.
An attempt was made to measure the response characteristics of the large tank using a B & K Type 8103 hydrophone as a sound source. The piezoelectric effect of the sensing element of the 8103 is reversible which allows the hydrophone to be used as a sound source. Unfortunately however the dimensions of the hydrophone are such that very little sound is produced below approximately 10kHz. To generate significant power at any frequency the dimensions of the source must be in the order of the wavelength of sound at that frequency.

The transmitting hydrophone was situated in the large tank in place of where the valve would be during recordings. The recording hydrophone was positioned 30cm horizontally to the side of the transmitting hydrophone. The transmitting hydrophone was connected to the output of a B & K Type 2636 power amplifier to which was fed a white noise signal. The signal detected by the recording hydrophone was amplified by the B & K Type 2635 amplifier, and the amplified signal at the output was analysed directly using the B & K Type 2032 signal analyser.

Figure 6.2 shows the measured frequency response up to 25.6kHz. The lack of power produced by the transmitting hydrophone at low frequencies is clear from the figure. However, at high frequencies an oscillation appears with a spacing of approximately 1.67kHz. The cause of this oscillation is discussed in the next section.

6.2.2 Detection of echoes and echo removal

It is possible that echoes may occur within the tank, despite its large dimensions. A technique called cepstrum analysis was used to look for the presence of echoes.

Cepstrum analysis is a specialised analysis technique which has been widely used for detection and removal of echoes in seismological investigations and underwater measurements. The cepstrum is basically a spectrum of a logarithmic
Figure 6.2
Frequency response of the large tank. Note the spectral ripple which has a spacing of approximately 1.67kHz.
spectrum (hence the word cepstrum) and it can extract valuable information from the spectrum in the same way that a frequency spectrum extracts information about a time signal.

The occurrence of an echo in the time domain signal appears as a spectral modulation or ripple in the frequency domain [76,77]. The "frequency" of this ripple is easily determined by calculating the spectrum of the log spectrum, wherein this "frequency" will appear as a peak. This "frequency" is actually the frequency of a frequency, and thus in fact has units of time. To avoid confusion it is known as a quefrency. Other words were paraphrased to avoid confusion, such as rahmonic for harmonic and liftering for filtering. These terms also have units of time.

The periodicity of the ripple in the spectrum is 1/\( \tau \) where \( \tau \) is the echo delay time. So the quefrency of the ripple is \( \tau \), and it appears in the cepstrum as a main peak and a series of rahmonics with a quefrency spacing of \( \tau \). The rahmonics are known to be a consequence of the echo, and the echo can be removed by a simple subtraction of the rahmonic peaks. This process is known as a liftering process. A reversal of the cepstrum operation (i.e. a forward Fourier transform) can then be performed on the liftered cepstrum to give a spectrum with the echo effect removed.

The process of echo removal by cepstrum analysis is explained more fully in Appendix C. A cepstrum analysis routine was written for the removal of echoes from any signal. This was written in HP Basic for the HP-310 computer and is given in Appendix E4.
6.2.3 Demonstration of echo removal using cepstrum analysis

The capabilities of the cepstrum analysis routine in echo removal can be demonstrated by use of a simple experiment. The experimental set-up is shown in figure 6.3.

A loudspeaker with amplifier was connected to the signal generator of the B & K Type 2032 signal analyser, which was set to generate random noise. A microphone was placed in front of the loudspeaker, and behind this was a reflecting surface at a distance of approximately 30cm (see figure 6.3). The signals received at the microphone were digitised on the Nicolet 310 oscilloscope before being input to the Hewlett-Packard 310 computer for analysis using the cepstrum analysis program.

The reflecting surface should cause an echo delayed by the time taken for the sound to travel to the reflecting surface and back. The extra path length travelled by the reflected acoustic signal is 60cm, and the propagation time should therefore be equal to \(0.6/c = 1.8\)ms, assuming a speed of sound, \(c\), of 340m/s in air. Thus an echo is expected at a time delay of approximately 1.8ms.

A random noise signal was generated, and the resulting spectrum is shown in figure 6.4(a). The ripple in the spectrum can be clearly seen, and its spacing is 535Hz. Figure 6.4(b) shows the cepstrum of figure 6.4(a), and here the periodic structure at 535Hz has been transformed to a rahmonic with a quefrency of 1.87ms. This rahmonic is obviously a result of the echo since \(1.87\)ms = 1/535Hz.

The rahmonic was removed using a coarse comb lifter which acts to set the cepstrum to zero at the rahmonic. The liftered cepstrum was then transformed back to the frequency domain to give the liftered spectrum of figure 6.4(c). Comparison with figure 6.4(a) shows that the periodic ripple structure caused by the echo has been removed.

Finally, the reflecting surface behind the microphone was removed, to directly
Figure 6.3

Experimental arrangement for demonstration of echo removal using cepstrum analysis.
Figure 6.4(a) & (b)

Example of echo removal by cepstrum analysis.
(a) Spectrum of white noise showing spectral ripple of 535Hz spacing, caused by echoes from the reflecting surface.
(b) Cepstrum of figure (a).
Figure 6.4(c) & (d)

(c) Spectrum after lifting of cepstral harmonic at 1.87ms.
(d) Spectrum from free field white noise.
remove any echoes from the recorded signals. Figure 6.4(d) of the series shows the spectrum obtained in this situation. The two frequency responses of figures 6.4(c) and (d) are identical within the limits of the noise, illustrating the effectiveness of the procedure for removing residual reverberation.

6.2.4 Detection of echoes in the large tank

The cepstrum analysis routine was used to look for the presence of echoes in the large tank. The dimensions of the tank are 2.7m x 2.4m x 1.2m, and the speed of sound in water is approximately 1500ms⁻¹. Echoes from the walls of the tank could therefore reasonably be expected between 1 and 2ms. Cepstrum analysis was performed on the signal output obtained from the large tank during measurement of its frequency response function in section 6.2.1. The resulting cepstrum (figure 6.5(a)) was examined for the presence of rahmonics. Significant peaks were visible at approximately 0.6ms and 1.2ms. A rahmonic peak at 0.6ms corresponds to a distance of approximately 90cm, taking the speed of sound in water to be 1500ms⁻¹. The echo, which has travelled an extra 90cm, would appear therefore to arise from reflections of sound at the water surface, which is approximately 45cm above the valve and hydrophone.

The rahmonics were removed by comb liftering, and the resulting liftered cepstrum was transformed back to the frequency domain. Figures 6.5(b) shows the frequency spectrum after echo removal by cepstrum analysis. This should be compared with the frequency response of the tank in figure 6.2 in which the effect of the echo is clearly visible. The echo caused a ripple in the spectrum of at a frequency spacing of approximately 1.67kHz, corresponding to the rahmonic at 0.6ms. After liftering in the cepstrum, the spectral ripple has been removed (figure 6.5(b)).
Echo removal from the large tank.
(a) Cepstrum of figure 6.2. The cepstral peaks at 0.6 and 1.2 ms are caused by echoes.
(b) Frequency response spectrum of the large tank after liftering of the rahmonic peaks indicated in the cepstrum.
It can be concluded that the walls of the tank do not cause significant echoes. Echoes caused by reflections at the water surface can be removed by cepstrum analysis. The tank therefore provides a reasonably anechoic environment for recording of acoustic signals generated by a closing prosthetic heart valve.

6.3 Calibration of the recording equipment

Although care has been taken in choosing the equipment for data acquisition to limit distortion of the signals in the frequency range of interest, knowledge of the system frequency characteristics is essential. In this section the frequency response of the recording equipment is investigated.

A white noise signal was fed into the input of the B & K Type 2635 amplifier and serially to the high pass 1kHz filter. The output signal from the filter was recorded on the Racal tape recorder. On play-back the recorded signal was filtered using the 20kHz low-pass filter. The resulting output was analysed directly using the B & K Type 2032 signal analyser. The frequency response of the recording equipment is shown in figure 6.6. The drops below 1kHz and above 20kHz are due to the two filters, but the response is flat otherwise.
Figure 6.6
Frequency response of the recording equipment.
**Chapter 7**

**Large volume tank experiments**

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Large volume tank experiments

The experiments described in this chapter study the acoustic emissions from prosth­thetic valves actuated and recorded in the large volume tank using the experimental methods and equipment described in chapters 4 and 5. The two main questions that the experiments attempt to answer are firstly "Are the sounds produced by a prosthetic heart valve reproducible over a period of time?" and secondly "Does the sound produced by a prosthetic heart valve contain adequate information to enable an assessment of the mechanical state of the valve to be made?". If the answer to both of these questions is "Yes", then it will have been shown that under ideal conditions, it is possible to use acoustic analysis to monitor the mechanical state of prosthetic heart valves.

In order to answer these questions, the following information was required:

- What is the nature of the acoustic time domain signals and frequency spectra produced on valve closure? Under what conditions are these functions stable?
- Following on from this, are they reproducible on subsequent recording occasions?
- Can a specific type of valve be characterised by its acoustic response?
- Does a structural alteration to a valve cause a measurable change to its acoustic response?
A series of experiments were performed to ascertain the answers to these problems, and these are presented below. For clarity, a brief discussion of the observed results is contained within each section, but a more detailed discussion of the experimental observations and their consequences is given in chapter 10.

7.1 Individual valve closure signals

A tilting disc valve was recorded within the large tank. Five typical time-domain acoustic signals produced on closure of the valve are shown in figure 7.1. The frequency spectrum associated with each of these signals was calculated using the FFT analysis parameters chosen in chapter 5. The spectra are plotted in figure 7.2, both (a) linearly, and (b) logarithmically in dB.

The data of figures 7.1 and 7.2 show a variation in both the time-domain and frequency-domain in the recorded valve closure signals. This variation (which was typical of all valves tested) occurred despite the signals being recorded under the same controlled actuation and recording conditions. The valve closure signals are caused by the valve occluder striking the valve frame. However, the valve occluder is held freely within the frame, and the loose-hinge nature of the valve design allows the valve to close in a variety of ways. The nature of closing of the valve is investigated in section 8.4 of chapter 8 where strobed photographs taken at 2ms intervals are used to observe the valve motion directly. During these photographic experiments a variety of closure modes of the valve were observed. The variability observed in the signals of figure 7.1 can most likely therefore be attributed to differences in the mechanics of closure of the valve.

Moreover, each time signal contains more than one impulse. This presumably is also a consequence of the loose-hinge valve design, whereby the valve occluder strikes different parts of the valve ring depending on the nature of closure. This is confirmed later in the photographs of section 8.4, chapter 8.
Figure 7.1

Five typical acoustic signals produced on closure of a tilting disc valve recorded within the large tank.
Figure 7.2(a)
Instantaneous spectra of the valve closure signals given in figure 7.1.
Spectra are drawn linearly.
Figure 7.2(b)

Instantaneous spectra of the valve closure signals given in figure 7.1. Spectra are drawn logarithmically in dB.
7.2 Spectral averaging

The variability between spectra from individual closures suggests that examination of an individual closure spectrum will not yield much information regarding the mechanical state of the valve. However, although the spectra of figure 7.2 relating to individual closures of the same valve are not the same, they are certainly similar with most spectral power contained in the 8-13kHz frequency range. This is more easily seen in the linear spectra of figure 7.2(a). They appear to have spectral peaks in common, for example a large peak at about 10kHz. With this in mind, linear averaging of the valve spectra from several consecutive valve closures was carried out to determine whether a stable averaged spectrum can be produced, or whether all information is lost from the averaged spectrum by the averaging process.

A series of valve closure signals was recorded from a tilting disc valve. Program E1 of Appendix E was used to obtain the averaged spectrum over different numbers of valve closures. Figure 7.3(a) shows the averaged spectrum obtained over 1, 2, 5, 20 and 50 valve closures.

To provide an indication of the increasing stability of the averaged spectrum as the number of valve closures used to calculate the averaged spectrum is increased, the chi-squared values between spectra containing incremental number of valve closures were calculated using the test statistic given in section 5.5.4 of chapter 5, and these are plotted in figure 7.3(b). It is clear from this figure that as the number of closures used to calculate the spectrum is increased above, the chi-squared values become very small. This indicates increasing stability of the averaged spectrum as the number of closures is increased. Above approximately 15 closures the spectrum becomes highly stable.

Moreover, as the number of valve closures used to obtain an averaged spectrum is increased, and the spectrum becomes more stable, information is still retained within the spectral response. Even after 50 closures, the averaging procedure has not smoothed out the spectrum to a flat response. The reason for this is that the same modes of vibration are
Figure 7.3 (a)

The effect of spectral averaging over (a) 1, (b) 2, (c) 5, (d) 20, (e) 50 valve closures.
Figure 7.3(b)

Figure to show the increasing stability of an averaged spectrum as the number of valve closures used to obtain the spectrum is increased. The figure shows the chi-squared value calculated between two spectra, the first averaged over N closures, and the second containing one additional closure (i.e. N+1 closures).
excited each time the valve closes, and so must occur in each spectrum, albeit with varying amplitudes.

7.3 Spectral reproducibility
The previous section has shown that by averaging over a number of spectra, it is possible to produce a stable spectrum which retains spectral information. The next important thing to establish was that the same information would be contained in a second averaged spectrum recorded on a subsequent occasion. This experiment examined the reproducibility of the averaged spectrum from a tilting disc valve as the number of signals used to produce the averaged spectrum was increased.

An averaged spectrum was obtained over a specified number of closures and stored as the baseline spectrum for that particular number of closures. A second spectrum was then obtained from the same number of closures of a different acoustic sample record recorded from the same valve. Actuation and recording conditions were the same for both sets of recordings. The digital filtering technique described in section 5.5.3 of chapter 5 was used to compare the two spectra.

This procedure was carried out for spectra obtained over different numbers of closures, 1, 2, 5, 10, 20, and 50. Figures 7.4(a)-(f) illustrate the log spectra and the filter output for each averaged pair of recordings.

To give a measure of the statistical equivalence of each spectral pair, chi-squared values for the pairs of spectra of figures 7.4(a)-(f) were calculated on the HP computer, using the program given in Appendix E3. Chi-squared values were calculated separately for the four frequency bands, 0-6.25, 6.25-12.5, 12.5-18.75, and 18.75-25kHz. The values for all four frequency bands are given on the figures, and are summarised in Table 7.1. Figure 7.4.1 following Table 7.1 illustrates the averaged chi-squared value across the entire frequency range for the pairs of spectra in figures 7.4(a)-(f).

The difference between the spectra of individual closures has already been demonstrated in section 7.1, and the large non-zero digital filter output (and associated
Reproducibility of valve spectra averaged over (a)1, (b)2, (c)5, (d)10, (e)20, (f)50 valve closures. The figures show the two spectra, filter output and associated chi-squared values for each averaged pair of recordings.

Figure 7.4(a) on this page; figures 7.4(b)-(f) are given overleaf.
Figure 7.4(b)
Reproducibility of valve spectra averaged over 2 valve closures.
Figure 7.4(c)
Reproducibility of valve spectra averaged over 5 valve closures.
Figure 7.4(d)

Reproducibility of valve spectra averaged over 10 valve closures.
Figure 7.4(e)
Reproducibility of valve spectra averaged over 20 valve closures.
Figure 7.4(f)
Reproducibility of valve spectra averaged over 50 valve closures.
Table 7.1
Chi-squared values from figures 7.4(a)-(f) showing the reproducibility of pairs of spectra averaged over different numbers of valve closures.

<table>
<thead>
<tr>
<th>Number of valve closures</th>
<th>Frequency band (kHz)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0 - 6.25</td>
<td>6.25 - 12.5</td>
<td>12.5 - 18.75</td>
<td>18.75 - 25</td>
</tr>
<tr>
<td>1</td>
<td>$\chi^2 = 16.2$</td>
<td>$\chi^2 = 20.8$</td>
<td>$\chi^2 = 40.6$</td>
<td>$\chi^2 = 20.5$</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>$\chi^2 = 5.5$</td>
<td>$\chi^2 = 13.2$</td>
<td>$\chi^2 = 14.1$</td>
<td>$\chi^2 = 8.8$</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>$\chi^2 = 4.3$</td>
<td>$\chi^2 = 8.9$</td>
<td>$\chi^2 = 3.7$</td>
<td>$\chi^2 = 7.3$</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>$\chi^2 = 2.7$</td>
<td>$\chi^2 = 7.6$</td>
<td>$\chi^2 = 4.9$</td>
<td>$\chi^2 = 4.7$</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>$\chi^2 = 3.2$</td>
<td>$\chi^2 = 6.1$</td>
<td>$\chi^2 = 4.4$</td>
<td>$\chi^2 = 4.7$</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>$\chi^2 = 0.7$</td>
<td>$\chi^2 = 2.4$</td>
<td>$\chi^2 = 1.7$</td>
<td>$\chi^2 = 1.8$</td>
<td></td>
</tr>
</tbody>
</table>
Figure 7.4.1

Plot of chi-squared values from Figures 7.4(a)-(f) and Table 7.1, showing the increasing reproducibility of the averaged spectra as the number of valve closures used to obtain the spectra is increased.
chi-squared values) of figure 7.4(a) emphasises the lack of reproducibility of the spectrum from an individual valve closure. However, as the number of closures used to obtain an averaged spectrum is increased and the spectrum consequently becomes more stable, the digital filter output from two averaged spectra becomes smaller, and the associated chi-squared values decrease. This indicates increasing reproducibility of the averaged spectrum.

As a result of the observations of this section, the number of valve closures used to compute the spectral average in future experiments was chosen as 20. Averaging over 20 closures produces a stable and reproducible spectrum.

7.4 Relative positions of valve and hydrophone

A series of 20 valve closures was recorded from a tilting disc valve by the hydrophone in its normal position 30cm vertically below the valve. The actuator rod was then rotated through 90°, causing the valve to rotate through 90° about an axis perpendicular to the plane of the valve. A further set of 20 valve closures was recorded.

The hydrophone was repositioned at 30cm horizontally to the side of the valve in the same plane as the plane of the valve. Two further sets of recordings were made corresponding to the two rotational orientations of the valve.

The spectra were computed for all four sets of recordings. The pairs of spectra corresponding to the two valve rotations are given for both hydrophone positions in figures 7.5(a) and (b). In addition figure 7.6 compares the two spectra obtained from the two hydrophone positions but with no rotation of the valve. The filter output and chi-squared values for each spectral pair were calculated and these are also shown on the figures. The results of figure 7.5 show that the horizontal orientation of the valve within the valve mounting does not significantly affect the sounds recorded by the hydrophone in either position. The spectra of figure 7.6 recorded from the two hydrophone positions are also very similar, although less so than those of figure 7.5. This is perhaps unsurprising due to the asymmetrical structure of the tilting disc valve.
The effect of 90° valve rotation on the measured spectrum, recorded by the hydrophone 30cm below the valve. Each figure shows the spectra from the two rotations, filter output and chi-squared values.
Figure 7.5(b)

The effect of 90° valve rotation on the measured spectrum, recorded by the hydrophone 30cm to the side of the valve. Each figure shows the spectra from the two rotations, filter output and chi-squared values.
Figure 7.6
Valve frequency spectra recorded at two hydrophone positions, 30cm below the valve (black), and 30cm to the side of the valve (purple). The figure also shows the filter output and chi-squared values obtained on comparison of the two spectra.
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The hydrophone has very good omnidirectional characteristics (illustrated in figure 5.3), and these results show that the relative valve/hydrophone position is unimportant in this experimental situation.

7.5 Effect of actuating pressure

In order to investigate the effect of force of closure on the valve, an experiment was performed whereby the air pressure driving the pneumatic actuator was altered. The filter pressure regulating valve was adjusted to obtain pressures of 1, 1.5, 2, 2.5, and 3 bar. Valve sounds were recorded at each pressure and an average spectrum over 20 closures computed. The spectrum obtained at each pressure is illustrated in figure 7.7(a).

Another set of recordings was made at the mean pressure of 2 bar, and this was used to construct a baseline spectrum to digitally filter the spectra of figure 7.7(a). The filter outputs are illustrated in figure 7.7(b), and the corresponding chi-squared are given in Table 7.2.

It appears that altering the pressure between 1 and 3 bar has no significant effect on the spectrum of the valve closing signals.

It should be realised that the pressures altered during this experiment represent the driving air pressure for the pneumatic cylinder of the actuator, and do not represent directly the closing pressure gradient across the valve. No attempt should therefore be made to compare the pressure range investigated in this experiment with the systolic pressure range encountered within the human cardiovascular system causing the valves to close. (The systolic pressure is approximately 120mmHg (0.16 bar) in a healthy person, although it may be elevated by up to 150mmHg (0.2 bar) above this level in a hypertensive patient.) The experiment aimed simply to investigate the effect of the force of closure of the valve on its acoustic spectrum. Results show that increasing the actuating pressure threefold does not affect the valve closure spectrum.
Figure 7.7
The effect of actuating pressure on the recorded valve spectrum. The five spectra in (a) relate to pressures of 1 (black spectrum), 1.5 (purple), 2 (blue), 2.5 (brown), and 3 bar (red). A second spectrum recorded at 2 bar was used as a digital filter for each of these spectra. Filter outputs are illustrated in (b). Chi-squared values are given in Table 7.2.
Table 7.2
Effect of actuation pressures on the reproducibility of averaged valve spectra from figure 7.7

<table>
<thead>
<tr>
<th>Pressure (bar)</th>
<th>Frequency band (kHz)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 - 6.25</td>
</tr>
<tr>
<td>1</td>
<td>$\chi^2 = 6.3$</td>
</tr>
<tr>
<td>1.5</td>
<td>$\chi^2 = 3.5$</td>
</tr>
<tr>
<td>2</td>
<td>$\chi^2 = 3.0$</td>
</tr>
<tr>
<td>2.5</td>
<td>$\chi^2 = 1.2$</td>
</tr>
<tr>
<td>3</td>
<td>$\chi^2 = 5.9$</td>
</tr>
</tbody>
</table>
Figure 7.8

Histograms showing the individual signal power content for valve signals obtained at actuating pressures of (a) 1, (b) 1.5, (c) 2, (d) 2.5 (e) 3 bar.
7.5.1 Signal power content at different pressures

The 20 valve closure signals recorded at each actuation pressure were analysed individually to obtain total power content of each signal in the frequency domain. This was achieved by integration of the linear frequency spectrum for each valve closure. The results are plotted in figure 7.8 as a separate histogram at each pressure.

Little can be concluded from these results. The histograms do not differ widely, showing the same range and spread of total power values.

7.6 Spectral difference between valves

In this experiment the spectra of a variety of different valves was examined, including a caged ball valve, a bileaflet valve and several different makes and sizes of tilting disc valve. For each valve, the averaged spectrum was obtained over 20 valve closures and these are illustrated in figure 7.9(a)-(f).

In addition, recordings were made from two tilting disc valves of the same make, type, and size, and with no obvious structural differences. The resulting spectra are illustrated in figure 7.10.

Examination of the spectra of figure 7.9 obtained from a variety of valve types shows that they are all very different. This is unsurprising since the valves are all structurally different to one another.

On the other hand the spectra of figure 7.10 were obtained from two valves with no obvious structural differences. Despite the similarity in the valves, their spectra are also clearly different. This is a consequence of the manufacturing process of the valves which contains a certain amount of individual attention to the valve. Thus each valve is subject to structural individuality, and this causes it to produce a unique acoustic spectrum on closure.
Figure 7.9(a) & (b)

Averaged spectra over 20 valve closures obtained from various different types of valve.
(a) Caged ball (Starr-Edwards). (b) Tilting disc (Lillichi-Kaster).
Figure 7.9(c) & (d)

Averaged spectra over 20 valve closures obtained from various different types of valve.
(c) Tilting disc (Monostrut). (d) Tilting disc (large Shiley P-type).
Figure 7.9(e) & (f)
Averaged spectra over 20 valve closures obtained from various different types of valve.
(e) Tilting disc (small Shiley P-type). (f) Bileaflet (St. Jude).
Figure 7.10

Averaged spectra from two tilting disc valves of the same size and type, and recorded under the same conditions.
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7.7 Reproducibility of spectra from a variety of valves

It was shown in section 7.3 that a tilting disc valve will produce a reproducible averaged spectrum, provided approximately 20 valve closures are used to obtain the average. In this experiment the reproducibility of the averaged spectra from a variety of different types of valves was investigated using the same averaging and digital filtering techniques. Averaging was performed over 20 closures.

The two averaged spectra, digital filter output, and chi-squared values for each of the valves are illustrated in figures 7.11(a)-(f). Table 7.3 summarises the chi-squared values. Spectra are highly reproducible for all the valves tested.

7.8 Structural alteration to a valve

The results so far have shown that, provided recording and actuation conditions are unchanged, every prosthetic heart valve produces a stable, reproducible, averaged acoustic spectrum on closure, unique to that particular valve. The next step was to determine whether a minor structural alteration to the valve would cause detectable changes in its frequency spectrum.

7.8.1 Simulated thrombus formation

The most common structural change to a valve occurs as a result of thrombus formation on part of the valve. The adhesion of thrombus may alter the natural frequency modes of the valve components.

To simulate the accumulation of thrombus on the valve, a small discrete mass was attached to a part of the valve in a position which did not affect the mechanical
The reproducibility of the averaged spectra from a variety of valves. Each figure (a)-(f) shows two spectra recorded from the same valve and the filter output for the spectral pair with corresponding chi-squared values.

(a) Reproducibility of a caged-ball (Starr-Edwards) valve.
Figure 7.11(b)

(b) Reproducibility of a tilting disc (Lillehei-Kaster) valve.
Figure 7.11(c)
(c) Reproducibility of a tilting disc (Monostrut) valve.
Figure 7.11(d)

(d) Reproducibility of a tilting disc (large Shiley P-type) valve.
Figure 7.11(e)

(e) Reproducibility of a tilting disc (small Shiley P-type) valve.
Figure 7.11(f)

(f) Reproducibility of a bileaflet (St. Jude) valve.
Table 7.3
Chi-squared values from figures 7.11(a)-(f) showing the reproducibility of pairs of averaged spectra obtained from different types of valves.

<table>
<thead>
<tr>
<th>Valve type</th>
<th>Frequency band (kHz)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 - 6.25</td>
<td>6.25 - 12.5</td>
<td>12.5 - 18.75</td>
<td>18.75 - 25</td>
</tr>
<tr>
<td>Starr-Edwards</td>
<td>$\chi^2 = 4.3$</td>
<td>$\chi^2 = 5.7$</td>
<td>$\chi^2 = 4.3$</td>
<td>$\chi^2 = 1.7$</td>
</tr>
<tr>
<td>Lillehei-Kaster</td>
<td>$\chi^2 = 4.3$</td>
<td>$\chi^2 = 1.9$</td>
<td>$\chi^2 = 1.8$</td>
<td>$\chi^2 = 4.0$</td>
</tr>
<tr>
<td>Monostrut</td>
<td>$\chi^2 = 7.9$</td>
<td>$\chi^2 = 5.1$</td>
<td>$\chi^2 = 3.9$</td>
<td>$\chi^2 = 2.1$</td>
</tr>
<tr>
<td>P-type (large)</td>
<td>$\chi^2 = 3.0$</td>
<td>$\chi^2 = 1.7$</td>
<td>$\chi^2 = 3.1$</td>
<td>$\chi^2 = 2.3$</td>
</tr>
<tr>
<td>P-type (small)</td>
<td>$\chi^2 = 1.9$</td>
<td>$\chi^2 = 5.8$</td>
<td>$\chi^2 = 1.6$</td>
<td>$\chi^2 = 2.4$</td>
</tr>
<tr>
<td>St.Jude</td>
<td>$\chi^2 = 2.3$</td>
<td>$\chi^2 = 5.7$</td>
<td>$\chi^2 = 5.7$</td>
<td>$\chi^2 = 5.3$</td>
</tr>
</tbody>
</table>
function of the valve. This extra mass effectively produced a small change to the mechanical structure of the valve, such as would be produced by a small build-up of thrombus. A large accumulation of thrombus on a valve could be expected to produce a much larger mechanical dislocation of the valve structure.

Before addition of the mass, an initial set of 20 valve closures was recorded from the unmodified valve, and this was used to create a baseline spectrum. The mass was then added to the valve without removing it from the actuator rod. A second set of 20 closing sounds was recorded from the mechanically modified valve, and a second spectrum obtained. The baseline spectrum was used to digitally filter the spectrum obtained from the modified valve.

Results from three valves are illustrated in figures 7.12, 7.13, and 7.14, which show the baseline spectrum from the unmodified valve, the modified valve spectrum, digital filter output and chi-squared values. Table 7.4 summarises the chi-squared values from the three sets of results.

The first valve (figure 7.12) was a bileaflet valve to which a small lump of wax was attached to one of the leaflets in order to modify it. Results in figures 7.13 and 7.14 were both obtained from a tilting disc valve. In the first case (figure 7.13) a small lump of wax was attached to the disc; in the second (figure 7.14), a short length of soft solder was fixed across the outlet strut of the valve ring. In each case the mass of the wax or solder was in the region of 0.02 gm.

The results show that the addition of a small discrete mass to a part of the valve causes a significant non-zero output from the digital filter. It can be concluded therefore that an additional mass on a valve causes a detectable change in the acoustic spectrum of the valve.
Figure 7.12

The effect on the averaged frequency spectrum of a bileaflet valve of the addition of a small mass to the valve leaflets. The figure shows the baseline spectrum of the unmodified valve (drawn in black), the spectrum from the modified valve (in purple), the digital filter output, and the chi-squared values.
Figure 7.13
The effect on the frequency spectrum of a tilting disc valve of the addition of a small mass to the valve disc. The figure shows the baseline spectrum of the unmodified valve (drawn in black), the spectrum from the modified valve (in purple), the digital filter output, and the chi-squared values.
Figure 7.14

The effect on the frequency spectrum of a tilting disc valve of the addition of a small mass across the outlet strut. The figure shows the baseline spectrum of the unmodified valve (drawn in black), the spectrum from the modified valve (in purple), the digital filter output, and the chi-squared values.
Table 7.4

Chi-squared values from figures 7.12 - 7.14 showing the lack of reproducibility of pairs of averaged spectra obtained before and after structural alteration to the valves.

<table>
<thead>
<tr>
<th>Alteration to valve</th>
<th>Frequency band (kHz)</th>
<th>0 - 6.25</th>
<th>6.25 - 12.5</th>
<th>12.5 - 18.75</th>
<th>18.75 - 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Added mass on bileaflet valve (figure 7.12)</td>
<td>$\chi^2 = 290.7$</td>
<td>$\chi^2 = 331.8$</td>
<td>$\chi^2 = 127.6$</td>
<td>$\chi^2 = 14.9$</td>
<td></td>
</tr>
<tr>
<td>Added mass on disc (figure 7.13)</td>
<td>$\chi^2 = 28.2$</td>
<td>$\chi^2 = 89.0$</td>
<td>$\chi^2 = 22.3$</td>
<td>$\chi^2 = 15.8$</td>
<td></td>
</tr>
<tr>
<td>Added mass on outlet strut (figure 7.14)</td>
<td>$\chi^2 = 2.1$</td>
<td>$\chi^2 = 32.8$</td>
<td>$\chi^2 = 16.6$</td>
<td>$\chi^2 = 8.9$</td>
<td></td>
</tr>
</tbody>
</table>
7.8.2 Strut fracture

Catastrophic failure of implanted prosthetic heart valves has occurred as a result of fracture of a component of the valve, commonly fracture of the outlet strut of a tilting disc valve.

To create such a fracture, one leg of the outlet strut of a tilting disc valve was sawn through with a high speed Carborundum cutter of thickness 0.5mm. The fracture was easily "repaired" using soft solder and orthophosphoric acid flux with a small electronics soldering iron.

A set of 20 valve closures was recorded of the fractured valve. A second set of 20 valve closures was recorded of the repaired valve. This "repaired" set of recordings was used to construct a baseline spectrum to use as a digital filter for the first "fractured" set of recordings.

The two spectra, digital filter output, and chi-squared values are illustrated in figure 7.15. The filter output shows a large non-zero element, and this is confirmed by the chi-squared values. The digital filtering technique is clearly sensitive to the spectral changes brought about by fracture of the valve strut.

7.9 Low frequency oscillation

During the course of the experimental work in the large tank, an interesting observation was made in the recordings from some explanted Bjork-Shiley convexo-concave (CC) tilting disc valves. On some occasions the analogue valve closing signals exhibited a large oscillatory component, which on analysis appeared as a significant low frequency peak in the associated spectrum at about 2.5 - 3kHz. An illustration of
The effect on the frequency spectrum of a tilting disc valve of a fracture to one leg of the outlet strut. The figure shows the baseline spectrum of the "repaired" valve (drawn in black), the spectrum from the "fractured" valve (in purple), the digital filter output, and the chi-squared values.
this phenomenon is given in figure 7.16 in which a dominant low frequency oscillation is clearly visible in both the time and frequency domains.

This oscillation must arise either from a vibration of part of the actuating system or from the valve itself. It is unlikely that it arises from vibration of the valve mounting or actuator rod for several reasons:

(a) The material chosen for the actuator rod (i.e wood) was chosen specifically so that its natural frequency of vibration is lower than the frequencies being measured in these experiments. This was to ensure that no such problem would occur.

However, to confirm that the actuator rod was not the source of the vibration, it was tapped lightly and its frequency response measured. No frequency components were observed around 2.5 - 3kHz.

Moreover, no vibration of the rod was detected by an accelerometer attached to the rod during an experiment described in section 6.1 of chapter 6.

(b) The rubber band mounting does not vibrate at 2.5 - 3kHz. This is confirmed in chapter 8, section 8.4.2, in which photographic evidence shows the rubber valve mounting to be oscillating at approximately 25Hz.

(c) The oscillation does not occur in every closing strike of the valve. Figure 7.17 shows several closures from the same valve, the first set of which (figure 7.17(a)) exhibit the low frequency component, and the second (figure 7.17(b)) in which it is absent. The associated spectra from the two sets are also illustrated in the figures.

Furthermore, in some cases the oscillations only occur in an individual impulse of a multi-impulse signal. For example in figure 7.18, the oscillation is only present in the first impulse; it has been damped by the second impulse.
Figure 7.16
Example of the large low frequency oscillation sometimes observed in the closing signals of Bjork-Shiley convexo-concave valves; (a) time domain, (b) frequency domain.
Figure 7.17(a)

Two sets of time domain and frequency domain signals recorded from a Bjork-Shiley CC valve. The first, (a), illustrated here, exhibits a large low frequency component, which is absent in the second (b), illustrated overleaf.
Figure 7.17(b)

Two sets of time domain and frequency domain signals recorded from a Bjork-Shiley CC valve. The low frequency component is absent in these recordings.
A recorded CC valve signal which contains a large low frequency component in the first impulse A, which is no longer present in the second impulse, B.

Figure 7.18
The oscillation was on no occasion observed in the closure signals produced by other types of valve, for example a caged ball or a bileaflet valve. It seems likely therefore that the oscillation arises from vibration of a component of the valve itself. An experiment was therefore carried out to measure the frequency of the acoustic emissions from specific components of a Bjork-Shiley CC valve, in an attempt to identify the source of the low frequency vibration. This experiment is described below.

### 7.9.1 Frequency of vibration of individual valve components

The acoustic measurements were carried out in air, although it is realised that resonant frequencies will be lowered slightly during valve operation in a fluid. A B & K Type 4134 microphone was used for the recordings and this was connected directly to the input of the B & K Type 2032 signal analyser.

The disc was removed from the valve ring and the two components of the valve were analysed separately. The disc was attached at its rim to a piece of cotton using a minute amount of sticky tape. It was then suspended by the cotton in front of the microphone, and tapped gently using a wooden rod. The sounds were recorded and the frequency spectrum of the disc was obtained. The spectrum is illustrated in figure 7.19(a).

Similarly, acoustic emissions were recorded from the valve ring. The valve ring with sewing ring and disc removed was suspended by threads in a horizontal plane. A small ball-bearing was dropped onto specific parts of the valve ring (the inlet and outlet struts, and the ring itself) individually, and sounds were again recorded and analysed by the 2032.

Figure 7.19(b) shows the frequency spectra obtained from the outlet strut of the
Figure 7.19(a)

Frequency spectrum from the disc of a Bjork-Shiley CC valve.
Figure 7.19(b)

The frequency spectrum obtained from the outlet strut of a Bjork-Shiley CC valve. Note the spectral peak at approximately 2.5kHz.
CC valve. The spectrum is characterised by a strong component at about 2.5kHz. The same results were obtained if the strut was tapped with a wooden rod or 'plucked' using a fingernail. A similar experiment performed previously by Walker [72] found a pronounced resonant frequency between 2.5 and 3kHz for a Bjork-Shiley CC outlet strut. He also reported that finite element analysis of the modes of vibration of the outlet strut gave a fundamental vibration frequency of approximately 2.7kHz.

No other components of the valve produced significant spectral peaks at this low frequency. The valve disc must contribute significantly to the valve closing sounds, but its frequency spectrum (figure 7.19(a)) does not contain a significant peak at 2-3kHz.

From these observations it can be tentatively concluded that the source of the 2.5kHz peak in the spectrum is vibration of the outlet strut as it is struck by the occluder disc. The vibration does not occur with every strike; however, observations made in section 7.1 have shown that the valve closes in a slightly different manner each time. It would seem likely therefore that the mode of closure affects whether vibration occurs or not. The generation of free vibration of the outlet strut can only occur if the occluder disc is not in contact with the strut. Increasing the clearance between the strut and the disc by bending the strut appeared to increase the probability of the vibration occurring in any closing sound, although the amount of data obtained was too limited for any significant conclusions to be drawn from this observation.
7.10 Summary of results

The experiments presented in this chapter have allowed the following observations to be made:

- Consecutive acoustic signals from the same valve being repeatedly actuated under the same controlled conditions are not identical. The signal from a single closure may contain multiple impulses. These two observations are a consequence of the loose-hinge design of the valves.

- The frequency spectrum of individual closures also varies between closures. When a valve closes, a number of modes of vibration of various components of the valve are excited. The same modes of vibration must be excited each time the valve closes, albeit to varying degrees depending on the way in which the valve closes. This allows the spectra obtained from individual closures of the same valve to be averaged over a number of closures without loss of spectral information.

- Every valve has a averaged frequency spectrum unique to itself. This is true even for two seemingly "identical" valves. This is a consequence of the individual attention given to the valves during the manufacturing process.

- As a result of this observation, it is clear that an initial spectrum must be obtained for each valve to use as a baseline comparison for future spectra. A digital filtering technique was developed as a method of spectral comparison. A chi-squared significance test was used to give a measure of the equivalence of two spectra.
Digital filtering was used to examine the reproducibility of pairs of averaged spectra obtained from several different valves. All the valves produced highly reproducible spectra.

The technique was then applied to see if it was possible to detect a minor structural alteration to a valve. The digital filter was found to be sensitive to the addition of a small mass to part of the valve, and also to a fractured outlet strut in a tilting disc valve.

Actuation pressure, and the relative position of valve and hydrophone were not found to be important.

A large low frequency oscillation at about 2.5kHz was observed in some of the recordings made from Bjork-Shiley convexo-concave tilting disc valves. The outlet strut of these valves shows a pronounced resonant frequency at about 2.5kHz. It was tentatively suggested therefore that the observed oscillation is a result of vibration of the outlet strut.

As a result of the large tank experiments, it is concluded therefore that it is possible to use spectral analysis techniques to detect the acoustic changes associated with a minor structural alteration to a valve.
Chapter 8
Model thorax

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<td>79</td>
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<td>80</td>
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<td>81</td>
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<tr>
<td>8.4.2 Results of photographing valve</td>
<td>83</td>
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<td>84</td>
</tr>
</tbody>
</table>
Model thorax

The experiments of the previous chapter have ascertained that spectral analysis of valve closing sounds using digital filtering techniques can be used to monitor the mechanical state of prosthetic heart valves. The large tank provides a reasonably anechoic environment, and the valve sounds can be recorded free from external influences. The potential for detecting changes in these sounds caused by structural alterations to the valves must be greatest in this experimental situation.

The finite volume of a human thorax will significantly alter the nature of the sound field generated by the closing of a prosthetic valve. The next stage in the research was to reduce the volume of the tank of water in order to investigate the effect of a finite volume on the valve recordings. A series of experiments was therefore performed in a small tank of water approximating the size of a human thorax. The actuating and recording equipment were the same as those used for the experiments in the large tank to allow comparisons between the two sets of results.

In addition the set-up allowed the valve to be photographed during actuation since the small tank or 'model thorax' was constructed from clear polythene. The photographs could be timed precisely to observe the mode of closure of the valve in relation to the sound pulses.
8.1 Methods

8.1.1 Description of the model thorax

The model thorax was constructed from a large heavy-duty polythene bag filled with water. The bag was attached at its open end to an approximately circular metal ring of diameter 35cm. When filled with water the surface of the water in the bag was 5cm below the metal fixing ring, and its depth was 60cm. The polythene was transparent which enabled direct observation of the closing valve. The model thorax was positioned below a rigid wooden frame to which was attached the pneumatic actuator.

8.1.2 Valve actuation and recording

The equipment used for actuating the valves and recording the valve signals within the model thorax was the same as that used in the large tank, apart from a few minor changes. These changes were all a consequence of the difference in dimensions between the two tanks, and they are outlined below. Analysis of the signals was performed using the same techniques as previously.

(i) Actuator rod

The valve mounting and wooden tripod arrangement was the same as that used in the large tank. However, due to the reduced dimensions of the model thorax the actuator rod was considerably shortened by removing its upper section. The valve was positioned in the centre of the model thorax, at a depth of approximately 20cm below the surface of the water.
(ii) Hydrophone position

The recording hydrophone was attached to a 10mm diameter wooden rod, and positioned in the model thorax at the same depth as the valve at a distance of 15cm from the valve. Previous recordings made in the large tank (chapter 7) had been made with the hydrophone situated at a distance of 30cm from the valve. Situating the hydrophone at 15cm from the valve brings it further into the near field of the valve, and it is possible that some signal distortion may occur at frequencies below 10kHz. However, the dimensions of the model thorax made it impossible to position the hydrophone at a distance of 30cm from the valve. More significant signal distortion will arise from standing waves within the finite volume of the model thorax. The maximum diameter of the model thorax is approximately 35cm. Given the dimensions and the velocity of sound in water of 1500ms\(^{-1}\), standing waves may therefore be expected to produce peaks in its spectral response above about 2.2kHz.

The model thorax with actuator rod and hydrophone in place is illustrated in figure 8.1.

8.2 Frequency response of the model thorax

The response characteristics of the model thorax were measured by the same method as used to measure the response function of the large tank (chapter 6, section 6.2.1), i.e. using one hydrophone as a sound source, and another to record the sound produced. The transmitting hydrophone was situated in the centre of the model thorax in the position where the valve would be during recordings. The recording hydrophone was positioned 15cm horizontally to the side of the transmitting hydrophone. An amplified white noise signal was fed to the transmitting hydrophone; the signal
Figure 8.1

Model thorax with valve actuator and hydrophone in position.
detected by the recording hydrophone was amplified and analysed directly using the B & K Type 2032 signal analyser.

Figure 8.2(a) shows the measured frequency response of the model thorax up to 25.6kHz. It should be remembered that, due to its dimensions, the hydrophone produces little sound energy below about 10kHz. Figure 8.2(b) shows the associated cepstrum. A cepstral peak appears at approximately 0.44ms.

8.2.1 Frequency response at low frequencies

In order to gain some information about the frequency response of the model thorax at frequencies below 10kHz, another experiment was performed, in which the thorax filled with water was tapped from the outside using a fingertip. The resulting sounds were recorded by the hydrophone within the bag. These sounds were analysed and their averaged frequency spectrum is given in figure 8.3.

The spectrum of figure 8.3(a) provides an indication of the frequency response at frequencies below 10kHz which is not available in figure 8.2(a). Significant peaks occur in this region at 3.7, 4.3, 5.7, 6.2kHz and a double peak at 8kHz. These are lettered A-E on the figure. These peaks are a consequence of standing waves within the finite volume of the model thorax.

The cepstrum of the data was calculated, and is illustrated in figure 8.3(b). Comparison with the cepstrum of figure 8.2(b) shows that the two cepstra have a common rahmonic peak at 0.44ms, which corresponds to a frequency of 2.2kHz (assuming the speed of sound in water is 1500ms⁻¹). A frequency of 2.2kHz has a wavelength of 70cm in water. The diameter of the model thorax is approximately half this wavelength. This cepstral peak is therefore a consequence of a standing wave.

Removal of the rahmonic peaks from figure 8.3(b) results in the liftered
Figure 8.2
(a) Frequency response of the model thorax.
(b) Cepstrum of (a).
Figure 8.3(a) & (b)

(a) Frequency response of the model thorax obtained by tapping the bag. Note the spectral peaks marked A-I.
(b) Cepstrum of (a).
(c) & (d) overleaf.
Figure 8.3(c) & (d)

(c) Liftered cepstrum having removed the rahmonic peaks of (b).
(d) Transformation of (c) to give the liftered spectrum.
cepstrum of figure 8.3(c), which is transformed back to the spectrum of figure 8.3(d). There is little difference between the spectrum before (figure 8.3(a)) and after (figure 8.3(d)) cepstral liftering. The peaks marked A-I on figure 8.3(a) are still visible on figure 8.3(d). The technique of cepstral liftering has not been able to remove the multiple standing wave effects from the spectrum in the same way that it was able to remove the effects of a single echo (demonstrated in section 6.2.3 of chapter 6).

8.2.2 Hydrophone position

The frequency response measurements described previously have been made with the recording hydrophone at 15cm to the side of the transmitting hydrophone. A further measurement of frequency response was made with the recording hydrophone situated directly below the transmitting hydrophone, and this is illustrated in figure 8.4. For comparison the figure also shows the spectrum obtained with the hydrophone positioned to the side.

The spectra are markedly different. The spectrum recorded by the hydrophone positioned below the signal source appears to increase in power at higher frequencies. In the large tank however, a similar experiment produced a far greater agreement between the spectra recorded from the two hydrophone positions. This observation is unsurprising, since the finite volume of the model thorax must be causing sound distortion.
Figure 8.4
Spectra recorded in the model thorax by the hydrophone positioned below (black) and to the side (purple) of the signal source. The figure also shows the filter output and chi-squared values obtained on comparison of the two spectra.
8.3 Valve recordings

A number of different types of valves were recorded within the model thorax. For comparison, the same valves were also recorded within the large tank. For the experiments previously performed in the large tank and described in chapter 7, the hydrophone was situated at 30cm from the valve. However the small size of the model thorax causes the hydrophone to be positioned closer to the valve at a distance of 15cm. Therefore for the large tank recordings in this section, the hydrophone was also positioned 15cm from the valve, in order that a more satisfactory comparison could be made between large tank and model thorax results.

8.3.1 Recordings from the model thorax

Figure 8.5 shows typical valve closures recorded from a tilting disc valve within (a) the model thorax, and (b) the large tank. Similarly, recordings made from another different valve in the two environments are given in figure 8.6.

These two figures illustrate the effect of the finite volume of the model thorax on the recorded valve sounds. In both cases there are two obvious differences between the time domain signals recorded from the two environments. Firstly the recordings made in the model thorax are of a greater amplitude than those made in the large tank (the signals from the large tank are plotted on a scale four times that of the signals from the model thorax). Secondly, the signals from the large tank are cleaner than those recorded within the model thorax. Both of these observations are a direct result of the finite size of the model thorax. In the large tank the sound from the valve is allowed to dissipate, whereas within the model thorax, the sound reverberates within the small volume.
Figure 8.5

Valve closure signals from a tilting disc valve recorded in (a) the model thorax and (b) the large tank. Note the difference in scale between the two sets of recordings. The signals from the model thorax in (a) are of a substantially greater amplitude.
Figure 8.6

As figure 8.6 but using a different valve.
The frequency spectra averaged over 20 closures was obtained for several valves of various types, and typical results are illustrated in figures 8.7(a)-(d). Although these spectra were obtained from different valve types, there appear to be peaks common to all four spectra. These are best seen in figure 8.8 where the four spectra are drawn together and their common spectral features indicated by letters.

On the other hand, examination of spectra obtained from valves in the large tank (shown in figure 7.9) had found no obvious similarities between spectra obtained from different valve types. It would appear therefore that the common spectral peaks of figure 8.8 have arisen from standing waves created within the volume. This is confirmed by comparison with the measured frequency response of the model thorax given in figures 8.3(a). Several of the spectral peaks indicated by letters A-I in figure 8.3(a) are present in the spectra of 8.8. They are identified by the same letter on both figures.

8.3.2 Reproducibility of valve spectra

Reproducibility of spectra from an individual valve was investigated in an experiment similar to that performed in the large tank in section 7.7 of chapter 7. An initial spectrum was obtained by averaging over 20 valve closures. This was then stored as a baseline spectrum and was used to digitally filter a consequently measured spectrum. The structural state of the valve was not altered between recordings.

Figure 8.9 shows typical results obtained from a tilting disc valve recorded within the model thorax. The digital filter output and chi-squared values for the spectral pair are also illustrated on the figure. Peaks due to standing waves within the model thorax are clearly visible in the spectra. However the standing waves peaks are
Averaged spectra over 20 valve closures obtained from various different types of valve.
(a) Caged ball (Starr-Edwards). (b) Tilting disc (Shiley P-type).
Figure 8.7(c) & (d)
Averaged spectra over 20 valve closures obtained from various different types of valve.
(a) Tilting disc (Monostrut). (b) Bileaflet (St. Jude).
Figure 8.8

The averaged spectra of figure 8.7 printed on the same figure for ease of comparison. Spectral peaks in common with those seen in the frequency response of the model thorax in figure 8.3(a) are marked A-I.
Figure 8.9

Example of the reproducibility of the averaged spectra from a valve recorded in the model thorax. The figure shows two spectra recorded from a tilting disc valve, and the filter output for the spectral pair with corresponding chi-squared values.
common to both spectra, and their presence does not appear to affect the reproducibility of the spectra. A variety of valves were tested; all showed similar spectral reproducibility.

8.3.3 Structural alteration to a valve

The previous section has shown that despite the presence of standing waves within the model thorax, spectra recorded within the thorax are reproducible. However these standing waves clearly have a significant effect on the spectra causing large spectral peaks, and it is possible that their presence may mask any spectral changes caused by a structural alteration to the valve.

Experiments were therefore carried out in the model thorax where the structural state of the valve was altered between the initial and consequent recordings of the valve. These experiments are identical to those performed in the large tank and described in section 7.8 of chapter 7. Three structural alterations were investigated. In the first experiment a tilting disc was altered by the addition of a small piece of solder across its outlet strut. In the second experiment, a bileaflet valve was used, and a small amount of wax added to its leaflets. The third experiment was performed on a tilting disc valve which had a single leg fracture of its outlet strut. The methods of altering the valves are described in detail in chapter 7, section 7.8.

Figures 8.10 to 8.12 show the spectra before and after alteration to the valve. In addition the figures show the digital filter output, and associated chi-squared values for the three experiments. In all three experiments, the valve modification has produced a significant change in the recorded spectrum.
Figure 8.10

The effect on the frequency spectrum of a tilting disc valve recorded in the model thorax, of the addition of a small mass across the outlet strut. The figure shows the baseline spectrum of the unmodified valve (drawn in black), the spectrum from the modified valve (in purple), the digital filter output, and the chi-squared values.
The effect on the averaged frequency spectrum of a bileaflet valve recorded in the model thorax, of the addition of a small mass to the valve leaflets. The figure shows the baseline spectrum of the unmodified valve (drawn in black), the spectrum from the modified valve (in purple), the digital filter output, and the chi-squared values.
Figure 8.12

The effect on the frequency spectrum of a tilting disc valve recorded in the model thorax, of a fracture to one leg of the outlet strut. The figure shows the baseline spectrum of the "repaired" valve (drawn in black), the spectrum from the "fractured" valve (in purple), the digital filter output, and the chi-squared values.
8.3.4 Comparison with large tank recordings

In this section the averaged spectrum obtained from a valve in the model thorax is compared to the spectrum obtained from the same valve in the large tank. In both experimental situations, the hydrophone is situated at 15cm to the side of the valve.

Figure 8.13 shows the two spectra obtained from a tilting disc valve. The coloured spectrum was measured in the model thorax, and the black spectrum was measured in the large tank. The overall shape of the two spectra is similar, however spectral peaks are present in the spectrum from the model thorax. The digital filtering technique was used to compare the two spectra. Examination of the filter output showed peaks in the filter output, at the frequencies of the standing waves occurring within the model thorax. The experiment was repeated for several different valves with similar results.

8.4 Photographic examination of valve closure

The transparent nature of the model thorax provided direct visualisation of the valve during actuation. This allowed photographs to be taken of the valve as it closed, and by precise timing of the photographs, the valve motion could be related to events within the acoustic pulse.

8.4.1 Methods for photographing valve closure

A camera was positioned close to the surface of the model thorax, and focussed onto a tilting disc valve mounted on the actuator rod. A white reflecting surface was placed on the far side of the model thorax to allow the valve to be photographed more easily.
Figure 8.13
Spectra from a tilting disc valve recorded in the model thorax (purple) and the large tank (black). The two spectra are compared using the digital filtering technique, and the filter output and chi-squared values are illustrated on the figure.
The room was blacked out, and the camera set to bulb mode. The flash was triggered automatically using a delayed trigger pulse taken from that used to initiate movement of the pneumatic actuator. By varying the trigger delay, the camera could be set to photograph the valve at different times during the valve movement. In this way, a sequence of photographs could be taken showing the motion of the valve disc during its closure.

The acoustic signal and the delayed trigger for the camera flash were input to the two channels of the Nicolet digital oscilloscope. The Nicolet was triggered from the acoustic pulse. By superimposing the two signals, the precise time at which the photograph was taken could be indicated on the acoustic pulse.

8.4.2 Results of photographing valve

Figure 8.14 shows a sequence of photographs of a tilting disc valve being actuated within the model thorax. The photographs were taken at 2ms intervals during the closing of the valve. A typical associated acoustic signal is also shown in the figure. Despite the multiple impulses visible in this signal, examination of the photographs shows that the valve appears to close in a single smooth movement with no obvious bouncing of the disc within the valve ring.

The loose-hinge design of the valve means that the free-floating disc is able to slide through the valve ring slightly as it rotates, and it can therefore strike the valve ring at any time during this movement before it closes fully. This can explain the initial acoustic impulse, a, which occurs just prior to the disc beginning to rotate (corresponding to frame 6 of the photographic sequence). The closing impact of the disc then produces the second sound pulse, b, (frame 19) and two subsequent sound pulses, c and d (frames 23 and 27).
Figure 8.14

Sequence of photographs taken at 2ms intervals of a tilting disc valve being actuated in the model thorax. An associated acoustic signal is also shown. The figure is explained more fully in the text.
The impact of the disc against the valve ring causes the entire valve to rotate in an anti-clockwise direction (frames 20-25). The valve ring, held within the elastic mounting, then oscillates with an approximate period of 40ms, which corresponds to a frequency of 25Hz.

8.5 Summary of results

The experiments described in this chapter were similar to those performed in the large tank, the only difference being the volume of the tank. The observations and results can be summarised as follows:

- The reduced volume of the model thorax causes standing waves to occur within it. These cause distortions to the time domain signals, and produce peaks in the frequency spectra.

- The standing wave peaks occurred at the same frequencies in both the frequency response of the model thorax, and in the spectra recorded from prosthetic heart valves actuated within it.

- Despite the presence of these standing waves, all valves tested produced stable averaged spectrum which were highly reproducible.

- Moreover, the digital filtering technique proved capable of detecting a minor structural alteration to the valve.

- The model thorax allowed strobed photographs of a valve to be taken whilst simultaneously recording the valve sound. This helped to relate the multiple strikes of the acoustic pulse with actual events during valve closure. The photographs also allowed the oscillation frequency of the rubber band mounting to be measured.
In conclusion, the results of this chapter have confirmed the presence of standing waves within the reduced recording volume, but have shown that, despite these standing waves, it is still possible to detect the acoustic changes associated with a minor structural alteration to a valve.
Chapter 9
Patient studies

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Chapter 9

Patient studies

The ultimate aim of the research presented in this thesis is to examine the possibility of detecting structural changes to an implanted prosthetic heart valve by spectral analysis of the sounds produced by the valve. The in vitro results presented earlier in chapter 7 have shown that it is possible to use spectral analysis techniques to detect acoustic changes associated with a minor structural alteration to a valve. These experiments were performed under "ideal" conditions - that is, they were performed in a large, reasonably anechoic tank of water, with the valve held elastically and actuated pneumatically to initiate valve closure. Under these conditions the system is virtually noise-free.

Having shown that minor structural changes to a valve are detectable under precisely controlled ideal conditions, the next stage of the research was to apply the techniques developed in the laboratory and large tank to the patient.

However, problems occur when acoustic emissions are recorded from valves implanted in patients. These are a result of the acoustic properties of the heart-thorax system. The thorax consists of a non-homogeneous network of tissues including in addition to the heart, the large blood vessels, the lungs and their associated structures, and numerous other blood vessels, lymph vessels, nerves and glands. The thoracic cavity is bounded mainly by the ribs, vertebrae and muscles, and by the diaphragm. Any of these structures can cause scattering and attenuation of the sound waves. The attenuation of the valve sounds will depend on the valve positioning, the characteristics of the surrounding tissues, and the location of the heart within the thorax. It is
It would seem likely however that the greatest signal distortion will occur as the sound passes through the surface of the chest. The velocity of sound in fat is 1450ms\(^{-1}\) and in muscle is 1585ms\(^{-1}\). In air however, sound travels at a speed of 340ms\(^{-1}\). Thus there is a substantial difference in acoustic impedance between the body and the air. This will cause the sound waves to be partially reflected at the chest wall/air interface and the sound will reverberate within the body.

On the other hand the velocity of sound of water is 1500ms\(^{-1}\), which is very similar to the sound velocities in fat and muscle. Therefore by replacing the chest wall/air interface with a chest wall/water interface this problem should be partly resolved.

It was therefore decided to perform the recordings with the patient submerged to the neck in water. This had the added advantage that it created an environment for the patient recordings very similar to that in which the \textit{in vitro} recordings were made - i.e. a large tank of water. Thus the same equipment could be used for both sets of recordings.

\textbf{9.1 Methods}

\textbf{9.1.1 Subject population}

The subjects were patients who had undergone mitral valve replacement surgery at the Groby Road Hospital, Leicester. The population was chosen randomly from both sexes covering an age range between approximately 30 and 70 years, and whose valves had been implanted as recently as 3 months, to over 12 years ago. 25 patients were monitored over a period of 12 months.
The patients were in reasonable health and were capable of entering the hydrotherapy pool unaided. All patients had normally functioning mitral valve prostheses. Valve function was considered normal in this instance when the subject had no symptom or auscultatory sign of valve degeneration or malfunction.

9.1.2 Hydrotherapy pool

Recordings were made in the hydrotherapy pool at Leicester General Hospital. The dimensions of this pool are 6m by 4m. The floor of the pool is flat with a water depth of 1.4m. The patient was positioned at a distance of 1.5m from the nearest side of the pool, facing towards this side.

The patient was asked to submerge himself to the neck in the water. For the shorter patients, this involved standing naturally. Taller patients had to squat slightly, or if this was uncomfortable, to sit on a stool specially constructed for this purpose.

9.1.3 Recording and analysis of valve signals

Recording of the acoustic signals from the implanted valves was performed using the same equipment as used to make the in vitro recordings in the large tank and model thorax.

The hydrophone was held by a horizontal arm which was attached to a belt made from strong webbing and secured around the patient’s waist. The horizontal arm of the belt located the hydrophone at a distance of 15cm from the patient’s chest (figure 9.1), directly in front of his sternum.

The acoustic signals detected by the hydrophone were amplified, filtered and stored on magnetic tape for later analysis in the laboratory. Digitisation and analysis of the signals was identical to that of the signals recorded in vitro.
Underwater recording of the valve sounds from a prosthetic valve patient. Simultaneous recordings are made of ECG and respiration phase.
Acoustic signals may be dependent on factors such as the respiration of the patient, or heart rate. Therefore simultaneous recordings were made of ECG and respiration (figure 9.1), and these were stored on two other channels of the Racal tape recorder.

9.1.4 ECG Recordings

Disposable ECG electrodes were attached to the forearms of the patient. The patient's forearms were supported out of the water, and care was taken to ensure that the electrodes did not get wet. ECG leads were attached to the electrodes. The ECG signals were amplified and low-pass filtered at 50Hz before being stored on magnetic tape.

9.1.5 Respiration

The patient's respiration was monitored through a mouthpiece containing a thermistor. This detected the changes in temperature associated with each stage of respiration, and allowed the phase of the patient's respiration to be monitored.

9.2 Stability of recordings over a short time period

The in vitro experiments in chapter 7 have shown that even under precisely controlled actuation conditions, the loose hinge design of a prosthetic heart valve allows it to close in a variable manner, and consequently the frequency spectrum of the acoustic signals varies between individual closures. However on averaging, the spectra were found during the in vitro studies to converge over approximately 20 closures to give a stable averaged spectrum (section 7.4). It was necessary to determine whether stable
reproducible averaged spectra could be obtained from a valve implanted in a patient where significant signal distortion may occur. If this was not possible, then the technique would be of no use for monitoring implanted artificial heart valves.

For each patient, recordings were made over a period of approximately 20 minutes. Typical valve closure signals obtained are illustrated in figure 9.2. In figure 9.3, recordings made from a patient having a bileaflet valve are shown. The asynchronous nature of the closing of the two leaflets is clearly visible, with the interval between the two closing strikes varying widely between traces.

Two sets of 20 consecutive valve closures within the 20 minute recording were used to obtain two averaged frequency spectra. The first spectrum of the pair was used as a baseline spectrum to digitally filter the second spectrum, and a chi-squared test was used to test the reproducibility of the two spectra. This is the same analysis technique used in chapter 7 to test for reproducibility of spectra recorded in vitro. Figures 9.4(a)-(e) show pairs of averaged spectra, filter output, and chi-squared values from recordings made from five different patients with unknown valve types. As expected spectra differ between patients. However, the pairs of spectra for each patient were found to be stable and highly reproducible provided the hydrophone was not moved between recordings.

9.3 Effect of hydrophone position

The previous section has shown that it is possible to obtain stable reproducible spectra from implanted valves when recording conditions are unchanged. However, during these experiments the positioning of the hydrophone was found to be critical.
Figure 9.2
Typical valve signals from different patients.
A series of valve signals from an implanted bileaflet valve. Note the asynchronous closure of the valve leaflets, and the variation in the degree of asynchronity.
Figure 9.4(a)

(a)-(e) Reproducibility of pairs of consecutively recorded averaged spectra from 5 different patients, A-E. Results from patient A shown on this page; B-E on the following pages. The figures show the two spectra, filter output and associated chi-squared values for each averaged pair of recordings.
Figure 9.4(b)
Reproducibility of consecutively recorded averaged spectra from patient B.
Figure 9.4(c)
Reproducibility of consecutively recorded averaged spectra from patient C.
Figure 9.4(d)

Reproducibility of consecutively recorded averaged spectra from patient D.
Figure 9.4(e)
Reproducibility of consecutively recorded averaged spectra from patient E.
Table 9.1

Chi-squared values from figures 9.4(a)-(e) showing the reproducibility of pairs of implanted valve spectra from five patients, A-E.

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</tr>
</tbody>
</table>
9.3.1 Movement of hydrophone around the body

To show the dependence of recorded spectrum on hydrophone position, a series of recordings were made from a patient in which the position of the hydrophone relative to the patient's body was altered. Movement of the hydrophone in a horizontal plane around the patient from directly in front of his sternum to a position approximately 10cm to the left of centre caused the changes in the measured spectra shown in figure 9.5(a). The spectra are obviously similar with a large spectral peak occurring at approximately 13kHz in both spectra. When the hydrophone was moved in the opposite direction (from the centre to 10cm to the right of centre), this large spectral peak disappeared (figure 9.5(b)).

A further set of results obtained by moving the hydrophone from left of centre to right of centre on a different patient are shown in figure 9.6. The two spectra have common features, but the position of the hydrophone has obviously affected the recorded spectrum.

9.3.2 Removal of the hydrophone and subsequent replacement

The above results indicate that maintenance of a fixed position for the hydrophone is necessary for the recording of stable reproducible valve spectra. In this section an experiment is described in which the hydrophone is removed and subsequently replaced between recordings, to see whether adequate repositioning of the hydrophone is possible.

Figure 9.7 shows two spectra recorded from the same patient. Between the two recordings the hydrophone belt was removed and then replaced fifteen minutes later as close to its original position on the patient as possible. While the two spectra
Figure 9.5(a)

The effect of moving the hydrophone horizontally around the patient from a position directly in front of the patient's sternum (black spectrum) to 10cm to the left of centre (purple spectrum). The figure shows the two spectra, filter output and associated chi-squared values.
Figure 9.5(b)

The effect of moving the hydrophone horizontally around the patient from a position directly in front of the patient's sternum (black spectrum) to 10cm to the right of centre (purple spectrum). The figure shows the two spectra, filter output and associated chi-squared values.
Similar to figure 9.5, from a different patient. In this experiment the hydrophone was moved horizontally around the patient from a position 10cm to the left of the patient's sternum (black spectrum) to a position 10cm to the right of his sternum (purple spectrum). The figures show the two spectra, filter output and associated chi-squared values.
appear similar, there has been an overall shift in power of approximately 2-3dB. This accounts for the large chi-squared values shown on the figure above the filter output. In order that the two spectra be more closely compared, the second spectrum was shifted linearly by 2.34dB and the chi-squared values recalculated. These are given below the filter output on the figure. It is clear from the recalculated values for chi-squared that the two spectra are very similar when allowance is made for the linear shift in power. The reason for the linear shift in power in the spectra is uncertain, but may be partly a result of an alteration in the distance between the hydrophone and the patient, or more likely of some cardiovascular change to the patient caused by being in the warm water for an extended period of time. (Water temperature was approximately 98°F.)

The same experiment was repeated with a second patient. Figure 9.8 shows the two spectra recorded. As in figure 9.7, the hydrophone belt was removed for fifteen minutes between making recordings for the two spectra. In this case, no linear shift of power occurred between the two recordings. Comparison of the two spectra using the digital filtering technique and chi-squared test showed that the two spectra are not significantly different.

These two results suggest that it is possible to reposition the hydrophone with sufficient accuracy to ensure reproducible spectra from implanted valves. However, spectra are less reproducible than those obtained without removing the hydrophone between recordings (section 9.2, figures 9.4(a)-(e)).
Figure 9.7

Figure to illustrate the sensitivity of the hydrophone to relative position in front of the patient. After the first set of recordings, the hydrophone belt was removed for 15 minutes, and subsequently replaced for the second set as close to its original position as possible. The two resulting spectra with filter output and chi-squared values are illustrated on the figure. There appears to be a linear shift of 2.3 dB between the two spectra, and the second set of chi-squared values take this shift into account.
Figure 9.8

As figure 9.7 but results are shown for a different patient. In this case, no obvious linear shift is visible between the two spectra.
9.4 Effect of respiration

To determine the effect of respiration on the valve spectra, two separate experiments were performed, one in which the patient was asked to hold his breath (static state), and the second in which the patient's breathing pattern was monitored, and divided into four separate phases (dynamic state).

9.4.1 Static state (breath holding)

Three sets of recordings were made from a patient who was asked to hold his breath during recording, firstly on full expiration, then on full inspiration, and finally at mid-lung inflation. For the three states, an average spectrum over 15 valve closures was measured, and these are illustrated in figure 9.9. It was not possible to obtain more than 15 valve closures at each state, because of the stress caused to the patient by breath holding.

The spectra obtained at full expiration and at mid-inflation were found to be similar. The spectrum obtained at full inspiration (i.e. when the lungs are fully inflated) was more significantly different.

9.4.2 Dynamic state

The respiration cycle was divided into 4 stages: inspiration, fully inspired, expiration, and fully expired. A trigger pulse was taken from the recorded respiration, and by use of suitable delay and width on this trigger pulse, the acoustic signal could be gated to obtain those valve closures associated with each phase of respiration. Figure 9.10 illustrates the respiration cycle and the ECG measured from a patient over a period of 6 seconds. The four phases of respiration are indicated on the figure.
Figure 9.9
Valve spectra obtained from a patient holding his breath at three static states of respiration; fully inhaled (purple spectrum), mid-inhalation (blue), fully exhaled (black).
Initially a baseline spectrum was obtained from 20 consecutive valve closures, irrespective of respiration state. An average spectrum over 20 closures was then obtained for each phase of respiration. The baseline spectrum was used to digitally filter these respiration-related spectra. Figures 9.11 and 9.12 show the spectra from the 4 phases, the filter outputs, and the chi-squared values for two different patients. The results indicate that no significant change occurs in the recorded spectra related to the phase of respiration.

9.4.3 Signal power content during different respiration phases

The 20 valve closure signals recorded during each respiration phase in section 9.4.2 were analysed individually to obtain total power content of each signal in the frequency domain. This was achieved by integration of the linear frequency spectrum. The results (using the data from the patient of figure 9.11) are plotted in figure 9.13 as a separate histogram at each pressure.

The same range and spread of total power values appear to occur for each respiration phase, indicating that no significant change in signal power content occurs during the respiration cycle.

9.5 Examination of the time delay between the ECG and valve closure

The time interval between ECG and valve closing sound must be related to the time taken for the valve to close. It is likely to depend upon the way in which the valve was oriented when it was implanted, and also likely to vary with blood pressure, heart rate, and patient posture. To measure this interval, ECG and acoustic signal were fed into
Figure 9.10
Respiration and ECG recorded from a patient over a period of 6 seconds. The four phases of respiration are illustrated: i.e. expiration (Phase 1), fully expired (Phase 2), inspiration (Phase 3) and fully inspired (Phase 4).
Figure 9.11

Average spectra obtained from a patient for each of the 4 phases of respiration illustrated on figure 9.10; i.e. expiration (purple spectrum), fully expired (black), inspiration (blue) and fully inspired (brown). Each spectrum is compared with a baseline spectrum obtained irrespective of respiration phase, and the resulting filter outputs are shown on the figure. The corresponding chi-squared values are given in Table 9.2.
Table 9.2
Chi-squared values from figure 9.11 showing the effect of dynamic respiration phase on the averaged valve spectra.

<table>
<thead>
<tr>
<th>Phase of respiration</th>
<th>Frequency band (kHz)</th>
<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0 - 6.25</td>
<td>6.25 - 12.5</td>
<td>12.5 - 18.75</td>
<td>18.75 - 25</td>
<td></td>
</tr>
<tr>
<td>Phase 1 expiration</td>
<td>( \chi^2 = 4.1 )</td>
<td>( \chi^2 = 2.4 )</td>
<td>( \chi^2 = 2.9 )</td>
<td>( \chi^2 = 4.4 )</td>
<td></td>
</tr>
<tr>
<td>Phase 2 fully expired</td>
<td>( \chi^2 = 3.5 )</td>
<td>( \chi^2 = 6.8 )</td>
<td>( \chi^2 = 3.3 )</td>
<td>( \chi^2 = 3.7 )</td>
<td></td>
</tr>
<tr>
<td>Phase 3 inspiration</td>
<td>( \chi^2 = 3.7 )</td>
<td>( \chi^2 = 4.0 )</td>
<td>( \chi^2 = 1.9 )</td>
<td>( \chi^2 = 2.7 )</td>
<td></td>
</tr>
<tr>
<td>Phase 4 fully inspired</td>
<td>( \chi^2 = 4.3 )</td>
<td>( \chi^2 = 2.0 )</td>
<td>( \chi^2 = 4.7 )</td>
<td>( \chi^2 = 3.9 )</td>
<td></td>
</tr>
</tbody>
</table>
Figure 9.12

As figure 9.11, but results obtained from a different patient. Chi-squared values for this figure are given in Table 9.3.
Table 9.3

Chi-squared values from figure 9.12 showing the effect of dynamic respiration phase on the averaged valve spectra.

<table>
<thead>
<tr>
<th>Phase of respiration</th>
<th>Frequency band (kHz)</th>
<th>0 - 6.25</th>
<th>6.25 - 12.5</th>
<th>12.5 - 18.75</th>
<th>18.75 - 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1 expiration</td>
<td>( \chi^2 = 2.1 )</td>
<td>( \chi^2 = 2.9 )</td>
<td>( \chi^2 = 5.4 )</td>
<td>( \chi^2 = 6.7 )</td>
<td></td>
</tr>
<tr>
<td>Phase 2 fully expired</td>
<td>( \chi^2 = 5.8 )</td>
<td>( \chi^2 = 2.0 )</td>
<td>( \chi^2 = 2.1 )</td>
<td>( \chi^2 = 4.4 )</td>
<td></td>
</tr>
<tr>
<td>Phase 3 inspiration</td>
<td>( \chi^2 = 1.3 )</td>
<td>( \chi^2 = 3.5 )</td>
<td>( \chi^2 = 6.7 )</td>
<td>( \chi^2 = 4.7 )</td>
<td></td>
</tr>
<tr>
<td>Phase 4 fully inspired</td>
<td>( \chi^2 = 2.3 )</td>
<td>( \chi^2 = 3.0 )</td>
<td>( \chi^2 = 5.8 )</td>
<td>( \chi^2 = 4.1 )</td>
<td></td>
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</tbody>
</table>
Figure 9.13

Histograms showing the individual signal power content at the four states of respiration for the valve signals whose spectra are illustrated in figure 9.11.
the two channels of the B & K 2032 signal analyser. Triggering was initiated from the acoustic signal, and the time period between R-wave of the ECG and this trigger point was measured for 100 closures. The zero-crossing point of the RS section of the R-wave of the ECG was taken as the reference point because it was the easiest point to monitor.

Results from two patients with the same type of tilting disc valve implanted, showed a clear difference between the two sets of results (figure 9.14). The valve of patient B closes approximately 12ms later than that of patient A. This is probably due to differences in haemodynamic conditions, cardiac function and valve orientation between the two patients.

On the other hand, results obtained from the recordings from one patient made on two different occasions separated by a time period of one month showed no significant difference between the two sets of results (figure 9.15).

9.6 Summary of results

The results of these studies on patients with implanted prosthetic valves can be summarised as follows:

- Stable averaged spectra were obtained from the closing sounds of implanted artificial heart valves.
- These spectra were highly reproducible provided the position of the hydrophone was kept constant. The response of the system was shown to be sensitive to the position of the hydrophone relative to the chest.
Figure 9.14

Time interval between ECG and acoustic signal at valve closure. Results are illustrated for two patients.
Figure 9.15

Time interval between ECG and acoustic signal at valve closure. Results are illustrated for one patient recorded on two different occasions separated by a time interval of one month.
The continuous respiration cycle did not affect results. On the other hand, static breath holding on full inspiration appeared to affect the recorded spectrum.

In addition to spectral analysis of valve sounds, it has also been possible to measure the time interval between ECG and valve closure. This interval is entirely unrelated to the spectral analysis, but may have some relation to the mechanical state of the valve.

In summary, despite significant distortion of the valve signals by the thoracic structures, reliable reproducible averaged spectra can be obtained from patients, provided recording conditions can be kept constant. This suggests that the techniques used represent a feasible method of monitoring of implanted artificial heart valves.


Chapter 10
Discussion

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Discussion

The research described in this thesis has been dedicated to the development of a method for evaluating prosthetic heart valves implanted in patients, with the aim of identifying the earliest signs of mechanical failure of the valve. The major experimental results and observations from the previous chapters are discussed below.

10.1 Discussion of large tank results

Initial experimental work was performed on valves in vitro. In vitro studies were considered important in order to gain information about the valves themselves in an ideal environment, or one in which minimal sound distortion from external influences occurs.

10.1.1 Variability in individual valve closure signals

In all tested mechanical heart valves, there was a beat-to-beat variability in the acoustic signal produced on valve closure, which was reflected in the frequency domain. This variability occurred despite the seemingly controlled actuation conditions.

Differences between the acoustic signal from consecutive closures of any individual valve have been observed previously. Thulin [73] noted that, despite the controlled conditions of a pulse duplicator, the valve closing sounds varied considerably in intensity and spectral appearance for consecutive closures. His observations caused him to express serious doubts as to whether sound analysis could be of any true help
in clinical practice. He was however concerned by the use of a pulse duplicator to obtain his results, since he thought that vibration and resonances in the system may be affecting the recorded valve sounds. While this is probably true, it appears from the results of the large tank experiments of chapter 7 that beat-to-beat variability is a real phenomenon, and not caused simply by signal distortion produced by the experimental conditions.

Other studies have corroborated the presence of a variation in the sound of individual valve closures, but they have all been performed in a pulse duplicator [70,72].

Since the valve was being actuated under reliable controlled conditions, and the recording conditions were unchanged, the variation between consecutive signals must be due to differences in the mechanics of closure of the valve. The free-floating loose-hinge nature of the valve design allows it to close in a variety of ways. The occluder is able to strike the valve seating in a number of places, depending on its closing pattern. This can lead to multiple closing impulses, such as those observed in the time signals of figure 7.1.

10.1.2 Stability and reproducibility of valve spectra

The frequency spectrum of individual closures was also found to vary between closures (figure 7.2). This is to be expected considering the variation in the time domain signals.

Schondube [70] found differences in the spectra of individual valve closures recorded in two different positions in a pulse duplicator. The spectra contained spectral peaks at the same frequencies but with different amplitudes. This he attributed to the different recording positions. While this is possible, and indeed, given the
problems caused by recording within a pulse duplicator, quite likely, the observations of chapter 7 show that individual closures will have different spectra even when the recording conditions are completely unchanged.

When a valve closes, a number of modes of vibration of various components of the valve are excited. The same modes of vibration must be excited each time the valve closes, albeit to varying degrees depending on the way in which the valve closes. On the other hand, the time signals are convoluted by their shape (or envelope), and the resulting complex spectra are not simply a series of peaks relating to normal modes of the valve. Despite this, results of section 7.2 show that a stable spectrum can be obtained by averaging the spectra from individual closures of the same valve over a number of closures, without loss of spectral information.

Moreover, the averaged spectrum recorded from an individual valve is highly reproducible on separate recording occasions provided sufficient (approximately 20) valve closure signals are used to obtain the average. This was found to be true for all makes of valves tested.

10.1.3 Spectral difference between valves

Another important observation made in this series of experiments is that every valve has a averaged frequency spectrum unique to itself. This is true even for two valves of the same type and size. Spectral differences between valves of the same type have been noted previously [72,73], but again only within the conditions of a pulse duplicator, where reliability of the recorded signals must be questioned.

Spectral differences between valves, even valves of the same type, is a consequence of the individual attention given to the valves during the manufacturing
process. Although the valves are constructed in the same way, parts of the manufacturing process of all types of valve involve individual attention to the valve. For example the final stage of construction of a tilting disc valve consists of hand-polishing of the valve ring and manual insertion of the disc by bending of the outlet strut. Thus each valve can be considered to some degree to be "hand-made" and subject to structural individuality. This causes each valve to produce a unique averaged frequency spectrum.

Although valves have been shown to produce a stable averaged spectrum, results show that there is no spectral "fingerprint" unique to any particular make of valve which can be used to characterise a specific valve model or type. Thus there could be no possibility, given a single averaged spectrum from a valve in an unknown structural state, even knowing what type of valve it was, of determining whether the valve was structurally sound.

This unique spectrum observation had profound consequences on the future development of the research, since it meant that for any individual valve, a baseline spectrum must be measured for that particular valve and used as a comparison with future measured spectrum. A digital filtering technique was developed as a method of spectral comparison, and a chi-squared test used to give a statistical significance to the equivalence of two spectra.

Thulin’s observations (beat-to-beat variability in closing sound, and spectral differences between valves) caused him to doubt whether valve sound analysis was feasible as a screening test for valve malfunction [73]. However, the results of chapter 7 suggest that, despite these two observations being real phenomena, sound analysis is potentially useful provided the techniques of spectral averaging and digital filtering are used.
10.4.4 Detection of structural alterations

The techniques of spectral averaging and digital filtering were applied in section 7.8 to see if it was possible to detect spectral changes associated with a minor structural alteration to a valve. Two specific alterations were simulated, thrombus formation on the valve, and strut fracture of a tilting disc valve. Both simulated valve alterations produced spectral changes in the acoustic response of the valve which were detectable using the digital filtering technique.

This is an important result, for if the changes to the averaged spectrum caused by a structural modification to the valve had been found to be within the expected variation of the unmodified spectrum then clearly the technique could have no potential as a screening tool to detect structurally modified heart valves.

Previous studies have claimed to be able to detect similar structural changes to a valve. Stein [78], for example, claimed to be able to detect strut fracture of a Bjork-Shiley tilting disc valve within a pulse duplicator. He examined the spectra from two identical valves, one fractured and one intact, and finding differences between the two spectra, he concluded that this formed the basis for noninvasive identification of sub-clinical strut fracture. However, if each valve has its own unique spectrum as the results of section 7.6 suggest, this conclusion cannot be drawn from his results.

Suobank [69] simulated thrombus formation in a similar fashion to the experiments of section 7.8.1 by applying silicone rubber gel to parts of the valve. Unlike Stein, he used recordings from the same valve in its unmodified state to provide spectra for comparison. He noticed a change in the position of the closing sound occurring from the abnormal valve compared to that from the normal valve. This was a result of a change in motion of the valve occluder, rather than a change in the spectral characteristics. In addition he observed a few minor changes in the frequency
spectrum of the closing sounds. However, his frequency analysis of the sounds only covered the frequency range from 0-1kHz, which does not cover the range of normal modes of prosthetic heart valves. Moreover, the recordings were carried out in a pulse duplicator.

10.1.5 Low frequency oscillation

A large low frequency oscillation at about 2.5kHz was observed in some of the recordings made from Bjork-Shiley convexo-concave tilting disc valves. On investigation the outlet strut of these valves showed a pronounced resonant frequency at about 2.5kHz, not occurring from other valve components (e.g. the disc, valve ring). It is tentatively suggested therefore that the observed oscillation is a result of vibration of the outlet strut.

There have been many reports of outlet strut fracture of the Bjork-Shiley CC tilting disc valve [25,33,79]. The CC valve was available in the United States from 1979-1986 and exported worldwide from 1976-1986. During that time, as a result of the outlet strut fracture problem, numerous changes were made in the manufacturing and quality control procedures of the valve, but eventually the valve was withdrawn from the market in 1986. However, nearly 82,000 valves had been implanted worldwide prior to this withdrawal.

The valve ring and inlet strut of a CC valve are chemically machined from a single piece of the alloy Stellite - in other words, the junctions between valve ring and inlet strut have a continuous crystalline structure. On the other hand, the outlet strut is fabricated separately from a length of Stellite wire electrowelded to the valve ring. The crystalline structure of the metal is thus discontinuous at the points of attachment of the outlet strut. In valves where fracture has occurred, the site of fracture has been
the welded junction of the outlet strut with the valve ring.

The reasons advanced to date for the fractures have focussed on the weld as the prime cause of failure. Those valves which failed were assumed to have defective welds. Most of the manufacturing changes during production of the valve therefore involved strengthening the weld of the outlet strut. While improvement in the weld resulted in an improved fatigue resistance at the weld, it did not however eliminate the strut fracture problem.

Strict quality control procedures were carried out during manufacture of the valves. Each valve was carefully examined for cracks during manufacture and if any were found it was sent back either for rewelding, or for surface scratches to be polished out. Later, evidence was unearthed to suggest that the alloy should not be rewelded, and from then on, rewelding was halted and cracked valves were discarded.

Another reason put forward for valve failure was that some valves exhibit a so-called ‘bimodal’ disc closure pattern where the disc does not fit snugly between the valve ring and outlet strut on closure, resulting in a constant rocking motion of the occluder, applying pressure on the tip of the outlet strut [71]. This would cause excessive bending stresses to be applied to the weld. However this postulated mode of outlet strut fracture has not been fully verified [71].

All prosthetic heart valves undergo extensive in vitro evaluations based on three unique test systems [80]. Pulsatile flow systems (pulse duplicators) are used mainly to analyse the flow characteristics and haemodynamics of the valve; steady flow studies are used to measure the pressure drop across the valve, and other fluid velocity and stress measurements. Finally, durability studies are performed on the valve using an accelerated wear test system such as those described by Fettel [81] and Reul [82]. The test involves vibrating the valve in fluid at typically 30-40 cycles per second for many
months.

In response to fracture problems, Shiley carried out exhaustive stress testing of the CC valves. However they were not able to create a strut fracture during accelerated wear tests, even when extreme opening stresses were used. Nevertheless those valves implanted in patients continued to fracture.

Since Shiley failed to fracture any valves during testing, and valves in patients continue to fracture, one or both of the following conclusions can be drawn:

(i) The randomly selected sample of valves used in the stress testing by Shiley did not represent adequately the spectrum of valves implanted in patients worldwide.

(ii) The tests carried out by Shiley did not reproduce the forces and stresses generated by the contracting heart on the implanted valves.

If, as tentatively suggested earlier, the observed 2.5kHz spectral peak arises from free vibration of the outlet strut, and since the amplitude of this vibration is substantial, then clearly this vibration will impose a stress on the ends of the strut where it meets the valve ring. This may eventually lead to fatigue fracture of the strut. During accelerated wear testing, the valve is shaken at rates of up to approximately 40 cycles per second, causing it to close every 25ms. Closure conditions are therefore very different from those experienced by an implanted valve, and it is possible that they did not allow free vibration of the outlet strut to occur.

10.2 Discussion of model thorax results

It was clear from the results obtained in the large tank that the acoustic signals from a prosthetic heart valve contain sufficient information to allow an assessment of the val-
ve's structural integrity to be made, under ideal recording and actuating conditions. However, problems caused by signal distortion could be anticipated from recordings made from within the finite volume of a human thorax.

In order to approximate more closely the finite volume of the human thorax, a model thorax was designed of similar dimensions to a human thorax, and made from a strong polythene bag filled with water. The same actuation and recording equipment could be used as had been employed in the large tank.

10.2.1 Time signals

A comparison was made in section 8.3 of chapter 8 between valve closure signals recorded in the model thorax and in the large tank. The valve actuation and recording conditions were the same in both cases, and any differences between the two sets of recordings were therefore a consequence of the reduced volume of the model thorax.

Results showed significant differences between the time domain signals recorded in the two tanks. The recordings made in the model thorax were of a substantially greater amplitude than those made in the large tank. Furthermore the envelopes of the signals from the model thorax were less well defined in shape than those recorded within the large tank (figures 8.5 and 8.6).

Both of these observations were a direct result of the volume difference of the two tanks. In any finite volume, sound waves will be partly reflected at the boundaries of the volume. The reflected sound creates a reverberant sound field. In a small volume such as that of the model thorax there are multiple reflections, which creates a complex sound field, and causes distortion to the sounds recorded within the model thorax. On the other hand, the large tank is of sufficient volume that the sound from the valve is allowed to dissipate.
10.2.2 Frequency spectra

The averaged frequency spectra obtained from different valve types within the model thorax had a number of spectral peaks in common particularly in the frequency range 5-12kHz (figure 7.8). This was in contrast to similar recordings made in the large tank which had found no obvious similarities between spectra obtained from different valve types. This suggests that the common spectral peaks in the spectra in the model thorax are a consequence of its small volume, and that they have arisen from standing waves created within the volume. On examination of the measured frequency response of the model thorax (figure 8.3(a)), the same spectral peaks were seen. This confirmed that the spectral peaks are due to standing waves.

However cepstral analysis was unable to remove the effects of multiple standing waves in the finite volume in the same way in which it was able to remove the effect of a single echo in the large tank in section 6.2 of chapter 6.

10.2.3 Detection of structural changes

In section 8.3.3, the digital filtering technique was shown to be able to detect changes to the spectrum caused by a minor structural modification to a valve (e.g. added mass or strut fracture), despite the presence of the standing waves. The standing wave frequency distribution pattern did not appear to change significantly after the structural alteration to the valve. On the other hand, direct visualisation of the spectral changes associated with a structural alteration to a valve in the model thorax was more difficult than in the large tank, since the presence of the spectral peaks caused by the standing waves tend to increase the complexity of the spectra. The digital filtering technique is helpful for spectral comparison in this situation.
10.2.4 Photography

The translucent nature of the polythene of the model thorax allowed the valve to be viewed directly as it was actuated. Strobed photographs of a valve could be taken, whilst simultaneous recordings of the valve sound were made. This helped to relate the multiple strikes of the acoustic pulse with actual events during valve closure.

Sequences of photographs (for example figure 8.14) taken in this way confirmed that some of the multiple impulses within a single valve closure signal are a consequence of the freedom of movement of the valve occluder within the valve structure, causing the occluder to strike the valve ring or cage at different places and times. No bouncing of the occluder was seen.

The photographs also showed the rubber band mounting oscillating as a result of the impulse from the valve occluder. The frequency of oscillation was measured to be approximately 25Hz, which was well below the acoustic frequency range being measured.

10.3 Discussion of results from patient studies

The final part of the research (chapter 9) was dedicated to the investigation of prosthetic heart valve monitoring of valves implanted in patients. These recordings were carried out underwater using the same recording equipment as used for the in vitro recordings.

Acoustic emissions from an artificial heart valve implanted in a patient will be distorted by the non-homogeneous network of tissues of the heart and thorax. The transmission properties of the heart-thorax acoustic system are not easily determined. The first published studies concerning this problem were those of Feruglio [83] in
1962 who developed a technique for observing the transmission of sound from within the heart to the surface of the chest. He produced a known acoustic signal within the various chambers of the heart, using a small water turbine at the tip of a catheter. Recordings of the sound were made by a number of microphones at the surface of the chest. A year later, Heintzen [84] reported a reversal of this technique whereby he placed a sound generator against various places on the chest surface, and detected the signals using a phonocatheter within the heart.

More recently Durand [85] attempted to measure the transfer function (or frequency response) of the heart-thorax acoustic system of dogs by simultaneously measuring the power density spectra of valve closure sounds recorded from within the left ventricle and from a position on the thoracic surface over the apex of the heart. He noticed that the frequency response appeared to be specific to each animal. This is unsurprising considering the variability in shape and size of the animals.

While these previous studies have confirmed that the transmission of sound through the thorax is an important factor determining the intensity and frequency distribution of heart sounds recorded at the surface of the chest, no quantitative information can be gained for use in this thesis. Unfortunately moreover, the invasive nature of such work forbids similar experiments from being conducted in this study because of ethical considerations.

Signals were therefore recorded underwater in order to minimise sound distortions caused by changes in acoustic impedance at the thoracic surface. Valve sound recordings made previously by other groups have used a variety of recording transducers and recording sites, but none to the author's knowledge have been made underwater. This prevents direct comparison between results.

Schondube [70] used a microphone positioned slightly to the left of the sternum
in the region of the third intercostal space. He was careful to avoid direct contact with
the skin, and claimed that valve signals could be recorded because of the spherical
characteristics of the microphone. Walker [72] also used a non-contact microphone
held in the apex position. Kagawa [66] used a microphone which he held against vari­
ous points of the chest wall. Other studies [71,86,87] used a phonocardiogram trans­
ducer to record the sounds. Baykal used a PCG amplifier to record the acoustic
signals from 11 different sites on the chest of a patient having a St. Jude bileaflet
valve. He found variation in the frequencies of the resonances between recording sites
but showed that this was within the range of the within-site variation.

The majority of these previous studies have concentrated on low frequencies, up
to 1 or 2kHz, which all found significant power at these low frequencies. However,
the normal modes of a mechanical heart valve have been shown to be at higher fre­
quencies up to at least 25kHz. Schondube [70] did make recordings at higher fre­
quencies up to 25kHz. His recordings appeared to contain a high frequency signal (up
to 25kHz) corresponding to the valve closure, with a large low frequency
after-vibration at a frequency of approximately 15Hz.

Schondube suggested that the large spectral components at low frequencies seen
in his recordings were due to the oscillation of the blood column in the ascending
aorta set into vibration by the closure of the valve. Certainly the sound recorded from
an implanted valve will be influenced by the surrounding biological structures, which
will show frequency dependent sound transmission and natural resonating modes.

Koymen [86] assumed that the short acoustic pulse from the valve acts as an
impulsive excitation and couples energy to the natural resonance modes of the physi­
cal system, the properties of which are determined by the anatomy of the structures in
the chest. The bandwidth of the impulsive excitation is determined by the temporal
duration of the acoustic pulse; the shorter the duration of the pulse, the greater the resulting bandwidth. Therefore he suggested that a structural change to a valve such as a build-up of thrombus would decrease the deceleration of the occluder at impact, so broadening the acoustic pulse and producing less energy at higher frequencies in the impulse spectrum. He found the spectra to have significant resonance components in the frequency band 100-500Hz, and that the frequency components of signals from patients both with bioprosthetic and mechanical valves were in the same low frequency range. He suggested that these observations indicate that, although the mechanical properties of the valves themselves may alter the signals recorded, the frequencies of different modes of oscillation are determined primarily by the resonances of the various anatomical structures of the heart and chest. These observations are however a result of the restricted low frequency range (up to 570Hz) which he used for recording his signals. It is unsurprising that the low frequency resonances recorded in this range should be primarily related to anatomical structures rather than the valve itself.

A large low frequency after-vibration similar to that described by Schondube was seen in the recordings made from implanted valves in this thesis. Since the low frequency components in the recorded signal can be attributed to vibrations of anatomical structures within the chest, and not directly to the valve, these were filtered out using a 1kHz high-pass filter. No sounds directly of biological origin are detectable above this frequency.
10.3.1 Stability and reproducibility of implanted valve spectra

For all recordings made from valves implanted in patients, the averaged spectrum obtained over 20 valve closures was found to show a similar stability and reproducibility to spectra recorded in vitro, provided the position of the recording hydrophone was not changed between recordings (see figure 9.4). This was an important and encouraging result, since if this was not possible, then the technique would be of little use for monitoring implanted artificial heart valves.

Careful repositioning of the hydrophone was however necessary if the hydrophone was removed between recordings. Clearly the recording system is highly sensitive to the position of the hydrophone relative to the chest. This was demonstrated in section 9.3.1. The recordings have been made with the hydrophone attached to the patient at his waist, which is soft tissue, and therefore makes exact repositioning difficult. However, recordings by other groups using hand-held microphones held against the chest wall must be far more sensitive to transducer position, and to contact pressure against the chest which will affect the input impedance of the microphone.

10.3.2 Examination of the valve spectra

The valve spectrum of an implanted valve must be influenced by the finite volume of the human thorax, in the same way as a valve spectrum within the model thorax. Sound waves from implanted heart valves are absorbed, transmitted and reflected by the surrounding anatomical structures, and clearly the sound field created within the thorax is highly complex. Standing waves may exist within the human thoracic cavity as they did in the far-simplified model thorax, and these may cause peaks in the recorded valve spectrum. However, the frequency at which these peaks may occur
will vary widely between patients, and it is difficult to be sure of their origin.

All spectra from implanted valves (for example those of figure 9.4) appeared to have their most significant spectral peak at a frequency between approximately 13 and 16kHz. On the other hand, spectra from valves recorded in vitro in the large tank (figure 7.9) did not show a similar trend. It is possible therefore that this peak is associated with standing waves within the thorax created by reflections of sound by one of the structures of the thorax, for example the large back muscles. However the limited supply of data does not allow any strong conclusions to be drawn from these observations.

Schondube [70] made recordings from a patient having both an aortic and mitral valve prosthesis. Comparing the spectra of the two valves he found a common peak at approximately 10kHz. While this may be a coincidence, it is likely that this spectral peak could be associated with standing waves within the thorax. Unfortunately, no patients with double valve replacement were available for this study.

10.3.3 Effect of respiration

There are several physiological reasons why respiration might affect the valve closure signals recorded. Firstly, the heart is enclosed in a fibrous sac known as the pericardium. The lower surface of the pericardium is attached to the diaphragm, and as the diaphragm descends during inspiration, it pulls the heart into a more vertical orientation. This change in orientation may affect the transmission of sounds through the body. In addition the degree of inflation of the lungs may directly alter the transmission properties of the heart-thorax acoustic system.

Arterial pressure fluctuates with respiration, rising by 15-20 mmHg during each inspiration. Furthermore, flow in the vena cava increases during inspiration, because
as the thoracic cavity expands, intrathoracic pressure falls, expanding the intrathoracic veins. Simultaneously, the abdominal venous pressure is raised as the diaphragm compresses the abdomen, and this increases venous flow from the abdomen to the thorax. For converse reasons, flow in the vena cava decreases during expiration. These oscillations in venous flow due to respiration cause oscillations in the stroke volume (the volume of blood ejected from the ventricles per contraction). On inspiration, venous flow is enhanced, the right ventricle blood volume increases and its stroke volume increases. On the other hand, the left ventricular stroke volume is reduced. This situation is reversed during expiration.

These oscillations in venous return cause two normal physiological phenomena associated with the ECG which were observed during recordings (figure 9.10). Firstly, the heart rate appears to increase during inspiration and decrease during expiration. This phenomenon is known as sinus arrhythmia. Secondly, there is a clear oscillation in amplitude of the R-wave of the ECG during respiration. The ECG arises from potential changes at the skin surface resulting from depolarisation and repolarisation of the heart muscle. During excitation the heart becomes an electrical dipole and the potential difference recorded measures the cardiac dipole. The orientation of this dipole with respect to the recording electrodes affects the measured potential. Therefore as the heart changes orientation during inspiration as the descending diaphragm pulls the heart into a more vertical orientation, the potential difference changes, and the size of the R-wave of the ECG is reduced.

The changing orientation of the heart and flow of blood through it associated with changing phase of respiration may alter acoustic properties of the heart-thorax system as well as the heart valve closing mechanisms. In addition, the degree of inflation of the lungs may directly alter the transmission properties of the heart-thorax
Results of section 9.4 showed that the acoustic spectrum of heart valve closure appears to be altered when breath is held on full inspiration. In the dynamic situation however, respiration does not appear to affect the acoustic spectrum of heart valve closure greatly, and the individual signal power content does not change throughout the cycle. While these two sets of results appear to contradict each other, the spectral changes appearing when breath is held on full inspiration may be a result of factors such as changes in haemodynamic status caused by the stress of breath holding, or increased muscle tension altering the transmission properties of the thorax.

If, as indicated by the dynamic state results, respiration can be disregarded, then the recording and signal analysis processes are greatly simplified.

10.3.4 Timing of the valve closure signals

In section 9.5, investigations were made into the time interval between ECG and valve closing sound. While the precise nature of this time interval is uncertain it must be related to the time taken for the valve to close. It would be reasonable to assume that, provided blood pressure and heart rate had not significantly changed from one set of recordings to the next, then the appearance of a large change in this interval over a period of time may point to a mechanical change in the valve.

In a series of *in vitro* experiments, Suobank [69] simulated thrombus formation on a valve by applying silicone rubber gel to parts of the valve. As a result of the alteration to the valve, he noticed a change in the position of the closing sound relative to its actuation due to the change in motion of the valve occluder. His use of a pulse duplicator to actuate the valve does not in this case cast doubt on his observations, since the time interval will not be distorted to any great extent by this
method of actuation and recording.

The measurement of this interval is entirely unrelated to the spectral analysis of the previous sections, and therefore could exist as a further test of valve function, which could be carried out simultaneously.

Examination of other time intervals may also prove to be of some use in monitoring prosthetic heart valves. Consider for example a bileaflet valve. The two leaflets function independently each producing a impulse of sound on closure. The closing of the leaflets is asynchronous, and as a result two sound impulses are visible in the acoustic signal associated with bileaflet closure (see figure 9.3). This is a normal finding [73,88], although a long time interval between the two closures has sometimes been attributed to the valve being tilted relative to the axis of blood flow on implantation [26] (see section 1.4.3 of chapter 1). The asynchronous nature of the closing strikes is also highly variable, but stable over a period of time for a particular patient. Donnerstein [88] studied the asynchronicity of a number of implanted bileaflet valves, and suggested that valve position, leaflet and hinge characteristics, gravity, and haemodynamics may affect leaflet closure. He speculated that a significant change in the pattern of asynchronicity for a particular valve may be associated with leaflet dysfunction.

A study by Shawkat [89] investigated the timing pattern of clicks from implanted valves. He observed that the timing pattern from a single patient was stable and reproducible, and suggested that changes in this pattern may be produced by thrombus on the valve.

The work presented in this thesis has been concerned primarily with the frequency analysis of prosthetic valve closing sounds, and the possible detection of
Chapter 10

10.4 Summary and conclusion

In the introduction to the *in vitro* studies, two questions were posed which the experiments would attempt to answer. The first question was "Are the sounds produced by a prosthetic heart valve reproducible over a period of time?" and the second "Does the sound produced by a prosthetic heart valve contain adequate information to enable an assessment of the mechanical state of the valve to be made?".

In answer to the first question, the acoustic spectrum produced by a prosthetic heart valve is reproducible over a period of time, provided spectral averaging is first performed over approximately 20 valve closures to obtain a stable spectrum.

The second question can be answered in the affirmative provided the recorded spectrum from a valve is compared with a baseline previously recorded from that same valve. This is a consequence of each valve producing a spectrum unique to itself. Spectral comparison can be performed using a digital filtering technique, which has been shown to be sensitive to minor structural changes to a valve, such as a small simulated thrombus formation, or strut fracture.

Since the answer to both questions is "Yes", it is concluded therefore that under the ideal recording and actuating conditions of the large tank, it is possible to use acoustic analysis to monitor the mechanical state of prosthetic heart valves. This conclusion was also shown to be valid in the reduced recording volume of the model thorax where the presence of standing waves leads to a certain amount of signal
distortion.

For an implanted valve complexities exist in the perception of valve sounds. Sound transmission interfaces within the tissues of the thorax and at the thoracic surface will affect the recorded sounds. However, many of the problems associated with the recording of spectra from implanted valves have been relieved by recording the valve sounds underwater. Provided recording conditions can be kept constant, reliable reproducible spectra can be obtained from patients. This suggests that the techniques described in this thesis represent a potentially successful method of monitoring prosthetic heart valve patients. The techniques have not yet been developed to the point where they can be applied clinically. Nevertheless further investigations into the development of acoustic monitoring of prosthetic heart valves are recommended.

10.5 Recommendations for future work

Obviously the content of a thesis such as this must be finite, and some limitations are set on the research by, for example, the availability of equipment and the requirement of technical skills beyond the scope of the thesis. In the case of studies on patients, limitations are set by lack of suitable patients and by ethical considerations.

However, the conclusion of a thesis does not imply the conclusion of the programme of research described in it. Indeed, a successful thesis should indicate paths that future studies may follow.

The following sections describe the research that the author anticipates in the future arising from the results and observations contained in this work.
10.5.1 Transducer design

Many of the difficulties encountered in obtaining reliable and repeatable recordings from valves implanted in patients can be directly attributed to the recording technique used. The major problem associated with the recordings appears to be the positioning of the hydrophone relative to the patient, since precise relocation of the hydrophone is difficult. The present recording technique has been dictated to a large extent by the hydrophone transducer used for the recordings. This hydrophone was selected as it was the only transducer available which had an adequate flat frequency response (1 to >50kHz). In addition, recording valve sounds from patients in a large pool of water is not feasible for a simple clinical monitoring test. If acoustic monitoring is to become a useful clinical tool, a transducer will need to be specifically designed, suitable for use in an out-patient clinic. The design of this transducer is beyond the scope of this thesis, and will involve external collaboration with experts in this field.

10.5.2 Long-term data collection

The studies of chapter 9 have demonstrated that it is possible to obtain reliable and reproducible recordings from prosthetic heart valves implanted in patients. However, it has only been possible to make recordings from a limited number of patients. This has restricted the amount of data collected. A future substantial programme of work concerned with the recording of a large number of patients is required, to obtain a large database of patient recordings.

It is possible when making recordings from an implanted valve, that the significant distortion of the signals from the anatomical structures within the thorax may mask any changes in the spectra which might indicate mechanical alteration of the
valve. Such a mechanical alteration however cannot be created voluntarily in an implanted valve in the same way as it could be in the *in vitro* experiments. However, if a large database of patient recordings is collected over a reasonably long time span, such mechanical alterations will occur naturally in some implanted valves, and this will enable further conclusions to be drawn.

### 10.5.3 "Understanding" the spectra and investigation of the thoracic transfer function

Once a large database of patient recordings is available, careful examination of the spectra from different patients may enable greater understanding of various spectral components. For example, it may be possible to identify those spectral peaks which can be associated with structures within the thorax (e.g. the lungs), and which arise from vibrations of the valve itself. This may allow, for example, detection of the low frequency oscillation from Bjork-Shiley convexo-concave valves.

A series of recordings should be made from patients with a double valve replacement. Valve spectral analysis in such patients would allow the comparison of valves in the aortic and mitral positions within the same patient. Detection of spectral peaks common to the two valves would suggest that those peaks can be associated with part of the anatomy rather than with the valves themselves.

Spectral understanding may be simplified if some measure of the frequency response of the heart-thorax acoustic system could be obtained. As mentioned earlier, no attempt has been made to measure this in this thesis for ethical reasons. To measure the frequency responses of the large tank and model thorax in chapters 6 and 8 respectively, a transmitting hydrophone was used in place of the valve, and its
sound recorded by the usual recording hydrophone. It may be possible to perform a similar experiment to measure the frequency response across the human thorax, by somehow introducing a transmitting hydrophone or similar sound emitter into the thorax.

10.5.4 Investigation of low frequency vibration

During the course of the research, *in vitro* recordings from Bjork-Shiley convexo-concave tilting disc valves sometimes contained a large low frequency spectral component at about 2.5kHz. In chapter 7 it was tentatively suggested that this arises from free vibration of the outlet strut. A future programme of work is necessary to confirm the hypothesis.

Initially it must be confirmed that the oscillation observed in the acoustic signals is indeed generated by the vibration of the downstream strut. Once this has been established, a precise measurement of the amplitude and frequency of vibration of the strut must be obtained. A vibration can then be applied to the strut at this measured frequency and amplitude, and its effect on the strut observed.

If the strut does eventually fracture when subjected to this vibration, this will provide vital information in the treatment of patients having implanted Bjork-Shiley CC valves. All valves which in their sound recordings generate a large component at a frequency related to vibration of the outlet strut would be suspect of eventual fracture. The "at risk" group could be closely monitored so that if one leg of the strut did fracture, this would be detected before fracture of the remaining leg, and the valve could be replaced.
Furthermore, any new valves being developed for manufacture could be examined before implantation for the presence of significant vibration of any part of the valve (and in particular the outlet strut of a tilting disc valve design). This may prevent a repeat of the Shiley CC valve problem.

10.6 Clinical application of the monitoring techniques

In the design of any new method or device, the needs and priorities of its intended users must be fully considered in order that its design is appropriate to its intended use. "Appropriate" diagnostic technology has been defined by the World Health Organisation as to suggest that the equipment and methods used for evaluation are scientifically valid, suitable for the situation in which they are used, and acceptable both to those who use them and to those for whom they are used. Moreover that they can be acquired, maintained and utilised with resources the community can afford. Obviously these criteria should apply to an evaluation technique for prosthetic heart valves.

A number of questions need to be asked in the development of such a technique. Firstly, does the test provide any additional information to information already available using other methods, and is this information important? The answer to the first question is clearly "Yes", since at present there is no method available for monitoring of prosthetic heart valves for mechanical function and structural integrity. The information obtained by the monitoring test is clearly important, since it allows detection of a potentially life-threatening situation. On the other hand, it is pointless to develop a diagnostic technique if there is no possible way of acting on the information provided. In the case of prosthetic valve monitoring, detection of a faulty valve would
recommend re-operation and replacement with a new valve.

Secondly, is the technique safe; what are the possible hazards for the patient? The techniques developed in this thesis are entirely non-invasive, and cannot harm the patient in any way. Other screening methods for prosthetic heart valves currently being investigated by other groups include for example X-ray techniques. The intensity of the X-rays has to be very high to have a chance of detecting minute structural changes in the valve, such as a strut fracture, and since screening has to occur regularly, this must be potentially harmful to the patient.

Of less direct concern to the patient, but still of importance is the question of cost. To be effective the screening of patients must take place regularly, perhaps every two months. Ideally therefore, the monitoring techniques should be developed so that screening can be carried out during the routine check-ups that prosthetic valve patients already attend. The test should be simple enough to be able to be performed by non-specifically trained staff, and the results output in such a way that extensive professional expertise is not required for their interpretation.

To fulfil these criteria, the screening should be available to the patient in the normal out-patient clinic. The recording technique as it has been developed in this thesis is not suitable for such a clinic - recordings should not have to be made with the patient submerged in a large tank of water. If acoustic monitoring is to become a useful clinical tool, a transducer will need to be specifically designed, as suggested in section 10.5.1.
# Appendices

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Appendix A

The cardiac cycle

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The cardiac cycle

The heart (figure A.1) consists in simple terms of two adjacent muscular pumps, the right and left ventricles, each filled from a reservoir, the right and left atria. The right ventricle pumps blood through the lungs to the left atrium (the pulmonary circulation), and the left ventricle pumps blood through the rest of the body and back to the right atrium (the systemic circulation). In healthy persons, the heart musculature contracts 60 to 80 times a minute to keep the blood circulating.

To keep the blood flowing in the right direction, four one-way valves are located within the circulation. These valves are situated in the following locations:
(a) between the right atrium and right ventricle (the tricuspid valve).
(b) at the outlet of the right ventricle to the pulmonary artery (the pulmonary valve).
(c) between the left atrium and left ventricle (the mitral valve).
(d) at the outlet of the left ventricle into the aorta (the aortic valve).
The tricuspid, pulmonary and aortic valves each have three cusps, whereas the mitral valve is bicuspid.

A1. Mechanical events of the cardiac cycle

The cardiac cycle has four phases, ventricular filling, isovolumetric contraction, ejection, and isovolumetric relaxation. The duration and valvular state of each phase is illustrated in figure A.2.
Figure A.1

Schematic diagram of a section through the heart. RA, LA, right and left atria; RV, LV, right and left ventricles; Tv, Mv, tricuspid and mitral valves; Av, Pv, aortic and pulmonary valves; A, PA, aorta and pulmonary artery; PV, pulmonary veins; SVC, IVC, superior and inferior vena cavae.

The right ventricle pumps blood through the lungs to the left atrium (the pulmonary circulation), and the left ventricle pumps blood through the rest of the body and back to the right atrium (the systemic circulation).
Figure A.2
Mechanical events of the cardiac cycle showing ECG, valve movements and the associated acoustic pulses on a phonocardiogram.
Ventricular filling

Initially the ventricles and atria are in diastole (relaxed), the inlet (tricuspid and mitral) valves are open, and the outlet (pulmonary and aortic) valves are closed. Blood flows passively into the ventricles until the ventricles reach their natural volume, when contraction (systole) by the atria force more blood into the ventricles causing distension.

This part of the cardiac cycle lasts for nearly two-thirds of the cycle-time at rest.

Isovolumetric contraction

At this point, atrial systole ceases and ventricular systole begins. There is a rapid rise in the pressure of the blood in the ventricles, and at the point when ventricular pressure exceeds atrial pressure the atrioventricular valves are forced shut.

Ejection

The outflow valves are forced open by the pressure in the ventricles and ejection of the blood begins. At first the blood is ejected very rapidly causing distension of the arteries, and causing arterial pressure to rise to its maximum (systolic blood pressure). As the rate of ejection falls, the arterial pressure begins to fall and the blood flow reduces. Ventricular contraction ceases, but the outflowing blood continues to flow for a while owing to its momentum. This prevents immediate closure of the valves. Ventricular pressure falls, and a reversed pressure gradient builds up across the (valves), decelerating the outflowing blood. Eventually there is a small backflow of blood, and this forces the valves shut.
Isovolumetric relaxation

With the aortic and pulmonary valves closed, the ventricles are once again closed chambers, and ventricular pressure falls rapidly. When ventricular pressure falls below atrial pressure, the atrioventricular valves open and blood from the atria flows into the ventricles. The cycle then repeats itself.

A2. Natural heart sounds as a consequence of the cardiac cycle

Sound is produced when a heart valve closes. This is true of natural valves, and with mechanical prosthetic valves the sounds are much more pronounced. In these valves, the opening sounds are also sometimes detectable.

Two sounds are clearly audible per beat, the famous "lubb-dubb". The first sound is caused by closure of the tricuspid and mitral atrioventricular valves. These two valves close virtually simultaneously. The second sound is generated by the closure of the aortic and pulmonary valves. The sounds from these two valves can sometimes be resolved with the pulmonary valve shutting fractionally later than the aortic valve. These sounds are shown on figure A.2 in relation to the opening and closing of the four heart valves.

Two other sounds can also be detected, although these are not valvular in origin. The third heart sound is caused by the rush of blood into the relaxing ventricles, and the fourth sound is caused by atrial systole.

The sounds generated by natural heart valves have a frequency of approximately 100 Hz. Prosthetic valves on the other hand generate much higher frequencies of sound. The third and fourth heart sounds are of very low frequencies.
## Appendix B

### Spectral analysis

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Spectral analysis

B1. Fourier Analysis

The Fourier Transform is a useful analytic tool for signal analysis and is well described in many textbooks [90,91]. This appendix summarises the most important points in Fourier analysis in respect of its use in the analysis of the type of signals produced by a closing heart valve.

The Fourier Transform \(X(f)\) represents the distribution of signal strength with frequency, and is therefore a density function. For a continuous time signal, the Fourier Transform is defined by

\[
X(f) = \int_{-\infty}^{\infty} x(t)e^{-j2\pi ft} dt
\]

for \(-\infty < f < \infty\). \(x(t)\) is the time signal, and \(X(f)\) is the function in the frequency domain. Conversely, if \(X(f)\) is known, then the inverse transform gives the time-domain function \(x(t)\) as

\[
x(t) = \int_{-\infty}^{\infty} X(f)e^{j2\pi ft} df
\]

where \(-\infty < t < \infty\).

These two associated relationships are known as a transform pair.

The Fourier spectrum \(X(f)\) is generally a complex number which can be expressed in terms of complex polar notation as

\[
X(f) = |X(f)|e^{-j\phi(f)}
\]
where $|X(f)|$ is the magnitude spectrum and $\Theta(f)$ is the phase spectrum.

The Discrete Fourier Transform (DFT) is a special case of the continuous Fourier Transform in which the functions are sampled in both the time and frequency domains. In other words, each function is represented by a sequence of values at discrete equi-spaced points. $N$ discrete time samples and $N$ frequency values represent one period of the time and frequency domain waveforms respectively. The forward DFT can be described by

$$X(k) = \frac{1}{N} \sum_{n=0}^{N-1} x(n) e^{-j2\pi kn/N}$$  \hspace{1cm} (4)

where $k=0,1,...,N-1$.

$x(k)$ is the $k$th coefficient of the DFT; $x(n)$ is the $n$th sample in the time series.

The inverse DFT is

$$x(n) = \sum_{k=0}^{N-1} X(k) e^{j2\pi kn/N}.$$  

The DFT is much better adapted to digital computations than the infinite continuous integrals of equations (1) and (2). Even so, in order to obtain $N$ frequency components from $N$ time samples requires $N^2$ complex multiplications. The time taken to evaluate a DFT on a digital computer depends principally on the number of complex multiplications involved, and this is therefore related to $N^2$. However this time can be shortened markedly by the use of a highly efficient computer algorithm known as a Fast Fourier Transform or FFT. Versions of the algorithm are readily available as subroutines in mathematical software. The number of complex multiplications required for an FFT is approximately $N \log_2 N$. Thus for a 1024 point transform, the DFT would take over 1 million operations, whereas the FFT would reduce this number to just over 5000.
B1.1 Digitisation of a continuous time series

Time signals are recorded as a continuous function. For analysis the continuous signals are digitised by taking values at discrete equal time intervals, $\Delta t$, and converted to digital signals by an analogue-to-digital converter. However, digitisation clearly leads to a loss of information, and $\Delta t$ must be chosen carefully so that no vital information is lost. If $\Delta t$ is too long, a phenomenon known as aliasing may occur, where high frequency components are mis-interpreted as low frequencies, and the Fourier transform values are corrupted. Two simple illustrations of the phenomenon of aliasing are given in figure B.1. In the first, a high frequency sine wave (drawn in black) is interpreted as a low frequency sine wave (drawn in purple), by using too low a digitisation rate. In the second, a sine wave (black) is interpreted as a dc offset (purple), by sampling at the frequency of the sine wave.

To avoid aliasing, the Nyquist criterion is used. This requires the digitisation rate, equal to the reciprocal of the time interval $\Delta t$, to be capable of sampling the highest frequency present in the signal at least twice in each cycle. In other words, if the continuous input signal contains no frequency components higher than $f_c$, then it can be completely recovered without distortion if it is sampled at a rate of at least $2f_c$. This is known as the sampling theorem.

Signals rarely contain no frequency component above any particular frequency. There is usually some sort of noise. When transient signals are being analysed (such as those produced by a heart valve closing impulse), the time-domain signal is time-limited, and as a consequence, the frequency-domain signal is not band-limited, and aliasing must occur. To overcome this problem, the maximum frequency of the desired information must be chosen, and a low-pass anti-aliasing filter used to remove frequencies higher than this, prior to digitisation.
Figure B.1

Two simple illustrations of the phenomenon of aliasing.
In (a), a high frequency sine wave (drawn in black) is interpreted as a low frequency sine wave (drawn in purple), by using too low a digitisation rate.
In (b), a sine wave (black) is interpreted as a dc offset (purple), by sampling at the frequency of the sine wave.
In each figure the sampling points are drawn as dots.
B1.2 Summary of Fourier transforms and digitisation

- Given an analogue time signal of length $T$, on digitisation the signal is converted into a sequence of $N$ equally spaced sampled values, at a constant time interval $\Delta t$, such that
  \[ T = N \Delta t. \]  
  The sampling frequency or digitisation rate is equal to the reciprocal of the time interval, i.e., $f_s = 1/\Delta t$.

- The frequency resolution of the analysis is equal to the frequency range of the analysis divided by the number of points, i.e.,
  \[ \Delta f = \frac{f_s}{N}. \]
  It is always equal to the reciprocal of the record length transformed.
  \[ \Delta f = \frac{f_s}{N} = \frac{1}{N \Delta t} = \frac{1}{T}. \]  
  The highest frequency that will appear in the sampled data is $f_s/2$. This frequency is known as the Nyquist frequency, and is given by
  \[ f_N = \frac{f_s}{2} = \frac{1}{2 \Delta t}. \]
  Any frequencies present greater than $f_N$ will cause distortion of the DFT, unless a low pass anti-aliasing filter is used. The value of the anti-aliasing filter is normally chosen to be approximately 80% of the Nyquist frequency.
B2. Convolution

The concept of convolution is an important one in spectral analysis and will be discussed here. The convolution of two time functions can be defined mathematically as

\[ g(t) = \int_{-\infty}^{\infty} f(\tau)h(t-\tau)\,d\tau \]  

(7)

and this relationship is often represented symbolically as

\[ g(t) = f(t)^*h(t). \]

An important property of a convolution is that the convolution of two signals becomes a multiplication in the frequency domain. This is stated in the Convolution Theorem.

B2.1 Convolution Theorem

Consider the convolution of two signals \( f(t) \) and \( h(t) \),

\[ g(t) = f(t)^*h(t). \]

The Convolution Theorem states that the forward Fourier Transform transforms a convolution into a multiplication.

In other words,

\[ G(f) = F(f)*H(f) \]

where \( G(f) \), \( F(f) \) and \( H(f) \) are the Fourier Transforms of \( g(t) \), \( f(t) \) and \( h(t) \) respectively.

The Theorem is also true for the inverse Fourier Transform, i.e. if

\[ G(f) = F(f)*H(f) \]

then

\[ g(t) = f(t).h(t). \]
B3. Application of the Convolution Theorem

Consider an ideal physical system. For such a system, its basic response properties are given by the response of a system to a Delta function input known as the unit impulse response function or the weighting function, $h(t)$.

Before proceeding further, the mathematical concept of a Delta function must be outlined.

B3.1 Delta function

A Delta function located at $x = x_0$ may be represented as $\delta(x - x_0)$. It is numerically zero for all values of $x$ except at $x = x_0$ where it is infinite. Integrating the Delta function over $x$, provided $x_0$ is included within the limits of integration, gives a value of 1.

In other words, $\delta(x - x_0)$ can be considered as an infinitely short pulse with infinite height, having unit area. i.e.

$$\delta(x - x_0) = \infty \quad \text{for} \quad x = x_0$$

$$\delta(x - x_0) = 0 \quad \text{otherwise}$$

and

$$\int_{x_0^-}^{x_0^+} \delta(x - x_0) \, dx = 1.$$ 

For the ideal system in figure B.2, input $x(t)$ producing output $y(t)$, the system output $y(t)$ is given by the convolution of $x(t)$ with a Delta function $h(\tau)$, the unit impulse response function. So from (7)

$$y(t) = \int_{-\infty}^{\infty} h(\tau)x(t - \tau) \, d\tau \quad (8)$$
An ideal system in which input $x(t)$ produces output $y(t)$. $y(t)$ is given by the convolution of $x(t)$ with a Delta function $h(t)$, the unit impulse response function.
or

\[ y(t) = h(t) \ast x(t). \]

In other words, \( y(t) \) is given by a weighted linear sum of the entire time history of the input \( x(t) \).

There are four basic conditions for an ideal physical system.

(a) \( h(t) = 0 \) for \( t < 0 \) since the system cannot respond to an input before that input is applied. Thus the lower limit for integration of equation (8) is 0.

(b) The unit impulse response function is not dependent on the time an input is applied, i.e. \( h(t, x) = h(x) \) for \( -\infty < t < \infty \).

(c) The system must be stable - in other words any finite impulse will produce a finite response, i.e.

\[ \int_{-\infty}^{\infty} |h(\tau)| \, d\tau \leq \infty \]

(d) A linear system is additive and homogeneous. For two inputs \( x_1 \) and \( x_2 \) producing outputs \( y_1 \) and \( y_2 \) according to equation (8), then additive means that input \((x_1 + x_2)\) produces output \((y_1 + y_2)\). Homogeneous means that input \( cx \) produces output \( cy \), where \( c \) is an arbitrary constant. This means that \( h(t) \) is not dependent on the input.

These conditions lead to

\[ y(t) = \int_{a}^{\infty} h(\tau)x(t-\tau) \, d\tau \]

for all \( x(t) \). This equation holds for any arbitrary input \( x(t) \) to a system producing output \( y(t) \) where \( h(t) \) is the weighting function.
B4. Windowing

A DFT calculation is made on a time record of a finite length $T$, and is therefore limited by a time window. Any signal outside this time window is ignored by the analysis. Thus the finite signal $x(t)$ can be viewed as an unlimited time history record $v(t)$ multiplied by a rectangular time window $u(t)$ where

$$
\begin{align*}
    u(t) &= 1 \quad \text{for } 0 \leq t < T \\
    u(t) &= 0 \quad \text{elsewhere.}
\end{align*}
$$

In other words

$$
x(t) = u(t)v(t) \quad \text{for all } t.
$$

It follows by the Convolution Theorem that the Fourier transform, $X(f)$, of $x(t)$ is the convolution of the Fourier transforms of $v(t)$ and $u(t)$. So from (7)

$$
X(f) = \int_{-\infty}^{\infty} U(\alpha)V(f - \alpha) d\alpha.
$$

The Fourier transform $U(f)$ of the rectangular function $u(t)$ is

$$
\frac{T \sin(\pi f T)}{\pi f T} e^{-\pi T f}.
$$

The proof of this can be found in many textbooks [90]. $u(t)$ and $|U(f)|$ are illustrated in figure B.3.

The function $|U(f)|$, known as the basic spectral window of the analysis, contains a main lobe which is twice the width of the line spacing $\Delta f$, and an infinite number of side lobes of width $\Delta f$. The large side lobes can introduce anomalies in the estimated spectra. This problem can be reduced by the use of different window functions $u(t)$, where the ends of the function are more gradually tapered.
Figure B.3
Rectangular time function $u(t)$, and its Fourier transform $|U(f)|$. Note the main lobe and side lobes of $|U(f)|$. 
B4.1 Choice of window

Prosthetic heart valves produce acoustic signals of a short duration, known as transient signals. A transient signal is a non-stationary signal of finite duration, which is analysed as an entity. The window must therefore be chosen so that the transient signal starts and finishes within the window (see figure B.4). Provided this is the case, there are no discontinuities at the ends of the records, since the signals are effectively equal to zero at these points. In the case of transient signals the obvious choice of window shape is a rectangular window. Rectangular weighting (also known as Flat or Boxcar weighting) is effectively equal weighting on all parts of a finite time record.

In the frequency domain the bandwidth is equal to the line spacing or resolution \( \Delta f \), where \( \Delta f = 1/T \) (equation (6)). Therefore the filter characteristic \( |U(f)| \) of figure B.3 will have no influence on the calculated spectrum of the transient signal.

B5. Spectral analysis

A measure of the relative amplitude of the frequency components in a signal is obtained via the Fourier Transform. The power content at each frequency is given by the square of the amplitude of the Fourier series component. The spectrum of the squared amplitudes is known as the power spectrum. This spectrum can be scaled in terms of decibels, where the scaling is defined as 10 log_{10}(power spectrum).

Due to the random nature of physical signals however we need an average spectral measure in order that we can obtain any useful information. For this we use the power spectral density (PSD) of the signal. The DFT from equation (4) is

\[
X(k) = \frac{1}{N} \sum_{r=0}^{N-1} x(r)e^{-2\pi ikN}
\]
Figure B.4
A typical transient signal, with a finite length of less than 20ms.
from which the PSD can be written as
\[
P(f) = \frac{1}{N} \left| \sum_{n=0}^{N-1} x(n)w(n)e^{-2\pi i fn} \right|^2.
\] (9)

\(w(r)\) is the window function which is used for the analysis. As discussed previously, this will be a rectangular function for the transient acoustic signals typically produced by prosthetic heart valves.

B6. Frequency response function

The dynamic properties of a physical system can be described in terms of its frequency response function. As discussed in Appendix B3, a Fourier transformation of the unit impulse response function produces a direct frequency domain description of the system properties. For a system with input \(x(t)\) and output \(y(t)\) characterised by an impulse response \(h(t)\), the output signal is the convolution of \(x(t)\) with \(h(t)\), so
\[
y(t) = x(t) \ast h(t)
\]
and by the Convolution Theorem
\[
Y(f) = X(f) \cdot H(f).
\]
Thus
\[
H(f) = \frac{Y(f)}{X(f)}.
\] (10)

In other words, the frequency response function represents the ratio of output to input in the frequency domain.
The frequency response function $H(f)$ is related to the impulse response function $h(t)$ by

$$H(f) = \int h(t) e^{-j2\pi ft} dt.$$ 

Consider equation (10). If this equation is multiplied top and bottom by the complex conjugate of $X(f)$, then a version of the frequency response function known as $H_1(f)$ is obtained.

$$H_1(f) = \frac{X'(f) Y(f)}{X'(f) X(f)}.$$ 

$X'(f) Y(f)$ is known as the cross spectrum from $X$ to $Y$.

$X'(f) X(f)$ is simply the power spectrum of $x(t)$.

Thus $H_1(f)$ is the ratio of the cross spectrum from input to output normalised by the input power spectrum.

$H_1(f)$ is used in preference to $H(f)$ in situations where the output only contains extraneous noise since errors introduced by this noise are reduced [91]. Better estimates of the cross spectrum and power spectrum are obtained by averaging over a number of records, and as the number of averages is increased, $H_1(f)$ approaches $H(f)$.

If the input to a system is white noise, then the power spectrum of the input is a constant, independent of frequency. In this case, $H(f)$ is characterised by the cross spectrum from input to output $(X'(f) Y(f))$ only.
Appendix C

Cepstrum analysis

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Cepstrum analysis

Cepstrum analysis is a specialised analysis technique which was developed for the detection of any periodic structure in the spectrum. The cepstrum is basically a spectrum of a logarithmic spectrum and it can extract valuable information from the spectrum in the same way that a frequency spectrum extracts information about a time signal.

The word cepstrum was coined from the word spectrum, it being a spectrum of a spectrum. The cepstrum was first defined by Bogert [76] in 1963 as the "power spectrum of the logarithmic power spectrum", but the most commonly used definition nowadays is the "inverse Fourier transform of the logarithmic power spectrum".

In mathematical notation, the power cepstrum may be written as

$$C_{p}(v) = \mathcal{S}^{-1}\{\log G(f)\}$$

where we use the symbol $\mathcal{S}^{-1}$ to denote the inverse Fourier transform. $G(f)$ is the power spectrum of a time signal $g(t)$.

C1.1 Deconvolution by cepstrum analysis

The idea of convolution was discussed in Appendix B2, where it was stated by the Convolution Theorem that two convoluted time signals become multiplied when transformed to the frequency domain. Several of the applications of the cepstrum involve deconvolution, and the deconvolution process using cepstrum analysis can be explained simply as follows. By the Convolution Theorem, two signals convoluted in
the time domain become multiplied in the frequency domain (Appendix B2.1). Thus

two convoluted signals, \( x(t) \) and \( y(t) \), such that

\[
y(t) = x(t) * h(t)
\]

are multiplied in the frequency domain, i.e.

\[
Y(f) = X(f) \cdot H(f).
\]

Taking logarithms this transforms the log spectrum into the sum of two components

\[
\log Y(f) = \log X(f) + \log H(f).
\]

(11)

The cepstrum is the inverse Fourier Transform of the log spectrum, \( \log Y(f) \). The

additive relationship of equation (11) is therefore maintained in the cepstrum, and the

cepstrum of the output signal \( y(t) \) is the sum of the cepstrum of \( x(t) \) and the cepstrum

of \( h(t) \). That is,

\[
\mathcal{F}^{-1}\{\log Y(f)\} = \mathcal{F}^{-1}\{\log X(f)\} + \mathcal{F}^{-1}\{\log H(f)\}.
\]

This additive relationship means that if one of the spectral components is known in

the cepstrum, it can be subtracted resulting in a deconvolution of the two signals \( x(t) \)

and \( h(t) \) in the time domain.

C1.2 Echo removal using cepstrum analysis

The cepstrum has the ability to detect periodic structures such as harmonics in the

logarithmic spectrum. Another effect which gives a periodic structure to the logarithmic

spectrum is the presence of echoes [76,77], and cepstral analysis has been

widely used for detection and removal of echoes in seismological investigations and

underwater measurements.

An echoic signal can be considered as the convolution of the noise directly from
the source, and its echo. Bogert [76] underlined the importance of the power cepstrum as a method of detection of echoes in a signal. He showed that the occurrence of an echo in the time domain signal will appear as a spectral modulation or ripple in the frequency domain. The "frequency" of this ripple is easily determined by calculating the spectrum of the log spectrum, wherein this "frequency" will appear as a peak. This "frequency" is actually the frequency of a frequency, and thus in fact has units of time. To avoid confusion it is known as a quefrency. Other words were paraphrased to avoid confusion, such as rahmonic for harmonic and liftering for filtering. These terms also have units of time.

The periodicity of the ripple in the spectrum is $1/x$ where $x$ is the echo delay time. So the quefrency of the ripple is $x$, and it appears in the cepstrum as a main peak and a series of rahmonics with a quefrency spacing of $x$. As shown previously, subtraction of a known spectral component in the cepstrum will deconvolute the signals. The rahmonics are known to be a consequence of the echo; therefore the echo can be removed by a simple subtraction of the rahmonic peaks. This process is known as a liftering process. A reversal of the cepstrum operation (i.e. a forward Fourier transform) can then be performed on the liftered cepstrum to give a spectrum with the echo effect removed.

The power spectrum is obtained by a squaring operation on the complex spectrum (Appendix B5), and as such the imaginary part of the spectrum which contains the phase information (equation (3)) is lost. The power cepstrum therefore contains no phase information and the cepstrum operation cannot therefore be reversed right back to the time domain. If it is desired to obtain the original deconvoluted wavelet the complex cepstrum must be used. The complex cepstrum is derived from the complex
spectrum and therefore retains information about the phase of the signal. However, discontinuities in the phase curve can cause problems when using the complex cepstrum and so the power cepstrum is used whenever possible. Moreover the power cepstrum is often superior to the complex cepstrum for echo arrival time estimation, since the phase contribution tends to mask the echo delay [92].
Appendix D

Significance test for spectral equivalence
Significance test for spectral equivalence

The general procedure for a significance test is as follows.

(a) Set up a null hypothesis.
(b) Find the value of the test statistic.
(c) Refer the test statistic to a known distribution which it would follow if the hypothesis were true.
(d) Find the probability of a value of the test statistic arising which is more extreme than that observed.
(e) Conclude that the data are consistent or inconsistent with the null hypothesis.

In this case, we want to test whether two spectra are equivalent. Thus the null hypothesis is that the two spectra are not equivalent.

A estimate of a power spectrum will have a sampling distribution which is approximately normal, provided the number of degrees of freedom, \( n \), is large. A logarithmic transformation of the power spectrum estimate has the effect of producing a distribution closer to normal than the original distribution.

Consider an estimated power spectrum \( \hat{G}(f) \) of a true spectrum \( G(f) \). It has been shown by [75] that the mean value and variance of \( \log \hat{G}(f) \) are given by

\[
E[\log \hat{G}(f)] = \log G(f)
\]

and

\[
\text{Var}[\log \hat{G}(f)] = \frac{2}{n}
\]
It should be noted that the variance is constant at all frequencies.

So, for two estimated power spectra, \( \hat{G}_i(f) \) and \( \hat{G}_j(f) \), with degrees of freedom \( n_1 \) and \( n_2 \), the sampling distributions can be given by

\[
\log \hat{G}_i(f) = y \left[ \log G_i(f), \frac{2}{n_1} \right]
\]

\[
\log \hat{G}_j(f) = y \left[ \log G_j(f), \frac{2}{n_2} \right]
\]

written in the form \( y[\text{mean}, \text{variance}] \).

If two variates are normally distributed, then their means are normally distributed, and their difference is normally distributed. Taking the difference of these two therefore gives

\[
\log \hat{G}_i(f) - \log \hat{G}_j(f) = y \left[ \log G_i(f) - \log G_j(f), \frac{2}{n_1} + \frac{2}{n_2} \right]
\]

subtracting the means and adding the variances.

Now if the spectra are equivalent, then \( G_i(f) = G_j(f) = G(f) \), and (12) becomes

\[
\log \frac{\hat{G}_i(f)}{\hat{G}_j(f)} = y \left[ 0, \frac{2}{n_1} + \frac{2}{n_2} \right]
\]

From this we obtain the statistic

\[
X^2 = \left[ \frac{2}{n_1} + \frac{2}{n_2} \right]^{-1} \sum_{i} \sum_{j} \left( \log \frac{\hat{G}_i(f)}{\hat{G}_j(f)} \right)^2
\]

which has a chi-squared distribution with \( N_j \) degrees of freedom.

For two spectra with the same resolution, \( n_1 = n_2 = N_j = N \). Thus

\[
X^2 = \left( \frac{N}{4} \right) \sum_{i} \left( \log \frac{\hat{G}_i(f)}{\hat{G}_j(f)} \right)^2
\]

(13)
Note that the term within the square brackets is in fact equivalent to the output from
the digital filter, described in section 5.5.3 of chapter 5.

This statistic in equation (13) can be used to test the hypothesis that
\[ G_1(f) = G_2(f), \]
and the region of acceptance is
\[ X^2 \leq \chi^2_{\alpha} \]
where \( \alpha \) is the level of significance for the test.
Appendix E

Computer programs

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Computer programs

The following programs were used to analyse the data. They are written in HP-Basic and were run on a Hewlett Packard 310 computer. An Ariel DSP-300 digital signal coprocessor board in the HP 310 performed the digital signal processing functions, which were called up as CSUBs at the end of the main programs.

Program E1
FFT analysis

Firstly this program sets up an I/O path between the computer and the Nicolet 310 digital oscilloscope via an RS-232 interface connection. The program then sequentially recalls digitised acoustic signals stored on floppy disks on the Nicolet into data arrays. FFT analysis is performed by the Ariel DSP-300. An FFT is performed on each of the time signals, and an ensemble average of the FFTs is calculated. The averaged FFT is displayed on the computer screen, and is stored on a floppy disk in the computer's disk drive.
Option Base 1

' INTEGER I,Number,Size_p2
Integer Xspace,Yspace,Lspace,Pspace,Dsp_sc
Integer Real_d,Complex_d,Averages
Integer Record,Startrec,Endrec

Xspace=0
Yspace=1
Lspace=2
Pspace=3
Complex_d=1
Dsp_sc=31 ! Select code for DSP-300
Size_p2=10 ! Set FFT size 2^10
Number=1024

Allocate Real Twiddle(4096),Window(4096)
Allocate Real Ampscale(Number)
Allocate Real Freal(Number),Fimag(Number)
Allocate Real R(Number),Im(Number),F(Number)
Allocate Real Flgt(Number),F_inst(Number)
Allocate Real Smooth(Number),Sm_lgt(Number)
Allocate Real Freq(Number)

Dim R(8),D(2048),Dx(2048),Dy(2048)
Dim D$(2048) BUFFER
Dim Valves$(14),Amplitude(Number),Time(Number)
Dim Filename$(10)

Output 704,"SRQON"
Mat F=(0)
Averages=0

Input "Valve ID?",Valve$

*****************************************************************************
Create rectangular weighting function
and initialise DSP board
*****************************************************************************

Assign #Disc to "twiddle:MEMORY,0,0"
Enter #Disc;Twiddle(*)
Assign #Disc to *
Mat Window=(.9999)
Init_dsp_fft(Size_p2,Window(*),Twiddle(*),Dsp_sc)

Loop to retrieve time signals from Nicolet
*****************************************************************************
For Record=Startrec to Endrec
580   OUTPUT 704;"R,A,0,":Record
590   A=SPOLL(704)
600   IF A=64 THEN
610      DISP "RECORD NUMBER":Record;"RECALLED FROM DISK"
620   ELSE
630      GOTO 590
640   END IF
650   IF Record=Startrec THEN
660      OUTPUT 704;"NO,A"
670      FOR I=1 TO 8
680         ENTER 704;N(I)  "Input scaling values from Nicolet"
690         NEXT I
700   END IF
710   H0=N(4)
720   V1=N(5)*10"N(6)
730   H1=N(7)*10"N(8)
740   ELSE
750   END IF
760   ASSIGN #Buff TO BUFFER D$  
770   ASSIGN #Path TO 704
780   OUTPUT 704;"DO,A,BHI,0,1024,4"
790   "This outputs from point 0 for 1024 points at 4 point intervals, i.e. from 0ms at 20μs intervals
800   for 1024 points, giving T=20.48ms time trace.
810   20μs gives a Nyquist frequency of 25kHz.
820   "  
830   TRANSFER #Path TO #Buff;COUNT 2048, WAIT
840   FOR I=1 TO 2048 STEP 2
850      Dx(I)=NUM(D$I[I])
860      Dy(I)=NUM(D$I[I+1])
870   NEXT I
880   ASSIGN #Path TO *
890   ASSIGN #Buff TO *
900   CLEAR 7
910   FOR I=1 TO 2048 STEP 2
920      D(I)=256*Dx(I)+Dy(I)-65536*(Dx(I)>=128)
930      D(I)=D(I)*V1  
940   NEXT I
950   MAT Amplitude=(0)
960   MAT Amplitude=(0)
970   FOR I=1 TO 2048 STEP 2
980      Amplitude((I+1)/2)=D(I)
990   NEXT I
1000  "Scale time signals so |Ampscale|<1
Min_amp = MIN(Amplitude)  
Max_amp = MAX(Amplitude)  
IF Min_amp < (-Max_amp) THEN  
   M = -0.9999/Min_amp  
ELSE  
   M = 0.9999/Max_amp  
END IF  
MAT Ampscale = Amplitude*(M)  

Perform FFT  
***********************************************************  
MAT Freal = (0)  
MAT Fimag = (0)  
MAT Frst = (0)  
MAT R = (0)  
MAT Im = (0)  
MAT Freal = (0)  
MAT Fimag = (0)  
MAT Frst = (0)  
MAT R = (0)  
MAT Im = (0)  

FOR I = 1 TO Number  
   R(I) = Rreal(I)*Rreal(I)/(M*M)  
   Im(I) = Fimag(I)*Fimag(I)/(M*M)  
   Frst(I) = R(I) + Im(I)  
NEXT I  
MAT F = F + Frst  
Averages = Averages + 1  
FOR I = 1 TO Number  
   IF F(I) = 0 THEN  
      F(I) = F(I) + 0.000000001  
   ELSE  
   END IF  
NEXT I  

MAT F = F/Averages  
MAT F = F/(Averages)  
FOR I = 1 TO Number  
   IF F(I) = 0 THEN  
      F(I) = F(I) + 0.000000001  
   ELSE  
   END IF  
NEXT I
FOR I=1 TO Number
    Flgt(I)=10*LGT(F(I))
NEXT I
FOR I=3 TO Number-2
    Smooth(I)=F(I-2)+F(I-1)+F(I)+F(I+1)+F(I+2)
NEXT I
MAT Smooth=Smooth/(5)
FOR I=1 TO Number : Cannot take log of 0
    IF Smooth(I)=0 THEN
        Smooth(I)=Smooth(I)+.0000000001
    ELSE
        END IF
NEXT I
FOR I=1 TO Number
    Sm_lgt(I)=10*LGT(Smooth(I))
NEXT I
***********************************************************
SCALING OF DATA
***********************************************************
FOR I=1 TO Number
    Time(I)=J*H1*4
    J=J+1
NEXT I
Plot FFT on computer screen
***********************************************************
CLEAR SCREEN
VIEWPORT 20,100,40,90
WINDOW 0.25,-60,0
FRAME
AXES 1.5,0,0,5,2.3
CLIP OFF
MOVE 12.4
LABEL "Frequency (kHz)"
FOR I=0 TO 25 STEP 5
    MOVE I,.5
    LABEL USING "#,K";I
NEXT I
LABEL USING "#,K";I
FOR I=-60 TO 0 STEP 10
    MOVE -.5,I
    LABEL USING "#,K";I
NEXT I
LORG 4
CLIP ON
FOR I=1 TO Number/2
PLOT Freq(I),Sm_lgt(I)
NEXT I

***********************************************************
Store averaged FFT on floppy disc
***********************************************************

INPUT "Name of data file?",Filename$
CREATE BDAT Filename$",";700,1";1,24590
ASSIGN #F TO Filename$",";700,1";FORMAT OFF
OUTPUT #F,1;Value6,Freq(*),Flgt(*),Sm_lgt(*)
ASSIGN #F TO *

***********************************************************
Ariel DSP sub-routines
***********************************************************

CSUB Read_int(INTEGER Space, Data(*), OPTIONAL INTEGER Sc)
CSUB Write_float(INTEGER Space, REAL Data(*), OPTIONAL INTEGER Sc)
CSUB Go_poll(INTEGER Data, OPTIONAL INTEGER Sc)
CSUB Real_fft(OPTIONAL INTEGER Sc)
CSUB Wind(INTEGER Space, OPTIONAL INTEGER Sc)
CSUB Init_dsp_fft(INTEGER Data, REAL Window(*), Twiddle(*), OPTIONAL INTEGER Sc)
CSUB Read_float(INTEGER Space, REAL Data(*), OPTIONAL INTEGER Sc)
CSUB Complex_fft(OPTIONAL INTEGER Sc)
Program E2

Digital filtering

Two previously stored FFTs are recalled from floppy disks in the computer. The first (or baseline) spectrum is used to digitally filter the second. The filter output is displayed on the computer screen.

```plaintext
10 REM **************************************************************************
20 REM Digital filtering
30 REM **************************************************************************
40 DIM Valvel$[14],Freql(Number),Flgt1(Number),Sm_lgtl(Number)
50 DIM Valve2$[14],Freq2(Number),Flgt2(Number),Sm_lgt2(Number)
60 DIM Filter(Number)
70 READ Valvel$,Freql,Fltl,Sm_lgtl
80 READ Valve2$,Freq2,Flgt2,Sm_lgt2
90 FOR I=1 TO Number
100 Filter(I)=Sm_lgt2(I)-Sm_lgtl(I)
110 NEXT I
120 CLEAR SCREEN
130 WINDOW 2,0,40,90
140 AXES X,0,0,5,2,3
```

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FOR I=1 TO Number/2
    PLOT Freq(I),Filter(I)
NEXT I
END
Program E3

Calculation of chi-squared to test for equivalence of two spectra

Two FFTs are recalled from floppy disk and they are tested for equivalence using a chi-squared test. The details of this procedure are given in Appendix D. There are two loops in the program from line 320. During the first loop the chi-squared values are calculated normally; during the second loop allowance is made in the calculation for any linear shift between the two spectra.

```plaintext
10  I  *******************************************************
20  I  
30  I  Chi-squared test for equivalence of two spectra
40  I  *******************************************************
50  I  
60  I  Number=1024
70  I  OPTION BASE 1
80  I  DIM Valuel$(14),Freq1(Number),Flgt1(Number),Sm_lgt1(Number)
90  I  DIM Valve2$(14),Freq2(Number),Flgt2(Number),Sm_lgt2(Number)
100  I  DIM Filter2(Number),Smdiff(Number),Smd(204)
110  I  *******************************************************
120  I  2 loops from here, one unadjusted, one adjusted for dc shift of second spectrum
130  I  *******************************************************
140  I  Retrieve spectra from floppy disc
150  I  ***********************************************
160  I  
170  I  INPUT "File 1 to recall?",File1$
180  I  ASSIGN #F TO File1$".700,1";FORMAT OFF
190  I  ENTER #F;Valuel$,Freq1$(*) ,Flgt1(*) ,Sm_lgt1(*)
200  I  ASSIGN #F TO *
210  I  
220  I  INPUT "File 2 to recall?",File2$
230  I  ASSIGN #F TO File2$".700,1";FORMAT OFF
240  I  ENTER #F;Valve2$,Freq2$(*) ,Flgt2(*) ,Sm_lgt2(*)
250  I  ASSIGN #F TO *
260  I  **************
270  I  FOR Loop=1 TO 2
280  I  
290  I  IF Loop=2 THEN
```
350       *********************************************************
360       Adjust 2nd loop for dc offset
370       *********************************************************
380       Smlgl_tot=0
390       Smlg2_tot=0
400       FOR  I=1 TO Number
410           Smlgl_tot=Smlgl_tot+Sm_lgt1(I)
420           Smlg2_tot=Smlg2_tot+Sm_lgt2(I)
430       NEXT I
440       Smlgl_mean=Smlgl_tot/Number
450       Smlg2_mean=Smlg2_tot/Number
460       Meansdiff=Smlg2_mean-Smlgl_mean
470       FOR I=1 TO Number
480           Sm_lgt2(I)=Sm_lgt2(I)-Meansdiff
490       NEXT I
500      END IF
510      ***********************************************************
520      Calculate difference between log spectra
530      i.e. \( \frac{10 \log a - 10 \log b}{10} = \log a/b \)
540      ***********************************************************
550      FOR I=1 TO Number
560          Smdiff(I)=(Sm_lgt2(I)-Sm_lgtl(I))/10
570      NEXT I
580      ***********************************************************
590      Take every 5th point and square
600      i.e. \((\log a/b)^2\)
610      ***********************************************************
620      FOR I=5 TO Number
630          K=I/5
640          Smd(K)=Smdiff(I)
650      NEXT I
660      FOR K=1 TO 100
670          Filter2(K)=Smd(K)*Smd(K)
680      NEXT K
690      ***********************************************************
700      Headings for printer output
710      ***********************************************************
720      PRINTER IS PRT
730      CLEAR SCREEN
740      810
IF Loop=1 THEN
PRINT "Chi-squared test"
PRINT Valuel$,File1$
PRINT Valve2$,File2$
PRINT "Frequency range","Chi-2","Probability"
ELSE
PRINT "If spectra adjusted for dc offset:
END IF

FOR Stnum=1 TO 76 STEP 25
FOR K=Stnum TO Stnum+24
Filtsum=0
Filtsum=Filtsum+Filter2(K)
Startf=(Stnum-1)/4
Endf=Startf+6.25
Chi2=Filtsum*Length/4
NEXT K
END f-Startf+6.25
IF Chi2<11.524 THEN
P=99
GOTO 1770
END IF
IF Chi2<12.697 THEN
P=98
GOTO 1770
END IF
IF Chi2<14.611 THEN
P=95
GOTO 1770
END IF
IF Chi2<16.473 THEN
P=90
GOTO 1770
END IF
IF Chi2<18.940 THEN

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1360  P=80
1370  GOTO 1770
1380  END IF
1390  IF Chi2<20.867 THEN
1400  P=70
1410  GOTO 1770
1420  END IF
1430  IF Chi2<24.337 THEN
1440  P=50
1450  GOTO 1770
1460  END IF
1470  IF Chi2<28.172 THEN
1480  P=30
1490  GOTO 1770
1500  END IF
1510  IF Chi2<30.675 THEN
1520  P=20
1530  GOTO 1770
1540  END IF
1550  IF Chi2<34.382 THEN
1560  P=10
1570  GOTO 1770
1580  END IF
1590  IF Chi2<37.652 THEN
1600  P=5
1610  GOTO 1770
1620  END IF
1630  IF Chi2<41.566 THEN
1640  P=2
1650  GOTO 1770
1660  END IF
1670  IF Chi2<44.314 THEN
1680  P=1
1690  GOTO 1770
1700  END IF
1710  IF Chi2<52.620 THEN
1720  P=.1
1730  GOTO 1770
1740  END IF
1750  P=0
1760  !
1770  !  ***********************************************
1780  !  Print chi-squared
1790  !  ***********************************************
1800  !
1810
1820  PRINT Startf,Endf,Chi2,"P >";P;"%"
1830  !
1840  !  **** End of loop for next frequency band *************
1850  !
1860  NEXT Stnum  ! Loop to 1060
1870  !
1880  !
1890
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1880  NEXT Loop
1890  :  ! Loop to 320
1900  END
Program E4

Cepstrum analysis

A full description of cepstrum analysis is given in Appendix C. This program calculates the power cepstrum of the input data. User-selectable liftering is then performed on the cepstrum, and the liftered cepstrum is transformed back to the frequency domain.

At this point in the program acoustic signals are input to data arrays using for example lines 10 to 1600 from Program E1.

```
70 FOR I=1 to Number
80 Flgt(I)=10*LGT(F(I))
90 Flogdiv(I)=Flgt(I)/100  ! To ensure |Flogdiv|<1
100 NEXT I
110  "Cepstrum analysis for deconvolution"
120  "Calculate power cepstrum"
130  "************
140  
150  "Write_float(Xspace,Flogdiv(*),Dsp_sc)
160  Real_fft(Dsp_sc)
170  Go_poll(I,Dsp_sc)
180  Read_float(Xspace,Cr(*),Dsp_sc)
190  Read_float(Yspace,CI(*),Dsp_sc)
210  "MAT Crn=Cr*(100)  ! To restore factor 100"
220  "MAT Cin=Ci*(100)  ! from line 90"
240  "MAT Crn=Cr*(1024)
250  "MAT Cin=Ci*(-1024)
270  "************
```
FOR I=1 TO Number
    Cepstrum(I)=Crn(I)*Crn(I)+Cin(I)*Cin(I)
    IF Cepstrum(I)=0 THEN
        Cepstrum(I)=Cepstrum(I)+.0000000001
    ELSE
        END IF
    NEXT I

******** Store original cepstrum ***************
MAT Bin=Cin
MAT Brn=Crn

******** Plot cepstrum (bottom left) ***************
CLEAR SCREEN
VIEWPORT 10,60,28,63
FRAME
WINDOW 1,Number/4,-5,5000
AXES 10,500,0,10,10,3
FOR I=1 TO Number/4
    PLOT I,Cepstrum(I)
NEXT I

******** Plot spectrum (bottom right) ***************
VIEWPORT 70,120,28,63
WINDOW 1,Number/2,-80,0
FRAME
AXES 10,5,0,0,10,10,3
FOR I=1 TO Number/2
    PLOT I,Flgt(I)
NEXT I

DISP "Press f2 to continue"
PAUSE

-------------------------------
Loop to here from line 1720 for further analysis
-------------------------------

Recall original stored cepstrum

MAT Crn=Brn
MAT Cin=Bin

Select liftering of cepstrum

INPUT "Shortpass(1),Longpass(2),Notch(3),None(4)?",Lifter
SELECT Lifter
CASE 1  ! Shortpass
INPUT "Value for shortpass?", Vshort
FOR I=Vshort TO Number-1
  C最重要的(I)=0
  Crn(I)=0
NEXT I
!
CASE 2  ! Longpass
INPUT "Value for longpass?", Vlong
FOR I=1 TO Vlong
  C最重要的(I)=0
  Crn(I)=0
NEXT I
!
CASE 3  ! Notch lifter
INPUT "Approximate value for lifter?", Approx
FOR I=Approx-20 TO Approx+20
  PRINT Cepstrum(I)
NEXT I
INPUT "Mean value for lifter?", Meanlift
FOR I=(-2+Meanlift) TO (Meanlift+2)
  C最重要的(I)=0
  Crn(I)=0
NEXT I
INPUT "More? Yes(1), No(2)", More
SELECT More
CASE 1
  GOTO 970
CASE 2
END SELECT
!
CASE 4  ! No lifting
END SELECT
!
END

***********************************************************
* Calculate lifter spectrum *
***********************************************************
FOR I=1 TO 1024
  Cepslift(I)=C最重要的(I)*C最重要的(I)+C最重要的(I)*C最重要的(I)
  IF Cepslift(I)=0 THEN ! Cannot take log of 0
    Cepslift(I)=Cepslift(I)+.000000001
  ELSE
    END IF
  END IF
FOR I=1 TO 1024
  MAT Crndiv=C最重要的/(100000) ! To ensure |Crndiv|<1
  MAT Cindiv=C最重要的/(100000)
END FOR
1340 Write_float(Xspace, Crndiv(*), Dsp_sc)
1350 Write_float(Yspace, Cindiv(*), Dsp_sc)
1360 Complex_fft(Dsp_sc)
1370 Go_poll(I, Dsp_sc)
1380 Read_float(Xspace, Lreal(*), Dsp_sc)
1390 Read_float(Yspace, Limag(*), Dsp_sc)
1400 |
1410 MAT Lreal = Lreal*100000 ! To restore factor 100000
1420 MAT Limag = Limag*100000 ! from lines 1310,1320
1430 |
1440 ! ******** Plot liftered cepstrum (top left) ***************
1450 !
1460 VIEWPORT 10,60,65,100
1470 WINDOW 1, Number/4, -5,5000
1480 FRAME
1490 AXES 10,500,0,0,10,10,3
1500 FOR I=1 TO Number/4
1510 PLOT I, Cepstrum(I)
1520 NEXT I
1530 |
1540 ! ******** Plot liftered spectrum (top right) **************
1550 !
1560 VIEWPORT 70,120,65,100
1570 WINDOW 1, Number/2, -80,0
1580 FRAME
1590 AXES 10,5,0,0,10,10,3
1600 FOR I=1 TO Number/2
1610 PLOT I, Lreal
1620 NEXT I
1630 |
1640 ! *************************************************************
1650 ! Loop to line 670 for further analysis
1660 ! *************************************************************
1670 !
1680 INPUT "Further analysis? Yes(1), No(2)?", Again
1690 SELECT Again
1700 CASE 1
1710 CLEAR SCREEN
1720 GOTO 670
1730 CASE 2
1740 END SELECT
1750 |
1760 END
References


References 172

[14] Davila JC, Palmer TE, Sethi RS. The problem of thrombosis in artificial cardia-
cardiac valves. In: Brest NN, ed. Heart substitutes, mechanical and transplant.

tial and complete prostheses in aortic insufficiency. *J Thorac Cardiovasc Surg*
1960;40:744-762

[16] Starr A, Edwards ML. Mitral replacement: clinical experience with a ball-

*Ann Thorac Surg* 1968;5:99-118

[18] Edmunds LH Jr. Thromboembolic complications of current cardiac valve pro-


obstruction of prosthetic heart valves due to lipid absorption by Silastic. *J
Thorac Cardiovasc Surg* 1970;59:413-425


1989;48:S49-50

[23] Antunes MJ, Colsen PR, Kinsley RH. Intermittent aortic regurgitation follow-
ning aortic valve replacement with the Hall-Kaster prosthesis. *J Thorac Cardio-
vasc Surg* 1982;84:751-754

[24] Sethia B, Quin RO, Bain WH. Disc embolisation after minor strut fracture in a

[25] Lindblom D, Bjork VO, Semb BKH. Mechanical failure of the Bjork-Shiley
valve: incidence, clinical presentation, and management. *J Thorac Cardiovasc
Surg* 1986;92:894-907
References


References


References


References


References


[83] Feruglio GA. An intracardiac sound generator for the study of the

[84] Heintzen P, Victor KW. The diacardiac phonogram. Am Heart J
1963;65:59-67

[85] Durand L-G, Genest J, Guardo R. Modeling of the transfer function of the
heart-thorax acoustic system in dogs. IEEE Trans Biomed Eng
1985;32:592-601

IEEE Trans Biomed Eng 1987;34:853-863

[87] Baykal A, Ider YZ, Koymen H. Energy distribution of the resonance
components of PCG signals on the surface of the chest. Ann Conf IEEE Eng

[88] Donnerstein RL, Allen HD. Asynchronous leaflet closure in the normally
functioning bileaflet mechanical valve. Am Heart J 1990;119:694-697

[89] Shawkat S, Petersen SA, Bailey JS. A new technique for the assessment of
mechanical prosthetic heart valves: analysis of their ultrasonic clicks. In
Proceedings of the 1989 International Symposium on Surgery for Heart Valve
Disease pp96-103


[91] Bendat JS, Piersol AG. Engineering applications of correlation and spectral

[92] Kemerait R, Childers DG. Signal detection and extraction by cepstrum