Cape Peninsula
University of Technology

THE RELEASE OF DAMAGED PROSTHESIS FROM IT'S CEMENTED POSITION IN HUMAN BONE.

By

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DECLARATION

I, Ahmed Mohamed kadoura, declare that the contents of this thesis represent my own unaided work and that the thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

Signed **Date**

ABSTRACT

Original surgery to replace a joint in the body with an implant is known as arthroplasty. There are cases where it is necessary to replace the implant with a revision surgery, because it has worn out or infection may have developed. Revision surgery is a long and complex procedure because the orthopaedic surgeon has to remove the implant that had been cemented in the bone cavity as well as the bone cement. A major problem is the hardness of the bone cement. Several methods are used in order to remove it, requiring excessive strength and sharp tools, that pose a danger to the human body long surgery time, from 3 - 4 hours.

In this study, modern methods were used attempting to soften bone cement by heating it using heating equipment (a hair dryer and a heat gun), by bombarding it with ultrasonic waves and finally applying mechanical vibrations.

The heating of the bone cement did not give satisfying results, as the temperature needed for melting or softening the bone cement was very high, which is not tolerable in operations, especially dealing with the human body.

The use of ultrasonic waves in trying to separate the implant from the bone cement did not give any positive results either. The exposure of bone cement to ultrasonic waves in a wide range of frequencies and for a long period of time resulted in some heating effect but did not produce any change in its mechanical or chemical properties.

Mechanical vibration produced a significant difference in results with the similar samples used in the first phase (heating) and the second phase of testing (the use of ultrasonic waves). After choosing an effective vibration source (a hammer drill), an adaptor was developed for securing the ‘implant test’ samples and ensuring that the source of vibration would apply an axial tension on the implant as it were cemented in the bone cavity.

The results were very positive, in that firstly and foremost the implant was separated from the bone cavity together with the body of the cement, i.e. leaving no remnants or leftovers in the inner surface of the bone where it was cemented. The frequency of vibration for best results was found to be 40 Hz and the time period of vibration for the complete extraction of the ‘implant’ with the cement attached to it, did not exceed 22 seconds.

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- Great thanks for all my family members.

DEDICATION

I am dedicated to my parents and my wife, to my brothers and sisters, my daughters Dana and Yasmin, also my son Adam who have been patiently waiting for my MTech to finish.

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GLOSSARY

Terms/Acronyms/Abbreviations	Definition/Explanation
FDA	the US Food and Drug Administration
CPC	calcium phosphate cement
T1	the temperature at the beginning
T2	the temperature at the end
Freq	Frequency
V	Voltage
DePuy	Kind of bone cement
C… to….S	distance’ (between the pivot point and the implant’s head)

CHAPTER 1

INTRODUCTION

1.1 Implants in the human body and associated problems

The increase in scientific development in surgical operations has precipitated research for manmade parts or components (implants) that compensate for loss or damaged parts/organs on the human body.

Orthopaedic surgeons when they need a method to fix for example an implant in the knee, hip or any part in the human body they have two choices, cemented or un-cemented as seen in Figure 1.1.

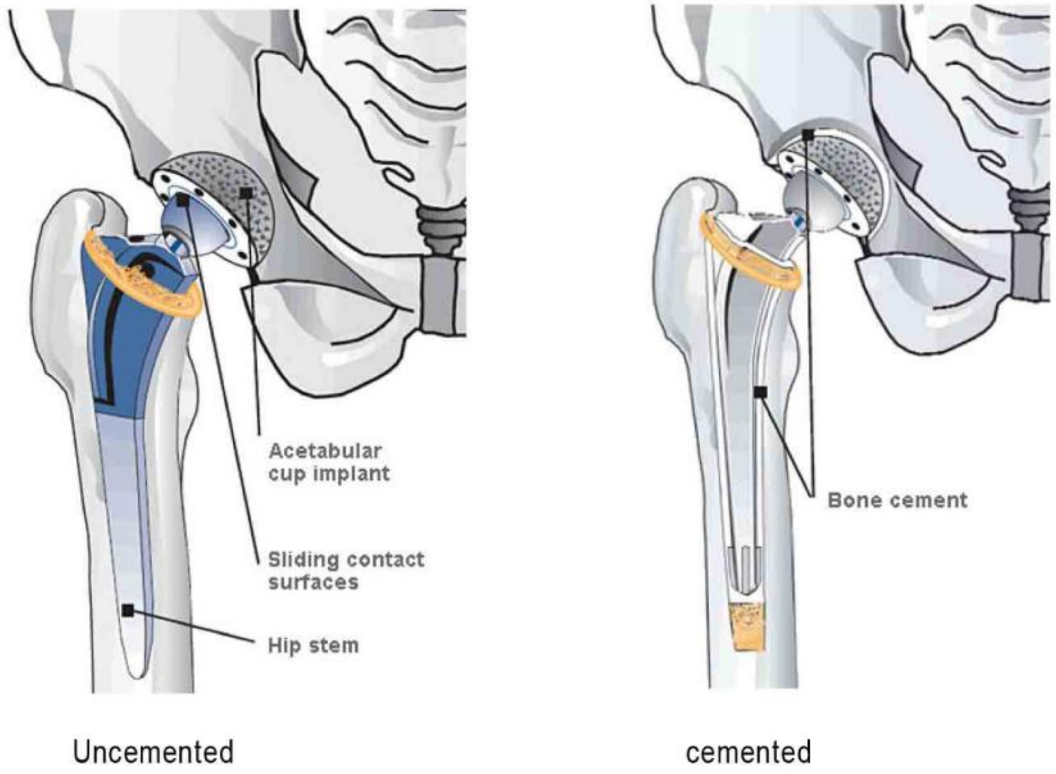

Figure 1.1: Un-cemented and cemented joint [1]

Bone cement is a substance used in fixing solid implants and artificial joints at the inner surface or hollow space of the bone in humans [2] and acts as a mechanical link that helps to increase the transfer of load between the bone and the implant [3].

Bone cement that holds metal implants into the cavity of a bone in the human skeleton is too strong to break up easily, and therefore it makes changing or repairing implants very difficult.

The problem arises when surgeons need to replace a cemented implant in other words how to separate implant from cement and cement from bone, in a safe and easy way, without collateral damage and without depletion of anaesthesia time, not to mention the physiological response of the patient and surgeon’s exhaustion.

The number of implant replacements has increased in recent years between 250,000 to 350,000 cases per year; for example in the United States and developed countries. Usually, 10% of these cases are because of malfunctioning after 10 years in service [4,5]. The importance of this project is contextual to yet another example; that more than 60,000 hip joints are replaced annually in England and Wales [6].

Historically, cement has been used in orthopaedic surgery as early as 1960 by Charnley [6,7]. During a short period it was dispensed by the orthopaedic surgeons[8], and in 1970, the US Food and Drug Administration (FDA) announced that bone cement could be used in surgical operations to fix implants in living bones [9].

Bone cement did not always enjoy great success because it caused several complications for patients. For example when fixing an implant, in a living organism, the cement may lose its mechanical properties due to the exposure of the body to recurrent bruises, as well as the length of exposure time to the structure of the bone, which consists of 60% inorganic material, 30% organic matter and 10% water [10]. Bone cement is also subjected to high pressure from the surrounding environment and unusual movements of the human body [11]. Also, “Thermal necrosis of bone interfacing cement", "Chemical necrosis of bone due to the monomer release”, and “Shrinkage of the cement during polymerization” occur. Therefore, repeating here…. the big problem is, how can the surgeons pry loose implants and prostheses easily from the bone cement [12]

Despite the widespread use and availability of various types of bone cement, which were developed during the last few decades, research is still ongoing firstly to develop applications that can use bone cement as well as work to reduce its negative effects. Bone cement is found in the medical markets in the form of a glass bottle containing a monomer and a bag of powder as shown in Figure 1.2

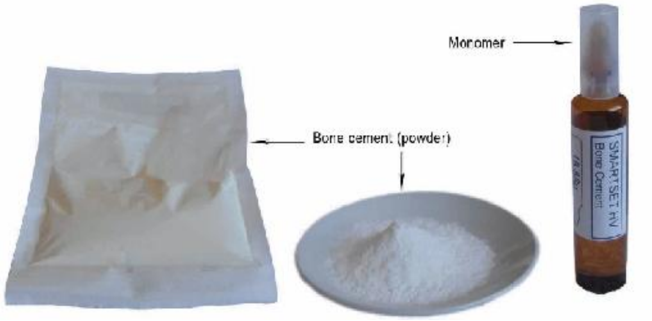

Figure 1.2: **Bone cement as a powder with monomer**

There are other alternatives to bone cement such as bioceramic, metal implant, polymeric materials, etc [13]. Although they differ in their chemical composition, their mechanical properties are almost identical for example calcium phosphate cement (CPC) [14][15]. However, bone cement is the most widely used and widespread in countries where implant replacement is abundant. Recent usage of bone cement is as an alternative to the bone [16] in the case of total collapse due to accidents.

Many challenges face the orthopaedic surgeon when there is a need to remove an implant cemented in bone. In some cases, removal of bone cement may not be difficult, such as in the case of a bone cement within the soft tissue, which can be removed by conventional methods. However, it is far more difficult to extract the bone cement from the cavity of solid bone [17].

There are cases where well-fixed cemented components need to be removed due to various reasons such as those listed as follows: infection [18], painful condition, polyethylene wear, implant/bone geometrical mismatch, malposition with chronic dislocation and removing distal cement plugs [19].

Sometimes it requires a great technical effort to remove the implant from the cement but even most important is to remove the bone cement from the surrounding bone without bone damage [20]. Breaking the bone during the removal will result in obviously unnecessary complications during surgery. Many surgical techniques are used in joint replacement surgery, many instruments and procedures are used for the removal of bone cement from the human body, but the important question is; How can it be done without damage [21].

There are multiple methods that are used to remove bone cement and most specialists prefer methods that depend on their experience. They would like the procedure to be swift with minimum or no damage to the body surrounding the implant's area. Methods that have become popular or common in the last ten years are the use of electromagnetic waves, ultrasound waves and vibration waves.

There is limited use of electromagnetic waves despite the results of tests pronouncing it safe for the human body [21]. The use of ultrasound waves for the removal of bone cement has been reported in the literature [10] is assumed safe, since the uses of ultrasound in ophthalmology to remove cataracts, as well as in dentistry to remove plaque and the use for other medical procedures of direct contact between ultrasound and the human body, indicates they are safe.

There is little data available on the effect of ultrasound on temperature generated in bone and its effects on surrounding tissues and on bone cement [22]. However, caution is imperative when dealing with ultrasound in the frequency range between (20-50) Hz, because it may cause burns to soft tissue [23].

Similarly, the use of mechanical methods may cause osteoporosis in the bone, taking into account age, physical composition and physiological structure [24] and particularly the removal of bone cement from the bone which involves the use of equipment such as chisels, saws, reamers, etc [25].

This work investigated the feasibility of high-frequency vibrations as means of changing the phase or consistency of the bone cement next to (the metal surface) of the implant, so as to facilitate removing it from its cemented position. Time lapsed and avoidance of collateral damage due to thermal effects with the procedure is of the essence. Therefore, the record of the approximate time of applying vibration and the temperature of the bone cement during the experiments is of importance.

The aim is also to have flexibility in the choice of changing the direction of the application of ultrasonic waves or vibrations to reach the implant, which depends on its placement or location in the body and how is the patient positioned during the process of replacement. The decision to determine the direction of impact on the bone cement should be carefully determined before beginning the process of the implant's removal so as not to encounter any sudden difficulties [5]

Cement inside the bone takes the shape of the inner cavity of the bone, therefore, it is intended to work with different forms of bones. In this manner, the influence of the shape that may create an asymmetric interlock and affect the process of future replacement [26] may be addressed. The difference in sample size also has an effect on the time involved in applying the vibration and the level of its frequency [27].

In this research, the bones that were used as models were obtained from animals like pigs, cows, and lambs. Figure 1.4 illustrates the bone shapes to be used as models instead of using X-Ray [28] or Modern imaging medical devices.

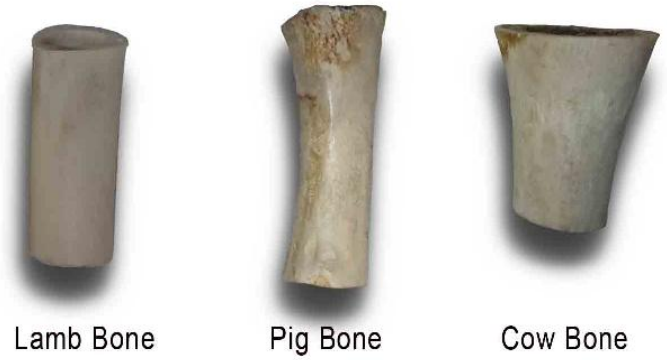

Figure 1.3: Types of bone used

1.2 Scope and Limitations

The aim of this study was the feasibility of a procedure using heating, ultrasound or mechanical vibration to soften or loosen the bone cement prior to attempting the removal of the implant. Time lapsed and avoidance of collateral damage with such a procedure is of the essence.

1.3 Structure of the thesis

Chapter 1
Introduction
The introduction to many problems associated with implants in the human body

Chapter 2
Literature review
This chapter comments on previous studies about bone cement used with implants; and the attempts to remove and separate them from the human body.

Chapter 3
Experimental work
A number of experiments were carried out with bone cement, bone cement with an implant and bone cement with an implant inside a bone.

Chapter 4
Summary of the experimental results, discussion, conclusion and recommendations
This chapter sums up the results obtained from the experimental work that was carried out, concludes the work with relevant reference to the literature and suggests future work.

CHAPTER 2

LITERATURE REVIEW

This chapter comments on previous studies to remove cemented implants (with bone cement) from a bone cavity and the problems that were encountered.

Researchers were and are still looking for procedures to extract the implant from its cemented position and in addition, remove the cement from the bone cavity. Whether in hip or knee replacement etc. surgeons nowadays try to avoid methods such as using metal tools that can scratch the bone because these scratches can undermine the strength of the bone [29]. Recently, the development of medical imaging techniques [14] has helped surgeons to avoid the risks they faced in previous decades.

2.1 Common methods for removing cement and implant from the bone cavity

2.1.1 Use of instruments and hand tools

Although many kinds of tools for the removal of implants are hand instruments, some are newly developed power and ultrasonic implements [15].

As a result, the replacement of the artificial implant, which began with using sharp hand tools has escalated to the use of mechanical vibration and ultrasound waves [11, 21, 24].

Older methods were based on drilling on the surface of the bone cement to reduce its mass accompanied by the use of sharp tools [30], such as reamers, saws, and chisels, as shown in Figures 2.1 and 2.2. Often associated with a lengthy time wise procedure, would be the harsh possibility of perforation or fracture of the bone [22].

Figure 2.1: **Cemented revision instrumentation** [31]

Figure 2.2: Hand tools for implant and cement removal [31]

2.1.2 Effect of ultrasound on the implant, bone cement, and bone

Ultrasonic testing is a type of non-destructive procedure [32]. As its uses and diversity have evolved, it is now being used to weld organic materials [33], diagnose tissue rupture [34], activate the interaction to form new substances or change the properties of substances [35]. Ultrasound is used to break up stones within the kidneys of the human body [36] and in the therapeutic role of strengthening the process of healing and activating bone growth or formation [37].

2.1.2.1 Effect of ultrasound on the implant

Implants in the human body vary in shape, type, and size according to their purpose. Figures 2.3, 2.4, 2.5 depict samples of implants and joints that are fixed by bone cement in the human body.

Figure 2.3: shoulder joints[38]

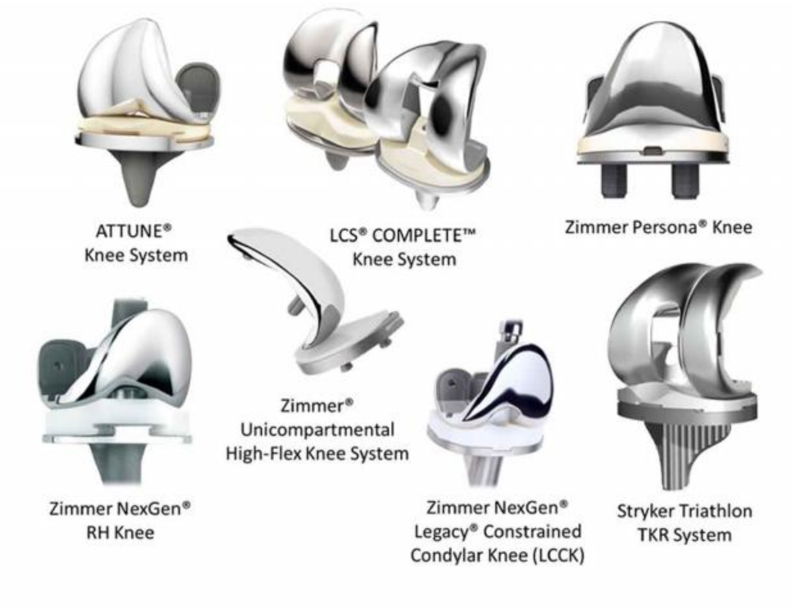

Figure 2.4: **Total knee joints**[39]

Figure 2.5: **Hip implants**[40]

The mechanical (strength) properties of implants in the body are normally assessed by mechanical analysis [41]. Resistance or reduction of the implant's movement, which may be the cause of the patient's failure to move [42], are not normally affected by ultrasound. However, the materials that implants are made of, should have a low-temperature affinity to ultrasound, so as not to affect the surrounding tissues, which differ in the absorption of temperature, especially when exposed to diagnostic and therapeutic radiation [43].

Most research studies that used ultrasound to replace an implant did not report any temperature generation, especially with implants made of titanium [44,45] However, the effect of temperature generated on the bone cement and the surrounding area of the implant was noticeable and depended on the exposure time to the ultrasonic waves.

2.1.2.2 Effect of ultrasound on the bone cement

Bone cement has biological properties that allow it to remain in the human body without any complications [46]. Attempts have been made to develop materials that help bone growth without losing the implant's installed characteristics [45,47] Adding antibiotics to bone cement [48–50] may have an effect on the mechanical properties, however, it has no effect on the movement and other factors related to the mechanical properties of bone cement [50]. Ultrasonic waves were successfully used to soften the cement holding an implant [21]. However, this process, despite its advantages, has the disadvantages of the cost of the device and associated equipment, which forced surgeons to use mechanical tools such as groover, scraper, piercer, hammer, and the osteotome, to remove large pieces of cement. Because of the hand tools, it is a time-consuming process of implant removal as well as dangerous, Figure 2.4 shows the Osteotome (an orthopaedic surgical instrument/chisel) used for the removal of bone cement from a bone's cavity [31].

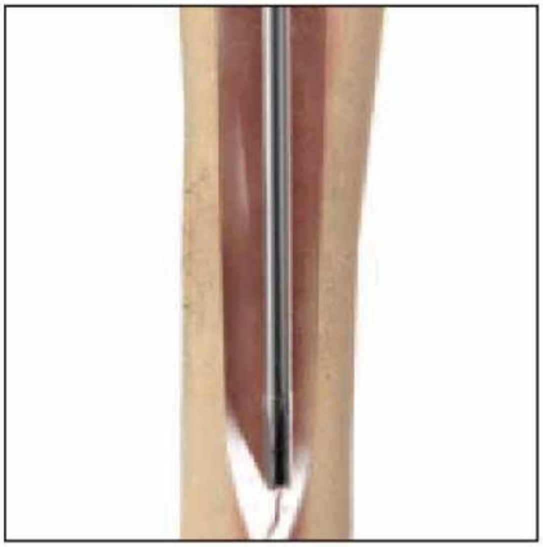

Figure 2.6: **The Osteotome instrument can be used to break up the cement mantle** [31].

Table 2.1: **Temperature's effect during ultrasonic cement removal** [18]

Maximum Temperatures (Celsius) During Ultrasonic Cement Removal

Cadaver	Control Room Temperature	Humerus	Radial Nerve	Triceps
1	23	50	53	42
2	24	73	62	40
3	24	57	48	24
4	24	57	38	26
5	24	58	65	69
6	24	81	46	27
Average temp	24	63+	52+	38

Bone cement can be softened by converting mechanical vibrations into thermal energy thus making the cement removal easier, but the occurrence of side effects through heat can lead to complications [18], especially when handling in vivo. Table 2.1 Demonstrates measured temperatures generated by the ultrasound on parts of the body [18].

The OSCAR system uses ultrasound waves for the removal of bone cement from within a bone cavity. The ultrasound is directed to a long probe that has an oscillating tip which liquefies the bone cement locally. Thereafter the cement can be removed by scraping.

The Oscar system was considered one of the most effective systems for removing cemented implants. Initially it was developed in the laboratory [51], however the newest Oscar 3 system now includes experimental data from recent studies with patients [24][52], hence differentiating between removing implants in the laboratory and those in Vivo [53],

Studies also show that the place of implantation in the body and its fixation position have an effect on the process of removal of the cement from the living body. For example, the replacement process of a femoral stem is difficult by conventional methods, especially if the implant is firmly anchored in bone cement [44].

In operations that surgeons use ultrasound with thin probes to remove bone cement that remains stuck inside the bone, they may take up to 15 minutes on a single spot [4].

Attempts to convert electrical energy to mechanical action and use it to heat and liquefy bone cement [25][54] has shown promise, as the removal process is easier, however, disadvantages in terms of time and temperature resulting from the process of liquefaction persist.

2.1.2.3 The effect of ultrasound on the bone

Bone is a biological compound made up of 70% of the inorganic structure, being the reason for bones to remain thousands of years unchanged [55]. The study of bone tissue engineering aims to seek alternatives to the bone after injury or damage due to ageing or accidents [55]. The growth of bone is possible by medications that help build bone tissue [56] such as magnesium, which has a clear effect on the histological structure of the bone [47] in terms of its ability to adapt to the cement and the implant [48].

Bone growth through ultrasound may cause an imbalance with the cemented implant's mass causing a malfunction [49]. There is also the possibility of thermal injury due to the transformation of mechanical vibration to heat on the bone tissue which contains bone cement [28,48], as well as its possible effect on the bone marrow it being less rigid than the bone tissue [57].

The use of piezo-driven ultrasonic devices may result in ultrasonic waves that have the least impact on the human body when compared with other devices and wave generators [9,58]

2.1.3 Use of other methods to removing implant and cement from the bone cavity

Reducing cement viscosity by low-frequency vibration has a direct effect, as confirmed through microscopic examination [59], however, the change is small and does not assist in easily extracting the implant from the bone cement.

The drilling process (using high-capacity drilling machines) which aims to weaken the cement block despite the short process time and high imaging techniques used with it, does not differ much, in terms of results, from the manual methods[60].

2.2 Background knowledge of bone cement

Knowledge of the mechanical properties of bone cement is important at the time which it is used to secure an implant (say in a bone cavity) so as to not impair the movement of the human body, but also during the time that is necessary to dispose the bone cement, for example during an implant's repair or replacement.

Compressive strength, and elastic modulus are the most important properties of bone cement [54] amongst other properties such as bending strength, shear strength, tensile strength, porosity, fatigue, etc. It should be determined what factors influence these properties during its preparation and its injection into the bone, as well as after the implantation procedure and bone cement hardening.

2.2.1 Factors affecting the mechanical properties of bone cement

Studies on bone cement have shown that there are factors that have direct and indirect effects on the mechanical properties of bone cement, as outlined below.

2.2.1.1 Factors affecting the mechanical properties of bone cement before hardening.

The extent of time of powder mixing with the monomer, just prior to the application, has an effect on the mechanical properties of bone cement [61], which is set at a maximum of 3 minutes, (agreed by most manufacturers) [62]. After this time injection inside the bone leads to increased or decreased porosity, which affects the cement's fracture and fatigue properties [60].

Bone cement strength is negatively correlated with the formation and spread of cracks [63] and pores in the bone cement, which leads to long-term effects on its fatigue life. Additional materials to the chemical composition of bone cement [64] may increase or decrease porosity because these materials could affect the process of adhesion of molecules.

During the process of mixing the powder with the monomer, the temperature of the mixture increases until it reaches a painful temperature when touched by hand [65], Although the body is not burned the temperature can change the mechanical properties of the bone cement because, during the implantation process, the gradual decrease in temperature may lead to the creation of spaces between cement and implant [62] and thus affect the transmission of loads.

2.2.1.2 Factors affecting the mechanical properties of bone cement after hardening.

Physical and chemical changes of/on bone cement appear after it has hardened [61], especially, the biological properties that allow it to remain inside the human body for a long time [46]. The success of the implant fixation is associated with the mechanical interlock between the cancellous bone and cement [65], therefore the implant's correct position inside the bone is very important [66].

Cracks and voids, as mentioned before, that may exist in bone cement after hardening have an effect on the loading efficiency of the implant and possibly the movement of the body as well [62]. Similarly adding materials to the components of bone cement have an effect on its mechanical properties even after hardening. For example materials like mesoporous silica nanoparticles affect the cement's static mechanical properties, fatigue life and absorption [64], However, what has more effect on the mechanical properties of bone cement after hardening within the body, is continuous stress, repeated rapid movement, sudden shocks to the body, and non-adaptation of the implant with the inhibition process [67].

2.3 Effect of temperature, waves, and vibrations on the mechanical properties of bone cement.

The process of removing bone cement from bones or its separation from the implant requires external influences such as temperature, mechanical and electromagnetic waves, and vibrations that change the mechanical properties of the bone cement.

2.3.1 The effect of temperature on the mechanical properties of bone cement

Properties such as ultimate strength, elastic limit, bending, shear and compression strengths, are affected by the temperature generated either by the various testing processes or by the environment surrounding the bone cement [68]. Increase in temperature of the bone cement may cause the destruction of the cement layer next to the implant, that leads to loss of its stability and causes a drop in the bone's stress[69].
The heat generated by ultrasound waves when directed to bone cement causes an internal change in the structure of the bone cement The high temperature that is generated converts bone cement from a microscopically spherical interlocked material to one that appears homogeneous and granular[25].

2.3.2 The effect of waves on the mechanical properties of bone cement

Mechanical waves have an effect on the materials that either transmit or absorb these waves, a fact depending on the level/value of the waves' frequency [70].

Ultrasonic waves are used in arthroplasty replacement, (modern methods that are developed by specialists) where bone cement is affected by a number of ways; as mentioned before the Oscar3 system [21] is one of them, where the bone cement is softened by reducing its viscosity. The use of vibration energy can also affect the load strength that binds the cement to the bone's interface [71].

Electron beam sterilization can enter through bone cement pores during the sterilization process and have an effect on the cement's mechanical properties. In some tests, the cement's compressive strength increased by 40% and the compressive modulus increased by 64% [72]**.**

2.3.3 The effect of Vibration due to movement, on the adhesive strength of bone cement

In implant fixation, the weakest bond is between bone and cement [69]. The repeated movement of the joints of the prosthesis, at various speeds and directions, produces vibrations which may lead to creating a space or a de-bond between the bone and cement [73].

2.4 Necessity for knowing the mechanical properties of mixtures of bone cement

This chapter has dealt with methods of removing the implant from the human body. It was shown that the implant when secured, by cement in a bone cavity, can be removed by procedures that affect the properties of the bone cement, particularly its mechanical properties. Hence the necessity of knowledge, as summarized below:

- It is important to know the mechanical properties of bone cement and the factors affecting it when dealing with the task of removing it in a safe manner without wasting time.

- Knowing the magnitude of the tensile and compressive strength of bone cement gives orthopaedic surgeons the possibility of avoiding bone fractures during surgical operations [70].

- It is possible to distinguish between additive materials to the chemical composition of bone cement and their effect on adhesion[74], hardness [75] and on increasing or reducing porosity [74].

- The effect of particles or fiber reinforcements, when added to the bone cement mixture during the preparation process, should be determined by testing the mixture’s fatigue life and absorption after hardening [64].

- Knowledge of the effect of antibiotics on the mechanical properties of bone cement is imperative [48–50].

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CHAPTER 3

EXPERIMENTAL WORK

3.1 Introduction

Laboratory experiments on loosening bone cement from bone and implants are described in this chapter. Approximately 70% of them were carried out in a laboratory in the Mechanical Engineering Department at the University of Cape Town (UCT) within a time period of about 11 months and the rest were conducted in the Mechanical Engineering Department at Cape Peninsula University of Technology (CPUT).

The early experiments investigated the effect of heat, ultrasonic waves, and vibrations on bone cement samples without implants or anything surrounding them. The next set of experiments involved samples of bone cement encased in materials other than bone and Instead of implants, cylindrical metal inserts. The third set of experiments were conducted with semi-real samples where the bone cement was used to secure real implants within the cavities of bones from animals.

3.2 Experiments investigating the effect of temperature, ultrasonic waves, and vibrations on the bone cement without implant and bone.

3.2.1 The effect of temperature on bone cement

During these tests, cylindrical bone cement samples were used as shown with their dimensions in Fig 3.1. The brand name of the bone cement that was used was Palacos as shown contained in its original packaging (Fig 3.2).

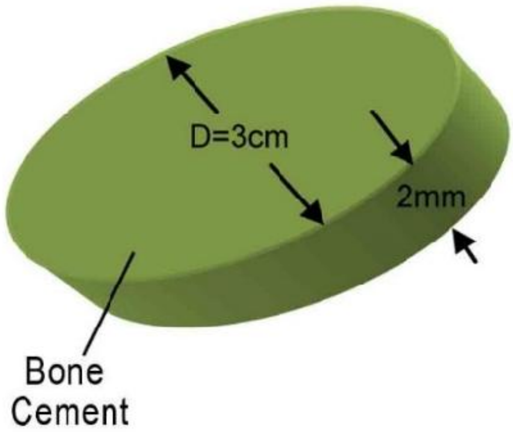

Figure 3.1: Sample of bone cement and its dimensions used in the early experiments

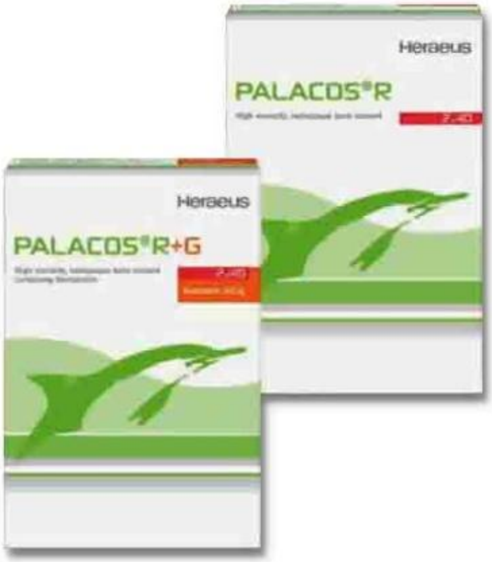

Figure 3.2: PALACOS R and PALACOS R+G (Bone Cement).
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3.2.1.1 The effect of heat from a hair drier on bone cement

In this experiment, the sample of bone cement was exposed to the flow of hot air from a hairdryer. Thermocouples were used to measure the sample's temperature and a timer was used to record the period of time the sample was subjected to heating (Fig 3.3). The data from this experiment and observations are presented in table 3.1.

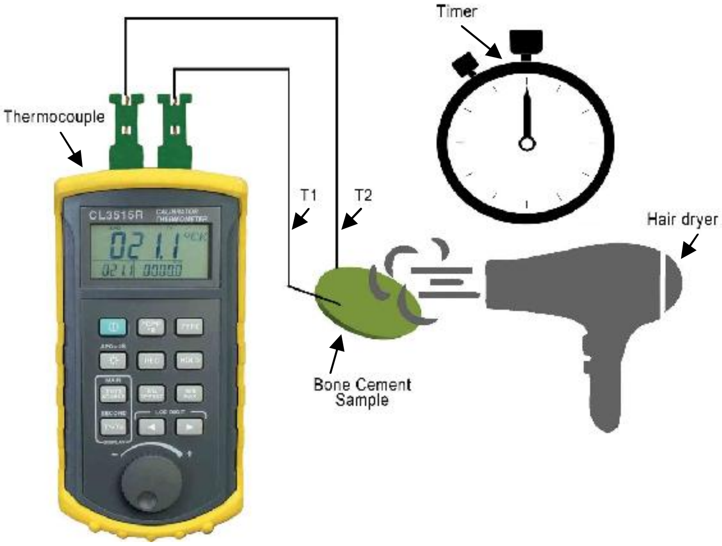

Figure 3.3: Bone cement exposed to hot air from a hair drier.

Table 3.1: Increase in the temperature of bone cement using a hair dryer

Period of application	Temperatures (T1)	Heating effect	Notes
25 minutes	100℃	No effect	
35 minutes	112℃	No effect	
50 minutes	114℃	No effect	
57 minutes	115℃	No effect	
1:05:00	120℃	No effect	
1:30:00	128.7℃	No effect	
2:00:00	136℃	No effect	
2:02:00	138℃	Nearly soft	
2:03:00	140℃	Nearly soft	
2:08:00	141℃	Nearly soft	
2:13:00	160℃	soft	

3.2.1.2 The effect of heat from a heat gun on the bone cement

In this experiment, the hairdryer was replaced by a heat gun see Fig 3.4. The data from this experiment and observations are presented in table 3.2.

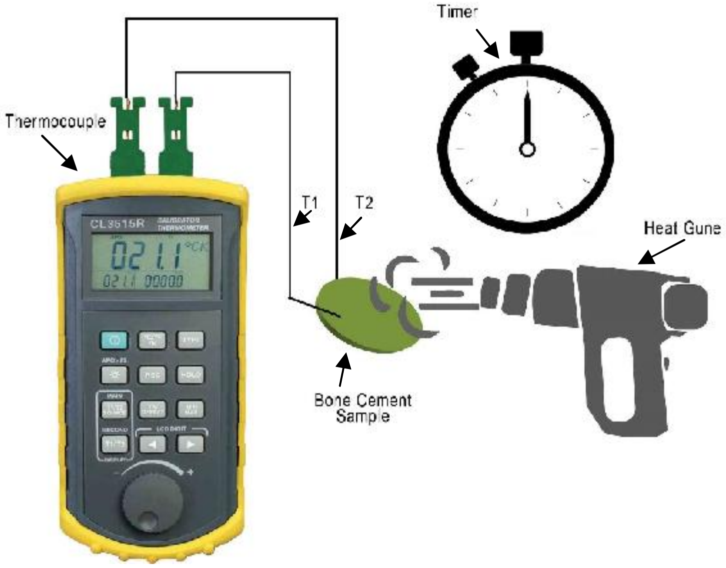

Figure 3.4: Bone cement exposed to hot air from a heat gun.

Table 3.2: Increase in the temperature of bone cement when using a Heat Gun.

Application time	Temperatures T1	Heating effect	Notes
30 sec	40℃	solid	
60 sec	86℃	solid	
90 sec	129℃	nearly soft	nearly wet
120 sec	172℃	soft	wet

Positive results were obtained in terms of the bone cement softening in a short time (120 sec), but the very high temperature of the air produced by the heat gun would be dangerous to the human body because it will cause burns.

3.2.1.3 The effect of possible heat generated from ultrasonic waves within the bone cement

In this experiment, a transducer was used to generate ultrasonic waves (Fig 3.5); the purpose of this experiment was to investigate the effect of possible heat being generated by the ultrasonic collisions within the bone cement (It was assumed a safe procedure since it has been confirmed that ultrasound is considered safe for living organisms).

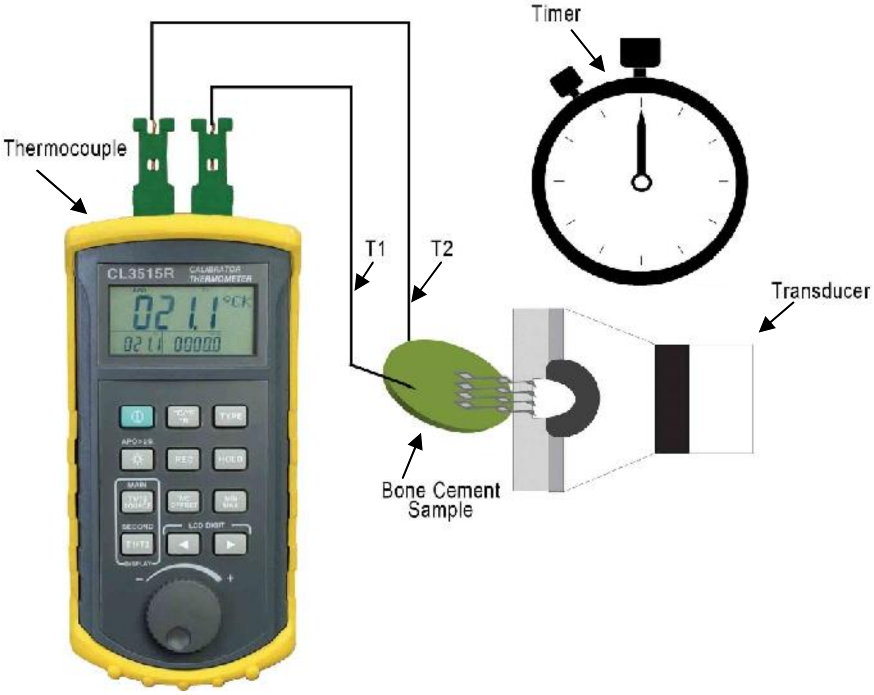

Figure 3.5: Bone cement subjected to ultrasonic waves.

Table 3.3 shows that there was no effect on bone cement, for the entire range of ultrasonic waves' frequencies that were applied.

Table 3.3: **The effect of ultrasonic waves' frequency on bone cement.**

Freq	TIME	V	Heating effect
20.5 kHz	30 min	105V	No effect (did not soften)
30.5 kHz	30 min	105V	↓
40.5 kHz	30 min	105V	
50.5 kHz	30 min	105V	
60.5 kHz	30 min	75V	No effect (did not soften)

The frequency of ultrasonic waves was reduced to 12k (Hz) (considered as Acoustic waves, and lower frequency waves penetrate deeper into solids).

There was an increase in the temperature of the sample, especially on the side that was exposed to the waves directly, However, it had no effect on the bone cement as it is shown in table 3.4.

Table 3.4: **The effect of Acoustic waves on the bone cement**

Freq	Time	T1(Star)	T2(Star)	T1(en)	T2(en)	Heating effect
12 kHz	15 min	28℃	26℃	37.3℃	35.1℃	No effect
↓	30 min	28℃	26℃	38.1℃	35.9℃	No effect
	45 min	28℃	26℃	38.8℃	36.6℃	No effect
	60 min	28℃	26℃	39.4℃	37.1℃	No effect

3.2.2 The effect of ultrasonic waves on the interface of bone cement and metal 'implant'

In these experiments, the transducer was used as a source for ultrasonic waves, on a sample of bone cement containing a metal rod used as an implant as shown in Fig 3.6.

The aim of these experiments was to determine the effect of ultrasound on the interface between the metal implant and the bone cement surrounding it.

During these experiments, ultrasound was introduced on the cylindrical sample of 'implant' and bone cement, from different directions as shown in Fig 3.7 Frequencies between 20Hz and 20MHz were experimented with, for fifteen minutes time periods of application, however, no positive results were obtained as seen in Table 3.5.

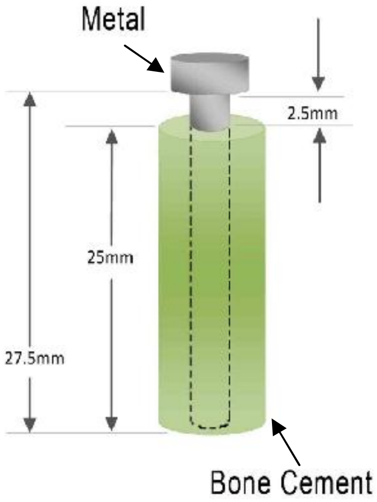

Figure 3.6: Bone cement (Cylindrical sample) containing a metal rod as an ‘implant’ for the ultrasonic experiments

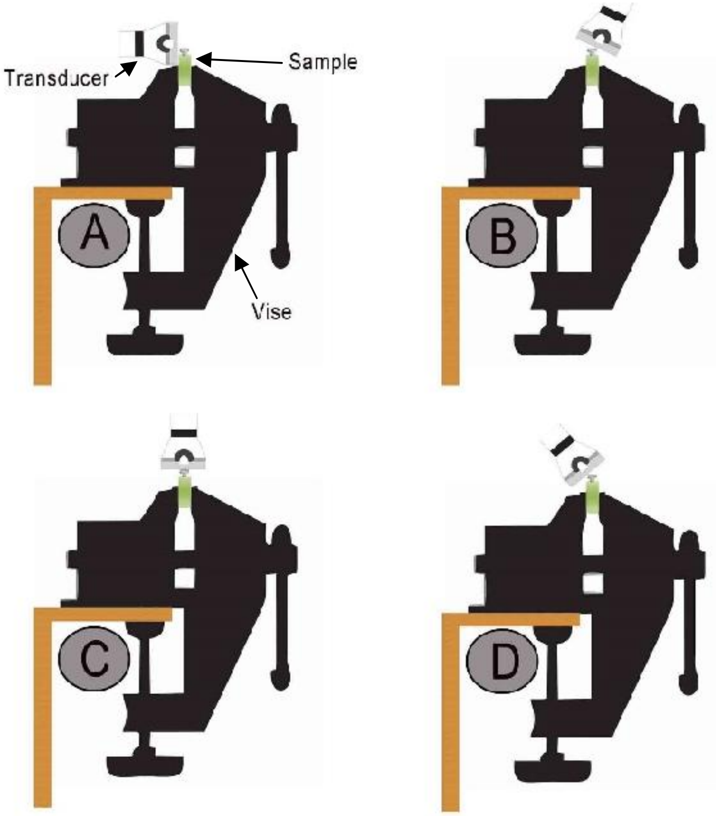

Figure 3.7: Introduction of ultrasonic waves on the cylindrical sample from different orientations

Table 3.5: Application of ultrasonic waves on the samples of cement and 'implant' from different orientations.

Experiments in positions A, B, C, D (in respective blocks)

Freq	Time	V	WAVE	Effect	notes
20kHz	15 min	108V	Square	NO	No cracks or separation
60kHz	15 min	90V	Square	NO	↓
90kHz	15 min	75V	Square	NO	
1MHz	15 min	75V	Square	NO	
2MHz	15 min	97V	Square	NO	
Freq	**Time**	**V**	**WAVE**	**Effect**	
20kHz	15 min	108V	Square	NO	
60kHz	15 min	90V	Square	NO	
90kHz	15 min	75V	Square	NO	
1MHz	15 min	75V	Square	NO	
2MHz	15 min	97V	Square	NO	
Freq	**Time**	**V**	**WAVE**	**Effect**	
20kHz	15 min	108V	Square	NO	
60kHz	15 min	90V	Square	NO	
90kHz	15 min	75V	Square	NO	
1MHz	15 min	75V	Square	NO	
2MHz	15 min	97V	Square	NO	
Freq	**Time**	**V**	**WAVE**	**Effect**	
20kHz	15 min	108V	Square	NO	
60kHz	15 min	90V	Square	NO	
90kHz	15 min	75V	Square	NO	
1MHz	15 min	75V	Square	NO	
2MHz	15 min	97V	Square	NO	

Several attempts were also made to separate the components of the cylindrical sample by ultrasound waves, for different times of application, however, there was no positive effect observed.

3.2.3 The effect of vibration on implant, bone, and bone cemen

In these experiments, two devices were used as source for mechanical vibration, and various samples in terms of size were utilized as is detailed in the following sections.

3.2.3.1 The effect of mechanical vibration on a cylindrical sample using a vibration generator.

During these experiments, a laboratory vibration generator as shown in Fig.3.8 was used as a source to transfer vibrations to the sample of bone cement containing a metal rod identical to the one shown in Fig 3.6.

The aim of the experiment was to determine the effect of mechanical vibration on the interface between the metal implant and the bone cement surrounding it. In the literature survey it was noted that the possibility of separating the implant from the bone cement by a mechanical effect (vibrations) could be more effective as well as desirable than attempting to change the chemical properties of the bone cement sample by heating, melting etc.

Figure 3.8: A Laboratory Vibrations Generator

Figure 3.9 shows a schematic diagram of the apparatus for the experiment. The vibration generator was fixed in a Vise while the sample of bone cement and ‘implant’ was fixed by a clamp so that the implant’s head touched the output shaft of the vibration generator.

In this arrangement, a vibratory motion was transmitted directly from the vibrations generator to the sample’s implant.

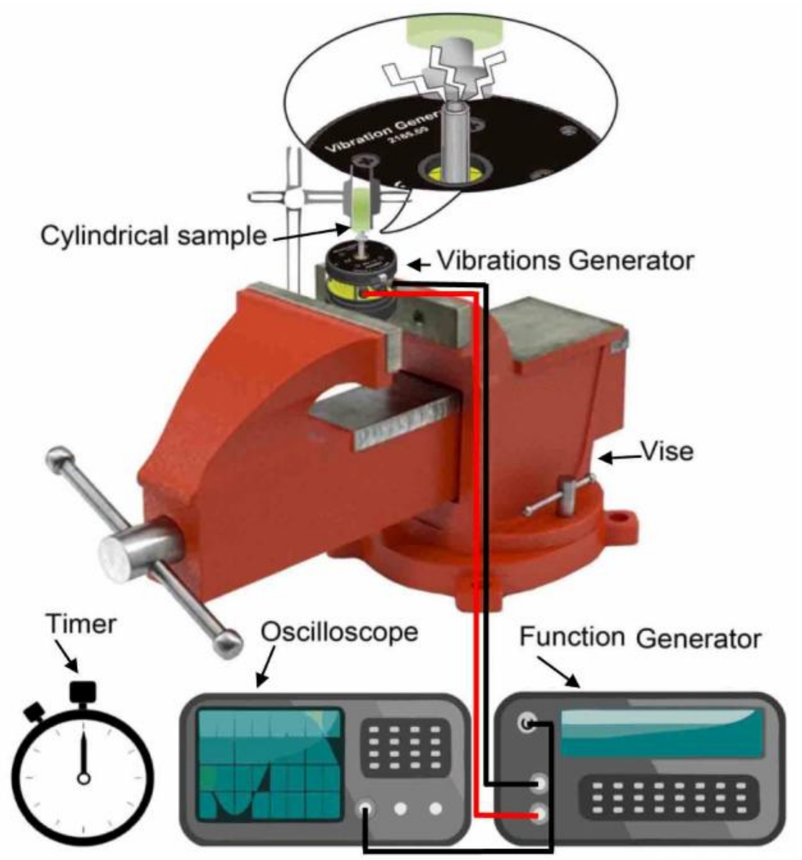

Figure 3.9: Using a vibrations generator directly acting on the sample's implant.

Three vibrational frequencies were selected to be outputted by the vibration generator (30Hz, 50Hz, and 80Hz) while the sample was being observed for possible effects. Table 3.6 shows that there was no effect when the sample was exposed for 15 minutes at each frequency, but when the sample was exposed for a lengthier time (reached 60 minutes) a positive effect was observed., A crack appeared in the bone cement and the 'implant' could easily be removed or separated from the bone cement.

Table 3.6: The effect of frequency of mechanical vibration and time of its application

Freq	Time	WAVE	Effect	notes
30Hz	15 min	Square	NO	No cracks
50Hz	15 min	Square	NO	No cracks
80Hz	15 min	Square	NO	No cracks
80Hz	60 min	Square	yes	Cracks at bone cement+ implant separation

3.2.3.2 The effect of mechanical vibration on cylindrical sample using copper, aluminium and plastic as bone.

During these tests, cylindrical bone cement samples were used as shown with their dimensions in Fig 3.10 Instead of bone to contain the bone cement and 'implant' other materials (copper, aluminium, and plastic tubes) were used. The brand name of the bone cement used was (DePuy) is shown contained in its original packaging (Fig 3.11).

The aim of these experiments was to determine the effect of mechanical vibrations on the interface between the metal implant and the surrounding bone cement. Also a possibility of an effect of the vibrations on the bone cement interface between the materials used as a bone (copper, aluminum, and plastic).

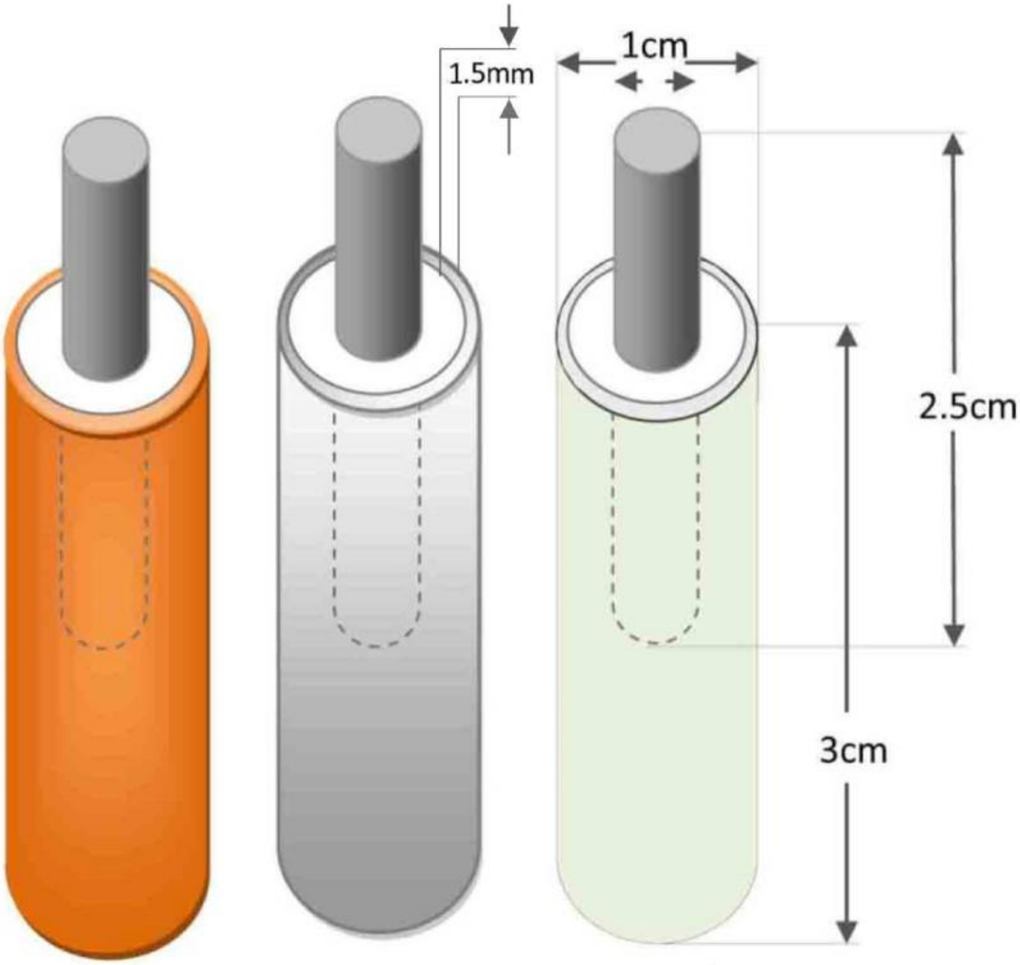

Figure 3.10: cylindrical bone cement samples with dimensions

Figure 3.11: DePuy (Bone Cement).

The three samples were tested so that each sample was subjected to frequencies ranging from 20 Hz to 65 kHz, for a period of 15 minutes for each frequency, however, no positive effect was observed as indicated in Table 3.7

Table 3.7 No positive effect was observed on the three samples (copper, plastic, and aluminum)

Copper tube				
Freq	**Time**	**WAVE**	**Effect**	**notes**
20Hz	15 min	Square	NO	No cracks
50Hz	15 min	Square	NO	No cracks
80Hz	15 min	Square	NO	No cracks
65kHz	15 min	Square	NO	No cracks

Plastic tube				
Freq	**Time**	**WAVE**	**Effect**	**notes**
20Hz	15 min	Square	NO	No cracks
50Hz	15 min	Square	NO	No cracks
80Hz	15 min	Square	NO	No cracks
65Hz	15 min	Square	NO	No cracks

Aluminium tube				
Freq	**Time**	**WAVE**	**Effect**	**notes**
20Hz	15 min	Square	NO	No cracks
50Hz	15 min	Square	NO	No cracks
80Hz	15 min	Square	NO	No cracks
65Hz	15 min	Square	NO	No cracks

In an identical set-up to the one depicted in figure 3.9, the experimental protocol as described in section 3.2.3.1 was repeated however in this instance holes were drilled in the bone cement at the boundary with the tubular material (plastic, copper, aluminium) pretending or substituted as being the bone. Using a Pillar Drill, holes were made as depicted in Figure 3.12 to diminish or weaken the cement bonding with the 'bone' but the results were not positive.

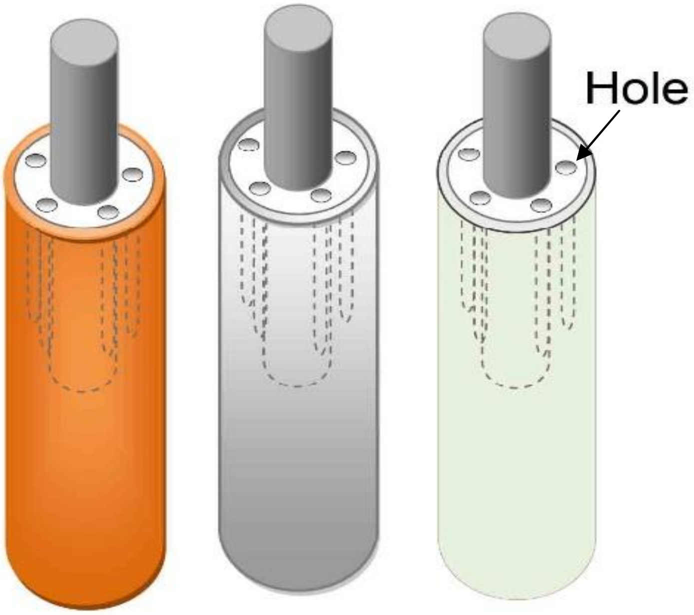

Figure 3.12: **Holes extending from the sample's surface to its middle with view to weaken the bond between 'bone' and cement**

The following possible reasons attempt to explain why there were no positive results:

- The first reason is that the contact force aided by the vibration is not enough in magnitude to separate the bone cement from the surrounding tube (copper, aluminum, plastic) in a reasonable time interval**.**
- The second reason is that the process of holding the pipes (copper, aluminum, plastic) needs to be altered to avoid compressing the sample and increasing the adhesion between the inner surface 'of the bone and the cement.
- The third reason is probably the process of transferring the vibration from center tap to the metal rod was not efficient.

3.2.4 Using a Rotary Hammer Drill as a source of vibration

During these experiments, a Rotary Hammer Drill was used as a mechanical vibration source to transfer vibrations to the test samples comprised of bone, cement, and implant.

The vibration and force obtained using the rotary hammer was expected to be higher in magnitude to those of the vibration generator.

Figure 3.13 shows the rotary hammer drill with an adapter to transfer the (axial hammering) vibration to the sample. The frequency of the vibrations depends on the speed of rotation of the drill.

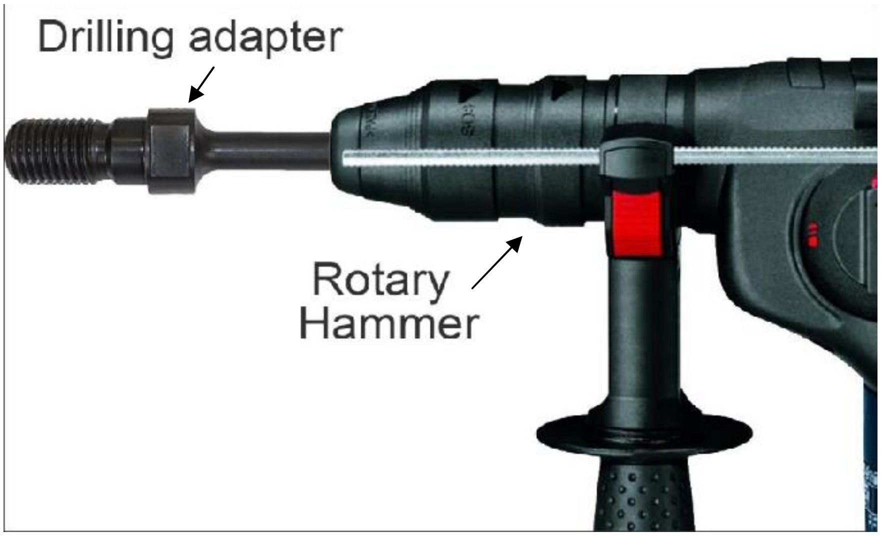

Figure 3.13: **A Rotary hammer with a drilling adapter**

The accelerometer used as a sensor recorded the frequency of vibration during the experiments with the Rotary hammer is shown in Fig 3.14.

Figure 3.14: **vibration sensor.**

The implants used in the samples for these experiments were of two types. The first type that was used in the small size samples, were metal (mild steel) rods ‘implants’ as shown in Figure 3.15. They were used with bone, plastic tube, aluminum tube, and copper tube.

Figure 3.15 Metal rods used as ‘implants’ for small samples

The second type, were real implants, those used in artificial joints of the human body, as shown in Figure 3.16, and in Figure 3.17 as an example when used in the human bone in total knee replacement.

Figure 3.16 Samples of real implants for use on humans

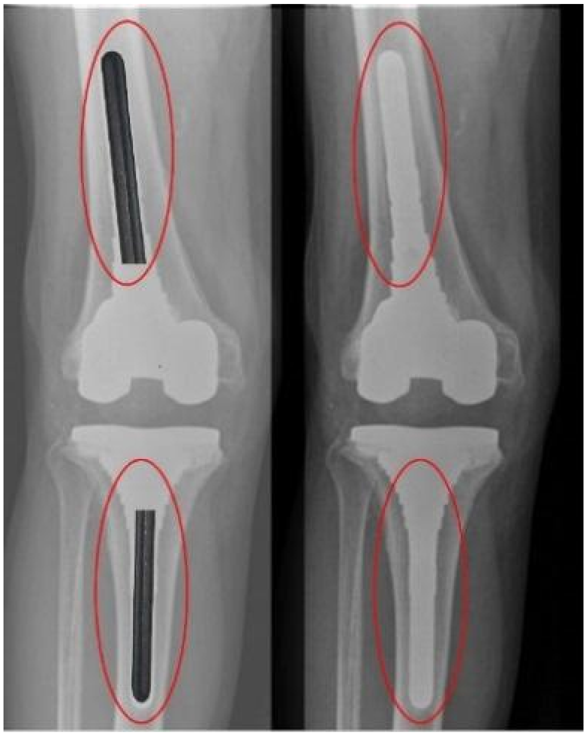

Figure 3.17: **Demonstrates the location and position of implantation within the bone in human total knee replacement** [76].

The ‘real’ implants were used in experiments with animal bones (see figure 3.18).

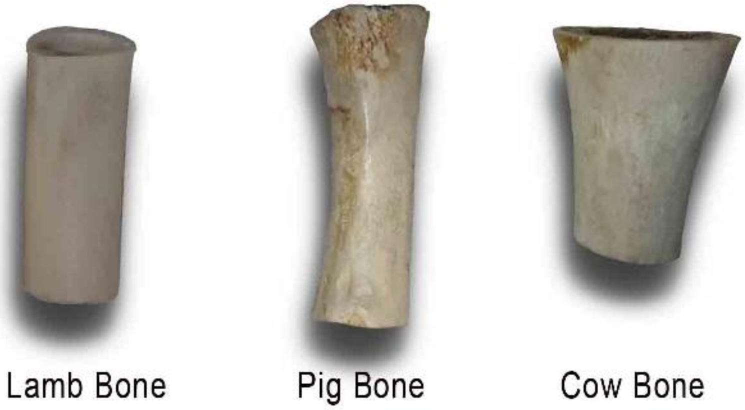

Figure 3.18: **Samples of the bones used with the real implants.**

3.2.4.1 The basic idea of the experiments: to separate the sample’s components

Several experiments were carried out with samples similar to the one shown in the schematic diagram Figure 3.19. All experiments aimed to separate the aluminium cylinder from the bone cement which contained the implant (ideal case) or the metal rod from the bone cement (not really desired since it left cement attached to the ‘bone’), using vibration. In each experiment, there was a gradual change in the intensity of vibration and extent or time of application

The schematic diagram in Figure 3.19 together with the following narrative, serves to summarize the physics of force/vibration application and how to handle/secure the sample so that the force/vibration on it, has the desired effect of separating the cement mass containing the implant, from the ‘bone’. With such a result there would be no further onerous task for the surgeon of having to remove cement from the bone cavity.

- It was desired to hold the sample tightly in a balanced manner by the source of vibration and apply an axial tension on the implant
- Arrange that the reaction to the applied tensile force on the implant is felt directly on the sample’s edge/end surface of the cylinder (‘bone’)
- The frequency of the vibration to be gradually changed during the experiments in order to establish the effective vibration for the desired separation of the components.

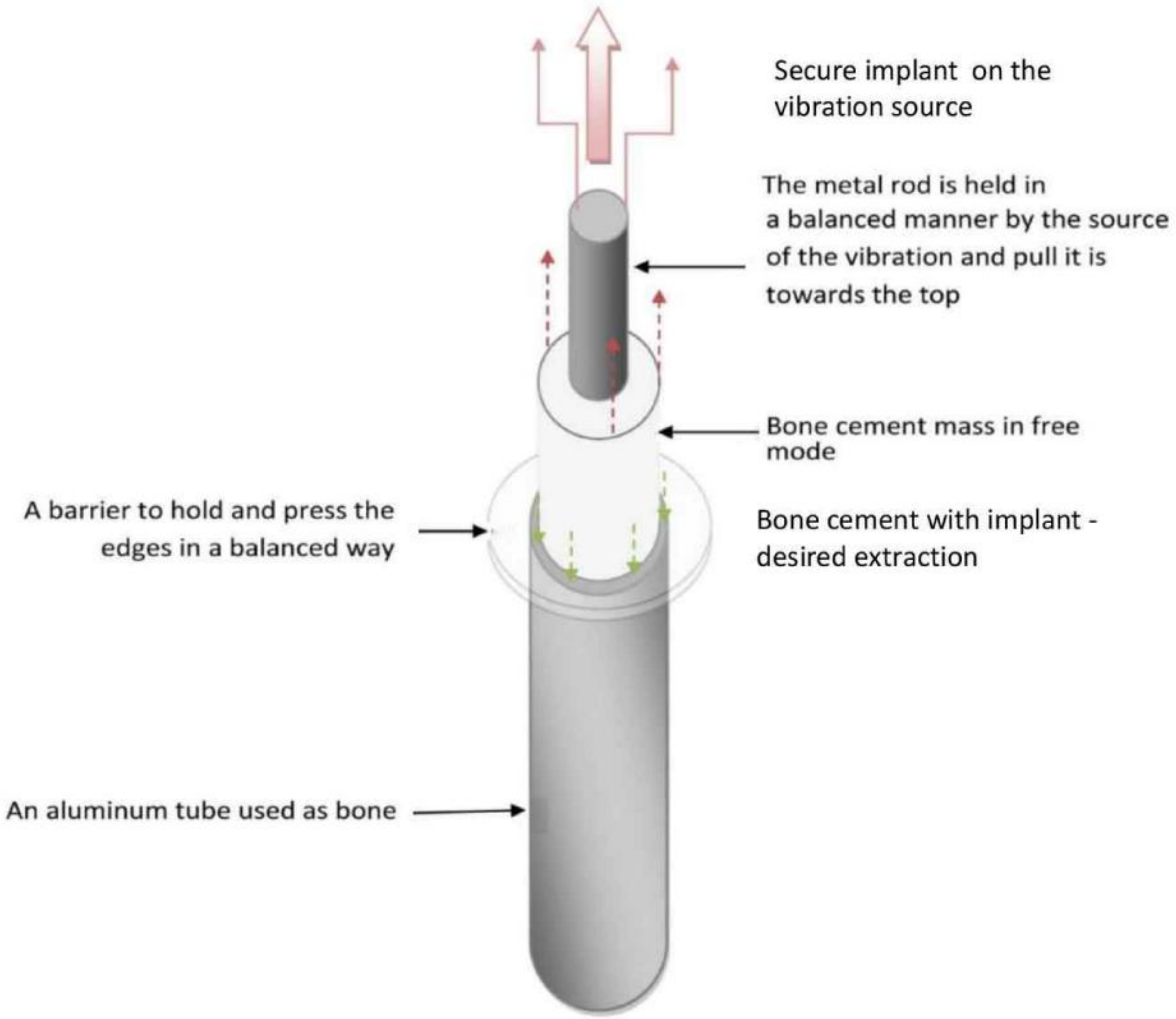

Figure 3.19: The physics of applying a vibration to the experimental samples

3.2.4.2 Developing the final model of sample-holding when using a Rotary Hammer Drill as a vibration source.

The process of methodically developing a model to hold the sample helped greatly in reaching positive results. Figure 3.20 is presented for the benefit of the reader. It represents a schematic of the whole assembly of the vibration source, the mechanism of transmitting the vibration to the sample, and the holding of the sample.

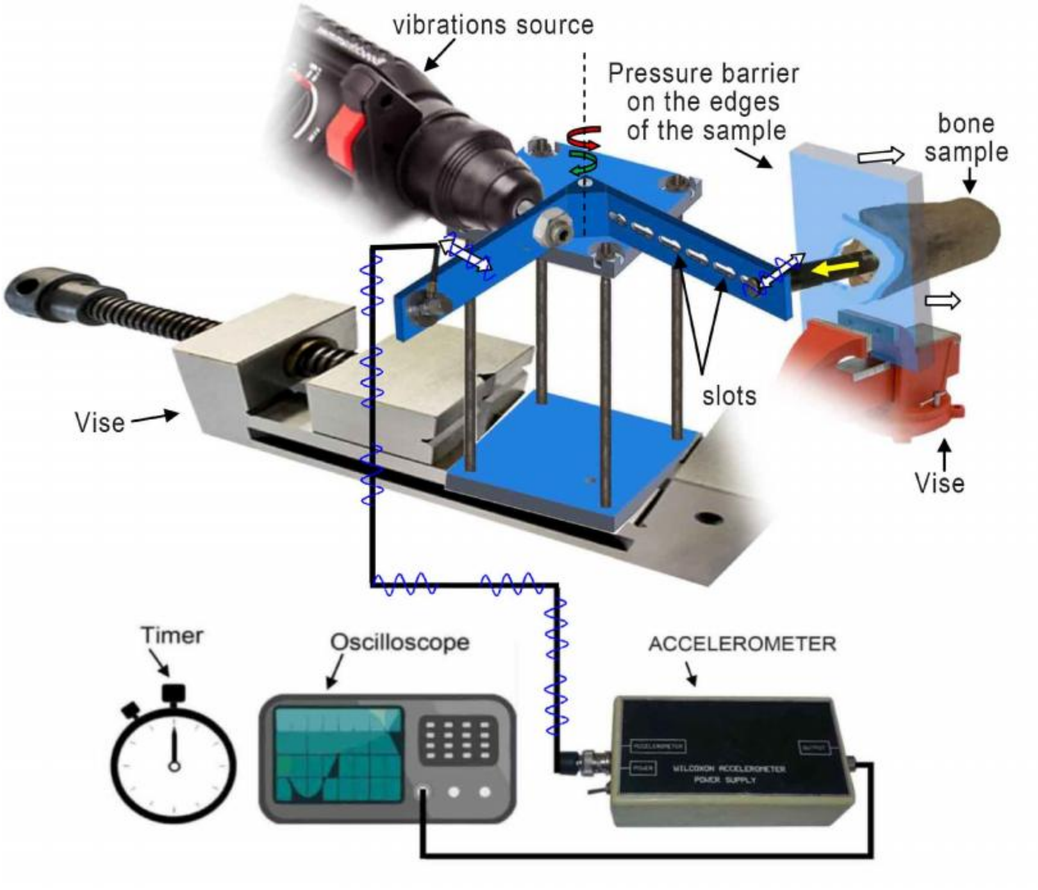

Figure 3.20: The final form of the model or the experimental set-up

The model or apparatus used in the final experiments as seen in Figure 3.21 above, has a central component which may be called 'vibration connector', which enables connecting or transmitting the vibration from the source to the head of the implant. It is fashioned after the classical 'bel crank' mechanism where mechanical advantage can easily be accomplished. In this case the different slots at distances away from the pivot point accomplish mechanical advantage in addition to the directional change (90 degrees) of the force/vibration applied. Figure 3.21 is a detail drawing of the 'vibration connector.

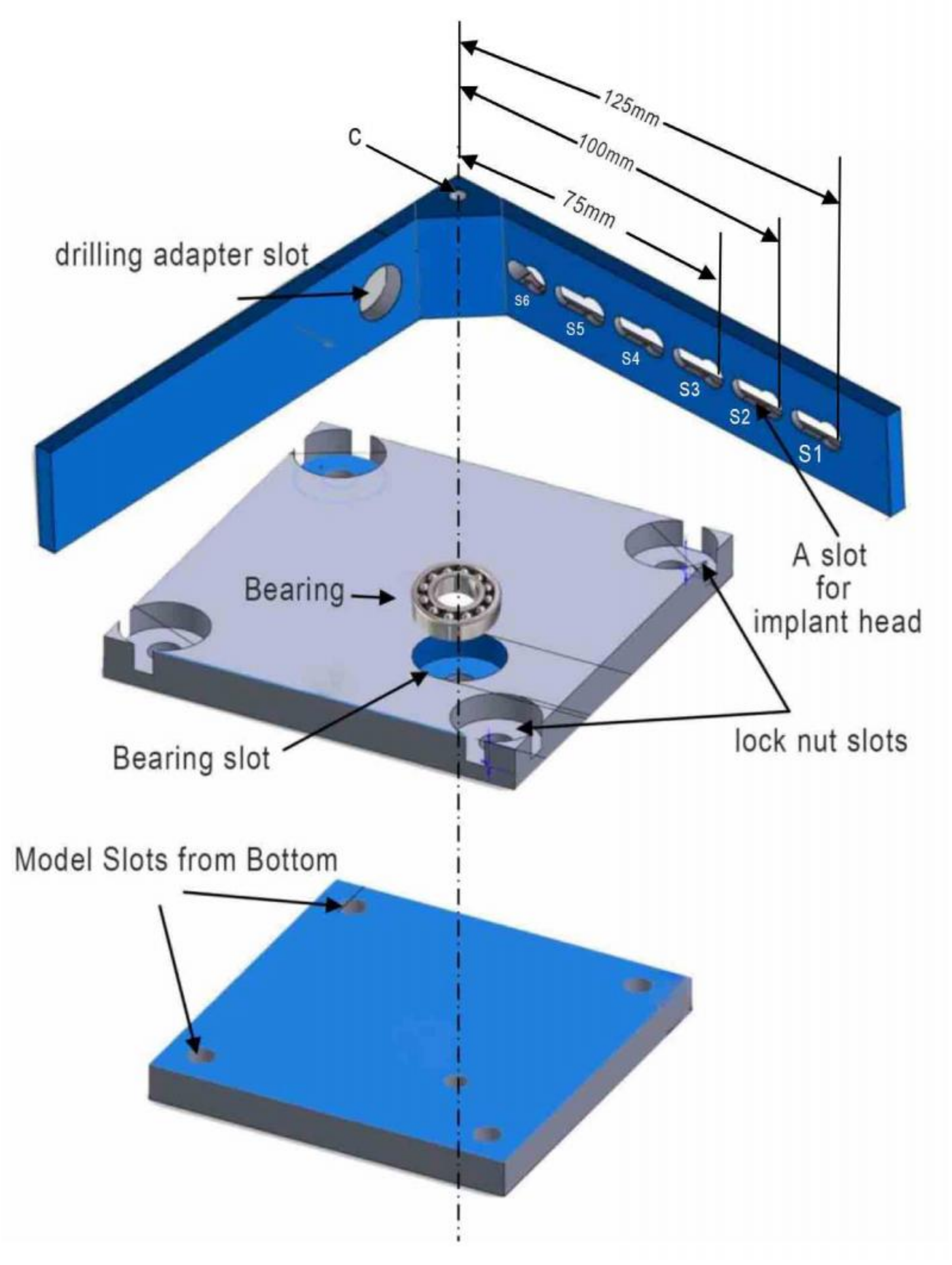

Figure 3.21 Detailed drawing or features of the 'vibration connector'

3.2.4.3 Experiments to determine the best frequency of the vibration source using the final apparatus.

After finishing the final form of the model/experimental set-up, a G clamp was used to regulate the pressure on the vibration source's (hammer drill) speed control button, shown in figure 3.22. In this manner, the vibration frequency was adequately controlled i.e. with stability or constancy.

Figure 3.22 Control of vibrational frequency by pressing the speed button of the hammer drill, using a G clamp.

Table 3.8 and figure 3.23 shows the typical results of a group of experiments that were performed. During this type of experiment the distance between the implant's head and pivot point was kept constant (125 mm), and the vibrational time for the chosen frequency was monitored until a result was obtained. As shown, the vibration of 40 Hz was more effective than other frequencies in that the implant was removed with the mass of cement together (i.e. ideally) at the shortest time (22 sec.)

Table 3.8 The distance between the pivot point and the implant head constant (125 mm) at different frequencies until a result was obtained

no	Freq	Time	Distance c.....to.....s(s1)	Effect on the sample
Sample 1	10 Hz	41 sec	125 mm	The implant was removed and the cement stayed inside the tube
Sample 2	20 Hz	39 sec	125 mm	The implant and the cement moved a little bit
Sample 3	30 Hz	22 sec	125 mm	The implant was removed but the cement remained partly in the tube
Sample 4	40 Hz	20 sec	125 mm	**The implant with cement removed as one mass**

Figure 3.23 Effect of frequency at a given distance on similar samples

3.2.4.4 Obtaining the best distance between the pivot point and implant head.

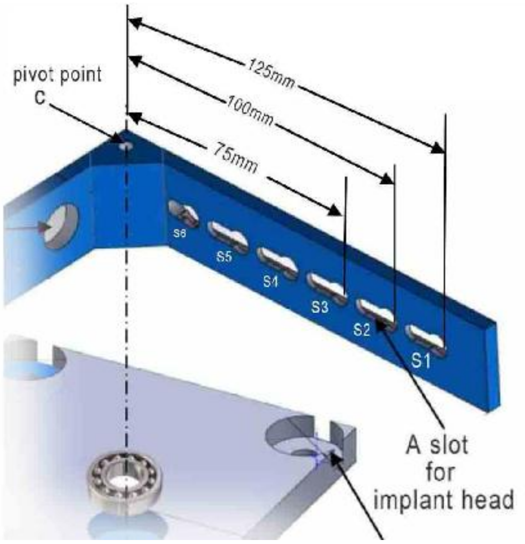

Figure 3.24: Distances between the pivot point (c) and slots(S1, S2...S6.)

A series of experiments were performed to determine the best distance from the pivot point to the implant in order to remove it ideally i.e. together with the bone cement.
Previously through experiments described in 3.2.4.3 the frequency of (40 Hz) was obtained or determined to be the most effective when the sample was subjected to vibration using the particular hammer drill. However, that was obtained for a fixed distance of 125 mm between the pivot point and the point of contact with the implant's head, which is one of the six available distances on the 'Vibration Connector" (see figure 3.24 above).

3.2.4.5 Experiments to determine the best distance between pivot and implant's head

A number of experiments were conducted, with specimens subjected to a constant frequency of 40 Hz, by positioning the implant's head at the five different distances from the pivot head, as provided on the 'vibration connector'. The sixth distance (the shortest) was not utilized because it did not offer any mechanical advantage. The time when a result was observed/obtained was recorded. The results are shown in Figure 3.25 and particularly in Table 3.9 where the shortest time (21 sec) of applying vibration yielded the ideal effect, at the 'distance' of 75 mm.

Table 3.9 **Determining the optimum 'distance' (between the pivot point and the implant's head) based on application time. Vibration at constant frequency (40 Hz).**

no	Freq	Time	Distance c.....to.....s(s1,s2...)	Effect on the sample
Sample 1	40 Hz	31 sec	125 mm(s1)	**The implant with cement removed as one mass**
Sample 2	40 Hz	28 sec	100 mm(s2)	**The implant with cement removed as one mass**
Sample 3	**40 Hz**	**21 sec**	**75 mm(s3)**	**The implant with cement removed as one mass**
Sample 4	40 Hz	22 sec	50 mm(s4)	**The implant with cement removed as one mass**
Sample 5	40 Hz	25 sec	25 mm(s5)	**The implant with cement removed as one mass**

Figure 3.25: Using vibration at a frequency of 40 Hz and varying the distance between the pivot point and the implant's head. Recording the time when positive result occurred.

The final experiments that were conducted, using the frequency of vibration (40Hz) and the distance (75mm) between the head of the sample and pivot point, confirmed the expected results. Using the animal bones to encase the cement and implant, the ideal results were obtained in a short time. Figure 3.26 and Table 3.10 illustrate the above.

Table 3.10: Positive results after optimizing the 'distance' and vibrational frequency

no	Freq	Time	Distance c.....to.....s	Effect on the sample
Sample 1	40 Hz	22 sec	75 mm	The implant with cement removed as one mass
Sample 2	40 Hz	19 sec	75 mm	The implant with cement removed as one mass
Sample 3	40 Hz	20 sec	75 mm	The implant with cement removed as one mass

Figure 3.26: Positive results with animal bones encasing the cement and implant at optimum distance and frequency of vibration.

CHAPTER 4

SUMMARY OF THE EXPERIMENTAL RESULTS CONCLUSIONS AND RECOMMENDATIONS

4.1 Introduction

The findings of this study suggest that mechanical vibration can be used to remove the implant and bone cement from a bone cavity, within an acceptable time, during surgery.
At the beginning of the study, during the early experiments, the aim was to obtain acceptable results by using heat and/or ultrasonic waves in an attempt to melt or loosen the bone cement. The idea, however, was quickly abandoned (because of the unsatisfactory results that were being obtained from the experiments), and focus was placed on applying mechanical vibrations in order to loosen or break the cohesion between the basic components: implant, bone cement, and bone.

4.2 Summary of the results of the experiments using heat, ultrasound, and vibrations

4.2.1 The effect of heat on bone cement

During the experiments on the samples of bone cement described in section 3.2.1, two devices were employed as a source of heat, namely a hair drier and a heat gun.

Using a hair dryer (section 3.2.1.1) the bone cement could not be softened to safe low enough temperatures and within a reasonable time period. The temperature of the bone cement sample reached 160℃ the bone cement became soft enough to be removed from any cavity. However, besides the very high temperature, the procedure took a long time (about 2:13:00).

Using the same shape and size of samples of bone cement, a Heat gun was employed in an attempt to reduce the excessively long time to soften them. Although the time recorded (for the sample to soften) was 120 seconds, the temperature generated by the heat gun was equally high and dangerous (it reached 172℃). Such temperatures cannot be tolerated in surgical procedures even for 120 seconds because it would cause burns to the tissues of the body and bones.

4.2.2 The effect of ultrasound waves on bone cement

Since it is confirmed that ultrasound is safe on the human body [21], the idea sprang, to use it in order to generate collisions of the bone cement's molecules and possibly loosen their cohesion. Ultrasonic waves in the frequency range of 20.5 kHz to 60.5 kHz on samples exposed for long periods of time (up to 30 minutes), the conclusion was that ultrasound waves were not effective, to separate the bone cement from the implant by weakening the cohesion between them.

4.3 The effect of mechanical vibration on bone cement

During the experiments on samples of bone cement as described in sections 3.2.3 two devices were employed as a source of mechanical vibrations namely a Laboratory Vibrations Generator and Rotary Hammer Drill.

4. 3.1 The effect of vibration on bone cement using a laboratory vibrations generator

In section 3.2.3.1, it was described how a laboratory Vibration Generator device was used attempting to separate the ‘implant’ from the bone cement and ‘bone cavity’ on various samples that were tested.

Different frequencies were applied on samples, in the range from 30 Hz to 80 Hz. The extend of time of applying vibration on each sample was 15 minutes. However, the results were not positive, and upon reflection, it was thought to apply the vibration on the sample for a longer period of time.
The period of time of applying vibration was extended, and at the frequency of 80 Hz, after approximately 60 minutes the bone cement was cracked making it easier to remove the implant. However, the time that it took to obtain the positive result was judged to be too long to endure in a real situation such as a surgical operation.

4.3.2 Discussion of the effect of vibration on bone cement using a Rotary Hammer

In section 3.2.4 the use of another vibration source has been described., It was thought that a more powerful source of vibration employed as described in section 3.2.3.1, (Laboratory Vibration Generator), was needed. The rotary hammer drill was therefore primarily attempted as a source of applying vibration to the ‘implant/cement/bone’ samples, In order to reduce the procedural time of vibrating the sample until its components could be separated.

The rotary hammer drill needed an adapter in order to come into grip with the ‘implant’s’ head as well as accommodating for a change of direction of the vibration relative to the implant.

The design of a mechanical adapter which besides providing various positions of the mechanical advantage of transmitting the contact force of the vibration, it also allowed for the change of direction of the vibration from its source to the application was described in section 3.2.4.2

Experiments were performed in order to obtain an optimal frequency, which was 40 Hz.
Several experiments were also carried out in order to obtain the mechanical advantage of transmitting the vibration to the implant. As described in section 3.2.4.5. The ideal distance between the pivot and the implant’s head of 75 mm was recorded as the best distance to work with the model.

Several experiments as described in section 3.2.4.5 with a variety of samples yielded good or acceptable results of the separation of the components of the samples in times that ranged from 19 to 22sec.

4.4 Conclusion

In this study, the preliminary experiments that were carried out by heating the samples confirm what was reported in the literature by previous studies [25,73]. Only high temperatures can soften bone cement, and when dealing with the human body, it would cause burns or damage to tissue or bones.

Studies (as reported in the literature [43–45] have confirmed that ultrasound is not harmful to the organism and does not cause any complications. After a series of experiments carried out in this study, it was found to be difficult to soften bone cement by the use of ultrasonic waves, contrary to what was reported in a previous study (OSCAR3) [21].

The results of this study obtained by using a rotary hammer drill as a vibration source yielded reasonable/acceptable results of the separation of the components of the samples. The procedure appears to be safe and is accomplished in a short time, commensurate with what is required in the replacement of joints in surgical operations.

4.5 Recommendation for future work

Using the basic component (The Rotary Impact Drill as a source of mechanical vibrations), ‘adaptors’ should be designed to enable its use on all joints in the human body and thus enable the ease of movement of the orthopaedic surgeons during surgery**.**

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APPENDIXES

Appendix A: The detailed description of measuring instruments and auxiliary equipment

Appendix A-1: Thermocouple reading

Thermocouple thermometer / digital / hand-held (CL3515R is a portable calibrator/ thermometer,
mV signal output, 2channels for Thermocouple temperature Measurement (T1 and T2) with offset Adjustment Ergonomic Rotary Knob Allows for one - Handed operation.
See figure A.1.

Figure A-1: Thermocouple reading

Appendix A-2: Transducer

60W 40KHz High Conversion Efficiency Ultrasonic Piezoelectric Transducer,
Large amplitude, piezoelectric ceramic materials provides good heat resistance.
Frequency: 40KHz. 1x transducer. Power: 60W. Homogeneous sounding board, see figure A-2.

Figure A-2: Transducer

Appendix A-3: Laboratory Vibrations Generator

A generator for producing mechanical vibrations when used with a signal generator. The input is fed to a coil, which is mounted within the field of a cylindrical permanent magnet. The unit is electrically secured by means of a fuse.
Dimensions: 100 x 100 x 120mm, , see figure A-3.

Figure A-3: A Laboratory Vibrations Generator

Appendix A-4: Function Generator

Frequency Range: 0.3Hz~3MHz

Waveforms: Sine, Triangle, Square, Ramp, TTL and CMOS Output

External Voltage Controlled Frequency (VCF) function

Two-Steps (-20dBx2) and Variable Attenuator

Built-in 6 Digits Counter with INT/EXT Function up to 150MHz, see figure A-4.

Figure A-4: Function generator

Appendix A-5: Analogue High Power Amplifiers

LE 150/100 EBW
Voltage range: 0V/+150V
Manual setting of DC-Offset (superimposed to external signal)
Variable attenuation, 70 kHz bandwidth (-3 dB), see figure A-5.

Figure A-5: Analogue High Power Amplifiers

Appendix A-6: DSO3062A Oscilloscope,60MHz

2 channels, 4kpts memory depth, 1GSa/s sample rate.
Color VGA display with 320X240.
Analysis: 20 automatic measurements, 4 math functions including FFTs.
see figure A-6.

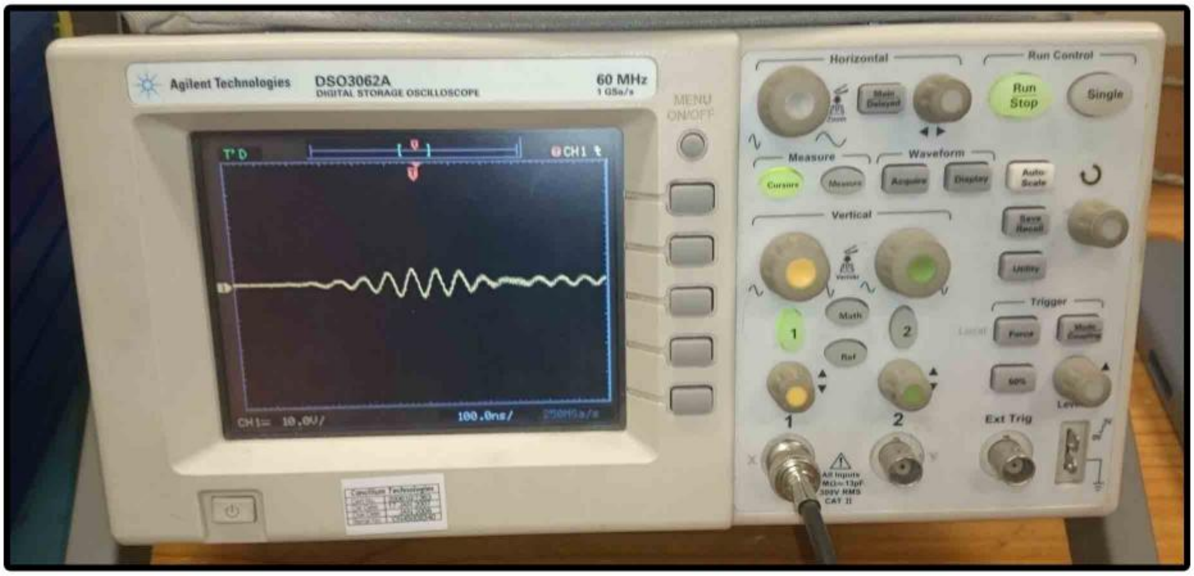

Figure A-6: Oscilloscope