QUALITY OF HEAT-ACTIVATED ACRYLIC DENTURE BASE RESINS CURED USING IMPROVISED TECHNIQUES IN PRIVATE DENTAL LABORATORIES IN NAIROBI, KENYA

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Thesis submitted in partial fulfillment of the requirements for the award of Masters of Dental Surgery Degree in Prosthodontics, Department of Conservative and Prosthetic Dentistry, School of Dental Sciences, University of Nairobi

AUGUST 2017

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I, Dr. Kaaria Mwirigi Mburu, V60/75834/2014 of College of Health Sciences, School of Dental Sciences, Department of Conservative and Prosthetic Dentistry, declare that this thesis titled "**QUALITY OF HEAT-ACTIVATED ACRYLIC DENTURE BASE RESINS CURED USING IMPROVISED TECHNIQUES IN PRIVATE DENTAL LABORATORIES IN NAIROBI, KENYA"** is my original work.

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DEDICATION

This work is dedicated to our son, Leon Mwaki Mwirigi.

ACKNOWLEDGEMENTS

First, I thank the Almighty God for good health and strength to accomplish this task.

Secondly, I would like to thank the following people:

My supervisors Dr. B K Kisumbi, Dr. J M Nyaga and Prof. F.G. Macigo of the University of Nairobi, School of dental sciences, for their immense support, forbearance and dedication.

The staff in the prosthetic laboratory of the School of Dental Sciences, University of Nairobi, who spared no effort to ensure the experimental work was completed in time. Special mention of Mr. Josphat Miyogo, Mr. Dennis Kota and Mr. Albert Mulewa for going the extra mile.

All the dental technologists who consented to participate in this study and allowed me into their private dental laboratories.

The staff at the Materials Testing Laboratory at the Kenya Bureau of Standards, in particular, Dr. Geoffrey Muriira and Mr. Boniface Mbithi for their generosity, dedication and tireless efforts to ensure the analytical work met international standards. In addition, I would like to thank Mr. Stephen Ndeti for assisting with the Vickers Hardness Tests.

My employer and sponsor, the University of Nairobi for giving me time off to study and for waiving the fees.

Mr. Desmond K'Owino of the School of Dental Sciences, University of Nairobi, who helped me with the data analysis.

And lastly, my dear wife and colleague Dr. Laura Edalia-Mwirigi for walking with me every step of the way.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

ANOVA	Analysis of variance
BDS	Bachelor of Dental Surgery
HAADBR	Heat-activated acrylic denture base resin
HPLC	High Performance Liquid Chromatography
ICT	Improvised Curing Technique
ISO	International Standards Organization
KNH	Kenyatta National Hospital
KHN	Knoop Hardness Number
LSD	Least Significant Difference
Mcg	Micrograms
MDS	Master of Dental Surgery
MHz	Mega Hertz
MMA	Methyl Methacrylate Monomer
MPhil	Master of Philosophy
Nbi	Nairobi
PMMA	Poly (Methyl Methacrylate)

PPM	Parts per million
SPSS	Statistical package for social sciences
UON	University of Nairobi
UV	Ultraviolet
VHN	Vickers Hardness Number
Wsi	Water solubility
Wsp	Water Sorption
Wt	Weight
µL	Microlitre

DEFINITION OF TERMS

Curing – Chemical reaction in which low-molecular-weight monomers or small polymers are converted into higher – molecular-weight materials to attain desired properties**.**

Denture Base Resin –That part of a complete or partial denture that rests on the basal seat and to which teeth are attached.

Monomer – A chemical compound capable of reacting to form a polymer.

Polymer – A chemical compound consisting of large organic molecules formed by the union of many repeating smaller monomer units.

Polymerization – Chemical reaction in which monomers of a low molecular weight are converted into chains of polymers with a high molecular weight.

Improvised curing technique – An alternative method used in the processing of heat-activated acrylic denture base resins in the absence of the recommended equipment.

High performance liquid chromatography - Is a technique in analytical chemistry used to separate, identify, and quantify each component in a mixture.

ABSTRACT

Background: Heat-activated acrylic resin based complete and removable partial dentures polymerized using improvised curing techniques are common in private dental laboratories in Nairobi, Kenya. There is no information regarding whether these improvised techniques have control for time and temperature which has a great impact on the quality of the final product obtained.

Objective: To evaluate the quality of heat-activated acrylic resins polymerized using improvised curing techniques in private dental laboratories in Nairobi.

Study Design: The pilot study was a descriptive cross-sectional study of the improvised curing techniques followed by an exploratory quasi-experimental laboratory study.

Materials and methods: A pilot study using a self-administered questionnaire was conducted on all the 41 registered private dental laboratories to identify techniques used to process heat-activated acrylic denture base resins (HAADBR). A large number, 31 (75.6%) of the dental laboratories used improvised methods and equipment with no form of time and temperature regulation. Three of the improvised techniques were selected (ICT 1, ICT 2, ICT 3) based on frequency of application and ease of replication. Using each of the three ICT and a conventional curing cycle as control (1.5 hours at 73 °C and 0.5hrs at 100°C), four sets of twenty specimens were fabricated and evaluated for residual methyl methacrylate monomer content (MMA), indentation hardness, water sorption and solubility and examined for porosities. A single batch of a heat-activated acrylic resin *(Lucitone 199®)* was used and was manipulated according to manufacturer's instructions by the investigator.

The specimens for the evaluation of residual MMA and water sorption and solubility were fabricated by investing rectangular stainless steel moulds in type II gypsum (*Kalabhai*, *Kaldent*) in conventional denture flasks. The stainless steel mould had a lathe-cut circular depression at the center with a diameter of 50mm and a depth of 3mm and a flat stainless steel cover. Indentation hardness and evaluation of porosities specimens were processed by investing rectangular stainless steel blocks (65mmx40mmx3mm) in type II gypsum (*Kalabhai, Kaldent*) to produce moulds of the same dimensions. Specimens for residual MMA evaluation were refrigerated at 3°C in dark sealed polythene bags to minimize monomer loss for four (4) days. Residual monomer levels were evaluated using the High Performance Liquid Chromatography method (HPLC). Indentation hardness was evaluated using a Vickers hardness tester. Water sorption and solubility was evaluated after desiccation followed by storage of the specimens in distilled water in an oven maintained at 37°C±1 for seven days. Evaluation of presence of porosities was determined after sectioning each specimen lengthwise into three portions and visual examining for voids in the acrylic plates under natural lighting.

Data were analyzed using SPSS v.20 (IBM, Corp.) and presented in tables and figures. Statistical analysis of the properties evaluated was completed using One-Way analysis of Variance (ANOVA) and differences between means identified with Fisher's Least Significant Difference (LSD) Post Hoc test at a level of $p \leq 0.05$.

Results:

The mean residual MMA content observed for the three ICTs was higher than that of the control group 0.04%wt (± 0.01, SD) while ICT 2 exhibited the highest percentage 0.19%wt (±0.02, SD). Mean residual monomer in HAADBR cured with the other techniques were ICT1 0.13%wt

(± 0.04, SD) and ICT 3 0.12%wt (±0.01 SD). One-way ANOVA test revealed a statistically significant difference ($p=0.001$) in the means of residual MMA content in the specimens. Fisher's Least Significant Difference (LSD) Post Hoc Analysis Test for the ANOVA results revealed a statistically significant mean difference of the residual MMA between the control specimens and those processed using the three ICT. The mean Vickers' Hardness Number of the specimens processed using ICT 2 19.37 (±0.55 SD), was higher than that of the control cycle and this was statistically significant ($p< 0.001$).

The specimens processed by the control cycle showed higher mean water sorption levels (18.29 µg/mm^3±0.8, SD) than all the three ICTs. There was minimal mean solubility observed in the specimens processed using the ICT 3 (0.0017µg/mm^3). The levels of water sorption for the three ICT's and the control specimens differed marginally, ICT 1 17.18 µg/mm^3 (± 0.18 SD), ICT 2 18.00 µg/mm^3 (± 1.35SD), ICT3 17.87 µg/mm^3 (±0.37, SD) and control 18.29 µg/mm^3 (±0.81 SD).There was no statistically significant difference between the mean water sorption of all the specimens processed by each of the ICTs and the control. There were no porosities observed in all the specimens processed using the improvised curing techniques and the control cycle.

Conclusion: Majority of private dental laboratories in Nairobi used improvised curing techniques. Within the limits of this study, acrylic denture base resins processed with the improvised curing techniques studied are within recommended ISO standard values with regard to hardness, water sorption and solubility and porosity.

CHAPTER 1: INTRODUCTION

Loss of teeth and supporting tissues has a detrimental effect on the well-being of an individual. It may lead to compromised oral function, unacceptable appearance and loss of occlusal stability. The desire to replace missing teeth dates back to ancient civilizations and it continues to be one of the challenges a dentist faces to date[1]. The need to replace missing teeth has led to the development of materials over the years that are utilized in the replacement of missing teeth and supporting tissues. One of the materials that is widely accepted and utilized in the replacement of missing teeth is poly (methyl methacrylate) (PMMA) resin. It is used as a denture base material to support artificial teeth formed from different materials in complete or partial removable dental prostheses.

Poly (methyl methacrylate) (PMMA) was discovered in 1937, and has been used as a denture base material for over half a century [2, 3]. Although PMMA resins do not meet all the requirements of an ideal denture base material, they possess some of the desired properties namely; biocompatibility, strength and durability, satisfactory thermal properties, processing accuracy, dimensional stability, low sorption of oral fluids, moderate costs and ease of repair, natural appearance and absence of taste and color[4]. However, it does have shortcomings. One significant shortcoming is the residual methyl methacrylate monomer. It is thought that this may be responsible for hypersensitivity reactions in some individuals[5]. According to the ISO 20795-1[6] standard on denture base polymers, the residual monomer content for heat-activated acrylic resins presented in a powder liquid form must not exceed 2.2% wt. In addition, low thermal diffusivity of acrylic denture base resins make it difficult for complete denture wearers to appreciate hot or cold foods in a timely manner when introduced into the oral cavity. Moreover, PMMA exhibits polymerization shrinkage which may adversely impact on the fit of denture prostheses [7].

A typical heat activated PMMA is presented as a powder-liquid system[8]. The powder contains prepolymerized spheres of PMMA, an initiator like Benzoyl Peroxide, pigments and dyed synthetic fibers. The liquid contains methyl methacrylate monomer, an inhibitor such as hydroquinone and a crosslinking agent such as Ethylene glycol dimethacrylate (EGDMA) [8].

To achieve optimal properties of the polymerized resin, manufacturers recommend the use of curing baths fitted with a thermostat to control and maintain the temperature during the curing process. The flasks containing the moulds must also be fastened using a clamp at the recommended pressure. However, in some countries such as Kenya, improvised methods of heat activation have been employed. This usually consists of boiling the flasks in an open pan or pressure cooker for a period of time. These methods lack the ability to control for time and temperature during the polymerization process. The resultant product may therefore be inferior in terms of quality as compared to that which has been processed as per the standard protocols. The rationale for improvisation is the cost implications of purchasing standard curing baths for processing heat-activated acrylic denture base resin especially in the small private dental laboratories that do not receive enough prescriptions for the fabrication of complete or partial acrylic resin based prostheses to justify the purchase of thermo-regulated processing water baths.

The consequences of inferior quality of a processed denture base are immense as regards the prosthodontic care of partially and completely edentulous patients. Allergic reactions could occur in patients who use acrylic resin based prostheses with high residual MMA monomer content with undesirable sequel such as pain, discomfort and oral mucosal ulceration[5]. In addition, monomer sensitization predisposes individuals to allergic reactions on subsequent exposures. Inferior mechanical properties due to inadequate processing could result in catastrophic failures such as fractures and loss of dimensional stability of partial or complete heat-cured PMMA based dentures. This would have cost and time implications to the dentist and the patient. However, on the other hand, there is a possibility that improvised methods of heat activation achieve adequate quality in reference to the set ISO standard.

There is no literature available on the use of improvised techniques and equipment for curing heat activated acrylic denture base resins despite the fact that improvisation is common in resource limited settings like Kenya. This goes to explain why data are lacking on improvised denture processing techniques and their applications because it is assumed manufacturer recommendations for processing denture base resins are always followed. This study sought to investigate the quality of heat-activated acrylic denture base resins processed through improvised curing techniques with reference to the ISO 20795-1:2013 standard for denture base polymers.

CHAPTER 2: LITERATURE REVIEW

This section details the historical development of denture base materials and the various processing protocols that have been developed over the years. Classification of denture base materials and certain aspects of their physical, mechanical and chemical properties are also presented.

2.1 Historical development of denture bases

Historical records indicate that the Greeks, the Etruscans and the Phoenicians made the earliest recorded dental prostheses out of gold structures[1]. It is reported that the first complete denture made of ox femur was discovered in Switzerland and dated back 1500 AD[9].

Etienne Bourdet (1775) described a gold base to support ivory teeth attached using gold pins[1, 3].

The first complete denture was first displayed by a French dentist named Nicholas Dubois de Chemant in 1788[1,9]. It was made from a single block of baked porcelain. In 1839, Charles Goodyear Jr, discovered that heating a mixture of natural rubber and sulfur resulted in a more flexible material with a wider range of applications[10] . This process is known as vulcanization and is still applied to date in the production rubber tyres. In 1851, Nelson Goodyear, a brother to Charles Goodyear developed a way of making hard rubber or “vulcanite” based on the discoveries of the brother earlier[1, 9, 10]. In 1853, the first denture was made using vulcanite and in 1855 a patent was issued for vulcanite as a denture restorative material [10]. Vulcanite as a denture base material became popular despite harsh patent restrictions at the time and by 1891 the use of vulcanite was considered universal[10]. It was affordable, mouldable onto dental casts and was insoluble to oral fluids[9, 10]. Its major disadvantage was the bulky processing equipment and the grey to black color once processed[10].Vulcanite served as the first substantive replacement to carved ivory[1].

In 1869, celluloid was discovered by J. Smith Hyatt whose interest was an appropriate material for billiard balls[1]. It produced better gingival likeness than vulcanite but tended to turn green with age and developed a foul smell once it absorbed saliva components[9, 10]. The popularity of celluloid was hence short-lived with vulcanite largely remaining the denture base material of choice even at the turn of the century[10]. At the beginning of the twentieth century there were rapid developments in the resin industry with accompanying recommendation of their possible use as denture base materials[10].

Notably, in 1907, bakelite, a phenol formaldehyde resin, was introduced to compete with vulcanite but its use was short-lived [9, 10]. The processing equipment was bulky and the procedure was extremely technique sensitive. Between 1935 and 1937, polymethylmethacrylate (PMMA) was introduced as a denture base material in an attempt to overcome the problems encountered with vulcanite[9]. It was deemed superior to vulcanite especially due its ability to accept pigments that allowed a life-like appearance of removable prostheses[11].

PMMA quickly overtook vulcanite as a denture base material and by 1946 PMMA dominated 95% of the denture base material market [9, 10]. It remains the material of choice for denture bases in the 21st century despite rapid advances in dental biomaterials' development. It has retained this position as the material of choice for the replacement of lost oral and circum-oral tissues due to its versatility, affordability, ease of production and superior esthetics. In addition, PMMA as a denture base bonds chemically to acrylic teeth used as artificial teeth in partial and complete heat-cure resin prostheses. In large defects in the oro-facial region that require prosthetic rehabilitation, PMMA plays a critical role in providing tissue support while maintaining light weight[4]. This may not be achieved optimally by other prosthodontic biomaterials such as base metal alloys, commercially pure titanium or ceramics that also have wide application in prosthodontics singly or in combination. Other clinical situations where PMMA resin may be used to replace missing soft and hard tissues is in partially dentate patients with advanced residual ridge resorption.

2.2 Classification of acrylic denture base materials

There have been modifications to PMMA to suit various needs of the dental profession since its introduction. In particular, denture base resin materials have been classified according to their mode of activation thus: Heat-activated acrylic resins, chemically activated or the self cure resins, light cure denture base polymers and the microwave energy activated denture base polymers[1, 8].

In addition there are the rapid cure acrylic resins, the rubber modified acrylic resins and the polyvinyl acrylic denture base materials[1, 8].

2.2.1 Heat-activated acrylic resins

The heat-activated acrylic resins derive their name from the use of heat either in the form of a heated water bath or microwave energy to activate the initiator. The most common initiator is benzoyl peroxide but Diisobutylazonitrile may also be used as an alternative to initiate polymerization of the monomer liquid when it is added to the powder[1]. Molecules of benzoyl peroxide dissociate in the presence of heat to produce free radicals that attack the carbon-carbon double bond in the methyl methacrylate to initiate the polymerization reaction. This creates more free radicals that initiate a chain reaction[8]. The lengthening of the polymer chain is referred to as propagation and occurs rapidly and depends on the rate of decomposition of the initiator. Termination of the growing polymer chain occurs when the free radicals are consumed either by linkage of two activated polymer chains, termed as annihilation reaction or by disproportionation reaction whereby two free radicals come together and are consumed by the formation of an unsaturated bond in one of the chains[12].

The most common application of heat activated acrylic resins is as denture bases for partial and complete removable dental prostheses. These resins have also been used to replace missing soft tissues in fixed implant supported full arch prostheses. It is evident from the chemistry of PMMA that the mere presence of heat will result in a polymer whose quality is difficult to determine if the recommended cycles are not followed.

The quality achieved when improvised curing techniques are utilized will be dependent on the design of the protocol and the temperature ranges achieved in the improvised water bath. Dental laboratories (especially in resource limited settings) have developed improvised techniques for processing heat-cured acrylic resin based dentures according to technical prescriptions provided by dentists. However, the quality of such dentures is not known. A laboratory analysis of specific chemical and mechanical aspects would be useful as a quality control measure.

2.2.2 Chemical cured acrylic resin

These are similar to the heat-cured resin in composition but rather than heat, a chemical accelerator is used to facilitate the peroxide decomposition causing polymerization at room temperature[12]. These accelerators are tertiary amines, sulfinic acids or salts of sulfinic acid. Commonly utilized amines are *N*,*N*-dimethyl-para-toluidine, and *N*,*N*-dihydroxyethyl-para-toluidine. These resins are referred to as self-curing, cold-curing, or auto-polymerizing resins[1, 12].

The self-cure acrylic resins have been shown to demonstrate lower linear shrinkage as compared to heat-activated acrylic resins hence better dimensional stability. This is thought to be due to the lower degree of polymerization achieved in self-cure systems[13, 14]. A major drawback of the self-cure systems is the high residual monomer content and decreased mechanical properties precluding their use for definitive removable partial or complete denture prostheses[13, 15].

2.2.3 Microwave-cured acrylic resins

These materials were first described by Nishii in 1968. He presented denture base materials that could use microwave energy for activation[16]. Microwave energy can be utilized to generate heat inside the unprocessed resin and activate the benzoyl peroxide catalyst. Microwaves are electromagnetic waves produced by a generator called a magnetron[17]. At a frequency of 2450 MHz, methyl methacrylate molecules position themselves in the electromagnetic field of the microwaves with their direction changing nearly 5 billion times per second. This leads to numerous intermolecular collisions that generate heat energy. The heat energy generated decomposes the benzoyl peroxide initiator to start the polymerization reaction[16, 17]. The reported advantages of this method are shorter curing time, cleanliness, and substitution of the brass flask and water-bath curing tank by plastic flasks and a microwave oven[18]. The physical properties of microwave-cured resins have been reported to be comparable to those of heat-cured resins. However, limitations for these types of denture base materials have been reported to be the need for a resin specifically formulated for microwave polymerization, presence of porosities in the processed products and special non-metal flasks[18]. In the light of this, microwave-activated denture base resins are not common.

2.2.4 Visible light-activated acrylic resins

Visible light-activated acrylic resins were introduced under the brand name “Triad” in 1985 by Dentsply International, Inc., York, Pa [19]. The material was similar to light-cured composites but contains organic filler rather than inorganic filler. It consisted of a matrix of urethane dimethacrylate and small amounts of microfine silica to control rheological properties. The filler was made of acrylic resin beads that formed an interpenetrating polymer network structure when cured. Polymerization of high molecular-weight acrylic resin monomers contained within the matrix is initiated by a camphoroquinone photo initiator[19]. Initial applications described included as complete and partial denture reliners and for interim and transitional prostheses. It is supplied in ropes and sheet forms in light-proof pouches to prevent spontaneous polymerization[8].

2.3 Processing techniques for acrylic based denture base resins

The various categories of the denture base resins demand that varying techniques be applied in the polymerization of the denture base resin. These include the compression molding technique, the pour technique, the injection molding techniques and the visible light cure technique. Moreover, a technique that utilizes the microwave energy may apply as well.

In the compression moulding technique, after the try-in procedure of the waxed up trial denture, the polymer and monomer are mixed according to manufacturer’s instructions. The mixed material goes through five distinct physical stages: sandy, stringy, dough-like, rubbery and stiff [4]. After wax elimination, the dough is packed under pressure into moulds for processing in a time and temperature controlled water bath to initiate polymerization of the resin.

Three processing cycles have been described by different authors. One involves placing the flask in a water bath at 74 °C for eight hours or longer without a terminal boil at 100 °C. Another technique processes the denture base resin at 74°C for eight hours or more followed by a terminal boil at 100°C for one hour. A shorter cycle involves processing the resin at 74°C for two hours then boiling at 100°C for one hour or more[4]. After the curing process the flasks are bench cooled and later the dentures are carefully harvested from the flasks, polished and eventually delivered to a patient.

Several measurable outcomes of the curing process of heat-activated acrylic denture base resins have been outlined by the ISO standard on Denture Base Polymers. These parameters demonstrate the quality of a specific category of denture base resins as claimed by the manufacturers when properly handled and processed. Conversely, it is possible to determine the effectiveness of improvised curing techniques based on the measurable outcomes, when they are applied in processing a heat-activated acrylic denture base resin. Effective improvised heat curing protocols will produce denture base resins whose measurable outcomes are within the accepted standards and hence a high quality dental prosthesis. Ineffective improvised curing protocols will produce a low quality resin which translates to a dental prosthesis that may not provide the desired clinical service to the patient. In this particular study the measurable parameters of interest are; residual methyl methacrylate monomer (MMA), hardness, water sorption, solubility and porosity.

2.4 Improvised curing techniques

Improvised curing techniques are alternative methods used in the processing of heat-activated acrylic resin in the absence of the recommended standard equipment. Anecdotal information indicated that as a cost cutting measure and convenience, ICTs are used in resource limited settings like Kenya to process acrylic based prostheses and that the practices were widespread. These alternative techniques are based on heat-activation but they lack control for time and temperature which is a key characteristic of conventional methods. Information on alternative processing techniques is unavailable in literature because they are customized to meet specific applications and vary from one dental laboratory to another. Their main advantages include ease of execution and use of inexpensive improvised equipment. The drawbacks include lack of control for time and temperature and lack of standardization. Problems pertaining to the quality of the heat-activated acrylic based prostheses have been reported. These include presence of surface and subsurface porosities in the finished prosthesis, inadequate retention due to dimensional changes, debonding of artificial teeth as well as fracture of the denture bases. These difficulties arising from prostheses processed using alternative methods have a significant impact on the cost of care, longevity of the prosthesis and the oral health status of the patients.

2.5 Residual methyl methacrylate monomer

Methyl methacrylate monomer is a transparent liquid at room temperature with a molecular weight of 100, a melting point of -48°C and a boiling point of 100.8°C. It has a high vapour pressure, is highly flammable and is an excellent organic solvent[20].

Powder and liquid presentation of heat-activated acrylic denture base resins is common with the liquid containing the MMA. On mixing, the monomer partially dissolves in the pre-polymerized polymer beads of the powder to form dough that is later processed. Processing conditions such as time, temperature and pressure affect the degree of conversion of the double bonds in the MMA to single bonds during the polymerization process. This affects the physical properties of the polymerized material such as hardness and fracture toughness[15]. Conventional processing techniques for heat-activated acrylic denture base resins must achieve residual MMA monomer below 2.2% wt [6]. Therefore, determining the level of residual MMA monomer in heat activated acrylic denture base resins processed using ICTs is crucial given that they are commonly utilized in resource limited settings.

The remnants of the methyl methacrylate after the polymerization process are released into the oral cavity over a period of time during the clinical service of a dental prosthesis[21]. Other substances such as cadmium and EGDMA may be eluated as well[22].

The residual monomer content of acrylic resin polymers is of clinical significance because it may cause allergic reactions or sensitization in some patients[5, 23, 24].

In a study on the eluation of residual methyl methacrylate monomer, it was reported that the release of residual methyl methacrylate monomer peaked one day after insertion of complete dentures at 0.3 ± 0.09 (μg/ml)[25]. The authors further stated that even though the monomeric methyl methacrylate monomer released was below toxic levels it had the potential to sensitize complete denture patients or initiate an allergic reaction.

In literature, it has been reported that residual monomer content of 0.19%wt and 0.23%wt in two suspected heat-activated acrylic denture base resins resulted in allergic reactions[26]. In addition, residual monomer contents of 1.7%wt and 3.2%wt resulted in allergic reactions in the form of mucosal irritation[27]. Moreover, in some patients, higher levels of residual monomer content did not result in allergic reactions.

Kalipcilar et al noted that MMA sensitization is important in the occurrence of allergic reactions in patients in addition to high residual monomer content in acrylic denture bases[28].

The most common clinical signs and symptoms reported in reactions involving MMA in patients include erythema, erosion of oral mucosa, and a burning sensation on the mucosa and the tongue[24]. The residual monomer content is an indicator of the conversion rate of monomeric units to polymer chains and points at the physicochemical properties of the denture base resin. Conditions of polymerizing a heat-activated acrylic resin polymer such as temperature, pressure and time, directly affect the residual monomer content in a processed denture base resin[29].

2.6 Resistance to indentation of the denture bases

Hardness of a material is defined as resistance to indentation[1,3]. Acrylic resin polymers for use as denture bases are subjected to considerable amounts of functional forces and degradation in the oral environment. They must withstand these forces to prevent failure of prostheses during service. Low surface hardness of a prosthesis may result in points of weakness from which cracks may originate leading to failure. Hardness of a denture base resin also makes it resistant to surface scratches that would result in compromised esthetics. These may result from routine hygiene procedures such as cleaning with a toothbrush and daily function of the prosthesis in the oral environment. The Knoop Hardness values for heat-activated resins have been reported to be between 18 and 20 (Kg/mm^2)[8]. This indicates that they are easily scratched and abraded. Low wear resistance is a known disadvantage of PMMA as a denture base resin.

A strong positive correlation has been demonstrated between flexural modulus values of an acrylic denture base resin and those of surface hardness, proportional limit and flexural strength[30]. Tensile strength, modulus of elasticity and surface hardness have been found to be lower with greater residual MMA content due to its plasticizing effect in the denture base resin[31]. The degree of hardness attained in a processed denture base is therefore of interest to the clinician to guarantee optimal function and for quality control purposes. In this study a Vickers Hardness machine was utilized to provide insight into the mechanical properties of heat-activated denture base resins processed using improvised curing techniques.

2.7 Water Sorption and Solubility

One of the desirable properties of a denture base is the inability to dissolve in oral fluids as well as low uptake of oral fluids into its structure[1, 3]. Adsorption is a process by which a liquid or gas adheres to the surface of the solid or liquid firmly by the attachment of molecules[1]. This process is important in wetting and makes the retention of the prosthesis possible in the oral cavity. Absorption on the other hand is the process by which a substance diffuses into a solid material by a diffusion process[1]. It is characterized by concentration of molecules at the surface of the solid. In situations where both adsorption and absorption are known to exist, as in a denture base in the oral cavity, the process is termed as sorption[1, 3]. Water sorption and release is a property of acrylic resin polymers that influences the dimensional stability of the acrylic resin denture base[4]. The ISO standard on denture base polymers stipulates that water sorption of heat-activated acrylic denture base polymers must not exceed 32µg/mm^3 while solubility in water must not exceed 1.6µg/mm^3. It has been reported that water molecules penetrate the polymer macromolecules by forcing them apart resulting in internal stresses that could result in crack formation and eventually fracture of the denture [32].

A correlation exists between the residual monomer content and water sorption. Jagger found that if residual monomer is present in a processed acrylic resin polymer, it points to less monomer conversion and this may result in increased sorption and solubility[33]. In turn, polymerization conditions affect the residual monomer content.

2.8 Porosity of the denture base

Denture base porosity is the occurrence of voids in a processed denture base. Three main types of porosities have been described; gaseous porosity, contraction (shrinkage) porosity and granular porosity[8]. Gaseous porosity occurs as a result of vaporization of the monomer while contraction porosities occur as a consequence of polymerization shrinkage or inadequate packing[8]. It has been demonstrated that adequate packing pressure and securing the flasks with clamps is necessary to prevent vaporization of the monomer and hence prevent gaseous porosity in the compression molding technique[34]. Porosities can either be located on the surface or the subsurface of the denture base. Other causes of porosities include inadequate pressure during packing, air inclusion during mixing and pouring procedures and improper mixing of powder and liquid components[8].

Porosities in a denture compromise its physical properties, strength and esthetics. They make a denture prone to staining and retain bacterial plaque deposits that if not removed calcify to form calculus deposits[35]. Bacterial plaque retained in such a prosthesis would result in unfavorable sequel in the denture supporting tissues such as denture stomatitis and therefore it is very critical that a processed denture be free of porosity. Hence the purpose of the study was to investigate the quality of heat-activated acrylic denture base resins processed using improvised curing techniques with reference to the ISO 20795-1:2013 standard for denture base polymers.

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CHAPTER 3: STATEMENT OF THE RESEARCH PROBLEM AND JUSTIFICATION

3.1 Statement of the research problem

Optimal chemical and mechanical properties are paramount in the functioning of acrylic denture bases in the oral cavity. These properties are greatly influenced by the handling and processing of the PMMA denture base resins and the polymerization cycles utilized. In resource limited settings, improvisation of curing equipment and variation of polymerization cycles is common in dental laboratories.

While the processed resin polymerized using improvised curing techniques are fitted and used by the patients, there has been no attempt to date to categorize the various improvised protocols utilized in the handling of heat activated PMMA with the aim of analyzing whether the recommended parameters set for heat activated acrylic denture base polymers are achieved. These parameters include residual monomer content, water sorption and solubility, resistance to indentation and presence of porosities which affect the clinical performance, patient safety and longevity of an acrylic resin based denture prosthesis.

3.2 Justification of the study

Heat activated acrylic denture bases processed using improvised heat curing techniques in modified equipment are common in private dental laboratories in Kenya today. Clinically, they seem acceptable. However, on one hand they may fall short of the recommended standards and on the other hand some may have attained the accepted standards. No studies have been done in Kenya to determine whether the improvised curing techniques result in heat-cured resin prostheses that meet the recommended quality set by the ISO standard for denture base polymers.

3.3 Study objective

To evaluate the chemical and mechanical properties of heat-activated acrylic denture bases polymerized by improvised curing techniques in private dental laboratories in Nairobi.

3.3.1 Specific objectives

- To evaluate the residual MMA monomer content of HAADBR processed by improvised curing techniques.
- To evaluate the hardness of a HAADBR processed by improvised curing techniques.
- To evaluate the porosity of a HAADBR processed by improvised curing techniques.
- To determine water sorption and solubility of a HAADBR processed by improvised curing techniques.

3.4 Hypothesis

3.4.1 Null Hypotheses (H_o)

1. There is no difference in the residual monomer content of a heat-activated acrylic denture base resin obtained after processing by improvised and conventional techniques.

2. There is no difference in hardness of a heat-activated acrylic denture base resin obtained after processing by improvised and conventional techniques.

3. There is no difference in water sorption of a heat-activated acrylic denture base resin obtained after processing by improvised and conventional techniques.

3.5 Variables

Independent Variables	Dependent Variables
1. Improvised curing techniques 2. Conventional curing techniques	1. Residual monomer content of the heat-activated acrylic denture base resin. 2. Surface hardness of the heat-activated acrylic denture base resin. 3. Water sorption and solubility of the heat-activated acrylic denture base resin. 4. Porosity of the heat-activated acrylic denture base resin.

CHAPTER 4: MATERIALS AND METHODS

4.1 Study area

This study was conducted in two parts. Part one, a pilot study to survey the curing techniques used for HAADBR in registered Private Dental Laboratories in Nairobi City. Part two, an exploratory quasi-experimental laboratory study to evaluate the quality of HAADBR cured with ICT's selected from the pilot study findings. Nairobi is the capital and the largest city in Kenya. The city has a very high number of dentists who work in private and public medical facilities. The direct result of such a large number of dental practitioners in one location is a high concentration of private commercial dental laboratories that provide technical support to dentists for fixed and removable prostheses within and outside Nairobi City.

4.2 Study design

The pilot study (Part one) was a descriptive cross-sectional study of the improvised curing techniques followed by an exploratory quasi-experimental laboratory study (Part two).

4.3 Inclusion and exclusion criteria

Specimens evaluated in this study were polymerized using improvised techniques identified in the pilot study. The selection was based on the following inclusion and exclusion criteria.

4.3.1 Inclusion criteria

- Improvised curing techniques used in dental laboratories that received technical prescriptions for complete and partial removable dentures.

- Improvised curing techniques used in dental laboratories that had in-house denture manufacture equipment, their equivalent or modifications.
- Improvised curing techniques used in dental laboratories with full time staff.

4.3.2 Exclusion criteria

- Improvised curing techniques used in dental laboratories owned by staff that did not consent to the study.

4.4 Identification of the improvised curing techniques (ICTS)

4.4.1 Pilot study

A preliminary survey of all the registered private commercial dental laboratories in Nairobi County was conducted and data collected on the improvised curing techniques utilized in the processing of heat-activated PMMA. A pre-tested, self-administered questionnaire was handed out to the persons' in-charge of the dental laboratories to collect data on the techniques utilized in the processing of heat-activated PMMA. Data were analyzed using SPSS v.20 (IBM,Corp.).

A large number, 31 (75.6%) of the dental laboratories used improvised methods and equipment with no form of time and temperature regulation. The improvised techniques and equipment varied, with the most common being the use of an immersion coil heater in a water bath as the heat source without temperature regulation (ICT 2), 17 (54.9%). The others included the use of a regulated electric hot plate, 9 (29.0%) to heat a water bath (ICT 1), with a variation in duration of cure distinguishing ICT 1 and ICT 3. The ICT 3 had a longer time for processing the acrylic denture base resins. A domestic pressure cooker was also used as a curing bath in one (3.2%) laboratory. Most of the respondents cited convenience as the most common reason for improvisation in the processing of heat-cure resin.

The three (ICT 1, ICT 2, ICT 3) most commonly applied improvised curing techniques were selected and used to process a single batch of a heat-activated acrylic resin (*Lucitone 199*®, *Dentsply*). The fourth improvised curing technique where a pressure cooker was used was not selected due to the inability of recording the temperature of the water bath progressively. Lucitone 199® *(Dentsply)* is a prototype conventional heat-activated acrylic denture base resin that has been used in similar studies and hence its selection for this study[29,36].

4.4.2 Sample size determination for the exploratory quasi-experiment

Properties and safety evaluation of all dental materials is executed in a standardized manner globally. This is achieved through adherence to the ISO standards that stipulate acceptable performance of materials amenable for clinical use in dentistry. Investigators use the ISO standards for various evaluation tests on acrylic resins. In a study on flexural strength tests for four types of PMMA-based heat-curing resins, the ISO Standard 1567:1999 (Dentistry - Denture base material) was used in specimen preparation[36]. The ISO 20795-1:2013 standard (Denture Base Polymers) was used in this particular study.

The number of specimens recommended per evaluation in the ISO 20795-1:2013 standard for denture base polymers is six for porosity, three for residual monomer and five for water sorption and solubility. Hence the derivation of the study sample size n = 80 is illustrated in Table 1, drawn from the three improvised curing techniques (ICT 1 to 3) and the conventional polymerization technique (control).

Table 1: Sample Size Calculation

Study Variable	**ICT 1**	**ICT 2**	**ICT 3**	**CT**	**Total**
Residual MMA Monomer	3	3	3	3	**12**
Hardness	6	6	6	6	**24**
Porosity	6	6	6	6	**24**
Water sorption and solubility	5	5	5	5	**20**
Total	20	20	20	20	**80**

4.5 Data reliability and validity

The principal investigator was trained by the lead supervisor on how to conduct the study and was calibrated. An 80% Kappa degree of agreement was achieved. Fabrication of all the specimens for all the parameters to be evaluated was done by the principal investigator. In the evaluation of the residual MMA content, the investigator worked with a trained chemical analyst. In addition, the investigator was trained by and worked with a technician who was acquainted with the working of a Vickers hardness tester for evaluation of surface hardness. All factors of the material that may have interfered with the variables were controlled by using one batch of the powder and the liquid of the heat-cure resin material. All the data collection tools were pre-tested so as to ensure they gave consistent results.

4.6 Laboratory procedures and techniques

4.6.1 Improvised curing techniques for heat-activated PMMA denture base resins

The following is a description of the three improvised curing techniques and the control cycle used in this study.

4.6.2 Improvised curing technique 1

This technique entailed the use of a stainless steel container with a lid and a capacity of approximately fifteen litres. The heat source was an electric hot plate (*Ramtons*) graduated from level 1 to 6, with level 6 generating the highest amount of heat. The electric hot plate was connected to mains by a fused plug. Clamped flasks containing the prostheses to be processed are placed into the water bath and placed onto the electric hot plate for a period of 3 hours (Figure 1:A&B). The temperature is controlled by turning the knob on the electric hot plate progressively starting from level 3. In this particular protocol the knob is turned to level 3 for a period of 1 hour, then to level 4 for 1.5 hours and finally to level 5 for 30 min. The temperature rise of the water bath is progressive from room temperature to the boiling point (94°C). When this technique is in use under normal circumstances, plotting of the temperature rise is not conducted, however, for the purpose of this study; the temperature was recorded at ten minute intervals from the start of the improvised curing cycle (Figure 2).

Figure 1; A: Apparatus assembly for ICT 1. B: Aerial View.

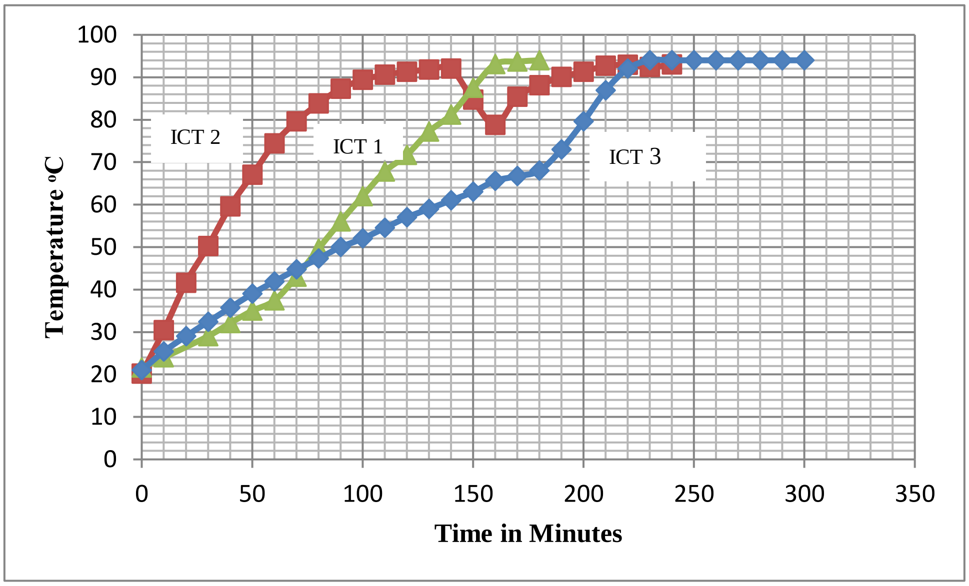

Figure 2: Time and temperature curves for the improvised curing techniques.

4.6.3 Improvised curing technique 2

This method utilized a plastic bucket with a capacity of twenty litres into which an immersion heater *(Illumat, Model No: L-028, 1000w, 240 V)* plugged to the mains electricity was placed.

Clamped flasks containing the prostheses to be cured are placed directly into the water bath as seen in Figure 3. The technique is executed as follows; the water bath is brought to boil after which the immersion heater is turned off for 20 minutes. The immersion heater is then turned on and the water brought to boil for 30 minutes. After these steps, the prostheses in the clamped flasks are presumed to have adequately cured. They are bench cooled and harvested in the conventional manner. In the application of ICT 2, the water temperature is not measured but for the purpose of this study, temperature was plotted against time at ten minute intervals from start of the curing cycle (Figure 2).

Figure 3: Apparatus assembly for ICT 2.

4.6.4 Improvised curing technique 3

This is a variation of ICT 1 in that the clamped flasks with the prostheses to be cured are placed in the water bath for a longer period of time. The idea is to try to mimic the conventional long curing cycle. The cycle begins with the water bath placed onto the electric hot plate and covered with a lid. The knob is turned to level 3 for a period of 3 hours. The temperature knob is then turned to level 4 for 1.5 hours and finally the regulator knob is turned to level 5 for 0.5 hours making a total of 5 hours (Figure 2).

4.6.5 The control cycle

The manufacturer recommended short curing cycle for *Lucitone 199*$^{®}$ *(Dentsply)* was selected as the control cycle. The stipulated time is 1.5 hours at 73 °C and 0.5 hour at 100°C. A standard thermo-regulated curing bath was used.

4.6.6 Heat-activated acrylic resin used for specimen preparation

Lucitone 199$^{®}$ *(Dentsply)* is a heat-activated acrylic resin material that was used in this study to prepare the specimen samples. It has a powder, liquid presentation (Figure 4). A single batch of the material was manipulated according to the manufacturer's instructions by the principal investigator for the preparation of all the specimens. The preliminary stages of specimen preparation such as preparation of the moulds, proportioning and mixing of the acrylic resin material, packing into moulds under pressure and clamping the denture flasks were done in the Prosthetic Laboratory of the School of Dental Sciences, University of Nairobi.

Processing of all the specimens by ICT 1 and ICT 3 was done in one of the private dental laboratories that utilized the improvised curing techniques under study by the investigator. Processing of the specimens by improvised curing technique 2 (ICT 2) was replicated and conducted in the Prosthetic Laboratory of the School of Dental Sciences, University of Nairobi.

The control specimens were processed using the manufacturer recommended short cycle for *Lucitone 199*$^{®}$*(Dentsply)* and a standard curing bath *(Acrydig 12,Manfredi,Italy)* in the prosthetic laboratory of the School of Dental Sciences, University of Nairobi. The manufacturer recommended cycle used as the control was as follows: processing the specimens in a thermo-regulated curing bath for 1.5 hours at 73°C and for 0.5 hour at 100°C.

The technical data of *Lucitone 199*® is as seen in Table.2.

Table 2: Technical data for the heat-activated acrylic resin used in this study.

Material brand name	**Lucitone 199**®
Doughing time (23 °C)	9 min
Working time (23 °C)	10 min
Curing time Stage 1	90 min at 73°C
Curing time Stage 2	30 min in boiling water
Mixing ratio:	21 g/10 ml
Lot:	1508211(powder) 1412091 (liquid)
Expiry:	2019-08(powder) 2019-12 (liquid)
Water sorption:	6 µg/mm^3
Solubility:	1 µg/mm^3

Figure 4: Powder and liquid presentation of heat activated acrylic denture base resin.

4.6.7 Specimen preparation for residual methyl methacrylate monomer evaluation

4.6.7.1 Apparatus

The apparatus needed for residual MMA evaluation were denture flasks, stainless steel moulds with a lathe-cut depression at the center of 50mm in diameter and a depth of 3mm (±0.1mm) and a flat stainless steel cover (Figure 5). A calibrated digital caliper accurate to 0.01 mm, a digital thermometer (-50 + 200 °C) and polishing metallographic papers with a grain size of 30μm were also required.

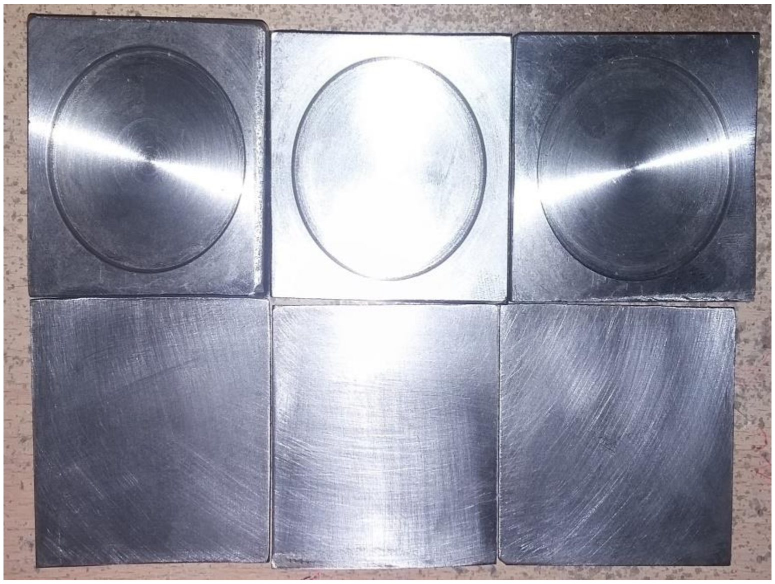

Figure 5: Stainless steel moulds and flat stainless steel covers

4.6.7.2 Procedure for specimen preparation

The stainless steel moulds and the covers were mounted in type II gypsum (*Kalabhai, Kaldent*) in separated halves of denture flasks (Figure 6). The denture base resin was manipulated according to the manufacturer’s instructions and packed into the moulds. Trial closures were conducted and the excess resin was removed. The flasks were then placed in the hydraulic press under 80 Pascals of pressure and clamped. The specimens were processed by each of the three improvised curing techniques (ICT 1, ICT 2, and ICT 3) and the control cycle (CT). This process generated three specimens for each of the three improvised curing techniques and three specimens for the control cycle. In the process of using the improvised curing techniques to polymerize the specimens, the temperature of the water in the modified baths was recorded at ten minute intervals from the start of a specific cycle to its end (Figure 2).

Figure 6: The stainless steel moulds and the covers mounted in type II gypsum.

Processed specimens were bench cooled and harvested from the flasks (Figure 7 and 8). The specimens were then stored in a dark sealed polythene bag for 24±5 hrs. Metallographic grinding paper was used to wet grind the specimens from either side until a thickness of 2mm ±0.1mm was obtained. The specimens were then stored in a calibrated refrigerator at 3 °C for four days awaiting monomer extraction.

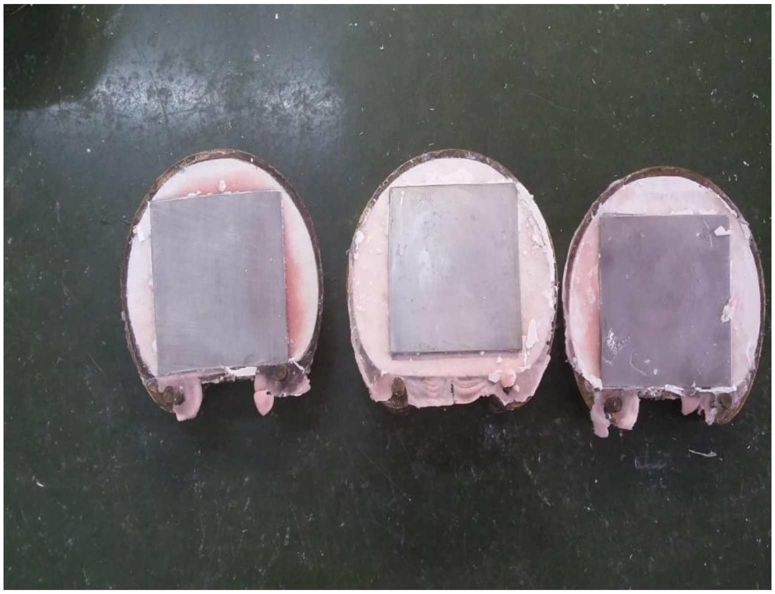

Figure 7: Open denture flasks with residual MMA specimens.

Figure 8: Specimen discs for residual MMA evaluation.

4.6.7.3 Monomer Extraction.

The standard (MMA monomer of 99.9% purity, Sigma Aldrich) and sample solutions preparation was through weight by weight method in order to minimize on measurement errors. A 1000 ppm concentration of the standard was prepared by dissolving 0.01 g in 10 ml of dichloromethane. Serial dilution of the stock solution (1000 ppm) was undertaken to the points, 29.7 ppm, 51.3 ppm, 63.9 ppm, 96.57 ppm and 118.13 ppm. These were used for the preparation of the calibration curve (Figure 9). Samples were prepared by obtaining 0.5 g of each of the specimens by splitting the specimen discs with a wire cutter and dissolving in 10 ml of dichloromethane (Figure 10A&B). Extraction of the analyte of interest was through sonication for 15 minutes followed by centrifugation for 20 minutes at 3500 rpm. The samples were filtered through filter paper and 1.5 ml transferred to closable vials ready for analysis using HPLC method. HPLC analysis was done by use of a HPLC machine (LC-10AT VP, Shimadzu) equipped with a UV-VIS detector (SPD-10A VP, Shimadzu) and a 125 x 4 mm Chrom Saphir 110 C18 5 µm reverse phase column with an isocratic pump. The HPLC conditions were as follows: a mobile phase of 60:40 (acetonitrile: water), a flow rate of 1.00 mL/min, UV-detection at 205 nm, pressure- 107 bar, with 2 µL of sample injection for analyzing methyl methacrylate monomer. A correlation coefficient (R^2) of 0.9930 was satisfactory to quantify the samples.

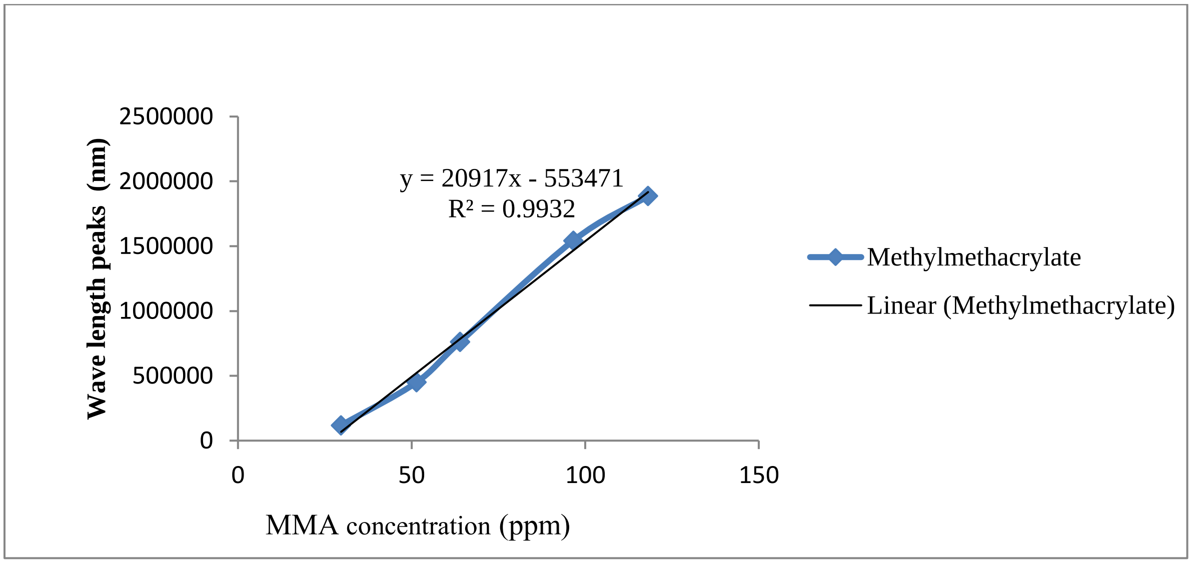

Figure 9: Methyl methacrylate calibration curve for HPLC method.

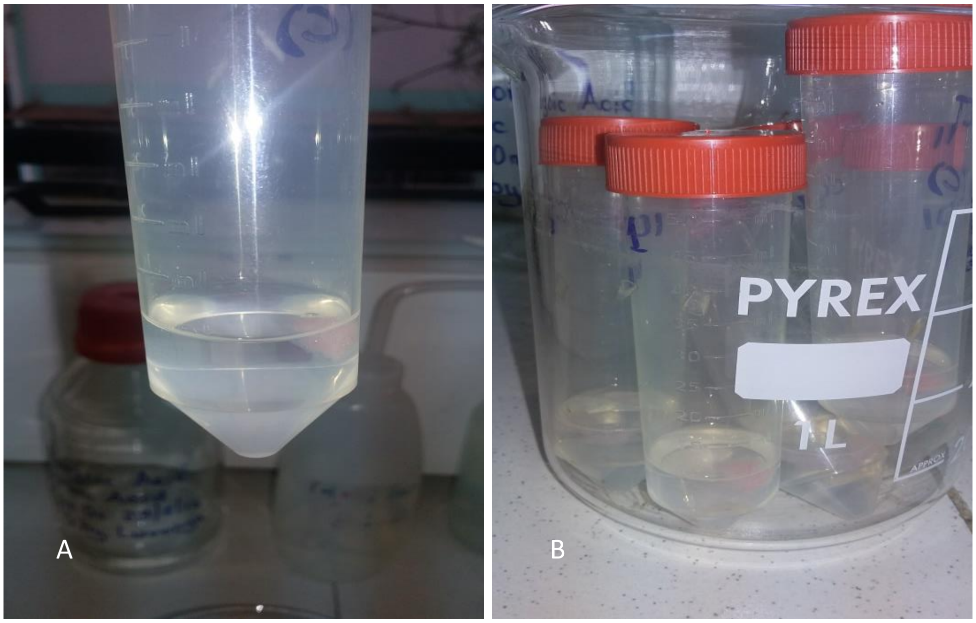

Figure 10; A: Specimen dissolution for monomer extraction. B: Specimen in dissolution test tubes.

4.7 Evaluation for water sorption (Wsp) and water solubility (Wsi)

4.7.1 Preparation of test specimens

Specimen preparation was conducted by processing five (5) specimens for each of the three ICTs being evaluated and the control specimens. The processing of these specimens was similar to that of the specimens for residual MMA monomer evaluation. Three of the processed specimens had a diameter of 50mm±1mm and two had a diameter of 40mm±1mm. All the specimens had a thickness of 1.5mm±0.5mm and flat top and bottom surfaces (Figure 11).

Figure 11: Specimen discs for water sorption and solubility evaluation.

4.7.2 Desiccated specimens

Processed specimens were placed in a desiccator with fresh self-indicating silica gel and put in an oven (Figure 12) maintained at 37 °C±1°C for 23 hrs ± 1 after which they were transferred to a second desiccator with freshly dried silica gel at 23 °C ± 2°C for 60min±1min (Figure 13 and 14). At this point the specimens were ready for weighing using an analytical scale (Figure 15). This two-step desiccation process was repeated until consecutive mass readings of the specimens did not differ by more than 0.2mg. This mass was their constant mass, $m_{1,}$ also called, conditioned mass. Conditioning of the specimens was followed by calculating their volume V, using their diameter and the average thickness that was measured using a calibrated digital caliper.

s

Figure 12: A Calibrated thermostatic oven (Memmert GmbH + Co. KG,Germany)

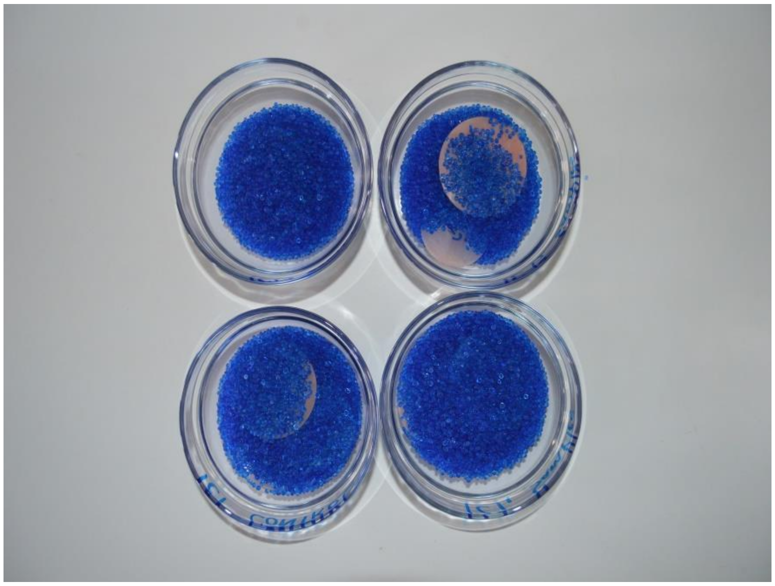

Figure 13: Specimens in the self-indicating silica gel (Sigma-Aldrich,USA)

Figure 14: Specimens inside the oven.

Figure 15: Analytical weighing scale (Sartorius, Goettingen, Germany)

4.7.3 Wet specimens

The conditioned specimens were then immersed in distilled water in an oven maintained at 37°C±1 for seven (7) days ± 2hrs (Figure 16) , after which they were retrieved and wiped with a clean dry towel until they were free from visible moisture. This was facilitated by waving them in the air for 15s ±1. They were weighed (60 ± 10) s after removal from the water to an accuracy of (0.0001g) and the mass recorded as m_2.

The specimens were then reconditioned by desiccating them using freshly dried silica (Figure. 13) in an oven as described in **4.7.2** to a constant mass, m_3.

Calculation of the water sorption and solubility results was as follows;

$$W_{sp} = \frac{m_2 - m_3}{V},$$

$$W_{si} = \frac{m_1 - m_3}{V}$$

Where,

m_1, is conditioned mass in micrograms.

m_2, is the mass of the specimen after immersion in water in micrograms.

m_3, is the reconditioned mass of the specimens in micrograms.

V, is the volume of the specimen in cubic millimeter.

Figure 16: Specimens immersed in distilled water in the oven.

4.8 Evaluation of resistance to indentation

4.8.1 Specimen preparation

Specimens were prepared by investing six stainless steel plates (65mmx40mmx5mm) in model plaster (*Kalabhai, Kaldent*) in denture flasks (Figure 17 A&B). The two halves of the denture flasks were separated and the stainless steel plates carefully recovered. A thin layer of sodium alginate separating media was applied on the two halves of the denture flasks and allowed to dry. The heat-activated resin was proportioned and mixed according to the manufacturer's instructions. The powder/liquid mix was left to stand for nine minutes for dough stage to be attained.

Each specimen was made from a separate mix. The dough for each specimen was packed into the six moulds created by the specimen plates. Trial closures of the denture flasks were conducted using a hydraulic bench press at 40 Pascal of pressure to remove the excess. The denture flasks were then subjected to 80 Pascal of pressure and clamped ready for processing. These procedures were repeated for each of the three ICTs and the control cycle. Time and temperature was charted for the three ICTs. The control samples were processed using standard equipment and the recommended short cycle for *Lucitone 199® (Dentsply).*

The specimens were finished to a high polish using pumice and a wet muslin wheel. This process of polishing was accomplished in no longer than a minute. The well finished specimens were now ready for a Vickers Hardness Test.

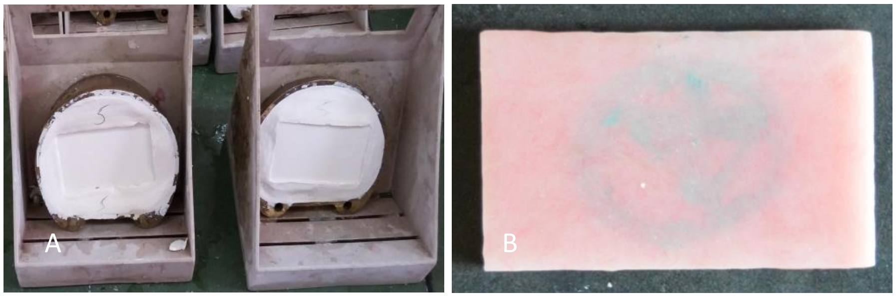

Figure 17 A: Moulds created by the stainless blocks **B**: Rectangular acrylic resin specimen block.

4.8.2 Vickers hardness test

The hardness test was done using a calibrated Vickers hardness tester (Figure 18) at room temperature. A quality control test was conducted before the tests with a reference stainless steel block at 10 kilograms and a dwell time of 15 seconds. The Vickers hardness number of the reference block and that at calibration had a difference of 1 VHN which was within the tolerance limit. The Vickers Hardness Number for each specimen was an average of three measurements of resistance to indentation made at three different points on its surface using a load of 10 kilograms and a dwell time of 15 seconds.

Figure 18: Vickers Hardness Tester (Amsler Otto Wolpert-Werke Gmbh D-6700 Ludwigshafen/Rhein) used in this study.

4.8.3 Denture base porosity

The specimens for denture base porosity had the same preparation procedure as those for evaluation of resistance to indentation. Each of the specimens was cut lengthwise into three equal strips with a hacksaw. The cut edges were polished using a wet muslin wheel and wet pumice. After polishing, the edges were inspected for any visible voids.

4.8.4 Data analysis and presentation

The data collection forms for the various parameters were collated and the data were entered into a computer and analyzed using the Statistical Package for Social Sciences version 20.0 (IBM, Corp).The data were submitted to one way ANOVA followed by Brown-Forsythe Robust Test of Equality of Means. Fisher's Least Significant Difference (LSD) Post Hoc Analysis Test was also used for all the parameters evaluated. The confidence level for this study was set at 95% and the p-value for statistical significance was set at less than 0.05.

4.8.5 Ethical considerations

Authority to carry out this study was obtained from the Kenyatta National Hospital/University of Nairobi Ethics, Research and Standards committee (P701/11/2015). In addition, a written consent was obtained from the persons in charge of all the dental laboratories that were surveyed. Participation in the study was voluntary and had no monetary implications on the participants. There was no influence by any manufacturer that could affect the study results.

CHAPTER 5: RESULTS

This section details the information collected from the pilot study and outcomes of the measurable variables in the specimens processed using the improvised curing techniques and the control cycle.

5.1 Use of a thermo-regulated curing bath

The pilot survey sampled forty one private dental laboratories covering the entire Nairobi city. Of the forty one laboratories included in the study, thirty one (75.6%) did not have a standard thermo-regulated curing bath for the processing of heat-cured acrylic resin. The other ten laboratories (24.4%) were in possession of the standard equipment required in the processing of heat-cured resin.

5.2 Reasons given for use of improvised curing techniques

The most common reason given for use of improvised curing techniques as opposed to following manufacturer recommendations was the convenience (47.6%) afforded by the improvised curing techniques (Figure 19). Other reasons included cost of the equipment (38.1%) and economic reasons. Only twenty one person’s in-charge responded to this question on the reasons for using improvised curing techniques.

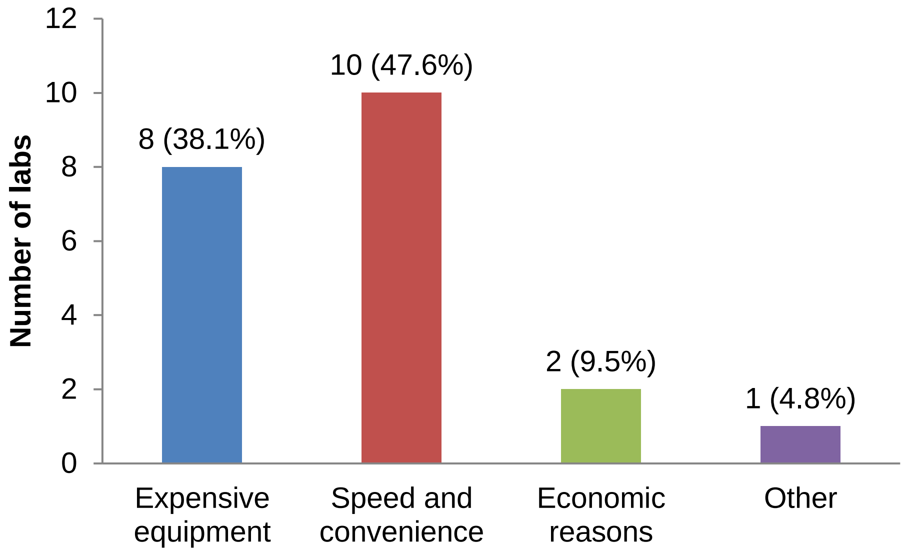

Figure 19: Reasons for use of improvised curing techniques

5.3 Improvised curing techniques utilized

Most of the dental laboratories surveyed used improvised curing techniques. Many variations of the improvisations were seen. However, the investigator categorized them as seen in Figure 20.

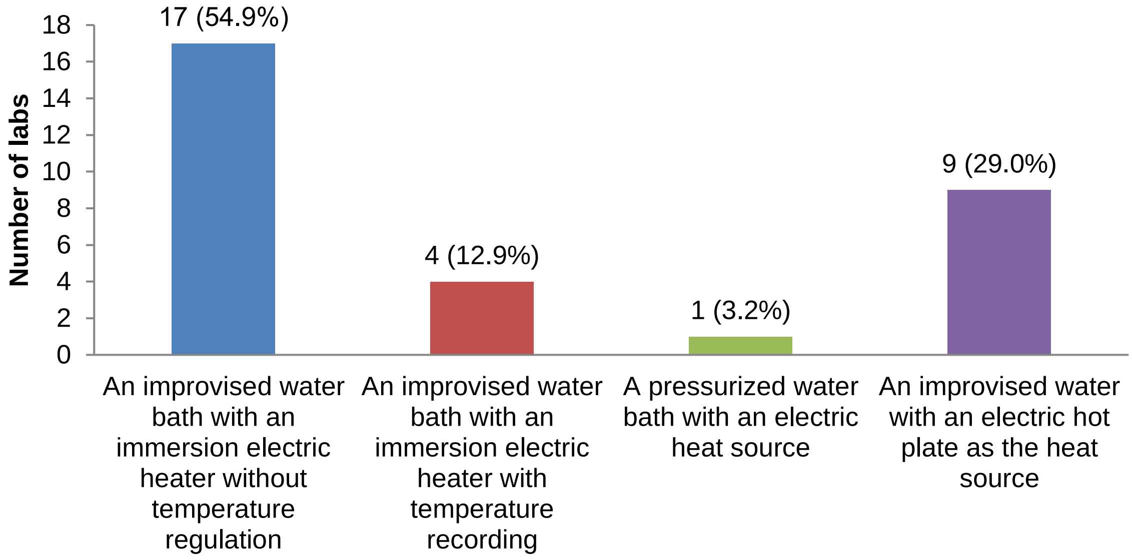

Figure 20: Distribution of the improvised curing techniques.

5.4 Evaluation of residual methyl methacrylate monomer

The mean residual MMA content observed (Figure 21) for the three ICT was higher than that of the control group 0.04%wt (± 0.01 SD) while ICT 2 exhibited the highest percentage 0.19%wt (± 0.02 SD). Mean residual monomer in HAADBR cured with the other techniques were ICT 1 0.13%wt (± 0.04 SD) and ICT 3 0.12%wt (± 0.01 SD).

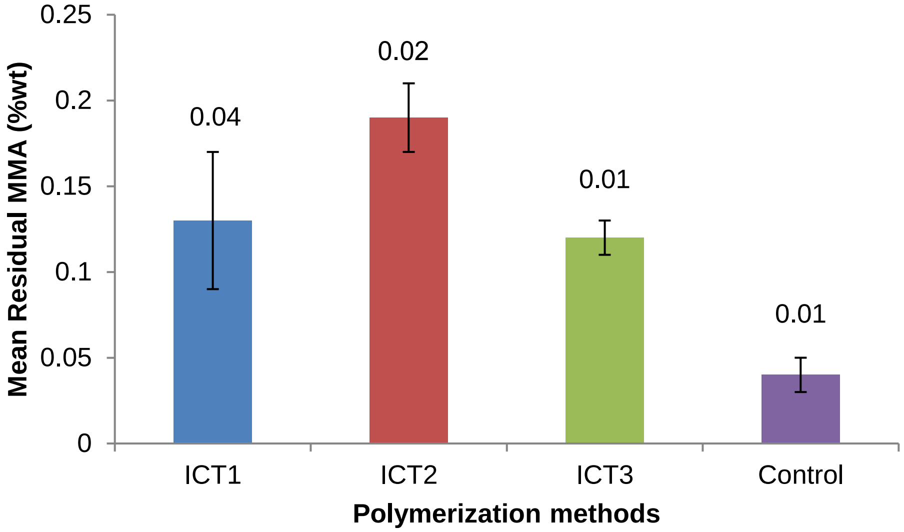

Figure 21: Mean Residual MMA content (Error bars represent SD).

A one-way ANOVA test revealed a statistically significant difference (p=0.001) in the mean residual MMA content in the samples (Table 3).

Table 3: One-way ANOVA test for the mean residual MMA levels for improvised curing techniques and the control cycle.

Residual monomer(%wt)	**n**	**M**	**SD**	**95% CI**	**Df**	**F**	**p**
ICT 1	3	0.13	0.04	0.02, 0.04	3, 8	16.204	0.001
ICT 2	3	0.19	0.02	0.14, 0.24			
ICT 3	3	0.12	0.01	0.09, 0.16			
Control cycle	3	0.04	0.01	0.02, 0.06			

Moreover, Fisher’s Least Significant Difference (LSD) Post Hoc Analysis Test for the ANOVA results (Table 4) revealed a statistically significant mean difference of the mean residual MMA content between the control specimens and those processed using each of the three improvised curing techniques; ICT 1 (p= 0.004), ICT 2 (p < 0.001) and ICT 3 (p=0.006).

Table 4: Fisher’s Least Significant Difference (LSD) Post Hoc analysis tests for Residual MMA Monomer.

	Residual Monomer(%wt)				
ICT 1	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 2	3	-0.06	0.02	-0.11, -0.01	0.019
ICT 3	3	0.01	0.02	-0.04, 0.05	0.784
Control	3	0.08	0.02	0.04, 0.13	0.004
ICT 2	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	3	0.06	0.02	0.01, 0.11	0.019
ICT 3	3	0.07	0.02	0.02, 0.12	0.012
Control	3	0.15	0.02	0.10, 0.20	< 0.001
ICT 3	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	3	-0.01	0.02	-0.05, 0.04	0.784
ICT 2	3	-0.07	0.02	-0.11,-0.02	0.012
Control	3	0.08	0.02	0.03, 0.13	0.006
Control	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	3	-0.08	0.02	-0.13, -0.04	0.004
ICT 2	3	-0.15	0.02	-0.20, -0.10	< 0.001
ICT 3	3	-0.08	0.02	-0.13, -0.03	0.006

5.5 Resistance to indentation

The mean Vickers Hardness Number of the specimens processed using ICT 2 was the highest 19.37 (±0.55 SD). The ICT 3 had the lowest mean hardness values 18.03 (± 0.2 SD).

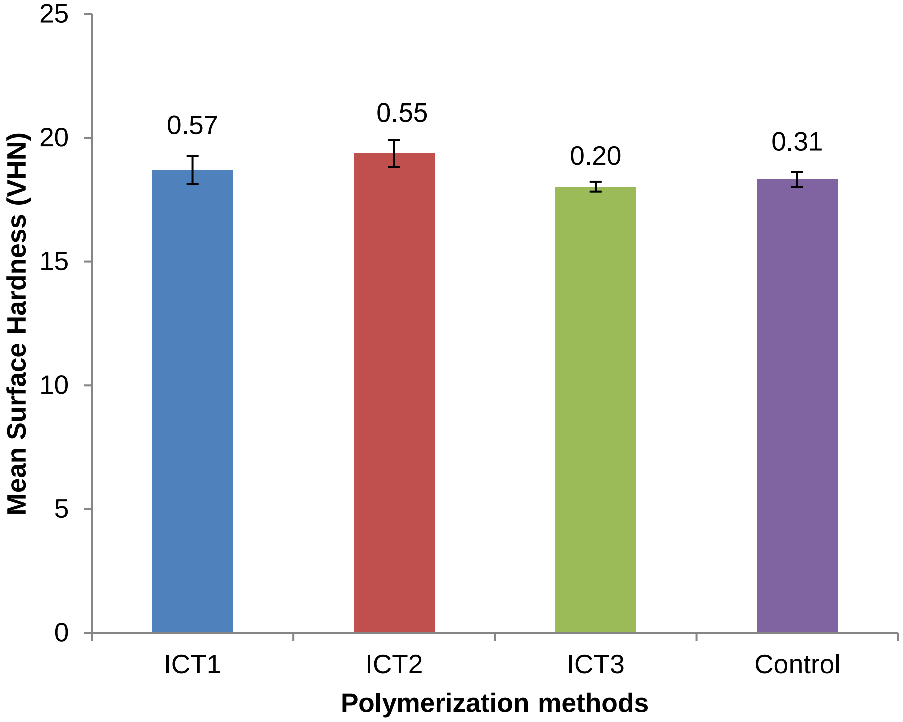

Figure 22: Mean surface hardness (Error bars represent SD).

A one-way ANOVA test (Table 5) revealed a statistically significant difference ($p=0.001$) in the mean VHN of samples processed using the three ICTs and the control, ICT 1 18.70 (± 0.57 SD), ICT 2 19.37 (± 0.55 SD), ICT 3 18.03 (±0.20 SD), control 18.32 (± 0.31 SD). Samples processed using the ICT 2 showed a statistically significant ($p< 0.001$) higher Vickers Hardness Number compared to the control.

Table 5: One-way ANOVA test for resistance to indentation.

	Resistance to indentation						
Vickers' Hardness Number	**n**	**M**	**SD**	**95% CI**	**Df**	**F**	**p**
ICT 1	6	18.70	0.57	18.11, 19.29	3, 20	10.586	0.001
ICT 2	6	19.37	0.55	18.79, 19.94			
ICT 3	6	18.03	0.20	17.83, 18.24			
Control	6	18.32	0.31	17.99, 18.64			

Additional statistical tests were done to probe the statistical differences in the mean VHN seen in the specimens prepared using each of the three ICTs and the control. Fisher's Least Significant Difference (LSD) Post Hoc analysis tests (Table 6) revealed that there was a statistically significant ($p<0.001$) mean difference between specimens processed using ICT 2 and the control specimens.

In addition, there was a statistically significant mean difference between ICT 1 and ICT 2 (p =0.015) as well as ICT 1 and ICT 3 (p=0.015) specimens. There was no statistically significant mean difference between the control specimens and specimens prepared using ICT 1 (p= 0.142) and ICT 3 (p=0.272).

Table 6: Fisher's Least Significant Difference (LSD) Post Hoc analysis tests for Hardness.

	Hardness (VHN)				
ICT 1	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 2	6	-0.67	0.25	-1.19, -0.14	0.015
ICT 3	6	0.67	0.25	0.14, 1.19	0.015
Control	6	0.38	0.25	-0.14, 0.91	0.142
ICT 2	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	6	0.67	0.25	0.14, 1.19	0.015
ICT 3	6	1.33	0.25	0.89, 1.86	< 0.001
Control	6	1.05	0.25	0.53, 1.57	< 0.001
ICT 3	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	6	-0.67	0.25	-1.99, -0.14	0.015
ICT 2	6	-1.33	0.25	-1.86, -0.81	< 0.001
Control	6	-0.28	0.25	-0.81, -0.24	0.272
Control	**n**	**Mean Difference**	**SE**	**95% CI**	**p**
ICT 1	6	-0.38	0.25	-0.91, 0.14	0.142
ICT 2	6	-1.05	0.25	-1.57, -0.53	< 0.001
ICT 3	6	0.28	0.25	-0.24, 0.81	0.272

5.6 Water sorption and solubility

The control specimens had the highest mean water sorption levels compared to the three ICTs studied (Table 7). There was minimal mean solubility associated with ICT 1.

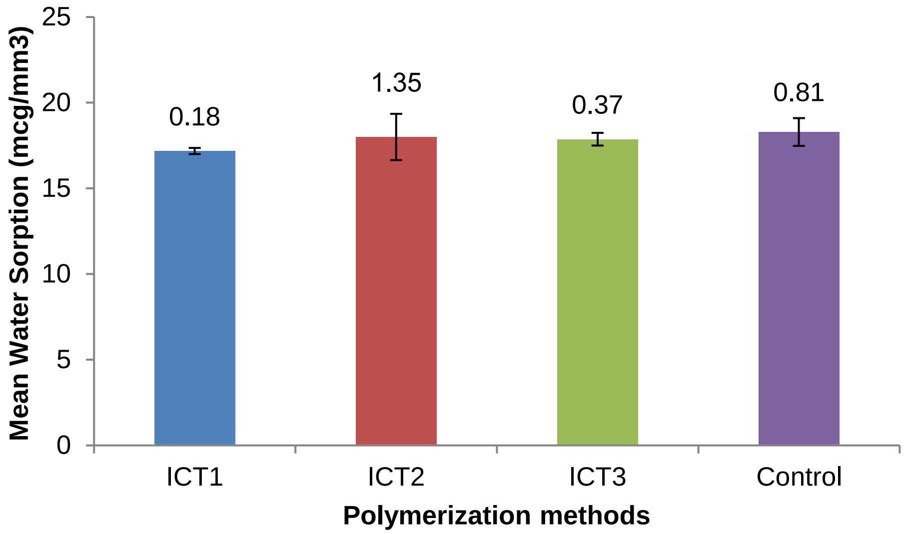

Figure 23: Mean water sorption (Error bars represent SD).

There was no statistically significant difference (Table 7) (ANOVA, p=0.215) in the mean water sorption of all the specimens processed by each of the ICT and the control, ICT 1 17.18µg/mm^3 (± 0.18 SD), ICT 2 18.00µg/mm^3 (± 1.35 SD), ICT 3 17.87 µg/mm^3, (± 0.20 SD), control 18.29µg/mm^3 (± 0.81 SD).

Table 7: A One-way ANOVA test for Water sorption.

Water sorption (mcg/mm^3)	**n**	**M**	**SD**	**95% CI**	**Df**	**F**	**p**
ICT 1	5	17.18	0.18	16.96, 17.90	3, 16	1.662	0.215
ICT 2	5	18.00	1.35	16.32, 19.68			
ICT 3	5	17.87	0.37	17.41, 18.33			
Control	5	18.29	0.81	17.29, 19.29			

5.7 Evaluation for porosity

There was no porosity seen in any of the specimens processed using the three improvised curing techniques and the control.

5.8 Overall Ranking

Table 8. Random ranking of the findings of this study where 1 is best and 4 is worst.

Curing technique	Residual monomer	Resistance to indentation	Water sorption	Porosity
ICT 1	3	2	1	1
ICT 2	4	1	3	1
ICT 3	2	4	2	1
CT	1	3	4	1

The overall ranking is a depiction of the outcomes for all the improvised curing techniques at a glance.

CHAPTER 6: DISCUSSION

6.1 Processing techniques for heat-activated acrylic denture base resins.

All the dental laboratories received technical prescriptions for the fabrication of partial and complete denture prostheses and improvised curing techniques (ICTs) for heat-activated acrylic denture base resins were common in the private dental laboratories in Nairobi, Kenya. A majority of dental laboratories did not adhere to manufacturer recommendations for the processing of HAADBR. This finding was of concern considering that dentists may not be aware of this fact and prosthesis failure and allergic reactions due to high residual MMA content could occur as a result. Use of ICTs has not been reported in literature but this study has revealed the existence of these techniques and their distribution especially in resource limited settings such as those that exist in Kenya.

The ICTs lacked control for time and temperature with the exception of a small number of dental laboratories, 4 (12.9%) that reported recording the temperature of the curing baths. A periodic check of the temperature in the improvised curing bath gives an insight into the temperature ranges achieved. A gradual increase in temperature is desired with the amount of time the water bath is above 70 °C being an important factor in achieving low residual MMA levels and superior mechanical properties [29]. In addition, the aspect of maintaining the temperature of the water bath at certain levels for specified periods of time as is recommended in the conventional curing cycles[4]. This was not possible with the ICTs because improvised equipment without thermostats were used. In contrast, there was a gradual increase in temperature of the water bath from the room temperature (approx. 22°C) to the boiling point (94°C) for all the three ICTs.

A steep rise in temperature was seen in relation to ICT 2, from room temperature to 74.4°C in sixty minutes compared to ICT 1 and ICT 3 that were at 37.4 °C and 41.9°C respectively in the same amount of time. This was probably due to the use of an immersion coil heater as the heat source. There was a gradual ascent in temperature of the water bath in ICT 1 and ICT 3 due to the stepwise increase in temperature of the electric hot plate used as the heat source. A shorter duration of time was applied for ICT 1 as compared to ICT 3, with the improvised cycles running for three hours and five hours respectively.

6.2 Residual Monomer Content

There was a statistically significant difference in the mean residual monomer levels between specimens processed using the three ICTs and the control. This finding led to the rejection of the null hypothesis that there is no difference in the residual monomer content of conventional heat-activated acrylic denture base resin processed by improvised curing techniques and that processed using conventional techniques. The specimens processed using ICT 2 demonstrated the highest mean residual monomer content (0.19 %wt) compared to the control (0.04 %wt). McCabe and Basker in 1976 demonstrated allergic sensitivity in subjects exposed to a suspected heat-cured acrylic resin with a residual MMA level of 0.19 %wt [26]. This demonstrates a potential risk of allergic reactions or MMA sensitization in persons exposed to acrylic-based prostheses processed using ICT 2 despite the fact that the residual MMA content is below the recommended limit of 2.2%wt according to ISO standard for denture base polymers[6]. It is reported that temperature and time of a particular cycle affect the residual MMA levels. The amount of time that the curing water bath is above 70°C has been shown to directly affect the level of residual MMA, with longer periods of time yielding lower residual MMA levels [29]. The initiator systems incorporated into the resins may also have an impact on the level of residual MMA. Tertiary amines may be incorporated into acrylic resins to yield a material in which polymerization is carried through both chemical and heat activators yielding lower residual MMA levels [4, 29]. The ICT 2 cycle had approximately 3 hours above 70°C yet the specimens processed using this cycle had the highest mean residual monomer levels. This was likely due to lack of maintenance of temperatures of the water bath at certain known levels as in the conventional cycles when thermo-regulated curing equipment are used. The ICT 3 cycle exhibited the longest duration of time of five hours and exhibited the lowest (0.12%wt) mean residual MMA content in the specimens of the three ICTs. This finding is in agreement with a study that reported extended curing times at temperatures above 70°C resulted in lower residual MMA content (0.07%wt) [31]. In a study on the effect of polymerization temperature and time on denture base polymers, the minimum MMA content achieved was 0.10 %wt after processing for 12 hours at 100°C [29]. In the current study the minimum MMA content achieved was 0.04%wt in the control cycle where the specimens were processed for 1.5 hours at 73°C and 0.5 hours at 100°C in a standard thermo-regulated curing bath.

6.3 Denture base porosity

It has been suggested that a polymerization cycle with a rapid rise in temperature is not desirable for processing heat-activated acrylic resins due to MMA monomer vaporization above its boiling point of 100.8°C resulting in subsurface porosities[4,8]. The risk of occurrence of subsurface porosities increases especially in the thicker sections of an acrylic based prosthesis. In contrast to the findings of this study no porosities were found in specimens processed using ICT 2 despite a rapid increase in temperature. Yang et al [33] demonstrated that monomer vaporization does not occur when denture flasks are subjected to the recommended pressure and clamped to maintain the pressure which was the case in this study. The authors further reported that there is no evidence that monomer vaporization occurs inside the curing resin even when it’s boiling temperature is surpassed. Adequate clamping of the denture flasks, maintenance of the clamping pressure during processing and the low boiling point of water (94°C) could explain the absence of porosities from all the specimens in this particular study. In addition, this study did not evaluate the temperatures achieved in the curing resin inside the denture flasks which may have given further insight into whether the boiling point of methyl methacrylate monomer was reached.

6.4 Water sorption and solubility

The maximum allowed water sorption and solubility for HAADBR is 32µg/mm^3 and 1.6µg/mm^3 respectively[6]. The three ICTs had lower mean water sorption figures compared to the specimen samples prepared by the control cycle though the difference was not statistically significant. Contrary to what other studies have shown, the mean water sorption level did not seem to be affected by the mean residual monomer content. Specimen samples processed using the control cycle had the highest mean water sorption levels even though the control cycle had the lowest mean residual monomer content. Jagger found increased water sorption levels with high residual monomer content in denture base resins[33]. These results seen as pertains to water sorption and solubility can be explained by the fact that the mean residual monomer was low across all the improvised curing techniques and therefore it did not affect the water sorption and solubility. All the improvised curing techniques revealed mean water sorption levels below the limit of 32µg/mm^3 as per the ISO standard for denture base polymers. Due to long-term contact with saliva, water molecules may be able to permeate the denture base resin, occupy the spaces between the polymer chains, and separate adjacent chains, causing degradation of the polymer[32],[37]. Water molecules also have a plasticizing effect, weakening the van der Waals forces between the molecules and causing polymer chains to slide over each other, thus reducing the degree of crosslinking of the polymer molecular chains [38, 39]. Moreover, water molecules can cause a slight expansion of the denture base materials, resulting in microcracks inside the denture base resins [40]. Masticatory force may accelerate this deterioration with extended use and result in the eventual fracture of the prosthesis [41].

6.5 Resistance to indentation

The resistance to indentation was the measure for surface hardness in this particular study. Specimens processed using ICT 2 showed a statistically significant higher VHN numbers compared to the control specimens and the other two improvised curing techniques. This finding was different from other studies that reported lower surface hardness with increasing mean residual monomer content [31]. High residual monomer content has a plasticizing effect on the acrylic denture base hence lowering the surface hardness. There is a possibility that the proximity of the heating element to the denture flasks may have contributed to this result. All the improvised techniques showed mean surface hardness values within the recommended limits of 18-20 Kg/mm^2. This compares well with the results of a study on the microhardness of heat activated acrylic resins that found mean hardness values of 18.6±0.3 (kg/mm^2) [42]. Low hardness values for an acrylic denture base resin may lead to early failure of prostheses based in heat-cured resin as the prostheses may not withstand intra-oral forces and oral hygiene procedures. Information on other mechanical properties such flexural and impact strength of HAADBR polymerized using improvised curing techniques may give more insight into the efficacy of the improvised techniques as regards the overall quality of the product obtained. Flexural and impact strength were not among the parameters evaluated in this study.

Overall, when the findings of the four parameters studied for the three improvised curing techniques were compared as seen in Table 8, there were mixed results. ICT 2 had the highest hardness values as well as the highest residual monomer levels recorded. Resistance to indentation is a crucial mechanical property for acrylic denture base resins but on the other hand high residual monomer levels are detrimental. The best ranked improvised method was ICT 3 with low residual monomer levels, water sorption and absence of porosities. ICT3 ranked poorly comparatively on surface hardness. Finally, ICT 1 ranked second as regards resistance to indentation, third on residual monomer content and first on water sorption and absence of porosities.

In the current study, the four properties evaluated were within the recommended ISO standard limits which may explain the widespread use of ICT's in most dental laboratories in Nairobi. A follow up study on the performance of the prostheses processed using these techniques as well as a further evaluation of the mechanical properties and patient feedback is required before their continued use is justified.

6.6 Study Benefits

This study offered a critical appraisal of the most common improvised curing techniques for heat-activated acrylic denture base resins in private dental laboratories in Nairobi, Kenya. The data obtained may be used to formulate innovative alternate techniques and to develop equipment to polymerize heat-activated acrylic denture base resins in low economic settings. In addition, the information obtained can be used by dentists to ensure that heat-cure acrylic based prostheses are adequately processed more so when improvised curing techniques are utilized.

6.7 Study Limitations

- Lack of temperature control for the improvised curing techniques.
- Evaluation of the various outcome variables was conducted at two locations namely the Kenya Bureau of Standards, Nairobi and the School of Pharmacy, University of Nairobi posing logistical challenges.

6.8 Conclusion

- Majority of private dental laboratories in Nairobi used improvised curing techniques.
- Within the limits of this study, acrylic denture base resins processed with the improvised curing techniques studied are within the recommended limits with regard to hardness, water sorption and solubility and absence of porosities.
- The residual methyl methacrylate monomer was higher in the specimens processed using the improvised curing techniques compared to those processed by the control cycle, however, it was below the recommended limit of 2.2% wt.

- Heat activated acrylic denture base resins processed with ICT 2 demonstrated significantly higher mean hardness values.

- There were no porosities seen in specimen samples processed using any of the improvised curing techniques.

6.9 RECOMMENDATIONS

- Research into the longevity and the irritancy caused by prostheses processed using the improvised curing techniques is needed.
- Evaluation of other key mechanical properties such as impact strength and flexural strength of heat-activated denture base resins processed using improvised curing techniques is recommended.
- Dental laboratories should indicate the protocols used to process acrylic based dental prostheses when sending the completed work to dentists.

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APPENDIX 1: CONSENT INFORMATION

I, Dr.Kaaria Mwirigi of the University Of Nairobi, School of Dental Sciences, am conducting a study title ‘Quality of heat-activated acrylic denture base resins cured using improvised curing techniques in private dental laboratories in Nairobi, Kenya’.

Study purpose: This study that seeks to investigate the improvised techniques utilized in the processing of heat-activated acrylic denture base resins and the quality achieved. The participant is expected to allow access to their private dental laboratory and demonstrate, if any, the improvised techniques utilized in processing heat-activated acrylic denture bases.

Benefits of participation: This study will be akin to a quality control exercise for the dental laboratories involved in the study. It will help dental laboratories improve their processing protocols for heat-activated acrylic denture base resins. In the event that some of the improvised curing techniques yield acceptable acrylic denture bases, then those protocols will be identified and documented and used in resource limited settings. Conversely, those improvised techniques found to be inadequate will be improved with the aim of achieving better quality.

Risks of participation in the study: This is a laboratory study with no risk of psychological or bodily harm to the human participants.

Voluntariness of participation: Participation is voluntary and one is at liberty to decline to participate or withdraw at any stage without any consequences.

Confidentiality: The information obtained will be treated with utmost confidentiality.

APPENDIX 2: CONSENT CERTIFICATE

I……………………(initials) having understood the purpose, benefits and risks of the study titled ‘‘Quality of heat-activated acrylic denture base resins cured using improvised curing techniques in private dental laboratories in Nairobi, Kenya’’ willingly accept to participate. I understand there are no risks anticipated from this study and that all the information provided to the investigator will be handled with utmost confidentiality.

Signed……………………………….. Date…………………………………

Investigators statement:

I certify that I have explained to the participant the nature and purpose of this study and potential benefits. I have answered any questions that have been raised. I have explained the above to the participant on the date on this consent form.

Investigator…………………………Date………………………………………..

In case of any clarifications or concerns regarding the study you may contact the investigator, the lead supervisor or the KNH/UON Ethics, Research and Standards Committee using the following contacts:

Dr.Kaaria Mwirigi (Principal Investigator) –P.O Box 2032-00202 NBI: +254723882944, email:cirigip@gmail.com

Dr. B K Kisumbi (Lead supervisor) P.O Box 19676-00202 NBI - Cell: +254722487096,email:bkisumbi@yahoo.com

KNH/UON-Ethics and Research Committee secretariat: Tel- 020 726300-9, email-uonknh_erc@uonbi.ac.ke

APPENDIX 3: QUESTIONNAIRE

QUALITY OF HEAT-ACTIVATED ACRYLIC DENTURE BASE RESINS CURED BY IMPROVISED CURING TECHNIQUES IN DENTAL LABORATORIES IN NAIROBI.

LABORATORY CODE…………………………

1. How long has this Dental Laboratory been in existence?
    a) Less than 1 year
    b) 1-3yrs
    c) 3-5yrs
    d) More than 5yrs
2. How many dental technicians work in this Dental Laboratory on a permanent basis?
    a) 1
    b) 2-5
    c) More than 5.

3. Do you have a thermo-regulated curing bath for processing conventional heat-activated acrylic denture base resin?

    a) Yes

    b) No

4. Are you familiar with the conventional long and short curing cycles for heat-activated acrylic denture base resin?

    a) Yes

    b) No

5. Please indicate the conventional long and short curing cycles for processing heat cured acrylic in words.

6. Do you use the conventional long and short curing cycles to process heat cured acrylic based dental prosthesis in this Dental Laboratory?

    a) Yes

    b) No

7. If the answer is No to question 6 please pick a reason from the following

    a) Expensive equipment
    b) Lack of expertise
    c) Speed and convenience
    d) Economic reasons

Other……………………………………………………………………

8. If you answered no to question 3,select what you use for processing heat-cured acrylic from the choices below:
    a) An improvised water bath with an immersion electric heater without temperature regulation.
    b) An improvised water bath with an immersion electric heater with temperature recording.
    c) A pressurized water bath with liquid petroleum gas as the heat source.
    d) A pressurized water bath with an electric heat source.
    e) An improvised water bath with an electric hot plate as the heat source.
    f) An improvised water bath with liquid petroleum gas as the heat source.

Other…………………………………………………………………………………………………
………………………………..

9. Do you achieve visibly acceptable results for both complete and partial dentures based in heat-activated acrylic denture base resin when improvised equipment is used?
    a) Yes
    b) No
    c) Sometimes.

10. Are you familiar with rapid cure acrylic resins?

    a) Yes

    b) No

11. What brand of heat cured acrylic do you use in your Lab?

12. How many partial and complete dentures do you process in your Dental laboratory per month?

APPENDIX 4: DATA COLLECTION TOOL

Residual Monomer evaluation

Specimens	Residual MMA Conc %wt	
CT 1		
CT 2		
CT 3		
ICT 1A		
ICT 1B		
ICT 1C		
ICT 2A		
ICT 2B		
ICT 2C		
ICT 3A		
ICT 3B		
ICT 3C		

Data collection table for water sorption and solubility

METHOD	M1/grams	M2/grams	M3/grams	M2-M1	µg	µg/mm3	M1-M3	mcg	µg/mm3
						sorption			solubility
ICT1									
A									
B									
C									
D									
E									
ICT2									
A									
B									
C									
D									
E									
ICT 3									
A									
B									
C									
D									
E									
CONTROL									
A									
B									
C									
D									
E									

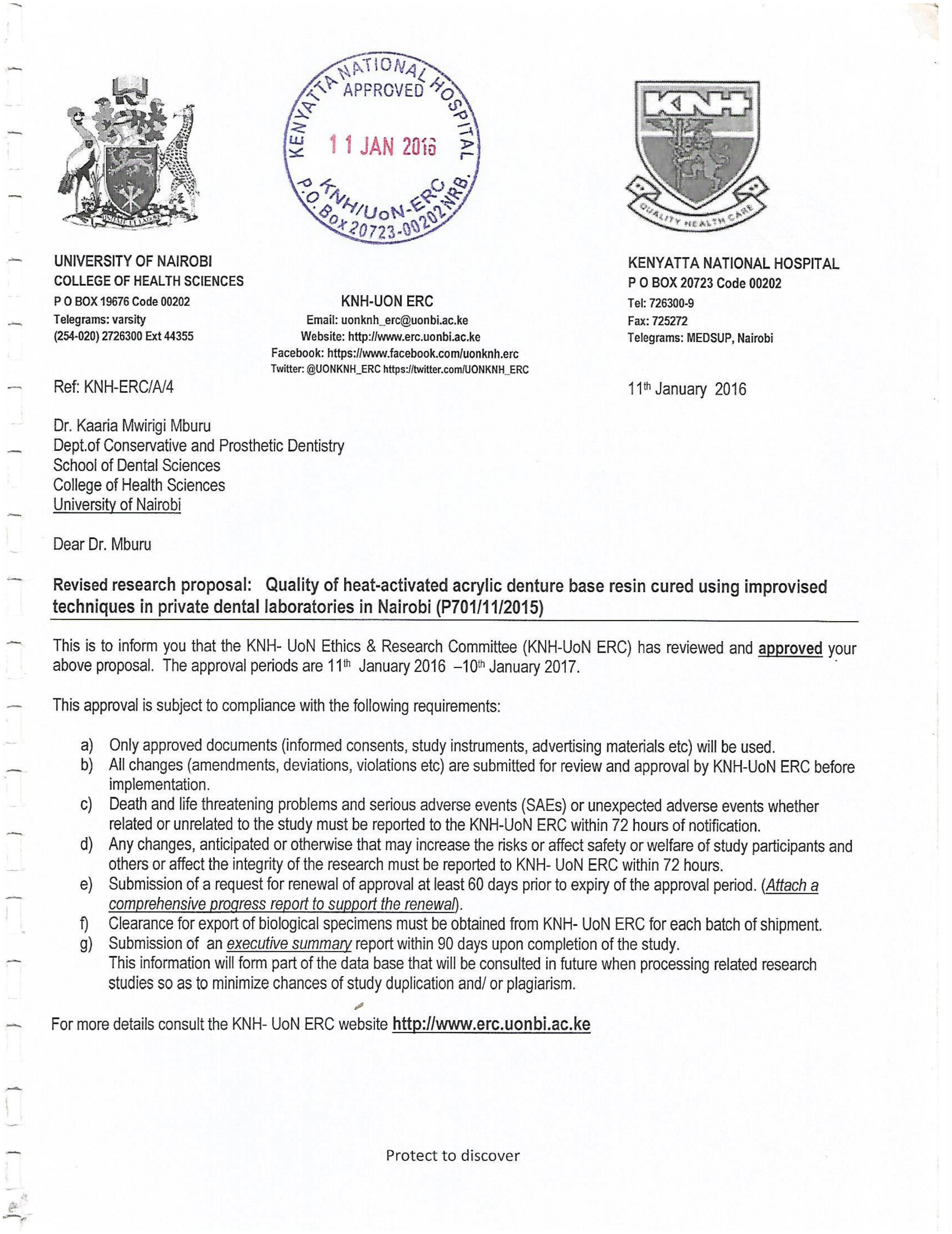
Resistance to indentation evaluation

HARDNESS					
	ICT 1 (H)	ICT 2(H)	1CT 3(H)	CONTROL (H)	
SPECIMEN	VHN	VHN	VHN	VHN	
1					
2					
3					
4					
5					
6					
AVERAGE					

Porosity evaluation

POROSITY					
	1CT 1	ICT 2	1CT3	CONTROL	
SPECIMEN	POROSITY	POROSITY	POROSITY	POROSITY	
1					
2					
3					
4					
5					
6					

APPENDIX 5 : ETHICAL APPROVAL



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Ref: KNH-ERC/A/4

11th January 2016

Dr. Kaaria Mwirigi Mburu
Dept.of Conservative and Prosthetic Dentistry
School of Dental Sciences
College of Health Sciences
University of Nairobi

Dear Dr. Mburu

Revised research proposal: Quality of heat-activated acrylic denture base resin cured using improvised techniques in private dental laboratories in Nairobi (P701/11/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval periods are 11th January 2016 –10th January 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study.
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c.
The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Chair, KNH-UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Dental Sciences, UoN
The Chair, Dept. of Conservative and Prosthetic Dentistry, UoN
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