POTENTIAL STUDY OF REGENERATING WASTE DIALYZER

MARYANI BINTI BASRI

Report submitted in fulfillment of the requirements
For the award of the degree of
B.ENG (HONS) CIVIL ENGINEERING

Faculty of Civil Engineering and Earth Resources
UNIVERSITI MALAYSIA PAHANG

JULY 2014

ABSTRACT

The purpose of this study is to characterize the malfunctioned Polysulfone membrane dialyzer and to determine the efficiency of dialyzer cleaning solution in regenerating the waste dialyzer. This study was conducted in the Clean Laboratory of FKASA , with the scope of study was limited in regenerating the membrane dialyzer by characterized it by leak of pressure and measure the TCV (Total Cell Volume) of the dialyzer and determining the effect of different concentration of cleaning solution towards the membrane dialyzer. Samples were taken from Islam Makmur Hemodialysis Center. The membrane dialyzer were reprocessed and regenerated by using an Automatic Dialyzer Reprocessor Machine and using AAMI (Association of the Advancement Medical of Instrumentation) standard and recommendation. All the sample dialyzer was characterized using parameters such as TCP (Total Cell Pressure) and TCV (Total Cell Volume). The function of conducted TCP and TCV test is to ensure whether the dialyzer in good condition and to measure the ability of dialyzer to transport solutes, respectively. In the meantime, the dialyzers were also being reprocessed using low and high concentration of dialyzer cleaning solution. The cleaning solution was used is diaclean. As a result, the dialyzer samples have different in TCV reading due to the low and high concentration of cleaning solution tested to the samples. The TCV reading of dialyzer which was tested using low concentration of cleaning solution is smaller whilst the TCV reading for dialyzer that tested using high concentration of cleaning solution is more higher. In conclusion, the used of high concentration of cleaning solution gave positive effect to the efficiency of regenerating membrane dialyzer. Because of that, the kidney patients will be able to undergo treatment in more quality performance.

ABSTRAK

Tujuan kajian ini adalah untuk mencirikan polisulfon dialyzer membran yang tidak berfungsi dan untuk menentukan keberkesanan larutan pembersih dialyzer dalam menjana semula sisa dialyzer. Kajian ini dijalankan di Makmal Bersih FKASA, dengan skop kajian adalah terhad dalam menjana semula membran dialyzer dengan mencirikannya dengan tekanan kebocoran dan mengukur TCV (Jumlah Isipadu Sel) daripada dialyzer dan menentukan kesan kepekatan larutan pembersih yang berbeza kepada membran dialyzer. Sampel telah diambil dari Pusat Hemodialisis Islam Makmur. Membran dialyzer telah diproses dan dijana semula dengan menggunakan mesin pemprosesan semula dialyzer automatic dan menggunakan standard dan perakuan AAMI (Persatuan Kemajuan dan Perubatan Instrumentasi. Semua sampel dialyzer telah dianalisis dengan menggunakan parameter seperti TCP (Jumlah Tekanan Sel) dan TCV (Jumlah Isipadu Sel). Fungsi ujian TCP dan TCV dijalankan masing-masing adalah untuk memastikan sama ada dialyzer dalam keadaan baik dan untuk mengukur keupayaan dialyzer untuk mengangkut bahan larut. Dalam pada itu, dialyzer juga diproses semula menggunakan larutan pembersih dialyzer yang rendah dan tinggi. Larutan pembersih yang digunakan ialah diaclean. Hasilnya, sampel dialyzer mempunyai bacaan TCV yang berbeza berikutan kepekatan larutan pembersih yang rendah dan tinggi yang diuji kepada sampel. Bacaan TCV pada dialzer yang diuji menggunakan kepekatan larutan pembersih yang rendah adalah lebih kecil manakala bacaan TCV untuk dialyzer yang diuji menggunakan kepekatan larutan pembersih yang tinggi adalah lebih tinggi. Kesimpulannya, penggunaan kepekatan larutan pembersih yang tinggi memberi kesan positif terhadap keberkesanan menjana semula membran dialyzer. Oleh yang demikian, pesakit buah pinggang akan dapat menjalani rawatan dengan pelaksanaan yang lebih berkualiti.

TABLE OF CONTENTS

TITLE **PAGE**

CHAPTER 1 INTRODUCTION

CHAPTER 2 LITERATURE REVIEW

CHAPTER 3 METHODOLOGY

CHAPTER 4 RESULTS AND DISCUSSIONS

CHAPTER 5 CONCLUSION AND RECOMMENDATION

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVATIONS

AAMI	Association for the Advancement of Medical Instrumentation
ED	Electrodialysis
HCFA	Health Care Financing Administration
MF	Microfiltration
NF	Nanofiltration
PV	Pervaporation
PSF	Polysulfone
RO	Reverse Osmosis
TCP	Total Cell Pressure
TCV	Total Cell Volume
UF	Ultrafiltration

CHAPTER 1

INTRODUCTION

1.1 Introduction

Dialysis was coined in 1861 by Scottish chemist Thomas Graham, who perceived that vegetable parchment coated with albumin which acted as a semi-permeable membrane were able to diffused through by crystalloids. He was able to extract urea from urine using this method (Maher JF, 1989). As methods used in chemical laboratories, osmosis and dialysis at first became popular, which allow the separation of dissolved substances or the removal of water from solutions through semipermeable membrane. Graham indicated in his work the potential uses of these procedure in medicine far ahead of his time. At the turn 60's and 70's, the dialysis and transplant therapy in the national range in the rich industrial countries was on the increase. The sophisticated dialysis technique produced in the factories, enable this expansion and by the fact that the governments were taking on all expenses of the therapy. The development of dialysis for the treatment of kidney failure in the last 20 years has brought about a resurgence of interest in dialysis for a wide range of separations (Klein, 1987).

Clinical evidence has shown that the artificial kidney is a good substitute with regard to electrolyte, solute and water balance in the absence of normal renal function. In fact, the number of dialysis patients increased to almost 15000 in 2006 from 59 in 1980. Latest statistic shows, in 1980 the dialysis acceptance rate increased from 3 per million population to 116 per million in 2006 and over the same period, the prevalence rate from 4 to 550 per million population (Lim Y. N.,2008). In addition, in 2001, over 1000 Malaysian died due to renal failure (Lim, 2001) and these figure are expected to soar.

In the early 1960s, dialyzer reuse has been practiced in the United State. To ensure safety and effectiveness of the reprocessing procedure, a variety of guidelines have emerged. In fact, the recommendations for dialyzer reprocessing techniques has been published by the association for the Advancement of Medical Instrumentation (AAMI). Plus, all dialysis centers that reprocess dialyzers were required by the Health Care Financing Administration (HCFA) to comply with the AAMI guidelines as a condition for reimbursement.

Using the same dialyzer for multiple treatments, dialyzer reuse is the practice of the patient. Dialyzers are reprocessed, they are not just reused. Before it is reuse for next treatment, the procedure of reprocessing involves cleaning, labelling, storing and rinsing the dialyzer (Corporation, 2007). In more than 75% of the dialysis units in the United State practiced dialyzer reuse in the treatment of end-stage renal disease (Okechukwu et.al, 2000). Dialyzer reuse has been practiced more than 30 years in United State due to its potential benefits for the patient as well as for the dialysis provider. For continued used of dialyzer reuse methods in United State, economic consideration are believed to be the driving force. Until the end of 70s, formaldehyde was the common disinfectant, followed by peracetic acid and glutaraldehyde in 1980s (Twardowski Z.J., 2006).

1.2 Problem Statement

While renal is fail to function normally, dialysis can temporarily aids the kidneys until they begin to work on their own again. In fact, dialysis is needed for the rest of the life and they rarely get better in chronic kidney failure or else a kidney transplant becomes an option (Krans B., 2012). For advanced haemodialysis therapy, Polysulfone membrane dialyzer that has malfunctioned has the potential to be reused. The problem faced by the kidney's patients the most is financial challenge. Moreover, the cost for dialysis treatment for single-use is most costly compared to the reuse dialyzer. Thus, the reused of Polysulfone (PSF) membrane dialyzer is capable in reducing maintenance and operational costs of membrane dialyzer. With the practiced of reuse dialyzer, the cost saving is substantial, particularly with expansive high-flux synthetic Polysulfone membrane dialyzers.

Apart from that, in the scope of environmental concern, the dialyzer single-use practice increase the dialyzer-related solid waste. Therefore, some alternative to reduce the solid waste is needed, and one of them is by reusing dialyzer for the deserving kidney ailment patient.

1.3 Objectives of study

The objectives of the study are formulated as below:

1) To characterize the malfunctioned Polysulfone (PSF) membrane dialyzer taken from Haemodialysis Centers using parameters such as Total Cell Pressure (TCP) and Total Cell Volume (TCV).

2) To determine the efficiency of dialyzer cleaning solution in regenerating the dialyzer.

1.4 Scope of Study

The following scopes of study were limited as following to achieve the objectives:

1) The Polysulfone membrane dialyzer that taken from Haemodialysis Center were cleaned with pure water.
2) Regenerationg the membrane dialyzer by characterized it by leak of the pressure.
3) Measuring the TCV (Total Cell Volume) of the dialyzer.
4) Determining the effect of difference concentration of cleaning solution towards the membrane dialyzer.

1.5 Significance of Study

In several ways, dialyzer reuse helps to reduce the negative enviromental consequences. The production of up to 46 million dialyzers would be eliminated by the reuse of all dialyzers in a single year and consequently the amount of medical waste ending up in landfills reduced by more than 62 million pounds. By waste processing, dialyzer reuse could also minimize the amount of dangerous toxins. Dialyzer first have to go decontamination process whether be incenerated or microwaved before sent to landfill in order to be properly disposed. Emission and ash are produced when the dialyzer are incenerated, which give the negative health effect to the surrounding communities. On the other hand, harmful toxin does not produced in the microwave process and it does nothing to minimize the amount of medical waste that ends up in landfills. Thus, the environmental impacts are lessened as a result from decreasing of waste disposal especially if reprocessing is done by heat disinfection.

Other than that, reuse practice also provide economic benefits to patients as well as for the providers. Current practice in United State and Canada proposes that significantly more patients could be treated with these therapies in spite of the fact that only a portion of patients may be eligible for this therapy, where the dialysis patients does having significant cost savings without compromising patients outcome. Furthermore, as the economic advantage be the major motivating factor behind the reuse practice, a survey being conducted revealed that 37% would increase reuse if 20% dialysis reimbursement were to decrease. As a result, the providers think of reuse practice as an important cost-cutting strategy.

CHAPTER 2

LITERATURE REVIEW

2.1 Membrane Definition

The word “membrane” was taken from Latin *(membrana)* which means skin. According to the Wiktionary, membrane is a form of film or a plane or a flexible enclosing that has function to separate between two compartments or phases. Membranes can be natural or artificial. The first use of membrane begun in the large scale in technology was microfiltration and ultrafiltration. Along with electrodialysis, these separation processes are employed in large plants since 1980’s, and until today, membrane were being used widely in medical, industrial, even a number of experienced companies serve the market.

In separation industry, membrane separation processes have very significant role until mid 1970. For mass transfer through a membrane, there are two basic models can be distinguished, which is the solution-diffusion model and the hydrodynamic model. In general approach, solution-diffussion model is where transport occur only by diffussion. For dense membranes, this principle is more important because the gradient of concentration is created by the molecules which cannot use pass through the membrane. This effect that occur during the filtration process leads to a reduced trans-membrane flow or flux.

On the other hand, done by convectively, hydrodynamic model is a transport through pore. It means that the size of the pores is required to be smaller than the separate component's diameter. Here, along the front of the membrane, the liquid to be filtered flows and separated by the difference in pressure between the front and the back of the fraction, thus leads to the crack of filter cake and lower the formation of fouling. Figure 2.1 below shows the membrane separation process.

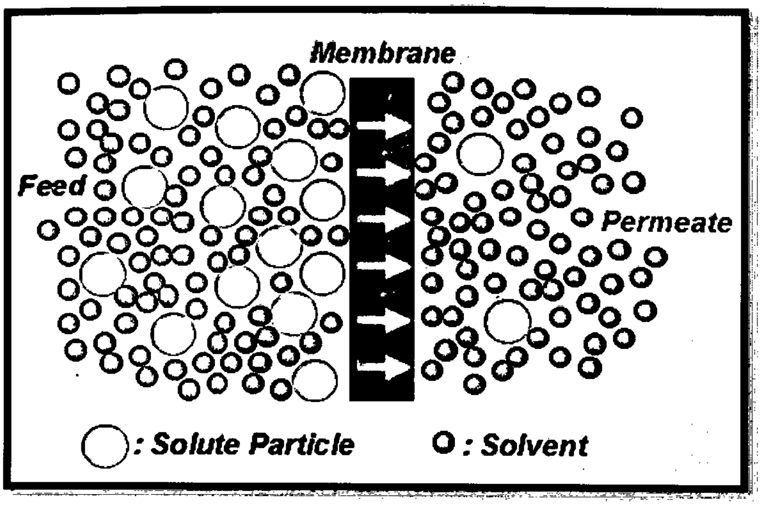

Figure 2.1: Membrane separation

Source: Google Image

2.2 Membrane Process

The purpose of membrane separation process is to separate the components of a solution or a suspension. Tha nature and magnitude of the driving force and the component's size to be separated provide the criteria for a classification of the membrane separation process. In membrane technology, there are several commonly used of membrane types, which are microfiltration (MF), ultrafiltration (UF), nanofiltration (NF) , reverse osmosis (RO), electrodialysis (ED) and pervaporation (PV). These processes differ in the size. Figure 2.1 below shows an overview on various separation process.

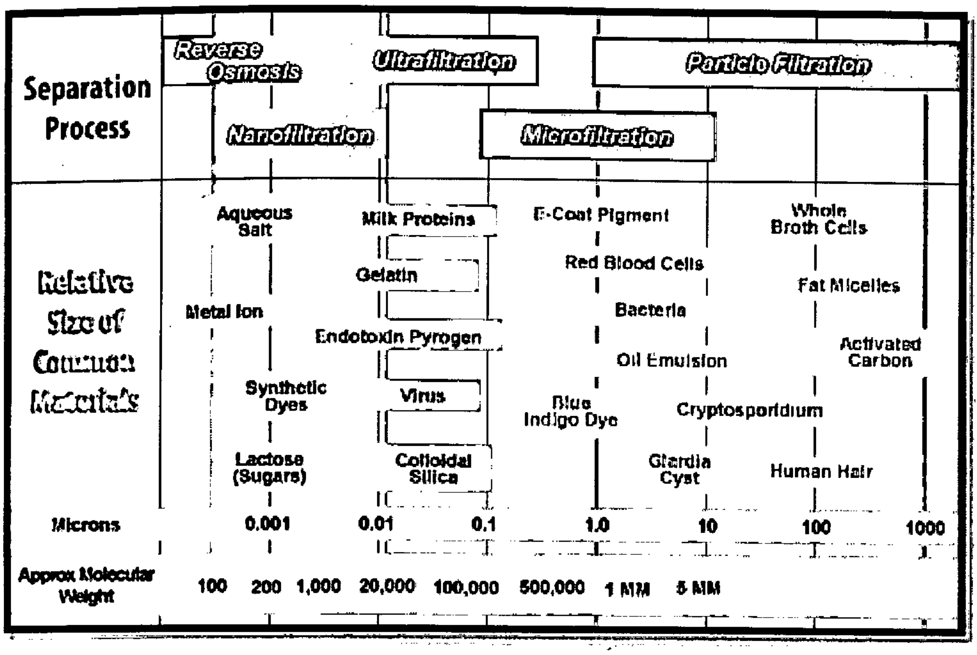

Table 2.1: Overview of various separation process. (Jebamani et al., 2009)

2.2.1 Microfiltration (MF)

Microfiltration is the process of separating microorganisms and suspended particle from a liquid by passing it through porous membrane under pressure lying between 0.02MPa and 0.5MPa. The most abundant application of microfiltration membrane are sterilisation, water treatment process, petroleum refining process including clarification and purification of cell broth. The figure below shows how microfiltration membrane works.

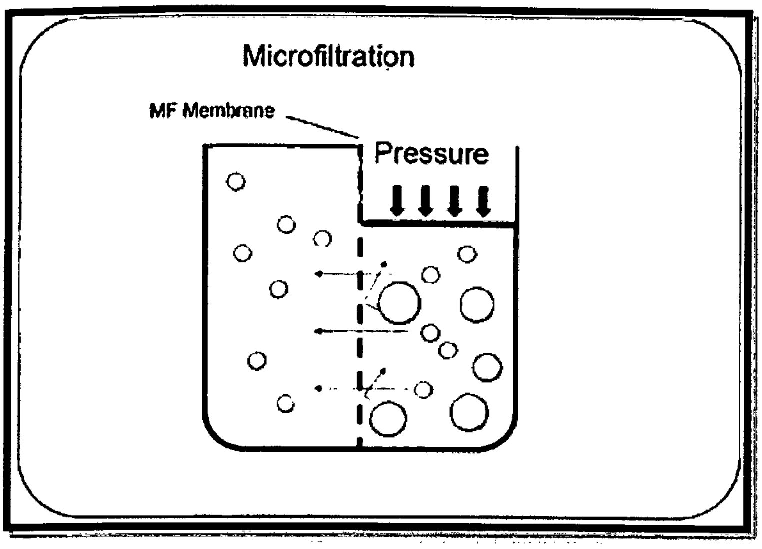

Figure 2.2: Microfiltration membrane process

Source: Google Image

2.2.2 Ultrafiltration (UF)

For the used of production of high purity water in biochemical process, food and beverage and biopharmaceutical industries, ultrafiltration (UF) plays a significant purification technology. In general, ultrafiltration is a process of low pressure membrane in separating small particle and dissolved molecule from stream while retaining the larger and high molecular weight.

In recent year, due to the advent use of portable devices and promising result of both mechanistic and clinical aspects of this therapeutic modality, signicant interest in the application of ultrafiltration has been generated.

2.2.3 Nanofiltration (NF)

Most organic molecules were removed by nanofiltration process. Nanofiltration is a process where carried out by membrane, it is a separation removing dissolved solid in a liquid-phase with a relatively high transmembrane pressure. Nanofiltration membrane is smaller than that used in microfiltration and ultrafiltration. It have 1-10 Angstrom of pore size, just larger than that in reverse osmosis. Historically, used for molecular separation, nanofiltration and other technology of membrane were used and applied on aqueous system entirely. In the scope of application, water can be "softened" by retaining scale-forming, hydrated divalent ion such as calcium and magnesiun ion while passing smaller hydrated monovalent ions. Referring to the whole range of engineering, scientific and manufacturing activities, the term "nanotechnology" is now very widely used involving the small thing.

2.2.4 Reverse Osmosis (RO)

Reverse osmosis (RO) occur when water is moved against the concentration gradient, from lower concentration to higher concentration. In this process, pressure is exerted on the side with the concentrated solution to force the water molecules across the memrane. Over the past 40 years, reverse osmosis membrane technology has developed to a 44% share in world desalting production capacity (Greenlee, 2009). Today, for new desalination installation, reverse osmosis membrane are the leading tchnology and they are applied to the variety of salt water resources by using membrane system design.

There are two distinct branches of reverse osmosis desalination, which are seawater reveerse osmosis and brackish water reverse osmosis. The differences between the two water resources have created significant differences in development process, implementation and key technical problems. Furthermore, for both type of reverse osmosis, the pretreatment option are similar and depend on tehe specific components of the water source. They will continue to be used worldwide, energy recovery technology, renewable energy as well as innovative plant design.

2.2.5 Electrodialysis (ED)

Electrodialysis is an another alternatives process in wastewater treatment, since it maximizing or even avoiding the galvanic sludge production, allowing the re-use of process water and the recovery of metal ions. With the use of electric field as driven force, membrane separation technique is employed where ions are transported through iron-selective barriers from one solution to another (Braz J. et al, 2002). As the electrodialysis has the capability on separating, concentration and purifying selected ions in aqueuos condition, this process can remove the unwanted total dissolved solids. Figure 2.3 below shows the principle of electrodialysis technique.

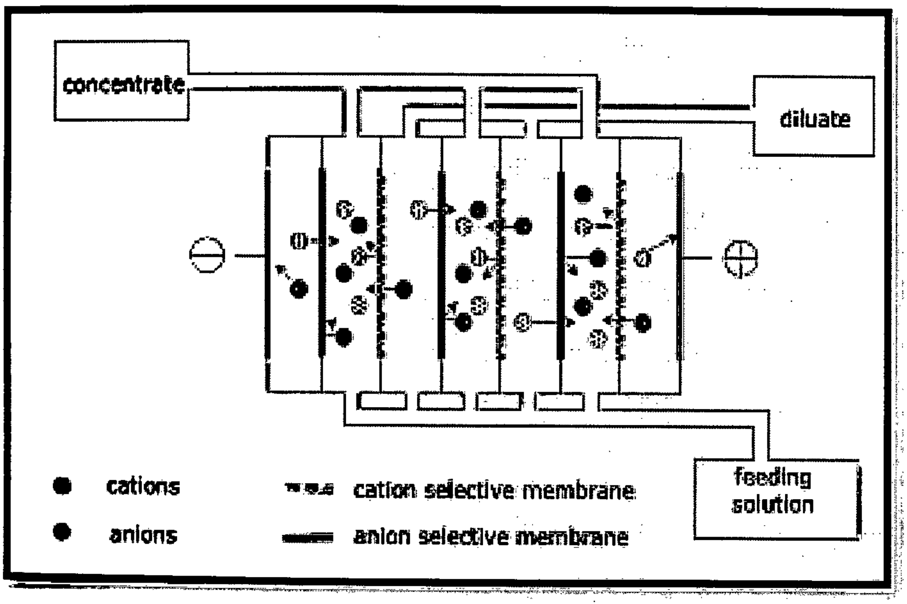

Figure 2.3: Principle of Electrodialysis technique

Source: Google image

2.2.6 Pervaporation (PV)

The term "pervaporation" are derived from between two processes which is permeability and evaporation in vapour phase. Due to its simplicity and in-line nature, a number of industrial for several different processes used this process including purification and analysis. The difference between partial pressure on the two sides component is the driving force for the separation.

2.3 Dialysis

2.3.1 Definition

The term "dialysis" was taken from Greek which is *dialusis* means a process of eliminating excess and unwanted water from the blood and especially for people who lost their kidney function. In medicine, dialysis is the primarily used as an artificial kidney due to the renal failure. In addition, dialysis also may used by the patients who has loss kidney function temporarily and even the final stage of chronic renal disease's patients. As the kidneys regulate the water body level and remove waste, kidney also produce part of the endocrine system, which is erythropoietin and 1,25-dihydroxycholecalciferol. However, dialysis does not correct the function of endocrine of failure kidney (Nordqvist C.,2009).

There are two types of dialysis, which are peritoneal dialysis and hemodialysis. In peritoneal dialysis, inside the body, the water and waste are removed using the peritoneal membrane as semipermeable membrane.

On the other hand, hemodialysis is a process of removing water and waste product from the blood outside the body by using external filter called dialyzer which contain semipermeable membrane.

2.3.2 Dialysis History Background

Acute and chronic kidney failure, if not treated for several days or week will lead to death. Thus, the current procedure to treat this problem including osmosis and diffusion that allow the separation of dissolved substances were used. Thomas Graham who known as the "Father of Dialysis", was the first scientist indicated his work on the potential of the uses of these procedure.

In 1945, a Dutch psycian, Dr Willem Kolff has successfully invented the first artificial kidney in a rural hospital, by trying his first experiment using sausage casing, beverage cans and various item that were available to improvise these kidney treatment. Eventually his patient who was coma regained consciousness after 11 hours of hemodialysis with the dialyzer successed to lived for another seven years and it became the first major breakthrough in the treatment of patients of renal disease (Blakeslee S., 2009).

2.3.3 Categerization of Dialysis

Dialysis can be categorized into two types of treatment, which are hemodialysis and peritoneal dialysis.

2.3.3.1 Hemodialysis

As stated by Twardowski, started and developed in the 20th century, hemodialysis as a practical means of replacing renal function. In fsct, at the beginning of 20 century, by using celloidin as a dialyzing membrane and hirudin as an anticoagulant, the original hemodialyzers were used in animal experiments and then there were a few attempts in humans inthe 1920s. In the late 1930s and 1940s, rapid progress started with the application of cellophane membranes and heparin as an anticoagulant.

Hemodialysis is a treatment for kidney patient using an advanced dialysis machine to remove waste prorduct from the blood. Hemodialysis was done in a hospital or in a dialysis centre. In hemodialysis, dialyzer is the key to hemodialysis. It consist of two section, the section for dialysate and the section for the blood. The purpose of dialysate is to pull toxins from the blood through diffusion. Due to the difference concentration, the waste will move through the semipermeable membrane so that an equal amount on both side created. Then, the dialysis solution is flushed down the drain along with the waste. To balanced the electrolytes in the atient's blood, the electrolytes in dialysis solution are also used. Then the extra fluid ispushed off by higher pressure on the blood side than on the dialysate side. Diagram of hemodialysis circuit was shown as below.

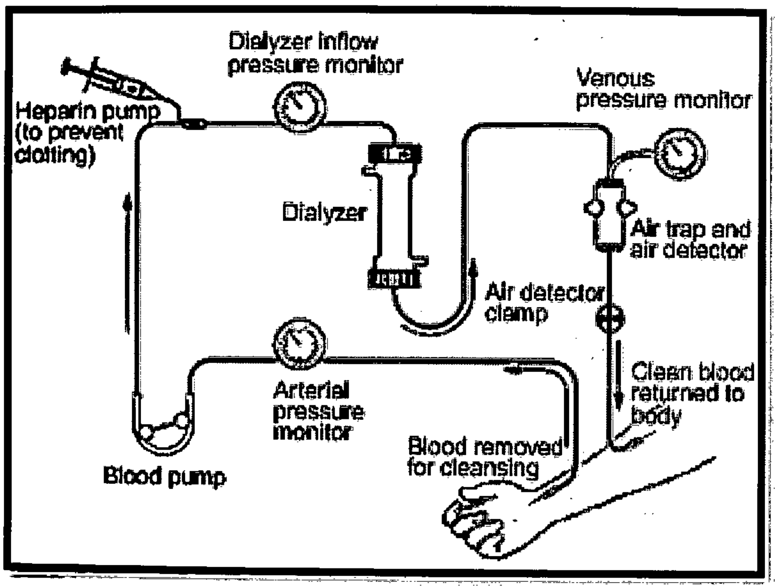

Figure 2.4: Diagram of Hemodialysis Circuit

Source: National Institute of Diabetes and Digestive and Kidney Diseases (2006).

2.3.3.2 Peritoneal Dialysis

Peritoneal dialysis is another way to remove waste products just like hemodialysis. Peritoneal dialysis traetment are performed at home. This treatment is done by filling the peritoneum in the abdomen with dialysate and using the peritoneal membrane as a semipermeable membrane.

The dialysate is left there for some time so that it can absorb waste products. Then it is drained out through a tube and discarded. This exchange, or cycle, is generally repeated several times during the day. The elimination of unwanted water occurs through osmosis, as the dialysis solution has a high concentration of glucose, it results in osmotic pressure which causes the fluid to move from the blood into the dialysate.

Although peritoneal dialysis is not as efficient as hemodialysis, it is carried out for longer period. The net effect in terms of total waste product and salt and water removal is about the same as hemodialysis.

2.3.4 Dialysis Membrane Material

For applications of filtration process, synthetic and natural membrane are commonly used. The most often used of membrane materials including the regenerated cellulose, cellulose acetate, polysulfone, polycarbonate, polyethelene, polyolefin, polypropylene and polyvinylidene flouride. Constructed from regenerated cellulose dialysis membrane material, diffusion samplers potentially have advantages over commercially available polypropylene cylinder diffussion samplers with cellulose acetate membrane filtrer ends (Ehlke T.A et al, 2002). In addition, membrane with the same polymer names may differ in their haemocompatibility, properties of flux and absorption characteristic due to varying polymer composition. Absorption by dialysis membrane to protein like beta 2-microglobulin, fibrinogen and coagulation factors are different and thus absorption contributes to the removal characteristics (Klinkmann H., 1995).

2.4 Environmental Concerns with Dialyzer Reuse

A number of significant environmental concerns raises regarding dialyzer reuse practice. The important potential pollutants associated with reuse are the heated contaminated water spillage into the sewer system, plastic waste from packaging materials used for reused chemical increased and disposal waste generated, for instance mask, gloves, plastic apron and many more. In addition, the amount of garbage with single use may be 5- 30 or more times higher compared to that generated with reuse, depending on the number of reuses. Other than that, in United State, waste in germicide that used for reprocessing the dialyzer would vary with increasing patients proportion who use dialyzer (Upadhyay A., 2007). Table below shows the environmental impact of dialyzer reuse practice.

No.	Advantages impact	Diadvantages impact
1.	Solid waste related dialyzer decreased.	Liquid waste related reuse increased (heated water, disinfection and chemical) and chemical vapors (formic acid and hypochloric acid).
2.	Packaging waste related dialyzer decreased such as cardboard boxes and wrapping materials.	Disposal waste related reuse increased such as mask, gloves, plastic apron, test strips and labels

Table 2.2 : Environmental impact of dialyzer reuse.