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Oral Health Assessment of Renal Transplant Recipients Undergoing Immunosuppressant Therapy

Coral Diaz
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ORAL HEALTH ASSESSMENT
OF RENAL TRANSPLANT RECIPIENTS
UNDERGOING IMMUNOSUPPRESSANT THERAPY

by

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A Thesis Submitted to the Faculty of
Old Dominion University
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ABSTRACT

THE ORAL HEALTH ASSESSMENT OF
RENAL TRANSPLANT RECIPIENTS
UNDERGOING IMMUNOSUPPRESSIVE THERAPY:
A PILOT STUDY

Coral Diaz
Old Dominion University, 1997
Director: Deborah B. Bauman

The purpose of this investigation was to assess the oral health, prevalence of intraoral manifestations/infections, and periodontal disease status of renal transplant recipients undergoing immunosuppressive therapy to determine their oral health needs. A purposive sample was selected via the Renal Transplant Center, Sentara Norfolk General Hospital, and Nephrology Associates of Tidewater LTD from which 22 renal transplant recipients who agreed to participate were examined. Three subgroups of the population were studied: individuals with a renal transplant for less than one year, individuals with a renal transplant for one to three years and individuals with a renal transplant for more than three years.

Bacterial plaque and dental calculus were assessed using Greene and Vermillion’s (1964) Simplified Oral Hygiene Index. Periodontal disease status was determined using Ramfjord’s (1967) Periodontal Disease Index; and grade of gingival hyperplasia was assessed using a combination of Aas et al.’s (1963) vertical component, and Seymour et al.’s (1985) horizontal component of the gingiva as utilized by King et al. (1993). Intraoral lesions/manifestations were recorded by location, color, size, and characteristic, using a self-designed form.

A pilot study was performed on the first ten participants examined to determine instrumentation threats to internal validity and intrarater reliability. Data were analyzed using the t-test for correlated samples and the nonparametric Kruskal-Wallis test. All analyses were made at the .05 level of significance.

Sixty-five percent of the individuals had a poor Simplified Oral Hygiene Index rating; 85 percent of the sample exhibited some degree of periodontal disease; and 75 percent of the individuals presented with moderate to severe degrees of gingival hyperplasia. Only one of the 22 participants exhibited signs of intraoral lesions. Results revealed no statistically significant difference in the oral health status of renal transplant recipients undergoing immunosuppressive therapy with a kidney transplant for less than one year, for one to three years and for three or more years.
DEDICATION

To all of you who were victims of my "mood swings" but nevertheless always stood by my side providing me with continuous encouragement. moral support....and a smile.
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CHAPTER I
INTRODUCTION

Renal disease is the fourth leading health problem in the United States affecting eight million Americans with an incidence of 10,000 to 18,000 new cases each year. Fortunately, medical advances for treating this fatal disease have resulted in the technique of renal transplantation. Renal transplantation, as defined by Brundage (1992), is the surgical insertion of a human kidney from a living donor or a cadaver into a patient with end-stage renal disease, to replace lost renal function. Transplantation prolongs the life of individuals with end-stage renal disease and offers the ability to live a near normal life. After transplantation, the individual no longer undergoes hemodialysis, lengthy hospital visits, or diet alterations.

Post transplant medication therapy includes immunosuppressants such as cyclosporin, and glucocorticosteroids such as prednisone. These medications must be taken by the transplant recipient throughout the life of the transplanted kidney to avoid rejection. Renal allograft recipients experience dental problems related to the side effects of immunosuppressive therapy. Research has demonstrated that immunosuppressive drugs affect the gingival condition of the patient and also may disguise signs or symptoms of oral infections, common in this population (Bennet, 1985; King, 1993 & 1994). Extensive research has been conducted on the side effects of immunosuppressive drugs, specifically cyclosporin-induced gingival hyperplasia. However, few studies have been conducted on the oral health needs and the dental management of this medically compromised population. Meticulous bacterial plaque control may not prevent the development of gingival overgrowth, but will improve the gingival condition of the renal transplant recipients medicated with immunosuppressive drugs (Thomason, et al., 1991).

Individuals with kidney transplants are in need of preventive oral care since consequences of previous renal disease may affect the dental management of this population. In addition, immunosuppressive medications contribute to a lowered resistance to infection and may mask the signs of oral infection (Westbrook, 1978). It is important that oral healthcare professionals have a knowledge base regarding the needs of the kidney transplant population to effectively assess both the oral needs and health needs of these medically complex individuals.

This investigation assessed the oral health status of renal transplant recipients undergoing immunosuppressive therapy from Sentara Norfolk General Hospital, Norfolk, Virginia, and from the Nephrology Associates of Tidewater LTD and documented the oral manifestations problems found in this medically compromised population. Results from this study provide the basis for
the development of a preventive oral healthcare protocol for kidney transplant recipients undergoing immunosuppressive therapy.

PROBLEM STATEMENT

The purpose of this investigation was to assess the oral health status of renal transplant recipients undergoing immunosuppressive therapy. The following research questions were addressed:

1. What is the oral hygiene status of renal transplant recipients undergoing immunosuppressant therapy?
2. What is the prevalence of intraoral lesions among renal transplant recipients undergoing immunosuppressant therapy?
3. What is the prevalence of periodontal disease among renal transplant recipients undergoing immunosuppressant therapy?
4. What is the prevalence of gingival hyperplasia among renal transplant recipients undergoing immunosuppressant therapy?

SIGNIFICANCE OF THE PROBLEM

Chronic renal failure is a slow, progressive, and irreversible impairment of renal function. This disease occurs over a period of months to years and can affect both the young and the elderly. Individuals with end-stage renal disease can prolong their life by hemodialysis. However, medical advances for treating this fatal disease have resulted in transplantation as a therapeutic option for some patients. Consequently, kidney transplantation has significantly decreased the mortality of kidney disease (Westbrook, 1978). When successful, a transplant restores the recipient to a healthy, useful life, without the restrictions associated with regular renal dialysis. If a transplant is unsuccessful, the person can return to dialysis or undergo a second transplant.

Currently, kidney transplants are performed worldwide. The United Network for Organ Sharing (UNOS), a federal organ procurement and transplant network in the United States and scientific registry, has been collecting, reporting, and analyzing data on all human transplants in the United States since 1986 (Williams, et al., 1991). In 1991, UNOS reported a total of 9,577 kidney transplants in the United States alone (UNOS, 1994). On February 8, 1995, there were a
total of 38,207 organ registrations: 27,709 of these were for kidney transplants (UNOS, 1994). UNOS reported 10,928 kidney transplants performed in 1993 out of a total organ transplant of 18,164 that same year (UNOS, 1994). UNOS membership includes 278 centers of which 248 include a kidney transplant program (UNOS, 1994). Seven of the 248 programs in the United States are located in the Commonwealth of Virginia (UNOS 1994). The seven Virginia kidney transplant centers include: Fairfax Hospital, Henrico Doctor's Hospital, Medical College of Virginia/Veteran's Affairs Medical Center, Roanoke Memorial Hospitals, Children's Hospital of the King's Daughters, University of Virginia Health Sciences Center, and Sentara Norfolk General Hospital/Sentara Health System (VTC. 1995). A total of 232, 225, and 269 kidney transplant operations were performed in 1994, 1995, and 1996 respectively, in the state of Virginia alone. Forty-seven kidney transplants were performed at Sentara Norfolk General Hospital/Sentara Health System in 1994, 35 in 1995, and 33 in 1996 (VTC. 1995). An annual average of 40-60 individuals undergo renal transplantation at Sentara Norfolk General Hospital/Sentara Health System (Sentara Video, 1994).

The greatest advantage of kidney transplantation is the ability to live a near-normal lifestyle. The individual with chronic renal failure no longer is required to interrupt his/her daily activities for dialysis, be confined to a restricted diet, nor suffer from the health problems associated with renal failure. Neither age nor pre-existing serious systemic conditions are contraindications to transplantation (Williams, 1978). Transplantation brings about a greater energy level to the individual, therefore improving his/her quality of life.

To ensure the success of the transplant, renal allograft recipients must take prescribed immunosuppressant medications throughout the life of the transplanted kidney to avoid rejection. Immunosuppressive drugs are indicated in post-operative treatment since they depress cell mediated immunity, preventing the recognition of the renal graft as foreign. This alteration in the host's immune response also alters the recognition of infectious microorganisms and leaves the immunosuppressed individual susceptible to a wide spectrum of bacterial, fungal, and viral organisms capable of becoming opportunistic infections. Most healthy immunologically competent individuals have an innate resistance to bacterial, viral, or fungal colonization. Many organisms reside in the oral cavity thus becoming part of our normal oral microflora. However, under conditions where an individual's immune system is suppressed by drugs, the normal oral microflora is capable of causing infection or disease, otherwise known as opportunistic infections (Murray, et al., 1994). It has been documented that infectious diseases are the ultimate cause of clinical post-transplant failure (Rifkind, 1967; Eickhoff, 1973; Bottomley, 1972). Candida
albicans, a fungal infection, is one of the most common oral infections seen in renal transplant patients. This infection is easily treated if detected early; however, its spread via hematologic or esophageal routes may lead to more serious problems that are resistant to treatment (Westbrook, 1978).

Extensive research findings exist on the side effects of immunosuppressant medications, particularly cyclosporin-A induced gingival hyperplasia (King, 1993; Mariani, et al., 1993; Barak, 1988; Bennet, 1985). Gingival hyperplasia can lead to bacterial plaque retention and increase the probability of potential periodontal infections. Moreover, evidence of intraoral lesions such as oral candidiasis, leukoplakia, traumatic ulcerations, acute necrotizing ulcerative gingivitis, angular cheilitis, and, though rare, oral malignancies, also have been reported (King, 1994).

Individuals with renal transplants have an increased need for outpatient dental treatment (Westbrook, 1978). Intensive preventive measures must be used in preoperative and postoperative oral care of these patients. Emphasis needs to be placed on frequent examinations and intense maintenance programs focused on the prevention and control of infections of dental origin (Westbrook, 1978). In addition, kidney transplant patients may experience a lowered resistance to infection due to their compromised state and prescribed immunosuppressant medications may mask the signs of oral infection such as Candida albicans. Consequently, this may result in undiagnosed oral conditions which may compromise the individual's systemic health and the success of the transplant. Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD lack a formal oral hygiene protocol for kidney transplant recipients. Pretransplantation dental considerations should include periodontal, endodontic, surgical, restorative, and prosthodontic treatment to eliminate pathoses and to restore function. A rigorous dental recall program should be established to prevent any oral or dental disease from progressing undetected. Patients should be educated and advised on the importance of contacting their oral healthcare professional concerning any abnormal oral signs or symptoms. A comprehensive oral health assessment of renal transplant recipients is necessary to identify and address the oral and periodontal needs of this population.

Unfortunately, due to the overwhelming nature of their disease and the high costs of medication, kidney transplant recipients often place a low priority on oral care. High costs of dental treatment impede these individuals from seeking oral healthcare. The importance of dental care for these patients must assume a higher priority, for the possibility of an oral focus of infection "seeding" the transplanted kidneys can be a serious problem (Westbrook, 1978).
Kidney transplantation is the most common organ transplant performed in the United States. Therefore, an increase in the number of kidney transplants performed each year is anticipated with more Americans living in compromised medical states. If an oral healthcare protocol is not developed, the oral health needs of this population will go unmet and may jeopardize the success rates of transplantation. A protocol will minimize problems related to oral disease, thereby reducing future healthcare costs and increasing the likelihood of long term transplantation success. If followed, an oral healthcare protocol will improve the quality of life of kidney transplant recipients as well as the life of the transplanted kidney. Renal transplant recipients will have a better sense of well being and will have an increased desire to interact with others, rather than living with dental pain, poor nutrition, poor oral and facial esthetics, and chewing difficulties.

The purpose of this study was to assess the oral health status, prevalence of intraoral manifestations and periodontal disease status in an attempt to reveal the need for preventive and therapeutic oral healthcare and dental treatment in kidney transplant patients undergoing immunosuppressive therapy. Results obtained have aided in the development of a post-transplant oral healthcare protocol to meet the oral and periodontal needs of individuals with renal transplants at Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD. Documentation of the present oral health status of this population will support the oral needs of these medically compromised individuals. It is important that dental hygienists and dentists provide support for the total health needs of these patients to deliver dental treatment required because of their altered health status. The more information obtained regarding kidney transplant recipients, the more comfortable oral care providers will become in providing treatment in the private practice environment.

**DEFINITION OF TERMS**

The following terms have been defined for use in this study:

1. **Bacterial plaque** - a complex, organized mass of bacterial colonies attached to the tooth surfaces or calculus (Case, Funke, and Tortora, 1994). Bacterial plaque was measured using the Debris Index, a component of the Simplified Oral Hygiene Index introduced by Greene and Vermillion (1964), used to evaluate oral hygiene status.

2. **Dental calculus** - a hard substance that contains inorganic and organic components such as calcium, phosphorus, protein, polysaccharide complexes, desquamated epithelial cells,
leukocytes and various types of microorganisms (Cohen, 1994). Dental calculus was measured using the Calculus Index, the second component of the Simplified Oral Hygiene Index introduced by Greene and Vermillion (1964).

3. **Gingival hyperplasia** - overgrowth of the soft tissue of the gums, often seen in persons treated for epileptic seizures with phenytoin (Mosby, 1983). Gingival hyperplasia will be assessed clinically using the Hyperplastic Index comprised of: a vertical component developed by Aas et al. (1963), and a horizontal component developed by Seymour et al. (1985).

4. **Immunosuppression** - the administration of agents that significantly interfere with the ability of the human immune system to respond to antigenic stimulation by inhibiting cellular and humoral immunity.

5. **Intraoral lesions** - atypical or abnormal lesions found in the oral cavity. For purposes of this study, intraoral lesions will be recorded by location, color, size, and characteristics.

6. **Periodontal disease** - inflammatory disease of the periodontium characterized by the loss of connective tissue attachment, destruction of bone, and possible tooth mobility (Darby & Walsh, 1995). Periodontal status will be measured by Ramfjord's Periodontal Index (1967).

7. **Renal allograft** - renal tissue graft from the same species; tissue transplanted from one human being to another (Powers, et al., 1994).

**ASSUMPTIONS**

For the purposes of this study, the following assumptions were made:

1. The results of this study can be used to make recommendations in the development of a standardized post-transplant oral healthcare protocol for renal transplant recipients to be implemented at Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD.


**LIMITATIONS**

The following limitations have been identified as possible threats to the internal and external validity of the research design.
1. Generalization of results beyond the sample of renal transplant recipients undergoing immunosuppressant therapy is limited due to the small number of subjects studied.

2. Internal validity could have been affected by intrarater variations when measuring pocket depths, gingival enlargement, and oral debris. A pilot study established the intrarater reliability of the examiner using the following indices: Simplified Oral Hygiene Index, Ramfjord's Periodontal Disease Index, and the Hyperplastic Index. Intra rater reliability was established at r=0.95.

3. Data collection took place in clinical examination rooms at Sentara Norfolk General Hospital/Sentara Health System, Nephrology Associates of Tidewater LTD, and at the Old Dominion University Dental Hygiene Care Facility; therefore, situation relevant variables could not be controlled.

4. Individuals who underwent periodontal surgery/treatment six months prior to the oral examination posed a threat to the validity of the Hyperplastic Index. Therefore, these individuals were excluded from the study.

5. Small sample size and unequal numbers of subjects within the three groups might have influenced the reliability of results.

**HYPOTHESES**

The following null hypotheses were tested:

1. There is no statistically significant difference, at the .05 level, in the oral hygiene status of renal transplant recipients with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the Simplified Oral Hygiene Index.

2. There is no statistically significant difference, at the .05 level, in the periodontal disease status of renal transplant recipients with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the Periodontal Disease Index.

3. There is no statistically significant difference, at the .05 level, in the degree and severity of gingival hyperplasia of renal transplant recipients with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the Hyperplastic Index.
METHODOLOGY

The oral health status of 22 renal transplant recipients undergoing immunosuppressive therapy was assessed by a single investigator. Renal transplant recipients were purposefully selected from the Renal Transplant Center at Sentara General Hospital / Sentara Health System and from Nephrology Associates of Tidewater LTD and were examined at the respective sites or at Old Dominion University Dental Care Facility. Individuals willing to participate were asked to sign an informed consent form prior to their participation in the study (See Appendix A). Selected subjects were stratified into three groups: individuals with a kidney transplant for less than one year, individuals with a kidney transplant for one to three years, and individuals with a kidney transplant for more than three years.

The oral examination was performed by a single investigator, therefore eliminating inter-examiner variations. On each renal transplant patient, Ramfjord teeth (#3, #9, #12, #19, #25, and #28) were measured for bacterial plaque and dental calculus using Greene and Vermillion's (1964) Simplified Oral Hygiene Index. Probe measurements were recorded to the nearest millimeter on Ramfjord teeth; and periodontal status was determined using Ramfjord's (1967) Periodontal Disease Index. Severity of gingival overgrowth was assessed in the maxillary and mandibular anterior sextants by the combination of two indices: Aas et al.'s (1963) vertical component, which measures the degree of gingival enlargement in an apico-coronal direction; and Seymour et al.'s (1985) horizontal component, which measures the degree of gingival thickness on both the labial and lingual aspects in a labio-lingual direction, as utilized by King et al. (1993). Intraoral lesions were recorded on a self-designed form in terms of location, color, size, and characteristics.
CHAPTER II
REVIEW OF THE LITERATURE

To establish the theoretical base for the study, literature was reviewed in the following areas: immunosuppressive therapy and side effects, infection in the renal transplant patient, intraoral manifestations of the renal transplant recipient, periodontal disease in the renal transplant recipient, effectiveness of a bacterial plaque control program on gingival hyperplasia, and dental management of the individual with a kidney transplant.

Kidney Disease, Renal Failure, and Renal Transplantation

Five major body systems are affected by the systemic disturbances in renal disease: the gastrointestinal, neuromuscular, hematologic-immunologic, endocrine-metabolic, and cardiovascular systems. Oral manifestations are directly linked with the gastrointestinal, hematologic-immunologic, and cardiovascular alterations.

The role of the kidneys is to help maintain the internal environment of the body (homeostasis) by regulating fluid balance, e.g., sodium excretion, water balance, electrolyte balance (needed for normal cell function), regulation of acid-base balance (pH, cell environment), and is also involved in hormone production (for blood pressure regulation and for red blood cell production). However, medical conditions such as changes in blood pressure can affect kidney function, thus leading to kidney disease. As the kidney fails, there is abnormal retention of nitrogen products in the blood, an impaired ability to concentrate urine, and mild anemia (Cohen, 1994).

Kidney disease has been reported to be the fourth leading health problem in the United States with an incidence between 10,000 and 18,000 new cases each year (Cohen, 1994). As defined by Little and Falace (1993), end-stage renal disease (ESRD) is the “bilateral progressive and chronic degeneration of nephrons that results in uremia and ultimately leads to death” and occurs when kidney function falls to 10 - 15 percent of normal. Nephrons, the working units of the kidney, receive and “filter” the blood containing the waste products left over after food and medications are metabolized by the body.

The early phase of ESRD is an asymptomatic disorder also called renal insufficiency. As time progresses, the kidney loses the ability to perform its excretory, endocrine, and metabolic functions; the nephron population and the glomerular filtration rate falls, and the blood urea
nitrogen rises. Uremia, or the retention of excretory products, is the resulting syndrome of ESRD and interferes with endocrine and metabolic functions. The uremic syndrome represents a number of clinical signs and symptoms that appear in the individual with renal failure (See Figure 1). Additional consequences of this disease include mild azotemia, impaired ability to concentrate urine, nocturia, and mild anemia. The systemic signs of renal failure and uremia important to the oral care professional are hematologic changes, changes in bone metabolism and alterations in immune status (Levy, 1988).

<table>
<thead>
<tr>
<th>Gastrointestinal</th>
<th>Nausea, vomiting, anorexia, ammonia taste and breath, stomatitis, parotitis, esophagitis, gastritis, gastrointestinal bleeding.</th>
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<tbody>
<tr>
<td>Neuromuscular</td>
<td>Headache, peripheral neuropathy, paralysis, myoclonic jerks, seizure, asterix.</td>
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<tr>
<td>Hematologic-immunologic</td>
<td>Normocytic-normochromic anemia, coagulation defect, increased susceptibility to infection, decreased erythropoietin production, lymphocytopenia.</td>
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<td>Endocrine-metabolic</td>
<td>Renal osteodystrophy (osteomalacia, osteoporosis, osteosclerosis), secondary hyperparathyroidism, impaired growth / development, loss of libido and sexual function, amenorrhea.</td>
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<td>Cardiovascular</td>
<td>Atrial hypertension, congestive heart failure, cardiomyopathy, pericarditis, arrhythmias.</td>
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<tr>
<td>Dermatologic</td>
<td>Pallor, hyperpigmentation, ecchymosis, uremic frost, pruritis, reddish-brown nail beds.</td>
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FIGURE 1. SYSTEMIC MANIFESTATIONS OF RENAL FAILURE / UREMIA (De Rossi & Glick, 1996).

Etiology of renal failure includes a wide variety of diseases which are immunologic, hereditary, bacterial, or idiopathic in nature. The two most common causes of ESRD are glomerulonephritis (28.3 percent) and pyelonephritis (17.1 percent). Glomerulonephritis represents a group of variant diseases with different etiologies and pathogeneses that produce an irreversible impairment of kidney function. These diseases are thought to be immunologic in nature as evidenced by recurrence of diseases in kidneys transplanted to individuals with a history of glomerulonephritis (Cohen, 1994). Pyelonephritis, a bacterial infection of the kidney, affects one or both kidneys and is most commonly caused by *Escherichia coli*. Pyelonephritis is predisposed by lesions that obstruct the urinary tract or by sepsis (i.e., patients with subacute bacterial endocarditis). Inability to retain sodium is more pronounced in pyelonephritis than in
glomerulonephritis. Other causes of ESRD include polycystic renal disease, nephrosclerosis, diabetes, collagen vascular disease, hereditary nephropathy, analgesic abuse nephropathy, obstructive nephropathy, gouty nephropathy, neoplastic nephropathy, and other unknown nephropathies (Cohen, 1994).

Renal failure affects several endocrine functions. It will decrease the production of renin which in turn will increase the sodium fluid volume and blood pressure of medically compromised individuals. Moreover, renal failure affects the erythropoietin formation, which controls the red blood cell production in the bone marrow, the production of prostaglandins, and the kallikrein-kinin system. Renal disease can alter one or more valuable bodily functions thus complicating the maintenance of stable composition of the body’s internal fluid environment.

Renal osteodystrophy refers to the skeletal changes resulting from chronic renal disease and is caused by the disorders in calcium and phosphorus metabolism, abnormal vitamin D metabolism, and increased parathyroid activity. In early renal failure, intestinal absorption of calcium is reduced because the kidneys are unable to convert vitamin D into its active form (1-25 dihydroxycholecalciferol). For this reason osteodystrophy patients are placed on protein-restricted diets and phosphate binders and are also given vitamin D supplements.

Medical management of ESRD begins with a conservative approach of dietary modification with protein restriction and monitoring fluid, sodium, and potassium intake. Nephrotoxic drugs or agents metabolized by the kidney are avoided and systemic or related conditions such as hypertension, congestive heart failure, infection, or urinary tract obstruction that may further deteriorate the function of the kidney are treated. Calcium and Vitamin D supplements should be administered (Cohen, 1994).

As ESRD progresses and more nephrons are destroyed, renal hemodialysis, the artificial filtration of the blood, is indicated. Renal dialysis has significantly decreased the mortality of this once invariably fatal disease. Two types of dialysis exist, hemodialysis and peritoneal dialysis. Hemodialysis is a process whereby the circulating blood is detoxified by artificial means (Westbrook, 1978). Individuals receiving hemodialysis usually require approximately three, six-hour treatment sessions a week. Between hemodialysis sessions, most persons can function as outpatients. Peritoneal dialysis is used in 20 percent of all dialysis. This type of dialysis is a slower process than hemodialysis and is less often used for long term treatment (Jameson, 1990).

Technological advances have led to transplantation as an alternative treatment for individuals with ESRD. The first successful kidney transplant occurred in 1954 and involved identical twin brothers. The first successful human kidney cadaver transplant was performed in
1962. The quality of life of an individual with a kidney transplant is far better than that on hemodialysis, as proved by the five-year survival rate (Cohen, 1994). The individual no longer has to undergo lengthy hospital visits, adhere to diet restrictions associated with the dialysis, be at continuous risk of Hepatitis B, C, or AIDS (due to multiple blood exposures from dialysis), nor alter daily lifestyles.

The transplanted kidney usually lies in the iliac fossa in an extraperitoneal plane (See Figure 2). The renal vein is anastomosed end-to-side to the iliac vein and the renal artery anastomosed either end-to-end to the hypogastric artery or end-to-side to the external iliac artery, depending upon the size and length of the renal artery and the presence or absence or arteriosclerosis in the recipient (Williams, 1978). Removal of the diseased kidneys is not indicated unless there is hypertension and infection. Urinary continuity is re-established by ureterocystostomy, a method which employs a submucosal tunnel and careful suturing of the ureter to the area of the trigone of the bladder. If this connection fails, the recipient's ureter is then anastomosed to the donor's renal pelvis as a secondary procedure (Williams, 1978).

FIGURE 2. ANASTOMOSED KIDNEY
The immune system is vital for the survival of an individual in a world full of bacteria, viruses, fungi, and diseases. However, it can complicate the life of an individual with a kidney transplant. Unless the allograft comes from an identical tissue such as an identical twin, the immune system will identify, recognize, and eliminate the foreign graft (Williams, et al., 1991). For the transplant to be successful and avoid kidney rejection, therapies which alter the immune system so that it is unable to recognize the graft as foreign have been developed and used with success.

**Immunosuppressive Medications**

Rejection of the transplanted kidney by the host's immune system is a major limiting factor in kidney transplantation. Kidney transplant recipients must follow a strict regimen of immunosuppressive medications to avoid rejection of the transplanted kidney. The usual drug regimen for renal transplant recipients consists of a combination of an immunosuppressive agent and an anti-inflammatory glucocorticoid to prevent graft rejection. Immunosuppressive agents include combinations of corticosteroids, azathioprine, antimyocyte globulin and antilymphocyte serum, monoclonal antibodies (OKT -3), and cyclosporin (Williams, et al., 1991; Sigardson-Poor & Haggerty, 1990). The drug regimen followed by renal transplant patients at Sentara Norfolk General Hospital/Sentara Health System and the Nephrology Associates of Tidewater, LTD are combinations of prednisone, cyclosporine or Prograph®, and Imuran® or Cellcept®. To be maximally effective these agents must be employed prior to transplantation. Renal transplant recipients must continue therapy throughout the life of the transplanted kidney to prevent graft rejection.

Corticosteroids such as prednisone and methylprednisolone sodium were first used in the 1960's to prevent graft rejection (Sigardson-Poor & Haggerty, 1990). These antiinflammatory agents are still effective in the prevention and treatment of acute rejection and are predominantly prescribed today. Corticosteroids affect both the humoral and cell-mediated immune response by altering the function of T-cells and causing their death (Sigardson-Poor & Haggerty, 1990). Corticosteroids prevent leukocyte migration and phagocytic activity to the site of inflammation, the transplanted kidney. Lymphocytes are not able to recognize antigens and are no longer attracted to the renal graft. Side effects of corticosteroids are usually dose related and include cushingoid appearance, glucose intolerance, sodium and water retention, increased appetite, osteoporosis, muscle wasting, gastric ulcers, cataracts, steroid psychosis, and increased susceptibility to infection (Williams, et al., 1991). Side effects of prednisone found in the oral
cavity include dry mouth, poor wound healing, petechia, and candidiasis (Gage & Picket, 1994). Candidiasis in the oral cavity is a result of the increased risk of infection and may pose a threat to the transplanted kidney.

Azathioprine, also known as Imuran®, has been used in kidney transplants since 1961 (Sigardson-Poor & Haggerty, 1990). Azathioprine is an antimetabolite drug that inhibits purine synthesis necessary for antibody production. Consequently, it prevents rapid cytotoxic T-cell division and stimulation needed in an immune response (Williams, et al., 1991). Side effects of azathioprine are dose-related and are associated with suppression of rapidly dividing cells. Azathioprine can cause bone marrow suppression initiating leukopenia, thrombocytopenia, anemia, gastrointestinal upset, hepatotoxicity, susceptibility to infection, and tumors (Williams, et al., 1991; Sigardson-Poor & Haggerty, 1990). Side effects found in the oral cavity include oral lesions such as stomatitis and ulcerations (Gage & Picket, 1994).

Antithymocyte globulins (ATG) and antilymphocyte serum (ALS) are preparations produced in horses, rabbits, or goats (Sigardson-Poor & Haggerty, 1990). These preparations have been found to be involved in the cell mediated immune response inhibiting the host's ability to reject the transplanted kidney. After injection into the host, antithymocyte globulins bind to T-cells altering the ability of an antigen receptor to combine with its antigen, and make lymphocytes more susceptible to phagocytosis (Williams, et al., 1991). Adverse effects related with antithymocyte globulins and antilymphocyte serum preparations vary with the preparation used (Williams, et al., 1991). Fever and chills due to serum sickness are associated with the administration of the first dose: leukopenia, thrombocytopenia, anemia, increased risk for infection, anaphylactic reactions, and bone marrow suppression are associated with ATG and ALS (Williams et al., 1991; Sigardson-Poor & Haggerty, 1990). Opportunistic infections with cytomegalovirus and herpes simplex and increased incidence in malignancy are seen in immunosuppressive patients who receive antilymphocytic preparations (Sigardson-Poor & Haggerty, 1990).

Advances in genetic engineering led to the development of Orthoclone® OKT-3, a monoclonal antibody, in 1979 after problems were found with the use of ATG and ALS (Williams, et al., 1991). Because of the way ATG and ALS were reproduced, effectiveness in potency and toxicity varied from batch-to-batch, thereby being inconsistent in achieving a standardized agent (Sigardson-Poor & Haggerty, 1990). Monoclonal antibodies are clones of antibodies to specific cell surface antigens in a T-cell. When indefinitely replicated, the problem of batch-to-batch variability is solved (Sigardson-Poor & Haggerty, 1990). OKT-3 was first
tested in humans in 1981 and received the Federal Drug Administration (FDA) approval in 1986 for use in human kidney allograft rejection (Sigardson-Poor & Haggerty, 1990). OKT-3 binds to a T-cell specific antigen receptor and blocks their proliferation and cytotoxic functions making these cells unable to recognize the foreign graft (Williams, et al., 1991). Side effects associated with OKT-3 include flu-like symptoms, fever, bronchospasm, aseptic meningitis, lymphoma, and development of antibodies against the medication. Unfortunately, the later can cause elimination of OKT-3 from the blood and may limit effectiveness of additional OKT-3 treatments (Williams, et al., 1991).

**Oral Complications Experienced by Renal Transplant Recipients**

**Oral and Cutaneous Infection.** Immunosuppressive drugs are essential in the medication therapy of the kidney transplant patient since they alter the host's immune system to prevent the recognition of the graft as foreign. In addition, these drugs also alter the recognition of infectious microorganisms, which can consequently result in systemic infection and even kidney rejection. Infections account for the majority of morbidity (80 percent) and half of the mortality in renal transplant patients (Brynger, et al., 1976). Infections frequently reported as the cause of death following renal transplantation have been bacterial and fungal. Infections with viruses of the herpes group (herpes zoster, herpes simplex, varicella, and cytomegalovirus), have been noted do not account for significant mortality.

Post-transplant infections can be classified by the organism, the system involved or the time of appearance in relation to surgery (Rubien, et al., 1981). Bacterial infections generally occur within the first month of surgery (~1 month), affect the urinary tract, respiratory system (*Streptococcus pneumoniae*), and wound and vascular access sites. These infections are common and all may lead to septicemia. Of the viral infections, herpes simplex infections tend to occur early, cytomegalovirus (CMV) infection is not usually seen in the first month after transplantation, and herpes zoster may occur at any time.

Overall, about 50 percent of infections are caused by viruses, 30 percent by bacteria and 5 percent by fungi. In 15 percent of cases, infection is polymicrobial (Naylor et al., 1988; Rubien et al., 1981). Opportunistic infections are most common in the one to six month post-transplant period, where immunosuppressive therapy is at its peak thus, this period becomes very critical since it is the period with greatest risk of life-threatening infection. Opportunistic infections seen in the one to six month post-transplant period are viral, fungal, and bacterial in nature. The most common viral infection in these renal transplant patients is caused by the cytomegalovirus (CMV). Cytomegalovirus infection is either primary or recurrent and has the potential for causing
hepatitis, leukopenia, thrombocytopenia, pneumonitis, chorioretinitis, a further state of immunosuppression, and allograft dysfunction. Other viral infections manifested in this period are the Epstein Barr virus, varicella-zoster virus, papovavirus, adenovirus, and herpes simplex virus. Hepatitis C. Herpes simplex viral infection is common in transplant patients on immunosuppressive therapy, characterized by a seven to 14 day eruption of lesions (Park, et al., 1967). Fungal opportunistic infections include Mycobacterium tuberculosis, and Pneumocystis carinii. Central nervous system infections are caused by Cryptococcus, Listeria and Aspergillus organisms. Immunosuppressive therapy is at its lowest levels six months post-transplantation. During this period chronic and reactivated viral infections, such as cytomegalovirus and hepatitis, and opportunistic infections, such as influenza, pneumococcal pneumonia, and urinary tract infections are observed.

Studies have demonstrated that infectious diseases are the ultimate cause of clinical post-transplant failure (Rifkind, 1967; Eickhoff, 1973; Bottomley, 1972). Eickhoff (1973) reviewed data from the University of Colorado's transplant program from 1962 to 1968. Infectious post-transplant complications were documented for 80 percent of the patients in the study. The infectious organisms in the study included bacteria such as Pseudomonas and Klebsiella, fungi such as Candida Albicans and Aspergillus, and viruses such as herpes virus. Furthermore, infection was the direct cause of death in 50 patients. This was broken down into 21 bacterial, seven fungal (two being candidiasis), four viral (one being disseminated varicella-zoster), three pneumocystic carinii infection only, and 15 mixed infections (i.e., bacterial/fungal, bacterial/fungal/pneumocystic, etc.). Nineteen of the cases were reported as ear, nose, and throat infections. This study, however, fails to identify the etiology of the infections; i.e., whether they are hospital-acquired or associated with immunosuppressant drugs. In addition, specific sites and pattern of infections were not elaborated (Tyldesley & Rotter, 1984).

Microorganisms residing in the oral flora become a potential hazard for an individual in an immunocompromised state, thereby causing infections. The organisms which cause the majority of infections can be found as part of the oral microflora. Among the microorganisms involved in many of these infections are gram-negative bacteria such as Klebsiella, Pseudomonas, and Proteus; fungi, such as Candida albicans, Aspergillus, and Mucor; and viruses, such as herpes simplex and herpes zoster (Cohen, 1994). These microorganisms can be aspirated or spread into the bloodstream by untreated oral conditions such as periodontal disease, pulpal infection, abscesses, or ulcers. However, the incidence of severe infection caused by oral bacteria or oral infection is not known.
The oral cavity acts as a portal of entry for the fungal infection *Candida albicans*, the most common oral infections seen in renal transplant patients. This infection can be developed as early as one to 36 months after renal transplantation (Zazgornik et al., 1975). If detected early, it can be easily treated. However, their spread via blood and esophagus may lead to more serious problems that are difficult to treat. Systemic fungal infections were found in 23 of 51 autopsy patients who had undergone kidney transplant and immunosuppressive therapy (Rifkind, et al., 1967). Twelve of these infections were produced by candidiasis. Fungal infection of the gastrointestinal tract by candidiasis was found in eight cases and the remaining four cases caused by candidiasis had gastrointestinal infection with no pulmonary involvement. Researchers concluded that the gastrointestinal tract may be an important portal of entry for *Candida* from which this infection disseminates into other organs.

Oral symptoms of fungal infections may include burning, tenderness, and dryness of the oral mucosa. Clinical manifestations of *Candida albicans* appear as soft, white, creamy patches that may coalesce and enlarge (Westbrook, 1978). This plaque-like lesion can be scraped off, leaving a raw, bleeding surface. Usual treatment for this condition are debridement of infected area and antifungal antibiotics such as Nystatin® or Amphotericin®.

Reyna et al. (1982) conducted a retrospective review of head and neck infections in 128 renal transplant recipients. Fourteen head and neck infections occurring in 12 of 128 recipients were found within a one-year follow up period. The infections included sinusitis, otitis media, dental abscess, Ludwig’s angina, parotitis, nasal abscess. No kidney rejection episodes were reported at the time the infections were observed. However, one patient died from disseminated herpes simplex. Three patients reported with dental abscesses and fever in the first two months after transplantation, but only one was experiencing pain. Radiographic examinations revealed typical periapical abscesses that were drained without complications. One patient who had been treated for dental abscess presented to the study presented with acute suppurative parotitis caused by the Gram-positive organism *Staphylococcus aureus*. Organisms causing infections were typical of those causing the same infection in nonimmunosuppressed patients. This study suggests that a careful examination of the head and neck should be performed in patients because pathogens residing in these areas can serve as a reservoir for infection.

Another example of the head and neck serving as a reservoir for infection-producing pathogens is evidenced in Greenberg and Cohen’s (1977) study on renal transplant patients. They attempted to determine whether the oral flora is a source of systemic infection in immunosuppressed patients. To identify oral and systemic factors which predispose
immunosuppressed patients to systemic infection with oral microorganisms, and to determine the
level of oral disease in these individuals. Periodontal disease was found to be as common as
pneumonia or urinary tract infections. Oral infections identified included dental abscesses, oral
ulcers, and candidiasis. Routine cultures of the oral cavity revealed Klebsiella, Pseudomonas, and
Candida organisms. No patient developed signs of systemic infection. Six of seven patients who
developed post-transplant infection had the same pathogen preoperatively in the throat, nose, or
skin.

Infections of the skin have not been as frequent as those in the oral cavity or the lungs;
however, several cases have been reported. Park et al. (1967) observed severe cutaneous
infections among renal transplant recipients undergoing immunosuppressive therapy. Some of the
infections were reported to be very unusual in appearance and with behavior that was not
immediately recognized. One case presented a patient with persistent vesiculobullous lesions on
the thigh, back, and lower lip. Clinical characteristics resembled those of severe varicella with
lesions attaining a full size of two centimeters. The patient had a history of severe varicella during
childhood. Biopsy and culture revealed varicella zoster to be the causative virus. Another case
involved a 13-year old boy with poor renal function despite medications and other therapeutic
measures. Pinhead-size vesicles typical of herpes simplex appeared on the vermilion border of
both lips, chin and in the inner aspect of the lower lip. Within three days the lesions were covered
with a hemorrhagic crust. Lesions did not resolve and continued to enlarge over a six-week period
until they covered large portions of the upper lip and nose. New lesions continued to appear in
unaffected and previously affected areas especially on the vermilion border of both lips. Cultures
revealed herpes virus hominis. Researchers were uncertain about whether patients on
immunosuppressive therapy have an increased susceptibility to new pathogens or whether the
infections represented reactivation of latent infections (e.g., persistent varicella patient) or
dissemination of organisms already present in the body.

Viral infections such as the herpes simplex virus and cytomegalovirus are prevalent in
renal transplant recipients. Herpes simplex is usually a benign virus, but in immunocompromised
patients it can initiate a chronic destructive process. Cohen and Greenberg (1985) studied eight
immunocompromised patients with chronic aggressive herpes simplex virus infection of the oral
mucosa. In all cases the oral cavity was the only or major involved site. Three of the eight
patients had kidney transplants and exhibited well-defined raised lesions with white borders on the
alveolar mucosa, gingiva, lip, tongue, palate, and esophagus. Chronic herpes simplex virus
infections have distinctive clinical characteristics and if detected in a renal transplant patient, the
individual should be referred for a complete medical/dental evaluation to rule out an underlying malignant condition and for early treatment to avoid dissemination to other organs or to the transplanted kidney.

The above studies demonstrate that there is considerable evidence to show that patients treated with corticosteroids and immunosuppressants have an increased susceptibility to bacterial, fungal, and viral infection. The organisms which cause the majority of these infections can be found as part of the oral flora.

**Cyclosporin-A Induced Gingival Hyperplasia.** Cyclosporin, discovered in 1972 by J.F. Bora and released by the Federal Drug Administration in 1983 for general use, has brought revolutionary changes in immunosuppressive therapy. With the dramatic improvement in transplant response, it is now the medication of choice for post-transplant therapy, especially in kidney transplant therapy where it enjoys a success rate of 95 percent (Mariani, G., et al., 1993). Sentara Norfolk General Hospital/Sentara Health System includes cyclosporin as part of the immunosuppressive regimen for its kidney transplant patients. (Personal Communication, McCune T.). The main action of cyclosporin-A is its ability to selectively suppress cell mediated immunity inhibiting T-cell proliferation while having minimal effect on humoral-mediated immunity. The major side effect of cyclosporine is nephrotoxicity, and this appears to be dose-related. Monitoring of blood levels is recommended as an aid to cyclosporin therapy (Murray, et al., 1986). Other adverse effects related to the use of cyclosporin-A include hepatotoxicity, hypertension, poor healing, increased risk for infection, malignancy, and gingival hyperplasia (Williams, et al., 1991).

Daley et al. (1986) indicated that cyclosporin-A therapy predisposes patients to gingival hyperplasia. A total of 100 patients (18 transplant, 78 type I diabetes, three multiple sclerosis, and one lupus erythematosus) treated with cyclosporin-A therapy for at least three months were examined clinically and an assessment of the presence and degree of gingival hyperplasia was made. Hyperplasia was assessed numerically with scores of 0-5, indicating no clinical evidence of noninflammatory hyperplasia to hyperplasia covering at least 3/4 of the tooth crown, respectively.

Results revealed that 70 percent of the patients sampled had signs of at least mild gingival hyperplasia with severity ranging from mild to severe. Mean daily oral dosage of cyclosporin-A ranged from 32mg/day to 920mg/day, and mean hyperplastic scores ranged from 0.0-4.16. Analysis of the data revealed a correlation coefficient of r=0.158 suggesting no direct relationship between dose of cyclosporin-A and severity of gingival hyperplasia. Mean serum concentration of cyclosporin-A ranged from 70mg/ml to 204 mg/ml with mean gingival hyperplastic scores of
Analysis of the data revealed a correlation coefficient of $-0.137$, suggesting no direct correlation between serum and concentrate of cyclosporin-A and severity of gingival hyperplasia.

Participants in this study differed in type and characteristic of systemic disease; however, cyclosporin-A was the common factor among them. The researchers concluded that cyclosporin itself, and not the patient's disease, caused gingival hyperplasia. It can be inferred from this study that renal transplant recipients who take cyclosporin as part of their immunosuppressive therapy may manifest gingival hyperplasia and that the severity of gingival hyperplasia may be due to differences in pharmacokinetic profiles between patients.

Clinical characteristics of cyclosporin-A induced hyperplasia are the same as those seen in dilantin-induced gingival hyperplasia (Tyldesley, 1984; Mariani, et al., 1993; Daley, et al., 1984). Studies have demonstrated that gingival hyperplasia begins in the interdental papillae and extends to the marginal gingiva. This gingival overgrowth is more common in the anterior region than in the posterior, and more common in the labial surfaces than in the lingual surfaces (Daley, et al., 1984; Roehrich, et al., 1994). Excess tissue has been reported to cover the teeth entirely causing major occlusal and masticatory problems (Roehrich, et al., 1994 & Rostock, et al., 1985).

An examination of a 19 year old black male undergoing cyclosporin-A therapy for a liver transplant revealed severe generalized facial and lingual enlargement (Rostock, 1985). The gingiva was erythematous, edematous, mobile and tender, and tended toward spontaneous hemorrhage. In addition, generalized incipient to moderate bone loss was present and the patient's appearance and masticatory function was affected. The patient was unable to perform oral hygiene because of pain and hemorrhage. The patient underwent periodontal surgery and oral hygiene instructions. Two months post surgery the gingival tissues healed well. Following periodontal surgery, large amounts of subgingival calculus deposits that had not been detected radiographically were found, suggesting that local irritants, bacterial plaque and dental calculus, may exacerbate the gingival hyperplasia.

The severity of gingival hyperplasia is predisposed by cyclosporin-A dosage is evidenced by an increase of gingival overgrowth soon after the patient's dose was increased. The patient's condition worsened at subsequent visits and he developed chronic liver rejection. A second liver transplant was performed. Researchers did not reveal if liver rejection was associated with the patient's gingival condition.

Tyldesley & Rotter (1984) observed renal transplant recipients over a period of two years. The investigation involved subjects treated with cyclosporin-A and a control group treated with conventional immunosuppressants (prednisone and azathioprine). Results demonstrated that
gingival hyperplasia occurred in all cases. Papillary gingival involvement from both lingual and buccal aspects was especially noted. A positive correlation between plaque and severity of enlargement was evidenced by pronounced gingival enlargement in individuals unable or unwilling to maintain a plaque-free mouth. Tooth loss was reported in individuals with uncontrolled hyperplastic changes and poor plaque control. Intra-rater/inter-examiner reliability was not established prior to investigation.

**Other intraoral manifestations.** Oral complications in kidney transplant patients undergoing immunosuppressive therapy are usually due to rejection, over immunosuppression, and side effects of immunosuppressive therapy (Little & Falace, 1993). Intraoral manifestations found in individuals with renal transplantation include:

- Enlarged (asymptomatic) salivary glands
- Decreased salivary flow
- Zerostomia
- Odor of urea on breath
- Metallic taste
- Increased calculus formation
- Low caries rate
- Enamel hypoplasia
- Dark brown stains on crowns (extrinsic and intrinsic)
- Pale mucosa with diminished color demarcation between attached gingiva and alveolar mucosa
- Low-grade gingival inflammation
- Petechiae and ecchymosis
- Bleeding from gingiva and mouth
- Prolonged bleeding
- Candida infections
- Burning and tenderness with dryness of mucosa
- Erosive glossitis
- Tooth erosion - secondary to regurgitation associated with dialysis treatment
- Dehiscence of wounds
- Loss of bony trabeculation
- Ground-glass appearance
- Loss of Lamina dura
- Giant cell lesions - brown tumors
- Socket sclerosis
- Pulpal narrowing and calcification
- Tooth mobility
- Arterial and oral calcifications
- Cyclosporine-induced gingival hyperplasia
- Perioral anesthesia

(Cohen, 1994)
King et al.'s (1994) prevalence study of intraoral manifestations in renal transplant recipients demonstrated that regular dental screenings are indicated in this population. The oral mucosa of 159 renal transplant recipients undergoing immunosuppressive therapy was examined and compared to a control group with no history of renal disease and no history of immunosuppressive therapy. Patients were asked about their current medication therapy, post and present smoking habits, and current alcohol consumption. Lesions were recorded by location, color, character, and clinical diagnosis. Biopsies were performed and subjected to histopathologic examination where indicated. Among the most common lesions found in these patients were gingival hyperplasia, hairy leukoplakia, leukoplakia, candidiasis, and lesions in the vermillion border of the lip. The less common lesions included fibroepithelial polyps, pyogenic granuloma, acute necrotizing ulcerative gingivitis (ANUG), black hairy tongue, papilloma, and geographic tongue.

Intraoral Malignancies. Intraoral malignancies are rare in renal transplant recipients. Nevertheless, one reported case involved squamous-cell carcinoma in an area of cyclosporin-A induced gingival hyperplasia. Shortly after the diagnosis, the patient developed carcinoma of the lateral border of the tongue which metastasized to the deep cervical lymph nodes (Tyldesley, 1979). The study suggests that certain agents such as cyclosporine may be associated with a higher incidence of cancers in immunosuppressed patients. Bleeding and poor healing are also related with side effects of immunosuppressive therapy, particularly with cyclosporine use (Little & Falace, 1993).

Periodontal Disease. Few studies are available regarding the degree of involvement, if any, of periodontal disease and its relation to kidney transplant patients undergoing immunosuppressive therapy. Sandler & Stahl (1954) conducted a study to determine if periodontal disease is influenced by the presence of systemic factors in individuals; and if so, to what degree of involvement. Intraoral examinations of the hard and soft tissues and full mouth radiographs were taken on white male patients admitted to the Brooklyn Veteran's Administration Hospital. To ensure validity of findings, patients were reexamined by a periodontist two to three days after initial examination. Patients who were hospitalized for uncomplicated conditions such as hernia, hemorrhoids, elective operations, and amputations were used as a control group. The experimental group consisted of patients with significant diseases such as endocrine, cardiovascular, liver, kidney or endocrine, among others. Periodontal disease was assessed by inflammation of the mesial gingival papilla, inflammation of the marginal gingiva, recession of
the marginal gingiva from normal contour, and degree of resorption of alveolar bone as determined from radiographs and clinical examination. Results demonstrated that individuals with kidney disease had a significantly greater proportion of inflamed papillae and a greater proportion of teeth with gingival recession as compared with the control group. Alveolar bone resorption was also found in these individuals. Results supported the researcher’s hypothesis that systemic diseases tend to influence the initiation and increase the severity of periodontal disease.

Antimicrobial Prophylaxis in the Renal Transplant Patient

An individual with chronic renal failure who has undergone renal transplantation and is following immunosuppressive drug therapy is susceptible to a number of infections. Asymptomatic bacteremias are common in dental interventions especially in those involving mucous membranes. Bacteremias may cause serious complications in these already medically compromised patients. It has already been established that infections are the major cause of morbidity and mortality in the renal transplant patient because of the immunosuppressive drug regimens. Therefore, antimicrobial prophylaxis is essential when renal transplant patients undergo dental procedures because morbidity and mortality is associated with infection in this population. Although there is no proof that antibiotics given to renal transplant recipients before dental procedures prevent infection in the transplanted kidney, experimental evidence in laboratory animals supports the use of a regimen to prevent sepsis in organ transplant patients. (Naylor, et al., 1988)

Both medical and dental professionals advise the administration of prophylactic antibiotics as specified by the American Heart Association before dental treatment to protect the patient’s graft site from bacteremias common after dental procedures and also because of the presence (usually) of an access site from previous dialysis (Westbrook, 1978; Cohen, 1994). In addition, infections as a result of immunosuppressive therapy dictate that antibiotic coverage be employed for all oral manipulations (Bottomley, et al., 1972). Amoxicillin, erythromycin, and clindamycin are the standard regimen recommended by the American Heart Association used in patients at risk for bacterial endocarditis and other high-risk patients (Little & Falace, 1993).

Erythromycin is normally used as a substitute antibiotic for penicillin in allergic patients. It has been documented that erythromycin enhances the pharmacokinetics of cyclosporine by interfering with hepatic metabolism of cyclosporine thus resulting in higher blood levels for a given dose of the drug. This increase in cyclosporine levels leads to nephrotoxicity. In a study by Murray et al. (1986) two cases were presented where the administration of antibiotic erythromycin
was followed by an increase in cyclosporin levels despite the reduction of the dose. Immediately after the erythromycin was discontinued cyclosporin levels dropped significantly. One case involved a renal transplant patient admitted to the hospital for evaluation of fever and renal dysfunction. Further examination revealed high blood pressure and diffuse rhonchi in both lungs. Erythromycin was administered to eliminate the possibility of *Legionella* infection. Cyclosporine dose was reduced because of elevated creatinine levels. Researchers confirmed the interaction between cyclosporin and erythromycin by independent laboratory testing. An experimental group treated with a combination of erythromycin and cyclosporin was compared with a control group treated with cyclosporin only. Serum creatinine and cyclosporin levels were obtained after one week of treatment and cyclosporin levels revealed to be significantly higher in the erythromycin/cyclosporin-treated group than in the cyclosporin-treated group alone. It was suggested that the administration of erythromycin should be closely monitored or avoided in patients receiving cyclosporin therapy.

The antibiotic premedication used by renal transplant recipients from Sentara Norfolk General Hospital/Sentara Health System and from Nephrology Associates of Tidewater, LTD who are allergic to amoxicillin is clindamycin (Personal Communication, McCune, T., 1995).

**Effectiveness of a Bacterial Plaque Control Program**

The control of dental plaque and calculus is an important factor in the prevention and treatment of cyclosporin-A induced gingival hyperplasia as it has been suggested that gingival overgrowth may be related to these irritants (Wysocki, et al., 1983). High costs of immunosuppressive medications or lack of knowledge contributes to the low priority renal transplant recipients place on oral healthcare.

Philstrom et al's (1980) longitudinal study investigated the effectiveness of a preventive dental program for individuals undergoing phenytoin therapy for seizure control. The 15 month study observed experimental and control groups; the independent variable was the phenytoin medication. Severity of gingivitis and amount of plaque and calculus was assessed at three month intervals. The dependent variable, the preventive dental program, included dental prophylaxis and reinforcement of oral hygiene at frequent intervals. Individuals underwent a dental prophylaxis and oral hygiene instructions prior to commencement of study. Subjects were recalled at weekly intervals for three weeks following the initial appointment and then on a monthly basis for plaque control reinforcement. Results demonstrated no significant gingival enlargement throughout the 15 month time period. In addition, gingivitis, plaque and calculus index scores decreased.
Researchers concluded that gingival enlargement associated with phenytoin therapy may be minimized by a preventive plaque control program of regular dental prophylaxis combined with oral hygiene instructions. Data collection instruments used. Ramfjord's (1967) Periodontal Disease Index: Ramfjord's (1967) Calculus Index: O'Leary's (1971) Plaque Index: and Ingle's (1959) Hyperplastic Index. all have established validity and reliability. Interexaminer reliability at the p<0.05 was 0.11 index units.

Seymour & Smith (1991) studied the effect of plaque control as means of preventing cyclosporin-A induced gingival hyperplasia. Twenty-seven renal transplant patients treated with cyclosporin-A were examined seven to ten days following transplant for baseline data. The patients were then randomly assigned to receive either an intensive program of plaque control with scaling and root planning (OH group) or no treatment (no tx group). After a period of six months patients were reexamined by the same observer. Bacterial plaque was measured by Silness & Loe's Plaque Index. the gingival condition was measured by Silness & Loe's Gingival Index, and gingival hyperplasia was measured by Seymour et al.'s Hyperplastic Index (1985). This study suggests that plaque control will not entirely eliminate gingival hyperplasia but rather it will minimize the degree of gingival hyperplasia.

**Dental Management of Kidney Transplant Patients**

The normal oral microflora may be a source of local or systemic infection for the renal transplant recipient. Therefore, the dental management of the kidney transplant patient begins before transplantation with the preoperative elimination of potential sources of infection (Cohen. 1994). An evaluation of the oral health status reveals signs of disease that should be treated before consideration for renal transplant. Coordination of oral healthcare is a joint responsibility of the dentist/dental hygienist and the patient's physician. These patients should have a thorough oral prophylaxis and/or periodontal scaling and curettage, oral hygiene instruction, a radiographic survey, pulp testing of each tooth, and any necessary restorative and/or surgical procedures. (Naylor. et al. 1988) Extractions are advised for patients with advanced periodontal disease and also for those individuals who have little interest or ability to improve their level of oral hygiene. Individuals with good levels of oral health are encouraged to keep their teeth, but should be advised on the risks and problems involved if dental disease is developed following transplantation (Little & Falace. 1993). This preliminary examination and treatment provides a basis for comparison so that oral manifestations occurring post-transplant can be evaluated. The importance of frequent oral healthcare maintenance and preventive care following transplantation
should be continuously emphasized so that the individual can be made aware of the repercussions oral disease can have on his/her general health.

Renal transplant recipients may experience gingival hyperplasia as a result of side effects of cyclosporine therapy. Meticulous oral hygiene and frequent maintenance appointments with an oral healthcare professional minimizes this side effect and complication.

Because infections are the major cause of illness and death in the renal transplant patient, and because dental intervention procedures involve the manipulation of oral mucous membranes, antimicrobial prophylaxis is necessary for the dental management of these individuals. An aggressive approach is recommended for acute oral infections with the appropriate therapy, antibiotics, and culture and sensitivity tests. The oral healthcare practitioner should be made aware of the increase incidence in candidiasis. Therefore early diagnosis is extremely important in the prevention of systemic spread of the infection to other areas or to the transplanted kidney. Topical antifungal agents such as nystatin are recommended for control of the localized oral infections such as candidiasis. (Naylor, et al., 1988) Ketoconazole or amphotericin is indicated for more resistant fungal infections. Local antiseptic applications of povidone iodine or chlorhexidine to the surgical site also reduce the incidence of infection. Acyclovir is indicated for herpes simplex mucosal lesions (ADA, 1993) However, before administering any anti-infective medication, the oral healthcare professional must consult the patient’s nephrologist, as these drugs may be nephrotoxic.

Following transplantation the dental management of the renal transplant recipient can be divided into three phases: the immediate post-transplant period; the stable graft period; and the chronic rejection period (Little & Falace, 1993). Dental treatments and precautions to consider during each phase are presented in Figure 3.
<table>
<thead>
<tr>
<th>Immediate post-transplant period (6 months)</th>
<th>Stable graft period</th>
<th>Chronic rejection period</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Continue oral hygiene procedures</td>
<td>2. Active recall program every 3 to 6 months</td>
<td>2. Follow recommendations for patients with stable grafts if dental treatment is needed</td>
</tr>
<tr>
<td>3. Emergency dental care as needed</td>
<td>3. Medical consultation regarding patient status and management</td>
<td></td>
</tr>
<tr>
<td>a. Medical consultation</td>
<td>4. Treat all new dental disease</td>
<td></td>
</tr>
<tr>
<td>b. Conservative selection of treatment</td>
<td>5. Infection control - use universal precautions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Staff vaccinated against HBV infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Avoid infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Medical consultation - need for antibiotic prophylaxis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Screening tests - WBC count, differential, CD4 and CD8 counts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. AHA standard regimen as option</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8. Avoid excessive bleeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Screening tests - BT, PT, APTT, platelet count</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Special precautions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9. Need to alter drug selection or reduced dosage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Liver or kidney failure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Avoid drugs toxic to liver or kidney</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10. Establish need for steroid supplementation and be able to identify and deal with acute adrenal crisis if it should occur.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11. Examine for oral signs and symptoms of over-immunosuppression or graft rejection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12. Monitor blood pressure for patients taking cyclosporin or prednisone; if blood pressure increases above baseline established, refer for medical evaluation.</td>
<td></td>
</tr>
</tbody>
</table>

**FIGURE 3.** PHASES OF DENTAL MANAGEMENT FOR THE PATIENT WITH TRANSPLANTED ORGANS Little and Falace (1993)
Consultation between the renal transplant recipient's dentist and primary physician is necessary before the delivery of professional oral healthcare services. Information on medical status, current medications, history of hepatitis, and presence of other systemic diseases is essential for a general understanding of the patient's condition. A complete blood cell count should be obtained to detect the effect of immunosuppressive drugs. Both medical and dental professionals advise the administration of prophylactic antibiotics as specified by the American Heart Association before dental treatment to protect the patient's graft site from bacteremias common after dental procedures and also because of the presence (usually) of an access site from previous dialysis (Westbrook, 1978; Cohen, 1994) (See Figure 4).

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>ADULT/CHILD</th>
<th>INITIAL DOSE</th>
<th>FOLLOW-UP DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>Adult</td>
<td>3.0 g 1 hour before procedure</td>
<td>1.5 g 6 hours after procedure</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>Adult</td>
<td>300 mg 1 hour before procedure</td>
<td>150 mg 6 hours after procedure</td>
</tr>
</tbody>
</table>

FIGURE 4. ANTIMICROBIAL PROPHYLAXIS FOR KIDNEY TRANSPLANT RECIPIENTS UNDERGOING IMMUNOSUPPRESSIVE THERAPY

Patients with kidney transplants are generally moderately hypertensive as a result of cyclosporin intake (Westbrook, 1978; Little & Falace, 1993). Taking vital signs before dental appointment allows for a "baseline" blood pressure reading for each individual and monitoring them during and after procedure allows for safe dental treatment. However, care should be taken to control and avoid an increase in the individual's anxiety levels. Antianxiety agents might be considered (Cohen, 1994).

Early detection and diagnosis of infection in the oral cavity should be of high priority. Involved pathogens should be identified with a culture, sensitivity, smear, aspiration technique, or biopsy (Cohen, 1994). This thorough identification and differentiation microbiologic process ensures proper antimicrobial management because of the enormous variety of microorganisms found in these individuals.

Not enough evidence is found on fluorides and water fluoridation as posing a risk on the patient with renal disease. On the same note, no studies have been reported on the dental use of topical fluoride or any related problems in this population (Little & Falace, 1993). Dental caries evident in these individuals is usually related to decreased salivary flow. Dental caries may be
prevented with the use of fluoride rinses (Little & Falace, 1993).

With proper precautions renal transplant recipients can be safely seen on an outpatient basis for dental treatment. Frequent recall examinations allow for early detection of oral conditions that may jeopardize the individual's oral health and the success of the transplant. Preventive measures need to be emphasized to avoid future need for extensive oral treatment. Kidney transplant recipients need to be made aware of the consequences of oral disease on their general health (Westbrook, 1978).

**Summary**

As medical advances improve, the number of individuals receiving kidney transplants will continue to increase. Individuals with kidney transplants may experience significant oral and dental complications. Increased incidence of oral infection as a result of immunosuppressive drug therapy and increased incidence of gingival hyperplasia secondary to cyclosporine have been established in this review. Gingival hyperplasia associated with the use of immunosuppressive medication poses a problem for the kidney transplant recipient. Gingival enlargement may probably never be completely prevented but it can be controlled with an intensive plaque control program consisting of dental prophylaxis and oral hygiene care. Infections of bacterial, fungal, and viral origin, predisposed by the individual’s immunosuppressed state, can spread systemically affecting the transplanted kidney. However, they are easily treated if detected early. Pre-transplant evaluation for infection is a routine approach at almost all transplant centers, but attention to the oral cavity is not commonly given. A complete dental evaluation with treatment of all oral diseases is recommended to avoid morbidity and potential hazards of untreated oral infections in the post-transplant period. The medical and dental healthcare provider, as well as the renal transplant recipient, should be alerted of the importance of meticulous oral hygiene care and dental consultation. By doing so, and by educating the renal transplant patient the quality of life of these individuals will be greatly improved.
CHAPTER III
METHODS AND MATERIALS

Three dental indices were used to measure the oral health status of renal transplant recipients undergoing immunosuppressive therapy. The indices included Greene and Vermillion’s Simplified Oral Hygiene Index (1964), Ramfjord’s Periodontal Disease Index (1967), and the Hyperplastic Index: comprised of Aas et al.’s (1963) vertical component and Seymour et al.’s (1985) horizontal component for the gingival tissues as utilized by King et al. (1993). Intraoral lesions were described in terms of color, size, location, and characteristics.

SAMPLE DESCRIPTION

A purposive sample was selected from Sentara Norfolk General Hospital/Sentara Health System’s Renal Transplant Center and from the Nephrology Associates of Tidewater LTD. Twenty-two (22) subjects were recruited through Belinda Sanders, Renal Transplant Coordinator and Social Worker at Sentara Norfolk General Hospital/Sentara Health System. Drs. Thomas McCune and Duane Womboldt, nephrologists at Nephrology Associates of Tidewater LTD, and by the principal investigator. Approximately 90 individuals were approached by the investigator at the Renal Transplant Center, Sentara Norfolk General Hospital/Sentara Health System and 12 at Nephrology Associates of Tidewater, LTD; an indeterminate number of individuals were approached by Belinda Sanders and the Nephrology Associates of Tidewater, LTD. A letter which described the study and invited participation was distributed to kidney transplant recipients (See Appendix A); those willing to participate were asked to sign a consent form (See Appendix B).

To be included in the study, renal transplant recipients must have been undergoing immunosuppressive therapy. Individuals who were experiencing graft rejection, under hospital care, and/or had periodontal treatment within the past year were excluded from the study. Arrangements for appointment scheduling were made at the subject’s convenience. Subjects (N=22) were then stratified into three groups according to time since transplantation: individuals with a renal transplant for less than one year (n=3), individuals with a renal transplant for one to three years (n=9), and individuals with a renal transplant for more than three years (n=10).

Subjects ranged in age from 31 to 50+ years of age (See Appendix C). Seventeen individuals were recruited from the Renal Transplant Center at Sentara Norfolk General Hospital/Sentara Health System and five from the Nephrology Associates of Tidewater, LTD.
Fifty percent of the individuals with a kidney transplant were of Caucasian descent while the remaining 50 percent were ethnically diverse: 31.8 percent African-American, 4.5 percent Hispanic, and 9.2 percent Asian. One individual reported to be of a different (unknown) ethnic background (See Table 1. Educational level varied within the sample: 9% completed junior high school and 54.5 percent completed high school. Twenty-seven percent reported to have received some college education while 9 percent had obtained a college degree. Fifty-five percent of the subjects were currently unemployed while 45.5 percent were able to work. Sixty-four percent of the kidney transplant population were economically disadvantaged with an income level of below $15,000 per year. Eighteen percent earned between $15,001 to $23,000 and the remaining 18 percent earned $23,001 and above.

TABLE 1. SOCIODEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE OF RENAL TRANSPLANT PATIENTS UNDERGOING IMMUNOSUPPRESSIVE THERAPY FROM SENTARA NORFOLK GENERAL HOSPITAL/SENTARA HEALTH SYSTEM AND NEPHROLOGY ASSOCIATES OF TIDEWATER, LTD (N=22).

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-39</td>
<td>10</td>
<td>45.3</td>
</tr>
<tr>
<td>40-49</td>
<td>9</td>
<td>40.7</td>
</tr>
<tr>
<td>50+</td>
<td>3</td>
<td>14.0</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>African-American</td>
<td>7</td>
<td>31.8</td>
</tr>
<tr>
<td>White</td>
<td>11</td>
<td>50.0</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>9.2</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>4.5</td>
</tr>
<tr>
<td>Education Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Junior High</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td>High School</td>
<td>12</td>
<td>54.5</td>
</tr>
<tr>
<td>Some College</td>
<td>6</td>
<td>27.3</td>
</tr>
<tr>
<td>Completed College</td>
<td>2</td>
<td>9.1</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently Employed</td>
<td>10</td>
<td>45.5</td>
</tr>
<tr>
<td>Unemployed</td>
<td>12</td>
<td>54.5</td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below $15,000.00</td>
<td>14</td>
<td>63.6</td>
</tr>
<tr>
<td>$15,001.00 to $23,000.00</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>$23,001.00+</td>
<td>4</td>
<td>18.2</td>
</tr>
</tbody>
</table>
Patient history revealed that 13.6 percent of the individuals who participated in this study have had their kidney transplant for less than one year, 41 percent for one to three years, and 45.4 percent for more than three years (See Table 2).

**TABLE 2.** KIDNEY TRANSPLANT HISTORY OF INDIVIDUALS SAMPLED FROM SENTARA NORFOLK GENERAL HOSPITAL/SENTARA HEALTH SYSTEM AND NEPHROLOGY ASSOCIATES OF TIDEWATER, LTD (N=22).

<table>
<thead>
<tr>
<th>LENGTH OF TIME SINCE KIDNEY TRANSPLANT</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than one year</td>
<td>3</td>
<td>13.6</td>
</tr>
<tr>
<td>1 - 3 years</td>
<td>9</td>
<td>40.9</td>
</tr>
<tr>
<td>greater than 3 years</td>
<td>10</td>
<td>45.5</td>
</tr>
</tbody>
</table>

The demographic questionnaire revealed that dental care varied among this population (See Table 3). Eighty-two percent of the kidney transplant recipients sampled in this study reported visiting their dentist within the past year. Sixty-three percent of the sample indicated that the purpose of their last dental visit was for a routine dental check-up. Eighteen percent of the visits were for either emergencies or for fillings/extractions. However, when questioned regarding the number of times per year they visit the dentist, 29 percent reported twice a year, 33 percent reported at least once a year while 29 percent reported never visiting their dentist. One subject failed to complete the entire demographic questionnaire, thus accounting for the 21 respondents.
TABLE 3. FREQUENCY OF DENTAL VISITS MADE BY RENAL TRANSPLANT RECIPIENTS UNDERGOING IMMUNOSUPPRESSIVE THERAPY (N=22).

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last visit to the dentist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month ago</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>6 months ago</td>
<td>9</td>
<td>40.9</td>
</tr>
<tr>
<td>1 year ago</td>
<td>5</td>
<td>22.7</td>
</tr>
<tr>
<td>greater than 2 years ago</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>Purpose of your last visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine / check-up</td>
<td>14</td>
<td>63.6</td>
</tr>
<tr>
<td>Emergency</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>Filling / Extraction</td>
<td>4</td>
<td>18.2</td>
</tr>
<tr>
<td>*How many times a year do you visit the dentist?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>once a year</td>
<td>7</td>
<td>33.3</td>
</tr>
<tr>
<td>twice a year</td>
<td>6</td>
<td>28.6</td>
</tr>
<tr>
<td>three times a year</td>
<td>2</td>
<td>9.5</td>
</tr>
</tbody>
</table>

*N=21

Participants in this study were queried regarding their oral self-care behavior (See Table 4). Ninety-five percent of the sample indicated they brushed their teeth daily. Frequency of brushing varied: 35 percent brushed once a day, 50 percent brushed twice a day, and 15 percent brushed three times a day. Only 52 percent of the participants reported flossing, while only 67 percent flossed daily and 52 percent suffered from bleeding gingiva. When questioned about oral hygiene instruction, 76.2 percent reported previously receiving homecare instruction. Forty-five percent of the sample indicated that they were currently experiencing some dental problems and needed to be seen by an oral healthcare professional.
TABLE 4. ORAL SELF-CARE BEHAVIOR OF KIDNEY TRANSPLANT RECIPIENTS

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>FREQUENCY</th>
<th>PERCENTAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Do you brush your teeth?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>20</td>
<td>95.0</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>5.0</td>
</tr>
<tr>
<td>**How many times a day?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a day</td>
<td>7</td>
<td>35.0</td>
</tr>
<tr>
<td>Twice a day</td>
<td>10</td>
<td>50.0</td>
</tr>
<tr>
<td>Three times a day</td>
<td>3</td>
<td>15.0</td>
</tr>
<tr>
<td>*Do you floss?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11</td>
<td>52.4</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>***How often do you floss?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Once a day</td>
<td>8</td>
<td>66.7</td>
</tr>
<tr>
<td>Three times a week</td>
<td>2</td>
<td>16.7</td>
</tr>
<tr>
<td>Once a week</td>
<td>2</td>
<td>16.7</td>
</tr>
<tr>
<td>*Received oral hygiene instruction?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16</td>
<td>76.2</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>*Do your gums bleed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>11</td>
<td>52.4</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>47.6</td>
</tr>
</tbody>
</table>

*N=21 / **N=20 / ***N=12

RESEARCH DESIGN

An expost-facto design was employed to assess the oral health status of renal transplant recipients undergoing immunosuppressive therapy to establish if a difference in oral health status existed among or within the three subgroups of the renal transplant sample (See Figure 5).

The nonmanipulated independent variables included individuals with a kidney transplant for less than one year, individuals with a kidney transplant for one to three years, and individuals with a kidney transplant for three or more years. The dependent variables were oral hygiene status, pocket depths and periodontal disease, gingival hyperplasia, and intraoral lesions as measured by the Simplified Oral Hygiene Index; the Periodontal Disease Index; the Hyperplastic Index; and color, size, location, and characteristics of intraoral lesions, respectively.
### TABLE 1

<table>
<thead>
<tr>
<th>Group</th>
<th>(IV.)</th>
<th>D.V.1</th>
<th>D.V.2</th>
<th>D.V.3</th>
<th>D.V.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>&lt; 1 year with kidney transplant</td>
<td>Simplified Oral Hygiene Index</td>
<td>Periodontal Disease Index</td>
<td>Hyperplastic Index</td>
<td>Intraoral Lesions</td>
</tr>
<tr>
<td>Group II</td>
<td>1 to 3 years with kidney transplant</td>
<td>Simplified Oral Hygiene Index</td>
<td>Periodontal Disease Index</td>
<td>Hyperplastic Index</td>
<td>Intraoral Lesions</td>
</tr>
<tr>
<td>Group III</td>
<td>3+ years with kidney transplant</td>
<td>Simplified Oral Hygiene Index</td>
<td>Periodontal Disease Index</td>
<td>Hyperplastic Index</td>
<td>Intraoral Lesions</td>
</tr>
</tbody>
</table>

I.V. denotes non-manipulated variable  
D.V. denotes dependent variable

### FIGURE 5.  EXPOST-FACTO RESEARCH DESIGN

The research design controlled threats to internal and external validity. The principal investigator performed all oral health assessments of kidney transplant recipients undergoing immunosuppressive therapy eliminating interrater variables. Indices used have been employed in past studies and have proven validity and reliability (Greene & Vermillion, 1964) (Ramfjord, 1967) (Aas et al., 1963) (Seymour et al., 1985). The use of the same evaluation tools minimized differences among environmental conditions. The use of the University of North Carolina probe, with its color coded millimeter markings promoted increased reliability of data collected. Light sources, however, differed among rooms at the three clinical sites where subjects were examined: Renal Transplant Center, Nephrology Associates of Tidewater LTD, and the Dental Hygiene Clinic. Intrarater reliability was established via a pilot study (See Appendix D).

### METHODOLOGY

Renal transplant recipients were recruited by direct questioning and distribution of a letter of invitation to participate in the study (See Appendix A). Prospective subjects were informed to directly contact the principal investigator or instruct Belinda Sanders, Renal Transplant Coordinator and Social Worker at Sentara Norfolk General Hospital/Sentara Health System if they would like to be included in the study. Patients from the Nephrology Associates of Tidewater, LTD were informed about the study by Dr. Thomas McCune. Interested individuals from both centers were contacted by telephone whereby purpose, benefits, and risks of the investigation were
communicated. Additional questions were answered and scheduling for the delivery of antibiotic premedication and for the oral assessment were determined. The day of the appointment, individuals were screened for date of transplant, present health status, present oral health status, date and purpose of last dental treatment, medications currently taken and demographic information. (See Appendix C).

Phase I: Pilot Test
1. A pilot test was conducted in January of 1997. Ten subjects who volunteered to participate were selected based on the previously defined criteria.
2. The subjects were examined using the Simplified Oral Hygiene Index, the Periodontal Disease Index, the Hyperplastic Index, and a self-designed intraoral manifestations screening form. Findings were recorded using an appropriate form (See Appendices E, F, G, and H, respectively).
3. After a period of five to ten minutes, the subject was re-examined by the investigator using a blank form. Results from this test-retest procedure were analyzed using the matched pairs t-test for correlated samples of two sets of scores. An intrarater reliability of $t=0$, $df=9$, $\alpha=0.05$; $t=0.33$, $df=9$, $\alpha=0.05$; and $t=0$, $df=9$, $\alpha=0.05$, was obtained for the Simplified Oral Hygiene Index, the Periodontal Disease Index, and the Hyperplastic Index respectively prior to initiation of the study. These results revealed that there was no statistically significant difference between the pretest and the posttest scores (See Appendix D). The use of the University of North Carolina probe, with its color coded millimeter markings promoted increased reliability of data collected.

Phase II: Subject Selection and Screening
1. A date was established for the oral examination to take place for those individuals who consented to participate. Subjects were scheduled a 20 minute appointment at Sentara Norfolk General Hospital/Sentara Health System, Nephrology Associates of Tidewater, or at Old Dominion University Dental Hygiene Clinic (at patient’s convenience).
2. Appropriate antibiotic premedication for subjects was arranged between the patient’s physician, and the renal transplant center staff. Antibiotic premedication was delivered by the pharmacy to the subject’s home.
3. Participants were asked to read and sign an informed consent form (See Appendix B) prior to the oral examination. Demographic information and verification of antibiotic premedication
administration were obtained prior to the examination. At that time, the purpose, benefits, and risks of the study were again explained and questions were answered.

Phase III: Appointment
1. A tape recorder was used to record data on individuals examined. Findings were later transcribed onto respective data collection forms.
2. Intraoral manifestations were assessed by direct vision of the oral mucosa, tongue, palate, floor of the mouth, and pharynx. Lips and extraoral cutaneous lesions were also assessed.
3. Circumferential periodontal probing of Ramfjord teeth (#3, #9, #12, #19, #25, and #28) was performed with the University of North Carolina periodontal probe to determine the periodontal disease status of the individual (See Appendix F).
4. A periodontal probe was placed perpendicularly to the teeth in a labio-lingual direction to measure the degree of gingival enlargement for the horizontal component of the Hyperplastic Index. The vertical component was estimated by size, contour, and extent of crown coverage (See Appendix G).
5. Oral debris and calculus were measured by the Simplified Oral Hygiene Index. Disclosing solution was used in the detection of bacterial plaque (See Appendix E).
6. Materials used to conduct the study included:
   - Front surface mouth mirror
   - University of North Carolina periodontal probe
   - Shepherd’s hook explorer
   - Disclosing solution
   - 2 x 2 gauze / cotton tipped applicators
   - Data collection forms for appropriate indices
   - Tape recorder to record findings
   - Latex gloves
   - Protective eyewear for both operator and subject
   - Infection control barriers
   - Light source
   - Autoclave bags

Protection of Human Subjects

Prior to implementation of the study, the investigator submitted the following research protocol to the Review Board for the Protection of Human Subjects at Old Dominion University, Eastern Virginia Medical School, Sentara Patient Care Committee, Medical Executive Committee, Medical Affairs Committee, and the Sentara Nursing Review Board for approval to implement
this study. Once approved, research protocol was submitted to the Nephrology groups in the area to familiarize the physicians with the study obtain antibiotic premedication prescriptions.

1. **Subject Population.** Renal transplant recipients who are at least three months post-transplant over five years of age and undergoing immunosuppressive therapy, were purposively selected from the Renal Transplant Center at Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater LTD. Subjects could be edentulous or possess all 36 teeth. Subjects must not have experienced rejection complications with the renal transplant. Individuals who have had dental treatment such as periodontal surgery within the past 12 months were excluded from the study. The population was appropriate because little is known about the oral health status of renal transplant recipients. Subjects required prophylactic antibiotic premedication one hour prior to the oral examination.

2. **Potential Risks:** Instrumentation that can cause intraoral bleeding is a potential risk for individuals with a transplanted kidney. Therefore, antibiotic premedication was mandatory to avoid the risk of infection and bacteremia. The American Heart Association's recommended standard prophylactic regimen for the prevention of bacterial endocarditis for kidney transplant patients undergoing immunosuppressive therapy was used (See Figure 2). Clindamycin was the alternate antibiotic for individuals allergic to amoxicillin. Individuals with inflamed hyperplastic gingival tissue may experience discomfort during the examination of the gingiva with the periodontal probe.

3. **Consent Procedures.** A complete explanation of the investigation's purpose, procedures, benefits, and potential risks was presented to the individual prior to participation. Subjects also were informed that data would be collected by Coral Diaz, a registered dental hygienist working on a Master of Science in Dental Hygiene Degree in the School of Dental Hygiene at Old Dominion University. Subjects were informed that they could refuse to participate in the study and could withdraw at any time without jeopardizing their relationship to Sentara Hospital or Old Dominion University. Questions about the study could be directed to Coral Diaz at 683-5233 or Deborah B. Bauman at 683-5235. Voluntary informed consent was obtained following explanation. Parental or guardian consent was required if the subject was less than 18 years of age.

4. **Protection of Subjects' Rights.** Confidentiality of the subject's medical and dental records was maintained throughout the study. Only individuals directly associated with the study had access to the data. Results from the study were presented in group form only and made
available to participants upon request. Data were stored in a locked file cabinet at Old Dominion University School of Dental Hygiene.

5. **Potential Benefits.** All subjects received a free screening, notification of their oral health status, referral to a dentist in their geographical area if indicated (see Appendix I), and information regarding dental hygiene services available to them at Old Dominion University. Subjects also were informed of the importance of proper oral hygiene and how good oral health contributes to overall systemic health and the long term retention of the transplanted kidney. Outpatients and healthcare providers at the Renal Transplant Center at Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD were made aware of the need for dental treatment in the renal transplant population.

6. **Risk/Benefit Ratio.** The benefits of optimal oral health status outweighed minimal risks associated with this study. Information obtained from the study was used to develop an oral healthcare protocol to be used at Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD for individuals with kidney transplants undergoing immunosuppressive therapy, and will, in turn, contribute to the overall systemic health, success of the renal transplant, and the reduction of medical costs associated with the oral cavity and the transplanted kidney. Documentation of oral health problems experienced by renal transplant recipients may serve as a foundation for the development of a grant to obtain funds for a comprehensive oral healthcare program for these individuals.

**INSTRUMENTATION**

The Simplified Oral Hygiene Index by Greene and Vermillion (1964), Ramfjord's Periodontal Disease Index (1967), and a King et al.'s (1993) Hyperplastic Index, a combination of Aas et al.'s (1963) vertical component and Seymour et al.'s (1985) horizontal component, were used for data collection. In addition, a self-designed screening form was used for intraoral manifestations present.

**The Simplified Oral Hygiene Index**

The Simplified Oral Hygiene Index was developed by Greene and Vermillion in 1964. It is widely used in epidemiological and clinical studies of periodontal disease, it is a simple and rapid method for evaluating oral cleanliness of renal transplant recipients undergoing immunosuppressive therapy. This index assesses the oral hygiene status of population groups by
means of its two components: The Debris Index (DI-S) and the Calculus Index (CI-S).

Each component of the S-OHI is measured on a scale of 0 to 3 using a mouth mirror and Shepherd’s hook explorer for the examination. Six tooth surfaces, four posterior and two anterior, were examined for the Simplified Oral Hygiene Index. The buccal surfaces of #3, #12, #19, #28 and the lingual surfaces of #9 and #25 were assessed for both the Debris Index (DI-S) and the Calculus Index (CI-S) (See Figure 6). Substitutions were not made for missing teeth and scores were derived from teeth examined.

FIGURE 6. SIMPLIFIED ORAL HYGIENE INDEX - SIX SHADED TEETH SCORED

**Debris Index.** This index evaluates soft foreign matter loosely attached to the teeth. Disclosing solution was applied with a cotton tipped applicator to the surfaces of the six teeth for rapid identification of oral debris (See Figure 7).
FIGURE 7. DEBRIS INDEX SCORING CRITERIA

Calculus Index. This index evaluates both supragingival and subgingival calculus. In this investigation the six teeth examined were dried with gauze squares and explored with an Shepherd’s hook explorer for calculus detection (See Figure 8).

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No debris or stain present.</td>
</tr>
<tr>
<td>1</td>
<td>Soft debris covering not more than one third of the tooth surface being examined, or the presence of extrinsic stains without debris, regardless of surface area covered.</td>
</tr>
<tr>
<td>2</td>
<td>Soft debris covering more than one-third but not more than two-thirds of the exposed tooth surfaces.</td>
</tr>
<tr>
<td>3</td>
<td>Soft debris covering more than two-thirds of the exposed tooth surfaces.</td>
</tr>
</tbody>
</table>

FIGURE 8. CALCULUS INDEX SCORING CRITERIA

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No calculus present</td>
</tr>
<tr>
<td>1</td>
<td>Supragingival calculus covering not more than one third of the exposed tooth surface.</td>
</tr>
<tr>
<td>2</td>
<td>Supragingival calculus covering more than one-third but not more than two thirds of the exposed tooth surfaces, or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth, or both.</td>
</tr>
<tr>
<td>3</td>
<td>Supragingival calculus covering more than two-thirds of the exposed tooth surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth or both.</td>
</tr>
</tbody>
</table>
Scoring:

For both indices, the sum of the scores for the teeth is divided by the number of teeth examined. It yields two separate scores, one for the DI-S and one for the CI-S which are interpreted using the criteria in Figure 9.

\[
\text{Sum of the scores of the teeth} = \text{DI-S or CI-S} \\
\text{Number of teeth examined}
\]

<table>
<thead>
<tr>
<th>SCORE</th>
<th>ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 - 0.6</td>
<td>Good Oral Hygiene</td>
</tr>
<tr>
<td>0.7 - 1.8</td>
<td>Fair Oral Hygiene</td>
</tr>
<tr>
<td>1.9 - 3.0</td>
<td>Poor Oral Hygiene</td>
</tr>
</tbody>
</table>

**FIGURE 9. INTERPRETATION CRITERIA OF THE DEBRIS INDEX AND CALCULUS INDEX**

The DI-S and the CI-S are then added to give a final OHI-S score which is interpreted using the criteria in Figure 10.

<table>
<thead>
<tr>
<th>SCORE</th>
<th>ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0 - 1.2</td>
<td>Good Oral Hygiene</td>
</tr>
<tr>
<td>1.3 - 3.0</td>
<td>Fair Oral Hygiene</td>
</tr>
<tr>
<td>3.1 - 6.0</td>
<td>Poor Oral Hygiene</td>
</tr>
</tbody>
</table>

**FIGURE 10. INTERPRETATION CRITERIA FOR THE SIMPLIFIED ORAL HYGIENE INDEX**

**Periodontal Disease Index**

Ramfjord's (1967) Periodontal Disease Index (PDI), used to measure prevalence and severity of gingivitis and periodontitis, yielded the periodontal status of renal transplant recipients undergoing immunosuppressive therapy. The Periodontal Disease Index combines the evaluation of gingival status with the probed attachment level (crevice depth measured from the cementoenamel junction). In addition, it provides a basis for estimating need for periodontal therapy in this population.

The six Ramfjord teeth, #3, #9, #12, #19, #25, and #28, used in this index, are representative of the six segments of the dentition (See Figure 6). Only fully erupted teeth were used and no substitutions were made for missing teeth. Scores were derived from the teeth
examined.

Gingival status was assessed first using the Gingival Index component of the Periodontal Disease Index (See Figure 11). Gingival color and form was noted by applying gentle pressure with the side of the periodontal probe to determine consistency and density of the tissue. When a color change indicated the presence of inflammation, the consistency was not checked. In health, the gingiva is uniformly pale pink in color; the healthy gingiva may or may not possess generalized brown pigmentation. If the gingiva is erythematous, appearing bright red, dark red, or blue red, the investigator recognized this as diseased tissue. In determining consistency of the gingiva, the investigator noted firm, resilient tissues in health. Soft, spongy tissues which dented easily when the side of the periodontal probe was pressed against the gingiva indicated disease. The free gingiva appears smooth and the attached gingiva appears stippled in health. In disease the attached gingiva may display a number of diseased states: loss of stippling, shiny surface, fibrotic with stippling, nodular or hyperkeratotic.

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Absence of signs of inflammation.</td>
</tr>
<tr>
<td>1</td>
<td>Mild to moderate inflammatory gingival changes, not extending around the tooth.</td>
</tr>
<tr>
<td>2</td>
<td>Mild to moderately severe gingivitis extending all around the tooth.</td>
</tr>
<tr>
<td>3</td>
<td>Severe gingivitis characterized by marked redness, swelling, tendency to bleed and ulceration.</td>
</tr>
</tbody>
</table>

FIGURE 11. CRITERIA FOR ASSESSING GINGIVAL STATUS

Scoring of gingival status:

a. For individual teeth. Scores for each area (buccal and lingual) are added and then divided by the number of areas examined (two).

b. Score for individual. Scores for all examined teeth are added and then divided by the total number of teeth examined. Scores range from 0 to 3.

The probed attachment level, or the sulcus depth form the cementoenamel junction to the bottom of the gingival pocket, was measured with the University North Carolina Periodontal Probe. All measurements were rounded to the nearest millimeter; anything close to 0.5 mm was
measured to next higher whole number.

Two measurements per tooth surface were obtained: the facial surface and mesiofacial contact area (See Figure 12). When the original Periodontal Disease Index was used, four measurements were taken for each tooth, but it was found that no significant loss in accuracy resulted from using only two measurements (Ramfjord, 1967).

![Figure 12. Periodontal Disease Index - Probe Positions for Measuring Crevice Depth](image)

Each measurement was taken from the gingival margin to the attached periodontal tissue, then the distance from the gingival margin to the cementoenamel junction was subtracted to determine the probed attachment level (See Figure 13).

![Figure 13. Periodontal Disease Index - Sulcus Depth from the Cementoenamel Junction](image)

The pocket depth was measured from the cementoenamel junction to the gingival margin. Position “A” shows the cementoenamel junction located with probe tip and distance from the gingival margin is measured; “B” shows the pocket depth from gingival margin to attached periodontal tissue; once measured, the distance to the cementoenamel junction is then subtracted;
and “C” when apparent recession is present. Measurement is directly from the cementoenamel junction. Scoring criteria are shown in Figure 14.

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3</td>
<td>Gingival crevice does not extend apical to the cementoenamel junction.</td>
</tr>
<tr>
<td>*4</td>
<td>Pockets of any 2 recorded areas extend apically from the cemento-enamel junction not more than but including 3 mm.</td>
</tr>
<tr>
<td>*5</td>
<td>Pockets of any 2 recorded areas extend apically from the cemento-enamel junction from 3mm to 6mm.</td>
</tr>
<tr>
<td>*6</td>
<td>Pockets extend more than 6mm apically from the cementoenamel junction in any 2 of the measured areas.</td>
</tr>
</tbody>
</table>

* the Gingival Index score is disregarded.

FIGURE 14. CRITERIA FOR THE PERIODONTAL DISEASE INDEX

Scoring of Periodontal Disease Index:
Scores of individual teeth are added and then divided by the number of teeth examined. PDI ranges from 0 to 6.

\[ PDI = \frac{\text{total scores}}{\# \text{ of teeth}} \]

<table>
<thead>
<tr>
<th>SCORE</th>
<th>EVALUATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 3 9</td>
<td>Gingivitis. Indicates gingival involvement only with increasing severity from 0 (no disease) through 3.9 (severe gingivitis)</td>
</tr>
<tr>
<td>4 - 6</td>
<td>Periodontitis. Indicates periodontal involvement with migration of the junctional epithelium and bone loss. Severity increases from 4 (early disease) through 6 (advanced disease).</td>
</tr>
</tbody>
</table>

FIGURE 15. EVALUATION OF PERIODONTAL DISEASE INDEX

For epidemiologic purposes, the individual PDI scores are totaled and divided by the number of individuals examined. Since only six teeth are examined, the periodontal health of the individual may not be truly representative. The University of North Carolina Probe, with its color coded millimeter markings promotes accuracy when measuring and determining probe depths. This feature, combined with the light probe weight, facilitated identification of the base of the
pocket and increased the reliability of data collected. A force of 20-25g is considered sufficient to reveal attachment level without causing pain to the subject.

Hyperplastic Index

Gingival hyperplasia was assessed clinically on 12 anterior teeth following King et al.'s 1993 study of gingival hyperplasia in renal allograft recipients, which was a combination of Aas et al.'s (1963) and Seymour's (1985) Hyperplastic Index (HI). These two components measure independently the vertical and horizontal extension of gingival enlargement. The maxillary and mandibular anterior teeth were divided into five gingival units, both buccally and lingually (See Figure 16). Each unit extended from the buccal or lingual midpoint of a tooth to the midpoint of the adjacent tooth. Where a tooth was missing, no substitutions were made.

FIGURE 16. HYPERPLASTIC INDEX - DIVISION OF MAXILLARY AND MANDIBULAR Sextants

The vertical component of the HI measured the degree of gingival enlargement in an apico-coronal direction (vertical) for a gingival unit and was graded by means of a 4-point interval scale (See Figure 17). The vertical component of the HI has been used as the sole index for assessing gingival enlargement in previous studies (Aas, 1963; McGraw et al. 1987).
<table>
<thead>
<tr>
<th>GRADE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No gingival hyperplasia</td>
</tr>
<tr>
<td>1</td>
<td>Mild hyperplasia (blunting of gingival margin)</td>
</tr>
<tr>
<td>2</td>
<td>Moderate hyperplasia (less than 1/2 of crown length)</td>
</tr>
<tr>
<td>3</td>
<td>Marked hyperplasia (greater than 1/2 of crown length)</td>
</tr>
</tbody>
</table>

FIGURE 17. HYPERPLASTIC INDEX - VERTICAL COMPONENT (APICO-CORONAL DIRECTION)

The horizontal component of the HI developed by Seymour et al. (1985) measured the degree of gingival thickening on both the labial and lingual aspects in a labio-lingual direction (horizontal) for a gingival unit (See Figure 18). The horizontal component is graded on a three-point interval scale (See Figure 19).

FIGURE 18. HYPERPLASTIC INDEX - GINGIVAL THICKNESS IN LABIO-LINGUAL DIRECTION

<table>
<thead>
<tr>
<th>GRADE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal width of free gingival margin</td>
</tr>
<tr>
<td>1</td>
<td>Thickening from the normal up to 2mm</td>
</tr>
<tr>
<td>2</td>
<td>Thickening from the normal &gt;2mm</td>
</tr>
</tbody>
</table>

FIGURE 19. HYPERPLASTIC INDEX - HORIZONTAL COMPONENT (LABIO-LINGUAL DIRECTION)
The vertical and horizontal scores were added, thus giving a hyperplasia score for each gingival unit. The maximum score obtainable for one unit is five. The degree of hyperplasia is expressed as a percentage. A Hyperplastic Index greater than 30 percent has been suggested by Seymour & Smith (1991) as indicative of significant gingival enlargement.

**Statistical Treatment**

All data was tabulated using the statistical package SPSS® for Windows™. Nonparametric statistical analyses were employed to determine significant differences among individuals with a kidney transplant for less than one year, individuals with a kidney transplant for one to three years, and individuals with a kidney transplant for more than three years. All analyses were made at the .05 level of significance and significant differences between the three groups were documented on the basis of oral hygiene status, periodontal disease status, and gingival hyperplasia. The nonparametric statistical procedure Kruskal-Wallis rank sums test was used to compare subjects in the three groups.
CHAPTER IV
RESULTS AND DISCUSSION

An ex post-facto study was conducted to determine the oral health status of kidney transplant recipients undergoing immunosuppressive therapy. Twenty-two oral examinations were conducted at the Renal Transplant Center at Sentara Norfolk General Hospital/Sentara Health System, Tidewater Nephrology associates, LTD, and Old Dominion University Dental Hygiene clinic in Norfolk, Virginia.

Data were analyzed using the nonparametric statistical procedure Kruskal-Wallis rank sums test to determine if there was a significant difference in the oral health status among those individuals who have had a kidney transplant for less than a year, individuals who have had a kidney transplant for one to three years, and individuals who have had a kidney transplant for more than three years. The computerized statistical package SPSS® for Windows™ was used for data tabulation and analysis.

RESULTS

Hypothesis one. The first hypothesis stated that there was no statistically significant difference, at the .05 level, in the oral hygiene status of kidney transplant patients undergoing immunosuppressive therapy with a kidney transplant for less than one year, for one to three years, and for more than three years as measured by the Simplified Oral Hygiene Index.

The sample was pooled and tabulated in group form after the nonparametric Kruskal-Wallis rank sums revealed no statistically significant difference in the oral hygiene status between groups in the sample (See Table 5). The combined Simplified Oral Hygiene Index score, which merely adds the debris index score and the calculus index score is presented in Table 6. None of the individuals in the sample had an excellent Simplified Oral Hygiene Index score, while three individuals had a good Simplified Oral Hygiene Index rating, ranging between 0.1 to 1.2. Four individuals had a fair Simplified Oral Hygiene Index rating which ranged from 1.3 to 3.0, while 13 individuals were found to have poor Simplified Oral Hygiene Index scores ranging from 3.1 to 6.0. Of the 22 individuals who participated in this study, two were edentulous and had full maxillary and mandibular dentures; therefore, they were excluded from this portion of the analysis. Of the two subjects, one was a candidate for dental implants while the other had very
poor oral hygiene, as evidenced by moderate to heavy calculus and stain on both dentures. The later subject reported to have received no oral hygiene education on denture care.

TABLE 5  
KRUSKAL-WALLIS RANK SUMS FOR SIMPLIFIED ORAL HYGIENE INDEX

<table>
<thead>
<tr>
<th>Group</th>
<th>No. in group</th>
<th>Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>6.0</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>11.22</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>11.38</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

H = 2.0588  df = 2  p = 0.3572

TABLE 6.  
COMBINED SIMPLIFIED ORAL HYGIENE INDEX SCORES FOR POOLED SAMPLE OF RENAL TRANSPLANT RECIPIENTS

<table>
<thead>
<tr>
<th>Rating</th>
<th>Score</th>
<th>Simplified Oral Hygiene Index</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceallent</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Good</td>
<td>0.1 to 1.2</td>
<td>3</td>
<td>15%</td>
</tr>
<tr>
<td>Fair</td>
<td>1.3 to 3.0</td>
<td>4</td>
<td>20%</td>
</tr>
<tr>
<td>Poor</td>
<td>3.1 to 6.0</td>
<td>13</td>
<td>65%</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

N = 20

The mean, standard deviation and range were found for each group (See Table 7). The Kruskal-Wallis test did not reveal statistically significant differences in the oral hygiene status of renal transplant recipients undergoing immunosuppressive therapy at the Renal Transplant Center, Sentara Norfolk General Hospital/Sentara Health System and Nephrology Associates of Tidewater, LTD with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the Simplified Oral Hygiene Index (H=2.0588, df=2, and p=0.3572); therefore, the null hypothesis was retained. The small sample size (N=20), compounded by unequal distribution of independent variable cell size (N= less than 1 year:3, one to three years:8, and three or more years:9) contributes to the inability to find a statistical significance p=0.3572.
TABLE 7. SIMPLIFIED ORAL HYGIENE INDEX SCORES FOR RENAL TRANSPLANT RECIPIENTS

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Variance</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>2.33</td>
<td>1.86</td>
<td>3.47</td>
<td>0.17 to 3.40</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>3.84</td>
<td>1.17</td>
<td>1.37</td>
<td>2.50 to 5.70</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>3.38</td>
<td>2.01</td>
<td>4.04</td>
<td>0.33 to 6.0</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>3.43</td>
<td>1.64</td>
<td>2.70</td>
<td>0.17 to 6.0</td>
</tr>
</tbody>
</table>

Box plots with summaries of the distribution of values for each transplant group were generated (See Figure 20). The horizontal line inside the box representing the median score and its position indicates the skewness of the data. Scores for individuals with a kidney transplant for less than one year and individuals with a kidney transplant for one to three years were negatively skewed since the median line is at the top of the box plot indicating scores disclosed fair to poor oral hygiene status scores. A negative skewness of the median line was also observed for individuals having kidney transplants greater than three years, also indicating poor oral hygiene status for this group. The vertical lines from the box extend to the lowest score at the bottom of the 25th percentile to the highest score of the 75th percentile. No outliers were observed, further supporting the homogeneity of the sample. While homogeneity of variance is evident, the small sample size influenced the results because it cannot be stated at a 95% confidence interval that the results are significant.

FIGURE 20. OVERALL SIMPLIFIED ORAL HYGIENE INDEX SCORES OF RENAL TRANSPLANT RECIPIENTS UNDERGOING IMMUNOSUPPRESSIVE THERAPY.
**Hypothesis two.** The second hypothesis stated that there was no statistically significant difference at the .05 level in the periodontal disease status of kidney transplant patients with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the Periodontal Disease Index.

The pooled sample revealed that 15 percent (n=3) displayed an absence of gingival inflammation, suggesting that various degrees of periodontal disease is present in 85 percent of the sample (See Table 8). The Gingival Index, a component of the Periodontal Disease Index revealed that 20 percent (n=4) of the sample scored 0.5 to 1.4 on the Gingival Index indicating that mild to moderate gingival inflammation limited to papillary areas was present, while 25 percent (N=5) scored 1.5 to 2.4 on the Gingival Index indicating that some subjects experienced mild to moderately severe gingivitis score extending from the interproximal area around the gingival margin; 15 percent (N=3) of the sample were found to have severe gingivitis scores of 2.5 to 3.9 on the Gingival Index which is characterized by marked redness, swelling, bleeding, and ulceration.

**TABLE 8. PERIODONTAL DISEASE INDEX SCORES FOR POOLED SAMPLE OF RENAL TRANSPLANT RECIPIENTS**

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>NUMBER (N)</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = Absence of signs of inflammation</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>1 = Mild to moderate inflammatory gingival changes, limited to papillary areas extending to proximal area only.</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>2 = Mild to moderately severe gingivitis extending marginally</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>3 = Severe gingivitis characterized by marked redness, swelling, tendency to bleed &amp; ulceration, not necessarily extending around the tooth.</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>4 = When the pocket of any two recorded areas extend apically to the CEJ not more than, but including 3 mm.</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>5 = When the pockets of any two recorded areas extend apically to the CEJ from 3 to 6 mm inclusive.</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>6 = When the pockets extend more than 6 mm, apically to the CEJ in any of the two measured areas.</td>
<td>2</td>
<td>10</td>
</tr>
</tbody>
</table>

* In 4, 5, 6 the gingivitis score is disregarded and Periodontal Disease Index applied.
Ten percent of individuals (N=2) displayed pocket depths extending apically from the cementoenamel junction not more than but including 3mm and scored between 4 and 4.4 on the Periodontal Disease Index, indicating early periodontitis. Five percent of the sample scored between 4.5 and 5.4 on the Periodontal Disease Index which revealed pocket depths of the two recorded areas (middle of the facial surface and at the facial aspect in the mesial contact area) extending apically from the cementoenamel junction from 3mm to 6mm inclusively indicating moderate periodontal disease. Three subjects were found free of disease. This sample did contain two individuals having severe periodontitis marked by pockets extending more than 6 mm apically to the cementoenamel junction.

The mean, standard deviation, variance and range were found for each group (See Table 9). These scores suggest that the average individual with a kidney transplant has mild to moderate inflammatory gingivitis. Eighty-five percent of the sample exhibited some degree of periodontal disease; however, only 25 percent displayed advanced forms of periodontal disease.

TABLE 9. PERIODONTAL DISEASE INDEX SCORES OF GROUPS OF RENAL TRANSPLANT RECIPIENTS

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Variance</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>1.31</td>
<td>.7663</td>
<td>.5872</td>
<td>0.83 to 2.20</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>2.46</td>
<td>2.02</td>
<td>4.11</td>
<td>0.10 to 5.50</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>2.76</td>
<td>1.67</td>
<td>2.78</td>
<td>0.20 to 5.60</td>
</tr>
<tr>
<td>Grand Totals</td>
<td>20</td>
<td>2.40</td>
<td>1.75</td>
<td>3.06</td>
<td>0.10 to 5.60</td>
</tr>
</tbody>
</table>

Kruskal-Wallis rank sums for periodontal disease status revealed no statistically significant difference, at the .05 level, in the periodontal disease status of kidney transplant patients undergoing immunosuppressive therapy at the Renal Transplant Center, Sentara Norfolk General Hospital/Sentara Health System and the Nephrology Associates of Tidewater, LTD who have had a kidney transplant for less than one year, for one to three years, and more than three years (See Table 10), as measured by the Periodontal Disease Index \( H=1.5738, \ df=2, \) and \( p=.4553 \), therefore the null hypothesis was retained. Again, the small sample size, unequal size of groups, and overlapping ranges of scores among the groups might be contributing to the failure to find significance.
TABLE 10. KRUSKAL-WALLIS RANK SUMS FOR PERIODONTAL DISEASE

<table>
<thead>
<tr>
<th>Group</th>
<th>No. in Group</th>
<th>Mean Ranks</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>7.00</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>10.33</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>12.00</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

\[ H = 1.5738 \quad df = 2 \quad p = 0.445 \]

Box plots were generated with summaries for each of the three groups (See Figure 21). The horizontal line inside the box representing the median score of the group revealed a positive skewness of the median line which appeared toward the bottom of the box. The median line was in the center of the much larger box plot for individuals with a kidney transplant for one to three years. The median score indicated a slight positive skewness for individuals with a kidney transplant for more than three years. Fifty percent of the scores fall within the box, which is also an indication of the spread of the scores. The vertical lines from the box extend to the lowest score of the 25th percentile to the highest score of the 75th percentile. No outliers were observed suggesting homogeneity of this small sample.

FIGURE 21. OVERALL PERIODONTAL DISEASE INDEX SCORES FOR RENAL TRANSPLANT RECIPIENTS UNDERGOING IMMUNOSUPPRESSIVE THERAPY
Hypothesis three. The third hypothesis stated that there was no statistically significant difference at the .05 level in the degree and severity of gingival hyperplasia kidney transplant patients with a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the combination of Aas et al. (1963) and Seymour et al. (1985) Hyperplastic Index used by King et al. (1993).

The sample was pooled and tabulated in group form after the nonparametric Kruskal-Wallis rank sums test revealed no statistically significant difference in the degree of gingival hyperplasia among groups. A Hyperplastic Index greater than 30 percent has been suggested by Seymour and Smith (1991) as indicative of significant gingival enlargement. A Hyperplastic Index score of less than 30 percent denotes mild gingival hyperplasia; a score greater than 30 percent represents moderate to severe gingival hyperplasia. Of the 22 renal transplant recipients examined, only 20 were evaluated using the Hyperplastic Index (two participants were excluded because they were edentulous). Four individuals (20 percent) were found to have mild hyperplastic index scores which ranged from 5 to 23. Fifteen individuals (75 percent) exhibited moderate to severe degrees of gingival hyperplasia with scores ranging from 31 to 83 percent.

The sample contained one individual who was not experiencing any degree of gingival hyperplasia (See Appendix K). Although the mean Hyperplastic Index progressively worsened with those having a kidney transplant less than one year, one to three years, and for more than three years (34.6%, 39.4%, and 46.28%, respectively), the differences did not reach statistical significance (See Table 11).

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Variance</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>34.67</td>
<td>13.32</td>
<td>177.42</td>
<td>20%-38%</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>39.44</td>
<td>28.73</td>
<td>825.41</td>
<td>0%-83%</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>46.28</td>
<td>9.21</td>
<td>84.82</td>
<td>31%-60%</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>41.46</td>
<td>20.41</td>
<td>416.38</td>
<td>0%-83%</td>
</tr>
</tbody>
</table>

The mean, standard deviation and range were found for each group (See Table 12). The Kruskal-Wallis test revealed no statistically significant difference in the degree of gingival
enlargement of renal transplant recipients undergoing immunosuppressive who have had a kidney transplant for less than one year, for one to three years, and for more than three years, as measured by the combination of Aas et al. (1963) and Seymour et al. (1985) Hyperplastic Index as utilized by King, et al. (1993) (H=1.1750. df=2. p=0.557), leading to a retention of the null hypothesis (See Table 12).

TABLE 12. KRUSKAL-WALLIS RANK SUMS FOR HYPERPLASTIC INDEX

<table>
<thead>
<tr>
<th>Group</th>
<th>No. in group</th>
<th>Mean Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>3</td>
<td>7.5</td>
</tr>
<tr>
<td>1 to 3 years</td>
<td>9</td>
<td>10.33</td>
</tr>
<tr>
<td>3+ years</td>
<td>8</td>
<td>11.81</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

H = 1.1750  p = 0.557  df=2

Box plots with summaries of the distribution of values for each transplant group were generated (See Figure 20). The horizontal line inside the box representing the median score of the group and the skewness of the data suggest a negative skewness of the median line toward the top of the box. The median line indicated a slight positive skewness for individuals with a kidney transplant for one to three years. The vertical lines from the box extend to the lowest score at the bottom of the 25th percentile to the highest score of the 75th percentile. No outliers were observed denoting homogeneity of this small sample.

FIGURE 22. OVERALL HYPERPLASTIC INDEX SCORES OF RENAL TRANSPLANT RECIPIENTS UNDERGOING IMMUNOSUPPRESSIVE
Prevalence of intraoral manifestations was assessed via the oral examination and findings recorded in a self-designed screening form. Intraoral manifestations were described by color, size, location, and characteristic. Of the 22 renal transplant recipients who participated in this study, only one exhibited signs of intraoral infection. Upon removal of a maxillary denture, a white plaque-like lesion resembling the fungal infection candidiasis was detected in the hard palate. The subject was unaware of this condition and immediately referred to his physician.

**DISCUSSION**

**Hypothesis one.** The Simplified Oral Hygiene Index was used to assess the oral hygiene status of individuals with a renal transplant for less than one year, for one to three years and for three or more years. The analysis of mean differences in the Simplified Oral Disease Index scores revealed no statistically significant difference in the oral hygiene status of the sample studied. Pooled group mean scores of 3.43 with a standard deviation of 1.64 revealed that individuals in this sample had poor oral hygiene and would benefit from oral hygiene instructions form an oral healthcare professional. These findings support Bottomley et al. (1972) who promote primary preventive measures targeted to the oral cavity to avoid risk factors that may precipitate sepsis or kidney rejection in this medically compromised population. There is little evidence in the literature to suggest that the renal transplant population has a poor oral hygiene status. However, it has been advocated that stringent bacterial plaque control programs for them are necessary and essential. Seymour et al. (1991) reported significantly lower plaque scores after renal transplant patients were allocated to a intensive plaque control program consisting of a minimum of four appointments in a six-month period.

Self-care behavior reported by the participants in this study revealed that 95 percent of the individuals brushed their teeth and only 52 percent reported flossing. In addition, 76 percent of the sample stated to have received oral hygiene instruction at some point. However, the combined Simplified Oral Hygiene Index scores for the pooled sample of renal transplant recipients revealed that only 15 percent of the participants had a good oral hygiene status. Twenty percent revealed a fair score and 65 percent showed signs of poor oral hygiene status. These scores suggest that comprehensive oral hygiene instructions at frequent intervals are required to improve the effectiveness of the homecare practices of individuals with renal transplants. Intensive preventive measures must be used in the preoperative and postoperative oral care of these individuals. An
effective oral hygiene instruction program that includes toothbrushing, flossing and irrigation education developed via videotapes or verbal communication should promote oral health. Bottomley et al. (1972) suggested that all measures of oral health management should be focused on the prevention and control of bacteremias of dental origin and that intensive plaque control program be considered “fundamental and mandatory”. In addition, Bottomley et al. recommend that if for any reason an effective plaque control program cannot be established, it would be advisable to render the patient edentulous before the transplantation operation.

Emphasis also needs to be placed on the prevention and control of infections of dental origin, as evidenced by the single oral infection found during the oral examinations. Renal transplant recipients may be experiencing lowered resistance to infection due to their compromised state and prescribed immunosuppressive medications may mask the signs of oral infections. Frequent examinations and an intense oral health maintenance program will prevent infections from progressing undiagnosed and untreated, ultimately compromising the individual’s systemic health and the success of the kidney transplant.

**Hypothesis two.** Statistical analysis of the Periodontal Disease Index scores of renal transplant recipient undergoing immunosuppressive therapy yielded a group mean of 2.40 with a standard deviation of 1.75. The ranges of scores for individuals with a renal transplant for less than one year, for one to three years and for three or more years overlap). While it seems that the mean scores (1.31, 2.46, and 2.76, respectively) get progressively worse as time since transplant elapses, the ranges of scores were similar. This compounded with the small cell and unequal groups (n=3:less than one year; 9:one to three years; 8:three or more years) does not make a significant difference in the Periodontal Disease Scores at a 95 percent confidence interval. Periodontal disease was measured according to inflammation of the mesial and marginal gingival papilla, and recession of the marginal gingiva from normal contour. Eighty-five percent of the sample showed some signs of periodontal disease, which supports Sandler and Stahl’s (1954) observations that individuals with kidney transplants have significantly greater proportion of inflamed papillae and a greater proportion of teeth with gingival recession than individuals with uncomplicated conditions. These findings suggest that the individuals sampled do not receive adequate periodontal care and that periodic nonsurgical periodontal maintenance therapy is indicated to restore these individuals to an acceptable level of periodontal health. It has been established that renal transplant recipients undergoing immunosuppressive therapy have an increase susceptibility to infection and that the organisms which cause the majority of these infections can be found in
the oral cavity. Bottomley et al. (1972) suggested that a stringent dental recall program should be established to prevent any oral or dental disease from progressing undetected.

Westbrook (1978) recommends that any active infection should be eliminated prior to transplantation. This will allow for diseased teeth to be removed or treated and periodontal disease to be controlled before immunosuppressive drug therapy is initiated. Fifty-nine percent of the participants in the study reported visiting their dentist within the past six months and 22 percent within the past year. However, these recent visits to the oral healthcare professional are inconsistent with the high prevalence of periodontal disease. In addition, 33 percent of the sample reported visiting their oral healthcare professional within the past year. Perhaps emphasis is not being placed on self-care instructions by oral healthcare professionals.

Renal transplant recipients need to be educated and advised on the importance of contacting their oral healthcare professional concerning any abnormal oral signs or symptoms. In addition, a rigorous continued care program with oral health education should be established to prevent oral disease and maintain and promote oral health.

**Hypothesis three.** A combination of Aas et al. (1963) and Seymour et al. (1985) Hyperplastic Index as reported by King et al. (1993) was used to assess the degree of gingival hyperplasia of individuals with a kidney transplant for less than one year, for one to three years and for three or more years. Statistical analysis using the nonparametric Kruskal-Wallis rank sums test revealed no significant difference in the incidence of gingival hyperplasia among the three groups. The mean group score was 41.46% with a standard deviation of 20.41, indicating that individuals in the sample experienced wide variation in gingival hyperplasia. Cyclosporin-A was a common factor in the immunosuppressive therapy regimen of the sample studied. This observation supports Daley et al. (1986) who found that renal transplant recipients who take cyclosporin as part of their immunosuppressive therapy manifest gingival hyperplasia to some degree. Group scores seemed to progressively worsen as time since transplantation elapsed for individuals with a kidney transplant for less than one year, for one to three years and for three or more years (34.67%, 39.44%, and 46.28%, respectively). The small number of individuals within the groups and the overlapping ranges of scores among the groups contributes to the inability to achieve significance.

As the number of renal transplants increases, cyclosporin-A induced gingival hyperplasia may increase in this population. Tyldesley et al. (1984) advocates that the reduction of bacterial plaque and the maintenance of optimum oral hygiene are of greatest importance to control gingival hyperplasia; however, in some cases gingival surgery is necessary. Daley et al. (1986)
recommend a prevention and treatment regimen including patient education and rigorous self-care methods consisting of brushing, flossing, prophylaxis, and removal of dental calculus before and in the early stages of cyclosporine therapy, as well as monitoring of oral conditions during cyclosporine therapy. Based on these reports, it is wise to initiate and implement an effective bacterial plaque control and dental hygiene care program for renal transplant recipients undergoing immunosuppressive therapy.

Local irritant factors, such as bacterial plaque, should not be considered the only cause of hyperplasia, since the severity of gingival hyperplasia in the sample varied. Varying degrees of this condition developed in 21 of the 22 subjects examined (23 percent had mild gingival hyperplasia, 31-83 percent had moderate to severe gingival hyperplasia and one subject was free of the disease). These results suggest that the degree of gingival hyperplasia varies within individuals among the groups, which might support King et al.’s (1993) conclusions that the degree of gingival enlargement was dependent on the individual’s sensitivity and ability to metabolize cyclosporin.
CHAPTER V
SUMMARY AND CONCLUSIONS

SUMMARY

The number of individuals receiving kidney transplants will continue to increase over the next few years. The individual with a kidney transplant experiences oral health problems due to side effects of immunosuppressive therapy. Infections may be detected early, if not, infections may spread systemically and lead to complications to the transplanted kidney. The dental professional must be prepared to work with these individuals and stress the importance of preventive educational and therapeutic measures. An intensive plaque control program and the periodic removal of gingival irritants by the oral healthcare provider improves the periodontal health of renal transplant recipients undergoing immunosuppressive therapy.

Systemic conditions such as ESRD have manifestations in the oral cavity. Oral disease may compromise the quality of life for the individual as well as the life of the transplanted kidney. Though seldom fatal, oral infections can be an important contributor to kidney rejection. The purpose of this investigation was to assess the oral health status of kidney transplant recipients undergoing immunosuppressive therapy to establish baseline data on the oral health status of this medically compromised population. The oral hygiene status of the sample was assessed via Greene and Vermillion's (1964) Simplified Oral Hygiene Index; periodontal disease status of the sample by way of Ramfjord's (1967) Periodontal Disease Index and degree and severity of gingival hyperplasia through a combination of Aas et al. (1963) and Seymour et al. (1985) Hyperplastic Index as utilized by King et al.'s 1993 study.

This investigation was conducted at Sentara Norfolk General Hospital/Sentara Health System, Nephrology Associates of Tidewater, LTD, and Old Dominion University Dental Hygiene Care Facility. Renal transplant recipients were invited to participate in the study and asked to sign an informed consent form prior to data collection. A total of 22 renal transplant recipients were examined at the aforementioned clinical sites. Data were analyzed using SPSS® statistical analysis program for Windows™ 95. The Kruskal-Wallis test was used to determine statistically significant differences in the oral hygiene status, periodontal disease status and degree of gingival enlargement among the three groups studied.

Two participants were completely edentulous; therefore, of the 22 renal transplant...
recipients examined. only 20 were evaluated using the Simplified Oral Hygiene Index, the Periodontal Disease Index and the Hyperplastic Index. Sixty-five percent of the individuals has a poor Simplified Oral Hygiene Index rating; 85 percent of the sample exhibited some degree of periodontal disease; and 75 percent of the individuals presented with moderate to severe degrees of gingival hyperplasia. One of the 22 participants manifested an oral lesion that appeared to resemble candidiasis. One of the 22 participants manifested an intraoral lesion resembling the fungal infection candidiasis. Findings from the statistical analyses revealed that there was no statistically significant difference among renal transplant recipients who have had a kidney transplant for less than one year, one to three years, and three or more years in terms of oral hygiene status and periodontal disease status, and degree of gingival hyperplasia resulting in retainment of all three null hypothesis.

CONCLUSIONS

Based on the results of this investigation, the following conclusions are made:

1. The oral hygiene status of renal transplant recipients undergoing immunosuppressive therapy is poor, indicating an increased need for oral hygiene education.

2. Periodontal disease was evident in the majority of the renal transplant recipients sampled. Preventive and therapeutic measures with a focus on instructions for meticulous oral hygiene and the initiation of a stringent periodontal maintenance regimen is needed prior to and post transplantation. This will contribute to the prevention of periodontal disease in the renal transplant population as well as control gingival hyperplasia.

3. Gingival hyperplasia was prevalent among renal transplant recipients sampled.

4. Undetected oral lesions or infections may be life threatening and may spread via blood or esophagus and lead to severe disease in immunosuppressed persons. Therefore, early detection is essential.

Considering the limitations of the study in relation to the results, the following recommendations for further research are offered:

1. Replication of this study using a larger sample of renal transplant recipients is necessary to verify the validity of the results. Utilizing a combination of renal transplant centers across the
nation would increase the generalizability of results.

2. Further research including the utilization diagnostic study models should be performed to assess the degree of gingival enlargement of this population is needed to clarify the relationship between bacterial plaque and gingival hyperplasia.

3. Further studies on the incidence of severe infection caused by oral microorganisms or oral infection to determine the correlation between kidney rejection and oral diseases.

4. Further studies should include groups of individuals on varying drug protocols to examine their oral responses to different immunosuppressant medications.

5. Evaluation of the efficacy of stringent periodontal maintenance programs including reinforcement of oral hygiene instructions and self-assessment instruments to assist renal transplant recipients in recognizing signs and symptoms or oral infection and diseases as well as what to do and when to seek care.

Renal transplant recipients are experiencing oral health problems associated with the immunosuppressive therapy. Oral health has not been given a high priority amongst renal transplant recipients. Overwhelming costs of medication, high costs of dental treatment, and lack of knowledge are contributing factors to the oral neglect found in this population. Prevention of oral infections, therefore, is critical in this medically compromised population to avoid any consequences oral disease may have on the transplanted kidney. Renal transplant recipients are not made aware of the importance of maintaining optimum oral health. An effective program for oral disease that combines primary prevention practices and therapeutic practices will ensure optimum oral health among this medically compromised population. The following protocol integrates oral health education and behavioral changes into daily activities to improve the oral health status of renal transplant recipients undergoing immunosuppressive therapy. To improve the oral health status of this medically compromised population, it is proposed that:

1. Renal transplant recipients receive continuous oral healthcare instruction and information regarding the possible complications of failing to maintain optimum oral health, both verbally and in writing from their oral healthcare professional prior to transplantation.

2. All renal transplant recipients receive a comprehensive oral examination including
periodontal, restorative, or surgical treatment prior to transplantation including the initiation of a periodontal maintenance regimen every three months thereafter.

3. All renal transplant recipients learn self-assessment techniques for the identification of intraoral manifestations, and when and where to seek appropriate care.

4. Preventive and therapeutic measures including oral healthcare instructions need to be emphasized, reinforced, and reviewed by the oral healthcare professional both pre- and post-transplantation on a regular basis.

5. The oral health maintenance regimen for renal transplant recipients undergoing immunosuppressive therapy should be reinforced by the nephrologist and transplant staff.

An appointment protocol has been developed to aid in the safe dental management of the renal transplant population (See Appendix L).

Further research is indicated to determine the effectiveness and outcome of implementing such a program. This program may have an initial high cost, but as oral health awareness and behavior modification occurs in the renal transplant population, it should prove to be cost-effective benefiting the success of the transplanted kidney and improving the quality of life of the recipient.
BIBLIOGRAPHY


Personal communication, (October 1995), Belinda Sanders, Social worker, Sentara Norfolk General Hospital, Norfolk, Virginia.
Personal communication. (October 1995). Thomas McCune, MD. Sentara Norfolk General Hospital, Norfolk, Virginia


Virginia Transplant Council (VTC), LIFENET. Virginia, January, 1995.


APPENDIX A

Invitation to Participate
Invitation to Participate

Date

Dear ______________:

I am conducting a research study on the oral health status of kidney transplant patients who are taking immunosuppressive medications, such as cyclosporin, to prevent rejection of the kidney. This study will enable us to determine the oral health status of kidney transplant recipients from the Sentara Health System, demonstrate the need for oral healthcare, and aid in the development of an oral healthcare program to be used by persons with kidney transplants. As a long term goal, this program will to help prevent dental disease in the kidney transplant population. Because you are an individual with a kidney transplant from the Sentara Health System, I would like to invite you to participate in this study. You will be 1 of approximately 30 individuals participating in this study to determine the oral health status of the kidney transplant population.

This study would involve 20 minutes of your time either before or after your regularly scheduled appointment at Sentara Norfolk General Hospital in one of the hospital’s examination rooms. Appointments can also be scheduled at Old Dominion University’s Dental Hygiene Clinic. No dental treatment will be rendered during this appointment, rather your current oral health status will be evaluated: selected teeth will be examined for plaque, tartar, gum bleeding, and gum disease. Mouth lesions will also be recorded. If you choose to participate, you will be required to see your Doctor to obtain an antibiotic medication that needs to be taken before and after the mouth examination. You need to take this to decrease the risk of infection from the mouth examination. The antibiotic premedication will be provided to you free of charge by the study. A benefit to you is that you will be made aware of any abnormal findings, so that you could voluntarily seek needed dental care if you so desire. Individual information will be kept confidential and findings will be reported in group form only. If you decide to participate, you will be free to withdraw your consent and discontinue participation at any time. No money will be given to you for participation in this study.

If you are interested in participating in this study, please notify Belinda Sanders, the social worker at Sentara Norfolk General Hospital or myself (683-5233, 519-9663) so we can determine a convenient date for the mouth examination. Results of this study will not be available until the Fall of 1996. At that time if you are interested in the results, please contact me through the School of Dental Hygiene at Old Dominion University, 683-5232 and I will share them with you.
Thank you for your time today. I am looking forward to hearing from you soon.

Sincerely,

Coral Diaz, BSDH, MPH
Master’s Degree Candidate
School of Dental Hygiene
Old Dominion University
APPENDIX B

Informed Consent Form
INFORMED CONSENT FORM

Oral Health Assessment of Kidney Transplant Patients
Undergoing Immunosuppressive Therapy: A Pilot Study

INVESTIGATORS: Coral Diaz BSDH, MPH, Master’s Degree Candidate
Deborah B. Bauman BSDH, MS, Associate Professor
Michele L. Darby BSDH, MS, Professor
Ralph Powers DDS, Adjunct Associate Professor
Truet Lineberger DDS, MS, Adjunct Associate Professor

SPONSOR: Old Dominion University
American Dental Hygiene Association (Applied for funding)
Hu-Friedy

DESCRIPTION:

This is to certify that I, _______________________, hereby agree to participate as a volunteer in a research study as a part of the educational and research program of Old Dominion University, under the supervision of Deborah B. Bauman, BSDH, MS (Faculty), and in collaboration with Coral Diaz, a dental hygienist, one who studies preventive oral healthcare and the management of behaviors required to prevent oral disease and promote health, who is a candidate for the Master of Science degree at Old Dominion University.

I understand that the study is being conducted to demonstrate the need for oral healthcare in kidney transplant patients. Results obtained from the study will provide baseline information for the development of an oral healthcare program to be used by persons with kidney transplants. As a long term goal, this protocol will lead to a program to help prevent dental disease in the kidney transplant population. I understand this study will involve a 20 minute mouth examination at Sentara Norfolk General Hospital/Sentara Health System or at the Dental Hygiene Clinic at Old Dominion University. No dental treatment will be rendered during this appointment, rather my current oral health status will be evaluated. Selected teeth will be examined by Coral Diaz for plaque, tartar, gum bleeding, and gum disease. The examination will include recording of any lesions or sores present in my mouth. A periodontal probe, a measuring device will be placed underneath my gums to detect any signs of gum disease in my mouth. The periodontal probe will also be used to measure the size of my gums. X-rays will not be taken during this appointment and a dental cleaning will not be performed.

I understand that I may chose not to participate in this study.

I understand that I will be referred to a dentist in my geographical area for treatment if needed and have been informed of the nonsurgical dental hygiene services available to me at Old Dominion University Dental Hygiene Clinic (804) 683-4308. Such care would be the responsibility of the participant to schedule and pursue on a voluntary basis.
EXCLUSIONARY CRITERIA:

I understand I will be excluded from this study if I am under 18 years of age, have had a kidney transplant within the past three months, and/or have less than 15 natural teeth. I understand that I will consult with my physician prior to the mouth examination so that I can obtain the antibiotic premedication I am required to take before my appointment. I also understand this medication will be mandatory to prevent rejection of the transplanted kidney due to infections (bacteremia). I understand I will be excluded from this study if I refuse to take the premedication or I am unable to take the medication. I further understand AIDS testing will not be performed in conjunction with this study.

RISKS:

I understand there is a chance of slight pain or discomfort in my gums and bleeding in my gums during the mouth examination. I also understand my mouth may be tender upon completion of the mouth examination. I understand that there is a risk of infection from the mouth examination and that the antibiotic premedication prescribed by my physician will aid in the prevention of infection (bacteremia). There may be other risks not yet identified.

BENEFITS:

I understand that a benefit to me personally is that I will be made aware of any abnormal findings in my mouth so that I may voluntarily seek the care I need. My participation in the study will contribute to the dental research of the kidney transplant population.

COSTS AND PAYMENTS:

I understand that this study involves no costs to Sentara Norfolk General Hospital/Sentara Health System. I further understand that participation in this study is strictly voluntary and no monetary compensation will be given. The cost of this study, including administrative fees, payments to volunteers, as well as payment of supplies and equipment for the examination is being paid for by the researcher. I understand that the antibiotic premedication will be given to me by my physician at Sentara Norfolk General Hospital/Sentara Health System or will be dispensed to me by Dr. Truet Lineberger / Dr. Ralph Powers at Old Dominion University’s Dental Hygiene Clinic.

NEW INFORMATION:

Any new information obtained during the course of this research that may affect my willingness to continue participation in the study will be provided to me.
CONFIDENTIALITY:

I understand that all personal information learned about me during this research will be kept strictly confidential and kept in a locked filing cabinet. Records will be protected within the limits of the law. I also understand that non-personal information learned from this study could be used in reports, presentations and publications, but I will not be personally identified. I understand that I am one in approximately 100 individuals participating in this research project and results will be reported in group form only. It may be necessary for my records to be inspected by federal regulatory authorities such as a representative of the Food and Drug Administration (FDA).

WITHDRAWAL PRIVILEGE:

I understand that I may refuse to participate in or withdraw from the project at any time without penalty or prejudice. If I do I will have exactly the same healthcare at this institution as I would normally receive. I also understand it may be necessary for Coral Diaz, the dental hygienist who will be conducting the mouth examination, to withdraw me from the study. If I do withdraw, or am withdrawn, I decide whether or not to follow up on the recommended referral for evaluation.

COMPENSATION FOR ILLNESS OR INJURY:

I understand if I suffer a physical injury or illness as a direct result of my participation in this research study, immediate medical treatment will be made available to me at an additional charge. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, I understand I do not waive the legal rights by signing this consent form.

The Eastern Virginia Medical School (EVMS), the Medical College of Hampton Roads (MCHR), the Sentara Health System (SHS), nor Old Dominion University (ODU) provides no compensation plan or free medical plan to compensate me for such injuries. If I believe I have suffered an injury as a result of my participation in any research program I may contact Dr. Gerald J. Pepe, (804) 446-8423, an employee of MCHR, or Steven Hoagland, (804) 683-3460, and employee of ODU, who will review the matter with me.

VOLUNTARY CONSENT:

I certify I have read all of this consent form or it has been read to me and that I understand it. If I have any questions pertaining to the research or my rights as a research subject I may contact Coral Diaz whose phone number is (804) 683-5233 or Deborah B. Bauman whose phone number is (804) 683-5235. I have been informed that I have the right to contact the Old Dominion University Institutional Review Board for Protection of Human Subjects (804) 683-3460 or Eastern Virginia Medical School (804) 446-8423 should I wish to express any opinions regarding the conduct of this study. I acknowledge that I may obtain a copy of the results of this research project by calling Coral Diaz or Deborah B. Bauman at the aforementioned phone numbers, and that upon making such a request, a copy will be provided without charge.
A copy of this consent form will be given to me. My signature below means I freely agree to participate in this study.

_____________________________  ________________
Signature of Volunteer         Date

_____________________________  ________________
Witness                        Date

INVESTIGATOR’S STATEMENT:

I certify I have explained to the above individual the nature and purpose of this study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date on this consent form.

_____________________________  ________________
Principal Investigator         Date
APPENDIX C

Demographic Characteristics of the Sample
DEMOGRAPHIC INFORMATION

Number: ___
Age: ___

Race: ___ Hispanic
      ___ African-American
      ___ White (Caucasian)
      ___ Asian / Pacific Islander
      ___ Native American
      ___ Other

Are you currently employed? ___ Yes ___ No

Income: ___ below $15,000
        ___ $15,001.00 to $23,000
        ___ $23,001 to $29,000
        ___ $29,001 to $35,000
        ___ greater than $35,000

What is your highest level of education? ___ elementary school
                                          ___ junior high school
                                          ___ high school
                                          ___ some college
                                          ___ completed college
                                          ___ master's degree of higher

How long have you had your renal transplant? ___ less than a year
                                               ___ 1 to 3 years
                                               ___ greater than 3 years

Do you smoke? ___ Yes ___ No

When was your last visit to the dentist? ___ Last month
                                            ___ 6 months ago
                                            ___ one year ago
                                            ___ three years ago
                                            ___ more than three years ago
What was the purpose of your visit?  
___ Routine check-up  
___ emergency  
___ filling / extraction  

How many times a year do you visit the dentist?  
___ Never  
___ once a year  
___ twice a year  
___ three times a year  

Do you brush your teeth?  
___ Yes  
___ No  
If yes, how many times a day?  
___ 1  
___ 2  
___ 3  

Do you floss?  
___ Yes  
___ No  
If yes, how often do you floss?  
___ Once a day  
___ three times a week  
___ once a week  
___ once a month  

Do your gums bleed?  
___ Yes  
___ No  

Have you ever received oral hygiene instructions?  
___ Yes  
___ No  

Are you experiencing any dental problems now?  
___ Yes  
___ No  
If yes, please specify:  
________________________________________________________________________________________

The biggest problem I have with my mouth is:  
________________________________________________________________________________________
APPENDIX D

Intrarater Reliability - Pilot Study
t-test for Correlated Samples
of Scores for Two Sets of
Simplified Oral Hygiene Index (x, y)

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>X</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
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<td>3.4</td>
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<td>2.5</td>
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<td>Total</td>
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t = 0
r = 0.95
INTRARATER RELIABILITY FOR
PERIODONTAL DISEASE INDEX

t-test for Correlated Samples
of Scores for Two Sets of
Periodontal Disease Index Scores (x, y)

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>X</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
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<td>0.92</td>
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<td>4.0</td>
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<td>0.2</td>
<td>0.2</td>
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<td>6</td>
<td>6.4</td>
<td>6.4</td>
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<td>5.2</td>
<td>5.3</td>
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<tr>
<td>8</td>
<td>4.3</td>
<td>4.3</td>
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</tr>
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<td><strong>Total</strong></td>
<td><strong>42.22</strong></td>
<td><strong>42.30</strong></td>
</tr>
</tbody>
</table>

\( t = 0.33 \)
\( r = 0.95 \)
### Intrarater Reliability for Hyperplastic Index

**t-test for Correlated Samples of Scores**

for Two Sets of

Hyperplastic Index Scores (x, y)

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>X</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

\[ t = 0 \]

\[ r = 0.95 \]
APPENDIX E

Data Collection Form
Simplified Oral Hygiene Index
Data Collection Form for the Simplified Oral Hygiene Index

Subject # _____
Time since transplant _____
Date _____
Location: _____ ODU Dental Hygiene Clinic
       _____ Sentara Norfolk General Hospital / SHS
       _____ Nephrology Associates of Tidewater, LTD

<table>
<thead>
<tr>
<th>Tooth # surface</th>
<th>Plaque (PI-S)</th>
<th>Calculus (CI-S)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>3B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9L</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25L</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>28B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B = buccal surface  
L = lingual surface

PI-S Criteria

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>no debris or stain present</td>
</tr>
<tr>
<td>1</td>
<td>soft debris covering not more than 1/3 of the tooth surface being examined, or the presence of extrinsic stains without debris, regardless of the surface area covered</td>
</tr>
<tr>
<td>2</td>
<td>soft debris covering more than 1/3 but no more than 2/3 of the exposed tooth surfaces</td>
</tr>
<tr>
<td>3</td>
<td>soft debris covering more than 2/3 of the exposed tooth surface</td>
</tr>
</tbody>
</table>

CI-S Criteria

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>no calculus present</td>
</tr>
<tr>
<td>1</td>
<td>supragingival calculus covering not more than 1/3 of the exposed tooth surface</td>
</tr>
<tr>
<td>2</td>
<td>supragingival calculus covering more than 1/3 but no more than 2/3 of the exposed tooth surfaces, of the presence of individual flecks of subgingival calculus around the cervical portion of the tooth, or both</td>
</tr>
<tr>
<td>3</td>
<td>supragingival calculus covering more than 2/3 of the exposed tooth surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth or both</td>
</tr>
</tbody>
</table>
APPENDIX F

Data Collection Form
Periodontal Disease Index
Data Collection Form for the Periodontal Disease Index

Subject # _____
Time since transplant _____
Date _____
Location: _____ ODU Dental Hygiene Clinic
       _____ Sentara Norfolk General Hospital / SHS
       _____ Nephrology Associates of Tidewater

Gingival Status

<table>
<thead>
<tr>
<th>Tooth #</th>
<th>3</th>
<th>9</th>
<th>12</th>
<th>19</th>
<th>25</th>
<th>28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lingual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

Periodontal Status

<table>
<thead>
<tr>
<th>Tooth #</th>
<th>3</th>
<th>9</th>
<th>12</th>
<th>19</th>
<th>25</th>
<th>28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial (F)</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Criteria for assessing gingival status

0  absence of inflammation
1  mild to mod. Interproximal gingival inflammation
2  mild to moderately severe gingivitis extending marginally
3  severe gingivitis characterized by marked redness, inflammation, tendency to bleed and ulceration

Disease Index

0-3  when the gingival crevice or pocket none of the measured areas extends apical to the cementoenamel junction

*4  when the pockets of any 2 recorded areas extend apically from the cementoenamel junction not more than but including 3mm

*5  when the pockets of any 2 recorded areas extend apically from the cementoenamel junction from 3mm to 6mm

*6  when the pockets extend more than 6mm apically from the cementoenamel junction in any 2 of the measured areas

* the gingival score is disregarded

Criteria for Periodontal
APPENDIX G

Data Collection Form
Hyperplastic Index
Data Collection Form for the Hyperplastic Index

Subject # _____
Time since transplant _____
Date _____
Location: _____ ODU Dental Hygiene Clinic
_____ Sentara Norfolk General Hospital
_____ Nephrology Associates of Tidewater. LTD

<table>
<thead>
<tr>
<th>Gingival Unit</th>
<th>LABIO-LINGUAL</th>
<th>APICO-CORONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Buccal</td>
<td>Lingual</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
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<tr>
<td>4</td>
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<tr>
<td>7</td>
<td></td>
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</tr>
<tr>
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<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LABIO-LINGUAL DIRECTION
0  no gingival hyperplasia
1  mild hyperplasia (blunting of gingival margin)
2  moderate hyperplasia (less than ½ of crown length)
3  marked hyperplasia (greater than ½ of crown length)

APICO-CORONAL DIRECTION
0  normal width of free gingival margin
1  thickening from the normal up to 2mm
2  thickening from the normal >2mm
APPENDIX H

Data Collection Form
Intraoral Manifestations
Data Collection Form - Intraoral Manifestations

Patient # _______________________
Time of transplant ______________
Researcher _____________________
Date __________________________

Location: ODU Dental Hygiene Clinic__ Sentara Norfolk General Hospital____
          Sentara Health System

Medications taken:  Dilantin________
                     Cyclosporin-A _____
                     Other__________

CLINICAL SIGNS OF:

___ Red lesions
    ____ tongue ______ < 3mm
    ____ floor of mouth ____ > 3mm
    ____ buccal mucosa
    ____ palate (hard or soft)

___ White lesions
    ____ tongue ______ < 3mm
    ____ floor of mouth ____ > 3mm
    ____ buccal mucosa
    ____ palate (hard or soft)

___ Other (specify)

_____________________________________________________________________

___ No lesions found

Referral:
    ___ Immediate referral to DDS indicated and made to _______________________
    ___ Referral to DDS indicated
    ___ No referral indicated

Original - sent to healthcare provider (dentist)
Copy - to client
Copy - to researcher
APPENDIX I

Referral Form
REFERRAL FORM

Patient Name

Phone

Patient Address

was seen by Coral Diaz, a dental hygienist, who is a candidate for the Master of Science in Dental Hygiene Degree at Old Dominion University / Sentara Norfolk General Hospital/Sentara Health System, on ____________ and a referral was made for a dentist to evaluate oral health status:

Date

___ The need for periodontal evaluation on the following teeth is indicated:

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17

___ The need for ____________________________ is indicated.

(Other)

* Radiographs were not taken during the appointment.

Patient requested referral to:

________________________________________
Dentist's Name

________________________________________
Street Address

________________________________________
City State Zip

I understand my need for dental referral ________________________________

signature

Original - sent to healthcare provider (dentist)
Copy - to client
Copy - to researcher
APPENDIX J

Thank You Letter
Thank You Letter

Dear volunteer:

Thank you for volunteering your time to participate in this scientific investigation on (Month/Year). Your participation in this study is greatly appreciated; without your cooperation this investigation would not have been possible. It is hoped that the information gained regarding your current oral health will serve as baseline data for the development of a post-transplant oral healthcare protocol to be used by renal transplant recipients.

The results of this investigation will be available in December 1996. Should you be interested in the results, please do not hesitate to contact me at Old Dominion University School of Dental Hygiene, 683-5233.

Again, thank you for your participation in this study. It was a pleasure working with you.

Sincerely,

Coral Diaz, BSDH, MPH
Master of Science Degree Candidate
APPENDIX K

Frequency Distributions of Raw Data
Raw Data - Simplified Oral Hygiene Index

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N = 20
### Raw Data - Periodontal Disease Index

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APPENDIX L

Dental Management of the Renal Transplant Recipient
Undergoing Immunosuppressive Therapy
Dental Management of the Renal Transplant Recipient
Undergoing Immunosuppressive Therapy

The following oral healthcare protocol has been proposed to aid in the safe dental management of the kidney transplant population.

Pre-transplant considerations:
1. A thorough evaluation of the dental status. If active dental disease found, appropriate dental care should be rendered before transplantation.
2. Extractions are advised only on patients with severe periodontal disease, extensive dental caries, and extremely poor oral hygiene.
3. All restorative and endodontic dental work, as well as periodontal work should be taken care of prior to transplantation.
4. Preventive dentistry with emphasis on the importance and maintenance of effective oral hygiene procedures (toothbrushing, flossing, and irrigation) should be reviewed and implemented.
5. Patients should be advised of the risks and problems involved if significant dental disease or infection were to develop following transplantation. Patients should be informed of the need to achieve and maintain an oral environment which minimizes any type soft tissue inflammation and on the importance of frequent recall visits following transplantation.
6. Before invasive dental procedures are initiated, the oral healthcare professional must consult with the patient’s physician to establish need for prophylactic antibiotics to prevent infection.
7. Rigorous oral hygiene measures should begin before the transplantation procedure.

Post-transplant
1. A thorough health history must first be obtained to determine time since transplantation, current medications taken, and other medical conditions that may alter oral care.
2. Consultation with the patient’s physician to establish need for antibiotic premedication prior to oral treatment.
3. A complete intra/extra oral examination including radiographs and observation of lymph nodes should be performed for the patient with renal disease to diagnose any pathology which may be present.
4. Baseline blood pressure should be determined prior to treatment for each patient treated with
cyclosporine or prednisone. If blood pressure becomes elevated, the physician should be consulted immediately.

5. Non surgical periodontal therapy should be performed as needed to remove bacterial plaque, dental calculus and extrinsic stain from tooth surfaces. A periodontal maintenance program of three-month intervals should be established soon after transplantation.

6. Chlorhexidine mouth wash should be used regularly as an adjunct to other oral hygiene measures.

7. Oral lesions should be cultured or biopsied for identification of specific causative agent. This helps to ensure proper antimicrobial management. Candidal infections of the oral mucosa should be treated with nystatin oral rinses or vaginal suppositories dissolved in the mouth four to five times a day. Ketoconazole 200 to 400 mg can be substituted but should be used with caution since it reduced cyclosporin metabolism, thus resulting in high blood levels and toxicity. Treatment of fungal infections such as aspergillus should require a reduction in immunosuppressive drugs, debridement of infected areas, and prudent use of amphotericin B.

8. Surgical drainage should be considered in infections not showing early and rapid improvement.