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An assessment of the effectiveness of Andolex-C ® mouth rinse on oral palliation in HIV-infected patients

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Declaration

I, Yolanda Malele (Student No. 8803104E), hereby declare that this report is my own work. It is being submitted for the degree of Master of Public Health at the University of the Witwatersrand, Johannesburg. It has not been submitted or presented for any degree or examination at this or any other university.

Signed at ……..(place) on the …..day of …..……
in the year 2006.

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Dedication

To my husband, the kids, and my parents for their tremendous encouragement, patience and support throughout.

In loving memory of my late brother, Dr TW Malele, for his ambition and earnest dedication to his work.

*'Seek **his** will in all you do, and **he** will direct your paths.'(New Living Translation; Proverbs 3:6)*

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- 3M Pharmaceuticals (South Africa) for supplying the Andolex-C Mouth rinse;
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List of Abbreviations

AIDS- Acquired Immune Deficiency Syndrome

ART- Antiretroviral treatment

CBO-Community-based organisation

CPITN- Community Periodontal Index of Treatment Needs

D1- Physical disability

D2- Psychological disability

D3 -Social disability

DMFT- Decayed Missing Filled Teeth

FL- Functional limitation

H - Handicap

HIV- Human Immunodeficiency Virus

NGO- Non-Governmental Organisation

NSAID- Non-Steroidal Anti-inflammatory Drug

OHIP- Oral Health Impact Profile

OHL- Oral hairy leukoplakia

P1- Physical pain

P2 -Psychological discomfort

PHRU- Perinatal HIV Research Unit

SA- South Africa

WHO- World Health Organization

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Chapter 1: Introduction and Background

1.1 Introduction

HIV/AIDS is a priority health problem worldwide. South Africa is second only to India in the number of new cases of HIV occurring per day (with 600 new infections occurring per day). Current estimates suggests that 4.8 million people in South Africa (11%) were living with HIV in 2005 (HSRC, 2005).

These facts and statistics are relevant to oral health, especially in the context of public health. Studies done throughout the world indicate that oral lesions associated with HIV occur in over half of HIV/AIDS patients (Arendorf et al., 1998; Ramirez-Amador et al., 1998; Lim et al., 2002). This finding is significant, as recent studies have shown that oral lesions associated with HIV-infection significantly affect quality of life of infected patients (Bajomo, 2004; Yengopal 2004).

Literature Review

1.2 Oral symptoms and HIV

The majority of HIV/AIDs patients present with at least one oral lesion associated with the infection during their lifetime (Sauer et al. 1995; Arendorf et al. 1998; Chattopadhyay et al. 2005).These oral lesions have been associated with pain, discomfort and a subsequent reduction in oral function and hence, quality of life, in affected patients (Coates et al., 1996; Bajomo, 2004; Yengopal, 2004).

Norval (2004) undertook a study with the aim of identifying and increasing awareness of the ten most prevalent symptoms and five most common sites of pain in 103 adult patients with advanced AIDS. The author reported that in a hospice in Soweto, Johannesburg, pain was the most prevalent symptom (98%). The common sites of pain in order of prevalence were lower limb (66%), mouth pain (50.5%) experienced by the AIDS patients followed by head pain (42.7%), pain in the throat (39.8%) and chest pain (17.5%). In another large multicenter study of persons living with HIV/AIDs, mouth pain was reported by 33% of patients (MacDonald & Doyle, 1999).

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These authors recommended that the palliative care team should strive to maintain and improve the patient's oral hygiene to prevent conditions like periodontal disease and stomatitis and immediately institute symptomatic control to decrease of loss of function and thereby improve the patient's quality of life.

The probable causes of mouth pain, excluding dental pain due to the carious process include viral (herpes simplex, varicella), fungal (oral candidiasis) and bacterial infections (necrotising gingivitis and periodontal disease). Other causes of pain were due to aphthous ulceration, salivary gland disease and Kaposi sarcoma (Norval, 2004).

Pain is subjective and it is usually the most common symptom reported by patients. In a study by Karus et al., 2005, 32 self-reported symptoms and the treatment received were obtained from patients of three palliative care programmes that provide services to seriously ill HIV/AIDS patients. More than 50% of patients that reported the symptoms such as pain, nausea, difficulty swallowing and mouth sores also reported receiving treatment for those symptoms. However, despite availability of treatment, patients still reported experiencing physical and psychological symptoms.

Pain can be pathological or functional in nature. Pathological pain is that pain related to some form of pathology in the body and can be divided into nociceptive pain – related to tissue distortion or injury and neuropathic pain - related to nerve compression or injury (Twycross, 1999). The type of mouth pain as a result of infections in the mouth is nociceptive because the inflammatory reaction results in tissue distortion.

About 70% - 90% of HIV-infected individuals present with oral lesions (Arendorf et al., 1998). A study by Sauer et al. (1995) found that 74.4% of HIV-infected patients presented with one or more oral lesions, of these, and of these 30.4% lesions were symptomatic. Six percent of patients were diagnosed with HIV infection after first presenting with oral lesions.

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Oral lesions associated with HIV often present as early signs and symptoms of the disease (Ramirez-Amador et al., 1998; Lim et al., 2001). Combined candidal lesions were seen in 37.8% of cases studied by Arendorf et al. (1998). About 20% of this cohort of patients was diagnosed with hairy leukoplakia, 8.5 % had combined gingival and periodontal infections, 2.9% had painful oral ulcerations, and 1-5% were diagnosed with Kaposi sarcoma. In a study among adult dentate patients in North Carolina, oral candidiasis and oral hairy leukoplakia were the most common oral mucosal diseases associated with HIV infection (Chattopadhyay et al., 2005).

There is increasing evidence from socio-dental indicators such as the Oral Health Impact Profile (an index measuring oral-health-related quality of life) that HIV dental patients experience profound discomfort, dysfunction or disability and greater levels of social impact than non-HIV patients (Coates et al., 1996; Bajomo, 2004; Yengopal, 2004). In addition, swallowing difficulties experienced by patients with mouth symptoms pose significant problems for patients and further impact on their quality of life (Nilsson, 2000). It is for this reason that management of HIV-infected patients should include management of pain in the mouth.

Advances in medical research make it possible for HIV/AIDS to be treated as a chronic manageable disease. This disease has “changed from an inevitably fatal infection to a chronic illness for which early and aggressive intervention can be beneficial” (Gilmore, 1992).

In keeping with the government's promise of improving the quality of life for all in the new South Africa (Department of Health, 2001), pain alleviating regimens that improve the quality of life of HIV-infected individuals should be provided.

With the current incidence and prevalence rate of HIV, there are in South Africa large sections of the population infected with the HIV and these individuals may present with oral lesions associated with the disease. Mouth pain and /or discomfort will be one of the common symptoms experienced by the patients and palliation of the pain and /or discomfort should become part of a comprehensive management plan for these patients.

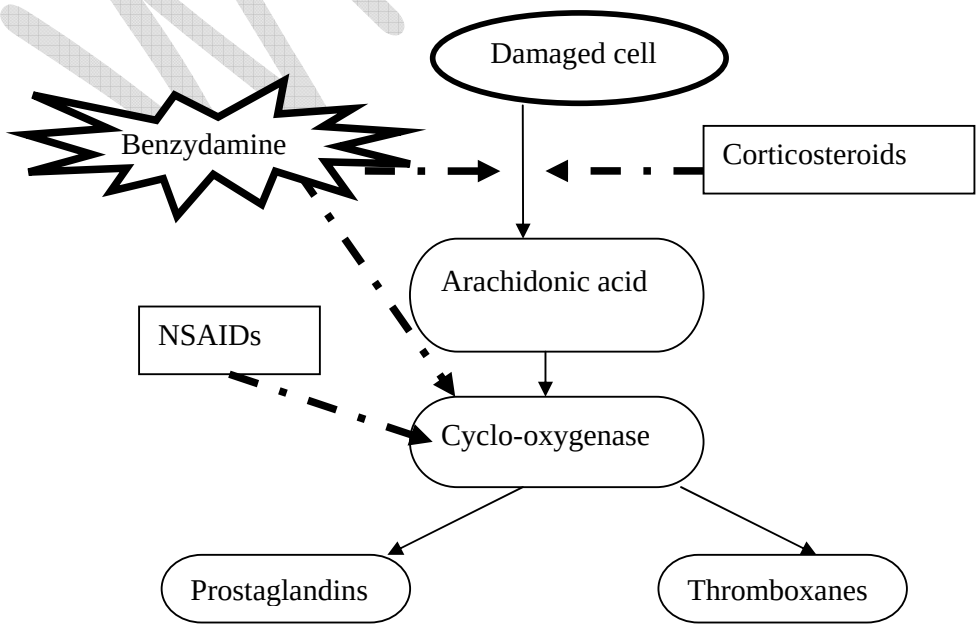
1.3 Andolex-C ® mouth rinse

For mouth lesions, certain mouth rinses are recommended for HIV-infected people. Andolex-C® mouth rinse has been on the South African market for eight years (3M Pharmaceuticals). Each 15 ml contains Benzydamine Hydrochloride 22.5 mg, Chlorhexidine gluconate 18 mg and 9% of alcohol.

Benzydamine is a non-steroidal anti-inflammatory drug (NSAID). It is different from the traditional NSAIDs in that it is an alkaline as opposed to other NSAIDs (for example Ibuprofen, Naproxen) which are acidic. It tends to concentrate on inflamed tissue (Turnbull, 1995). Benzydamine stops the inflammatory process at two points:

1. Similar to corticosteroids, it stabilises the cell membrane of the damaged cell by preventing the release of arachidonic acid, which initiates the inflammatory process.
2. As with other NSAID's, it inhibits cyclo-oxygenase, reducing synthesis of prostaglandins and related substances (Figure 1.1).

Figure 1.1: A flow diagram illustrating the normal pain pathway and the mechanism of action of benzydamine hydrochloride in the pain pathway.



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Benzydamine hydrochloride in Andolex-C® mouth rinse has analgesic properties because it reduces oedema and interferes with the inflammatory process (Quane et al., 1998).

In addition to its anti-inflammatory effects, benzydamine has local anaesthetic effects and analgesic effects. The analgesic effect is greatest against pain emanating from the inflammatory process (Turnbull, 1995).

Benzydamine has been found to reduce prostaglandin production in human gingival fibroblasts (Modeer & Yucel-Lindberg, 1999). Benzydamine is also known to improve oral mucosal health in the immuno-compromised patient and is recommended as a prophylactic mouth-rinse for such patients (Arendorf et al., 1996).

In number of studies, using animal models and human subjects, benzydamine has displayed non-specific antiseptic activity (Turnbull, 1995).

In a clinical evaluation of benzydamine and chlorhexidine carried out on 18 patients with recurrent aphthous ulceration, patients preferred benzydamine because of the pain relief brought about by the anaesthetic effect (Matthews et al., 1987). Edres et al. (1997) showed that patients with aphthous stomatitis preferred benzydamine HCL because of pain control.

Chlorhexidine gluconate, another ingredient in Andolex-C® mouth rinse, is active against a broad spectrum of microbes. The positive charge of the chlorhexidine molecule, reacts with the cell surface of the micro-organisms and destroy the integrity of the cell membrane, penetrates the cell and disorganises the cytoplasm. This process results in cell death (Clinical pharmacology of chlorhexidine).

Chlorhexidine was also used in a randomised controlled trial in seventy five HIV-infected patients. The objective of the study was to determine if chlorhexidine mouth rinse can be used as an intervention after antifungal therapy to prolong recurrence of oral candidiasis. The study concluded that the mouth rinse played only a small role in the maintenance of an oral candidiasis-free period among HIV/AIDS subjects

compared to normal saline. The minimal effect may have been a result of the small sample size in the study (Nittayananta et al., 2004).

Chlorhexidine gluconate rinse was used in an intervention study in HIV-infected children. The purpose of the study was to evaluate its effect on the clinical and microbiologic manifestations in order to prevent and treat fungal infection in HIV-infected children (Barach & Safford., 2004). In this study the *Candida* colonies decreased from 6.2 at baseline to 2.7 after the treatment. The results suggest that the topical disinfectant chlorhexidine gluconate rinse may be an effective agent for treating and preventing oral candidiasis in HIV-infected children.

Chlorhexidine also significantly reduced the total number of ulcer days experienced by 20% of patients in a double-blind, placebo-controlled cross-over trial. This study sought to investigate the effectiveness of chlorhexidine gluconate mouthwash in the management of minor aphthous ulceration. Patients had a five-day increase in the number of ulcer-free days (from 17 to 22 days) (Hunter & Addy, 1987).

Costa et al., (2003) assessed chlorhexidine for its effectiveness in preventing oral mucositis in children with acute leukaemia receiving anticancer therapy. There was significant decrease in oral mucositis and ulceration in the children who used chlorhexidine mouth rinse (Costa et al., 2003).

Chlorhexidine mouth rinse alone can significantly reduce plaque areas (Addy et al., 1983). Chlorhexidine 0.2% was used in a split-mouth clinical trial. The aim of the study was to compare the anti-plaque effect of warm and cold chlorhexidine rinse on human plaque. The findings concluded that chlorhexidine showed a significant anti-plaque effect, especially when the mouth rinse is warm (Konig et al., 2002).

Andolex-C® mouth rinse has reported side effects of oral numbness from the anaesthetic effect, stinging sensation, dryness or thirst. Reversible discolouration of teeth or tongue may occur with prolonged use (3M Pharmaceuticals).

It is evident from the above studies that Andolex-C® mouth rinse has pain relieving properties and may be used for palliation of mouth pain and /or discomfort due to oral lesions in HIV-infected patients.

1.4 Palliative HIV care and oral health care

The World Health Organization (WHO) defines palliative care as an approach that improves the quality of life of patients and their families facing problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification, impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual (WHO, 2002). Palliative care, therefore, aims to provide relief from pain and other distressing symptoms and to promote patient comfort. Oral palliation aims to provide relief from mouth pain and/or discomfort and promote patient comfort and improve the oral-health –related quality of life.

Twycross (1999) emphasises that the primary aim of palliative care is to promote patient comfort and provide relief from suffering. The effectiveness of palliative care is usually measured by an improvement on quality of life (Twycross, 1999). Palliative care is usually provided by a team that includes patient, family and professionals and it has three essential components: - psychological support, symptom relief and teamwork cooperation (Twycross, 1999).

The present study focuses on the relief of symptoms in the mouth i.e. oral palliation. The evaluation of patients regarding symptom relief should not only include physical problems but should incorporate psychological and social problems as well (WHO, 1998). This approach helps to build a picture of the effects of oral symptoms on the patient's oral-health-related quality of life. It is for this reason that a socio-dental indicator such as the Oral Health Impact Profile (an index measuring oral-health-related quality of life) was used to assess the impact of mouth pain and /or discomfort on quality of life in this current study.

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According to Twycross (1999), palliative care should start concurrently with the treatment for the underlying conditions be it cancer treatment or treatment for underlying infections and should not be left for end-of-life care only.

There are 39.4 million people living with HIV worldwide (UNAIDS, 2004) and these patients would require palliative care at various stage during the course of their infection. This factor makes quality of life care for HIV infected individuals a global public health problem. End-of-life care from the patients' perspective refers to adequate pain and symptom management in addition to achieving a sense of control, relieving the burden on loved ones, and strengthening relationships with loved ones (Singer & Bowman, 2002). Oral health care should be part of the symptom management (MacDonald & Doyle, 1999). Hence oral palliation should form an important component of other palliative regimens that are provided to improve quality of life in affected patients.

In countries such as Zimbabwe and South Africa, HIV/AIDS care and prevention is taught at grass root level through community-based programmes. Care-givers and family members are instructed in care-giving techniques which include symptom relief (Singer et al., 2002).

With the current HIV pandemic, the health services are faced with an increasing number of AIDS patients. Hospitals, hospices and home-based care centres are and will continue to be in demand. For an example, 17 Non-Governmental Organisations (NGOs) and Community-Based Organisations (CBOs) provide care and support for almost 7, 000 beneficiaries in the inner city of Johannesburg, South Africa (Dlamini & Rudolph, 2004).

The value of symptom relief in palliative care will be important in alleviating suffering for these patients. The general public and health care professionals have an ethical and a moral duty to reduce discomfort and suffering.

Currently, very little emphasis is placed on the palliation of HIV/AIDS related symptoms such as pain, cough, dyspnoea, diarrhoea and others (Norval, 2004). While

strenuous effort and progress should be made in providing treatment, future strategies and solutions to the HIV/AIDS calamity should be finding other appropriate treatment modalities, preventing infections and managing current chronic infections. Symptom control should not be neglected or reserved for patients in the AIDS stage of the disease but rather it should be an element of the management in all HIV-infected patients (Norval, 2004).

At the Fourth International Workshop on the Oral Manifestation of HIV Infection it, was noted that there was a paucity of intervention studies related to the treatment or management of oral lesions associated with HIV (Shirlaw et al., 2002). This study focused on the palliation of oral symptoms (mouth pain and /or discomfort) in HIV-infected patients as part of overall management of HIV/AIDS disease.

1.5 The Oral cavity and HIV/AIDS

Oral health can be seen as part of health in general, and is related to quality of life (Ingram et al., 2005). Management of pain and / discomfort caused by oral lesions in HIV-infected patients is recommended in order to reduce suffering and improve the quality of life of HIV/AIDS patients (Coates et al.,1996; Bajomo, 2004; Yengopal, 2004).

The oral health of HIV/AIDS patients becomes more affected as their condition worsens (Aldous & Aldous, 1991). It therefore becomes paramount to treat and also relieve oral syptoms so that oral function is maintained. Oral hygiene habits and maintenance of oral health have an influence over quality of life, in that alleviation or reduction of pain has a direct and positive influence on oral function.

It is important for HIV patients to maintain a healthy mouth for two reasons. Firstly, a mouth without infection reduces stress on the already compromised immune system. Secondly, proper oral function is needed for eating essential foods for maintaining the immune system and general health (Aldous & Aldous, 1999).

Oral health care in HIV and AIDS patients does not differ from that of non-infected patients. They need the highest standard of care that is available. In HIV-infected patients, oral care of soft tissues has concentrated on oral lesions as classified by

European Community (EC)-Clearinghouse classification published in 1993 (EEC Clearinghouse, 1993). These lesions are opportunistic in nature and are bacterial, viral, fungal, non-specific and neoplastic in origin.

Routine oral care should be given to the patients, with the exception of those in the very terminal stage of the disease where, patients are incapable of functioning optimally. In the latter cases routine care should be modified and prioritised for reducing pain and treating infection (Shirlaw et al., 2002).

1.5.1 General oral hygiene

There is substantive evidence to show that preventive care can reduce oral problems. Tooth brushing (manual or non-manual) has been proven over many years to prevent supragingival and subgingival plaque formation in areas accessible to a toothbrush (Waerhaug, 1981, Hochenedel et al., 1982, Terezhalmy et al., 1995, Bustillo et al., 2000, Sgan-Cohen & Vered, 2003).

An analysis of the effect of adult tooth brushing by Zhang and Cheng (2003) concluded that people should spend more time on tooth brushing especially when plaque indices are high. In a study done by Taani et al. (2003) it was found that the plaque indices of teenagers who brushed their teeth were lower than those of teenagers who did not brush their teeth. Fluoride toothpastes have preventive and therapeutic effects and are used primarily, but not exclusively, for aiding in the removal of plaque through affecting its metabolic activities (Embery & Rolla, 1992).

A recent systematic review, which sought to update the mechanical oral hygiene practices discussed at a 1986 State-of-the-Science conference, was done on mechanical oral hygiene practices. The review found that there was good evidence to recommend tooth brushing twice daily with fluoridated toothpaste and flossing and personal supragingival irrigation as an adjunct to toothbrushing (Brothwell et al., 1998). Health promotion activities, such as repeated oral hygiene instructions, have been shown to increase the frequency of oral hygiene performed. Repeated oral hygiene instructions and prophylaxis can result in a high level of oral hygiene and, therefore, a reduction in dental caries and periodontal disease (Axelsson & Lindhe,

1978). A single dental health education session and tooth brushing instruction reduced microorganisms by 25% (Seow et al., 2003).

HIV-infected patients are advised to maintain meticulous oral hygiene like daily brushing and flossing to remove debris. Daily use of antiseptic mouthwashes may be considered for patients unable to maintain optimum oral health through routine preventive care (American Dental Association Council on Scientific Affairs, 1995).

1.6 The Oral Health Impact profile

The importance of health-related quality of life has found widespread acceptance in medicine (Guyat et al, 1993). It has been recognised that objective measures of disease give minimal insight into the impact of oral diseases on quality of life. It has been proven that some people with chronic diseases or disorders perceive their quality of life to be better than that of healthy individuals. This means, therefore, that poor health does not necessarily mean poor quality of life (Allen, 2003). It is for this reason that subjective patient-based quality of life measures should be considered.

Many of the indices used in dentistry are clinician-based, objective and measure or reflect the end-point of disease process (Allen,2003). These indices provide no information about the impact of disease process and psycho-social well-being of the patient.

Patients' assessment of their oral-health-related quality of life is often different from the assessment carried out by health care professionals. Therefore, a patient-based assessment of health status is important in measuring health. This kind of assessment provides information about the kind of perceptions patients have about their oral health and about oral-health-care-seeking behaviour (Allen, 2003). The psycho-social impact of disease may be a determinant of health-seeking behaviour.

Oral health has incorporated oral-health-related quality of life as a subjective measure of oral health only in the last 10 to 15 years. Oral diseases are highly prevalent and can have physical, economic, social and psychological consequences for the patient

(Bajomo, 2004; Yengopal, 2004). Oral lesions seriously impair the quality of life in large numbers of individuals and may also affect other aspects of life, including function, appearance, and interpersonal relationships (Gift & Redford, 1992).

Various methods of measuring oral-health-related quality of life have been developed. The following indices have been developed (Allen, 2003):

1. General Oral Health Assessment Index (GOHAI) a 12-item questionnaire that measures functional and psychosocial impact; (Atchison et al., 1990)
2. Social Impacts of Dental Disease(SIDD); (Cushing et al., 1986)
3. Subjective Oral Health Status Indicators (SOHSI); (Locker et al., 1994)
4. Dental Impact Profile (DIP) a 25-item questionnaire that assesses the function, well-being and social relations; (Straus et al., 1993)
5. The Dental Impact on Daily Living (DIDL); (Leao & Sheiham, 1996)
6. The Oral Impacts on Daily Living (OIDL) ; (Adulyanon et al., 1997); and the
7. Oral Health Impact Profile (OHIP) (Slade & Spencer, 1994)

These indices measure both frequency and severity of oral problems on function and psycho-social well-being (Allen, 2003).

1.6.1 Oral Health Impact Profile development

The Oral Health Impact Profile (OHIP) was developed by Slade and Spencer (1994) in Australia. OHIP is a 49-item measure divided into seven domains or dimensions and has five components:

- A conceptual model which describes disease as a process that can lead to impairment, discomfort and functional limitation which can lead to disability and/or handicap (Locker, 1997).
- A set of statements about social impacts was obtained from a group of 64 dental patients in private dental offices, dental primary care clinics, and prosthodontic clinics.
- Weighting of 49 statements was obtained from Thurstone's method of paired comparisons.

- Reliability of OHIP was ascertained through re-phrasing 49 questions, and internal consistency was assessed through Cronbach's reliability coefficient.
- Validity of OHIP was assessed by comparing pattern of responses at the 20-month follow-up of the cohort.

The authors declared it to be the most sophisticated measure of the social and psychological impact of oral conditions developed to date (Slade & Spencer, 1994). The advantage of the index is that the statements were derived initially from a representative patient group and were not conceived by dental researchers.

1.6.2 Studies that have used OHIP

The initial study population used in the development of this instrument consisted of a group of adults from Adelaide, Australia. The instrument was also tested in Ontario, Canada. It has proved to be reliable and valid and has shown that oral conditions have a vast impact on the daily lives of the majority of people (Slade & Spencer, 1994).

OHIP was used in a study by Llewellyn and Warnakulasuriya (2003) where they compared two groups to test whether patients attending an oral medicine clinic had a worse oral-health-related quality of life than the general population. It was found that the patients who attended the oral medicine clinic had significantly lower oral-health-related quality of life scores than the general population on all domains assessed.

Coates et al. (1996) used the OHIP to assess the impact that oral lesions associated with HIV had on the quality of life of 54 HIV positive patients in Adelaide, South Australia. They found that while the typical indicators used in planning and evaluation of oral health (DMFT and CPITN) showed no particular disadvantage for HIV dental patients. There was clear evidence obtained from the OHIP that HIV dental patients who presented with oral lesions associated with HIV experienced a profound impact on their quality of life, the impact of which was not measured by the DMFT and CPITN indices.

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Yengopal (2004) and Bajomo (2004) used the index in HIV-positive patients in Cape Town and Johannesburg resepectively. Yengopal (2004) reported from a case-control study, that patients who present with oral lesions associated with HIV infection have a significantly lower oral-health-related quality of life than HIV positive patients without oral lesions. Bajomo's study (2004) demonstrated that there was a significant difference in oral-health-related quality of life between HIV-positive and HIV-negative patients with the latter experiencing a lower oral-health-related quality of life because of the oral lesions.

1.6.3 Responsiveness of OHIP to change

In order to capture the aspects of oral health treatment that provide greatest benefit, it is important to consider treatments that improve quality of life. Assessment of change, both at individual level and societal level is central to health care planning. For this reason, measures with good evaluative properties are essential (Allen et al., 2001).

OHIP can be used to measure change in quality of life, as illustrated by Slade and Spencer (1994). The authors used the tool to measure quality of life at baseline and at a two-year follow-up to observe change. The study reported that both improvement and deterioration of oral-health-related quality of life can occur at the same time.

1.6.4 OHIP in a cross-cultural setting

The validity and applicability of OHIP to broader cultural settings that differed from the initial population, for which the tool was originally developed, i.e. older adults in South Australia, showed a reasonable consistency. Allison et al. (1999) obtained OHIP item weights from an English-speaking Ontario population and a French-speaking Quebec population and compared these weights with the originals obtained in South Australia. Their results suggested a reasonable degree of cross-cultural consistency and, hence, of validity for the OHIP.

Hunt, Slade and Strauss (1995) used OHIP to investigate variations in the impact of oral disorders of older black adults and older white adults living in North Carolina,

USA. Older dentate blacks reported a greater impact from oral problems than did older dentate whites. The differences in reported impact are linked to differences in oral status and history of dental visits rather than race per se, again suggesting the cross-cultural validity of OHIP when it is used with different race groups (Hunt et al., 1995).

Both Yengopal (2004) and Bajomo (2004) used the OHIP index in HIV-positive and HIV-negative black patients in South Africa in Cape Town and Johannesburg respectively. Yengopal (2004) demonstrated the use of OHIP in a group of culturally homogenous black South Africans to have high internal reliability, consistency and validity.

Yengopal (2004) reported that patients who present with oral lesions associated with HIV infection have a significantly lower oral-health-related quality of life than HIV positive patients without oral lesions. Bajomo reported that HIV-positive patients had a reduced quality of life compared to non-HIV patients, which demonstrates the response to change in races different from those of the original study.

In summary, there is evidence that mouth pain and /or discomfort affects quality of life in HIV-positive patients. Palliation is an accepted principle to improve the quality of life of infected patients. Oral palliation can therefore improve oral-health-related quality of life. The Oral Health Impact Profile (OHIP) index- using subjective patient input has been proven to be able to measure the effect of oral lesions and oral symptoms on oral-health-related quality of life.

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Chapter 2: Methodology

2.1 Aim

The aim of the study was to assess the effectiveness of Andolex-C® mouth rinse on oral palliation in HIV-infected patients. Oral palliation was assessed by determining the symptomatic relief of mouth pain and/or discomfort in the cohort of patients. The effectiveness was assessed the using the Oral Health Impact Profile (an index measuring oral-health-related quality of life).

2.2 Hypothesis

There will be no difference in the Oral Health Impact Profile scores between the group that received standard routine care (toothbrushes, toothpastes and oral hygiene instruction) and the group that received Andolex-C® mouth rinse in addition to routine care in terms of quality of life measures.

2.3 Objectives

1. To assess the effectiveness of Andolex-C® mouth rinse for oral palliation in HIV-infected patients using OHIP.
2. To determine the prevalence of oral lesions associated with HIV among a cohort of patients.

2.4 Materials and methods

2.4.1 Study population

The study population comprised adult HIV-infected patients with self-reported mouth pain and/or discomfort, attending the Wellness Clinic of the Perinatal HIV Research Unit (PHRU) situated in the Chris Hani Baragwanath Hospital, Soweto, South Africa. The PHRU is a research unit of the University of the Witwatersrand (Wits); the Chris Hani Baragwanath Hospital is part of the academic complex of teaching hospitals at Wits University.

The patients who utilised the Wellness clinic at the unit were routinely recalled for monthly check-ups at the clinic. They were treated for all opportunistic infections

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with the appropriate drugs- i.e., if a patient had oral candidiasis, the patient was provided with anti-fungals.

It is important to note that Andolex C® mouth rinse was not given as a substitute for any of the standard drugs that were used to treat opportunistic infections that may have been present at the time of oral examination.

2.4.2 Sample

The study was carried out in collaboration with the PHRU in order to facilitate the recruiting of HIV-infected patients from the PHRU database. A sample of 299 HIV-infected patients were recruited from the Wellness Clinic of the PHRU. They attended the clinic for treatment of all opportunistic infections, as well as for education on healthy living and prophylaxis of major HIV related infections. At the time of the study the "wellness package" did not include routine oral health care. Patients were mostly from a low socio-economic background and all of patients were from the Black population group.

2.4.2.1 Sample power

The power is the probability of rejecting a false hypothesis when it should be rejected. In the current study, the sample was fairly large, and the results indicated a strong significant rejection of the null hypothesis. The power for Functional Limitation subscale for Group 2 (with Andolex-C ® mouth rinse) was >0.99.

2.4.3 Inclusion/exclusion criteria

Table 2.1: Inclusion and exclusion criteria for patient selection

Inclusion	**Exclusion**
1. Patients with documented HIV-positive status as determined using ELISA method. 2. Patients willing to be seen again at a 4 week follow up appointment. 3. Patients over 18 years. 4. Patients with self reported mouth pain and /or discomfort. 5. Patients providing informed consent to participate in the study	1. Patients with dentures. 2. Patients on antiretroviral drugs. 3. Patients who were too sick to answer the questionnaire. 4. Patients who could not read or communicate in English

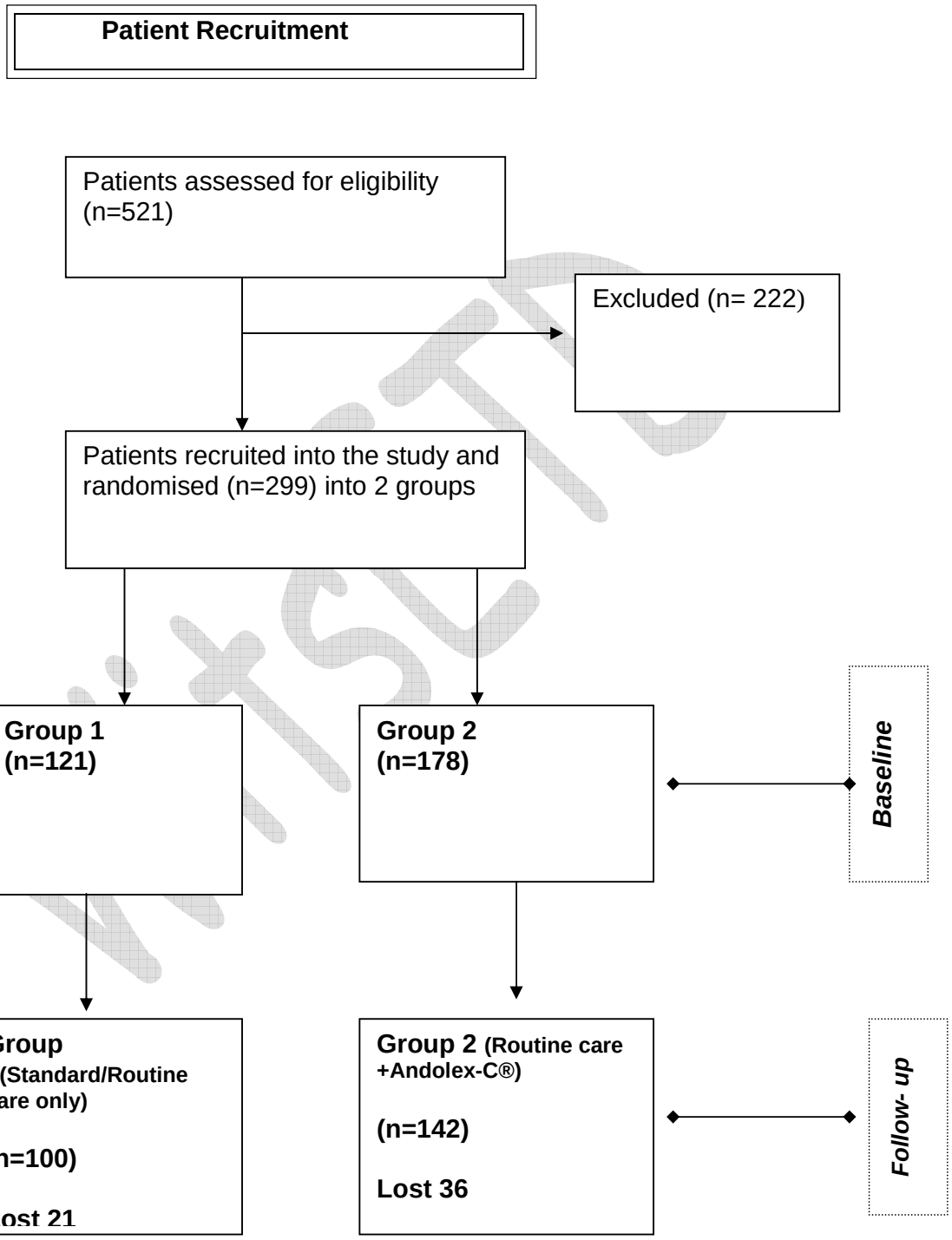
2.4.4 Study design

The study was intervention in design and consisted of Groups 1and 2 (See Table 2.2). All potential patients who met the inclusion/exclusion criteria described in Table 2.1 were included into the study. Initially patients were randomly assigned into seven intervention groups as described in 2.4.7 and each group had an average of 43 patients. Subsequently, a decision was made to collapse the seven groups into two intervention groups according to the intervention package explained in Table 2.2. At baseline visit, an assessment using an oral examination and the administering of the OHIP questionnaire was performed. Patients were then given the intervention and re-assessed using the same tools after four to six week period (Figure 2.1). Some of the patients could not attend the 4 week follow-up visit because of transport and other social problems and were given a two week leeway for the follow-up visit

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2.4.5 Patient recruitment

Figure 2.1: Diagram illustrating patient selection



2.4.6 Data collection

Data was collected through a clinical oral examination and the administering of a questionnaire at baseline and follow-up after approximately 4 weeks.

2.4.7 Randomisation and allocation concealment

Randomisation was done through computer-generated numbers for a sample of 299. Randomised numbers were placed in opaque envelopes. Envelopes were sealed and numbered 1 to 299. As patients were accepted into the study following an examination and complaint of mouth pain and/ or discomfort, they were each allocated one envelope. The envelope contained the group number to which the patients were assigned. The investigator and the patient were not blinded to the particular intervention the patient received. However, each patient was seen individually so that she/he would not know: -

1. What other interventions were being investigated.
2. Who the other patients in the study were.
3. Who the other patients in their group were.
4. What type of intervention the other patients received.

After assignment into groups, individual patients received the following treatment package:

Table 2.2: Intervention package

Group	Intervention
1(Standard routine care group)	Toothbrush, toothpaste (one month supply) and oral hygiene instruction
2(Andolex-C®)group)	Toothbrush, toothpaste (one month supply), oral hygiene instruction and Andolex- C® mouth rinse

2.4.8 Calibration

The principal investigator was calibrated on the presumptive clinical diagnosis of common oral lesions seen in HIV-infected patients as classified by the European

Community (EC)-Clearinghouse-1993. Slides of common oral lesions were shown and investigator was required to diagnose the lesions. Thereafter, each slide was discussed in a session and the calibrator provided the correct diagnosis. After the discussion, the same slides were re-shown in a different sequence and investigator was required to diagnose the lesions again. Examiner displayed a high level of reliability with a kappa score of 0.98.

Calibration for the application of the OHIP instrument was done according to the process detailed in 2.4.10.

2.4.9 Pilot study

The questionnaire was tested on a cohort of patients (n= 25) in the PHRU who were not included in the study. The pilot study was carried out to check for the appropriateness of the questionnaire and the length of time it would take to administer and provide the necessary explanations.

2.4.10 Treatment allocation, oral examination and application of OHIP instrument

The format of allocating the intervention to patients was standardised for all patients. This format is set out in numbered form below:

1. Introduction by the investigator.
2. The investigator explained the aims and objectives of the visit to the patients and gave them a consent form (Appendix IV) to read. The content of the consent form was also explained verbally to the patient and any query that arose from the patient about the study was addressed.
3. Once patients understood all the details of the study, they were asked to sign the informed consent form.
4. An oral clinical examination was performed using a dental mirror and a dental light and with the patient seated on a supine chair and the mouth opened. All oral lesions were diagnosed according to the presumptive criteria of EC Clearinghouse and were recorded as per Appendix II.

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5. The OHIP questionnaire (Appendix I) was administered in English in an interview format to establish baseline data. Questions 17, 18 and 30 in the questionnaire were not asked as they pertained to dentures only. For all questions, the term 'teeth' and 'dentures' were omitted and the investigator referred to the 'mouth' only. E.g. "have you found it uncomfortable to eat any foods because of problems with your mouth?"

   Patients were informed that they would be asked a series of questions for which there was no right or wrong answer. They were told that each of their responses could be any of the following: 4=very often; 3= fairly often; 2= occasionally; 1= hardly ever; 0= never. The participants were encouraged to give an answer that immediately came to mind rather than spend time thinking about a response that they felt would be appropriate.

   Patients were also encouraged to ask the interviewer to repeat questions or explain any aspect of the question that they could not understand before they gave their response.
6. After the OHIP questionnaire was completed, the patients were then asked to open the opaque envelope which contained their group allocation. The intervention was then administered according to the group that to which the patient was assigned (Table 2.2).

Patients were recalled after four to six weeks. Step 4 and 5 were repeated as set out above. An oral examination was performed at the recall visit and any lesions present were recorded as per Appendix II and then OHIP questionnaire was administered again to assess the impact of the intervention on the patient's oral-health-related-quality of life. During this follow-up visit, the investigator did not know(blinded) to which group the patient was originally assigned.

2.5 Data analysis

2.5.1 Quality of life outcome measure

The Oral Health Impact Profile (OHIP) questionnaire (49 items) was used to measure patient-based oral-health-related quality of life for seven subscales, namely:

- Functional limitation (FL);
- Physical pain (P1);
- Psychological discomfort (P2);
- Physical disability (D1);
- Psychological disability (D2);
- Social disability (D3); and
- Handicap (H).

The question format during recall visit was: "How often have you had… because of problems with your mouth in the past 4 weeks"? The response options were never=0, hardly ever=1, occasionally=2, fairly often=3, and very often=4. Each statement had a weight derived using Thurstone's method of paired comparisons. The OHIP questionnaire was used to gather baseline data on oral-health-related patient-based quality of life and was administered again at a follow-up appointment to assess change that took place approximately four weeks after the initial visit.

The coded responses (e.g., 0,1, 2, 3, or 4) were multiplied by the corresponding weight for each question(Appendix I) and then added to the product within each of the 7 subscale to give 7 sub-scores, ranging from 0 (no impact) to 40 (maximum impact). This method considered all range of responses and produced scores reflecting the severity and frequency impacts. Each sub-scale was standardised as follows: the statistician subtracted the sample mean sub-scale value (e.g**. r**) from each individuals sub-scale score (e.g. **t**) and divided the result by the sample deviation **(r sd)** for that sub-scale, creating 7 **'z' score**. Therefore, **(r-t)** divided by **r sd = 'z' score**. Eventually all these standardised score for each respondent were added. All data was captured and analysed in Microsoft Excel 2000.

2.5.2 Clinical outcomes

A clinical examination was performed to determine oral lesions present at baseline. Mouth pain and/or discomfort were recorded as reported by the patients and they were not ranked according to severity. The clinical diagnosis of oral lesions was based on

the presumptive criteria of EC Clearinghouse (1993). The follow-up examination assessed the same variables and a “before” and “after” comparison was carried out.

2.6 Ethical considerations

Patients who had oral lesions in both groups were part of the wellness programme and were being managed by clinicians in the PHRU as explained in 2.4.1. It must be stressed that during this month of the intervention, patients in the trial received exactly the same amount of care from clinicians within the wellness programme as they had been receiving since inception into the programme.

Candidates were recruited and invited to the study out of their own will after a thorough explanation was given and informed consent was obtained (Appendix IV). The identity of the participants was protected through confidentiality. The proposal was approved by the Ethics Committee for Research on Human Subjects, University of the Witwatersrand. (Appendix V).

2.7 Limitations of the study

- When patients were included into the study, mouth pain and/or discomfort were one of the inclusion criteria. A shortcoming of the study was that mouth pain severity was not graded. All patients that reported mouth pain and discomfort were included whether the pain was mild or severe.
- Patients were provided with the intervention and instructed to use it at home. The compliance of the patients was not measured.
- The questionnaire was administered in English only and therefore excluded those that could not comprehend English. The OHIP questionnaire is standardised and could not be translated into other languages without it being first tested for validity and reliability. In addition, it could not be translated in this current study because of logistical problems and time constraints.
- The other limitation from the study was the use of self-reported mouth pain and/or discomfort symptoms only as opposed to objective measures of pain.

2.7.1 Limitations of OHIP index

It is important to acknowledge that OHIP has some disadvantages. The 49 questions make the questionnaire lengthy to administer. The questionnaire has not been translated into any of the South African (SA) languages, which makes it difficult to capture the different nuances in different languages in a SA.

OHIP can assess the impact of disease on groups and on individuals. However, there is no evidence for attaching clinical significance to individual scores.

OHIP has never been used as a tool in a study for palliation intervention and, therefore, there are no comparable studies of this nature.

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Chapter 3: Results

Five-hundred-and-twenty-one (521) male and female patients were examined at the PHRU and two-hundred-and-ninety-nine (299) met the inclusion criteria for admission into the study. Of that sample, two-hundred-and-forty-two (242) patients were examined again as recall patients four to six weeks post treatment. The retention rate was 81 %. Two files were not included in the final analysis because of insufficient data which left the final number of patients at a recall visit to 240.

Reasons for drop out are set out below:

- Some patients were admitted into hospital (n=7).
- Some were too sick to walk to the PHRU clinic (n=8).
- Some of the patients could not be traced through the contact details they provided (n=14).
- Some had left Johannesburg to live in another area (n=5).
- Some went back to their homes (n=15). (Some patients come to JHB especially to the PHRU clinic but unfortunately it is not sustainable for them to come often because of the distance to be travelled. Some come from as far as KwaZulu-Natal (500km) and Eastern Cape (900km) so when they get better or worse they stop coming to the PHRU).
- Although a few patients promised to come back after they were phoned, they did not (n=5).
- Three patients passed away during the duration of the trial (n=3). This was not related to the oral intervention being tested.

3.1 Gender and distribution

The majority of the patients in the study groups were female. Both groups were similar in terms of gender ratios at baseline and follow-up (Table 3.1 and 3.3).

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Table 3.1: Baseline and follow-up by gender and group distribution of the patients selected for the trial

Visit	Group	Number (n)	Male (%)	Female (%)
Baseline	1	121	19 **(16)**	**102** (84)
	2	178	29 **(17)**	**149** (83)
Total at baseline	1 & 2	299	48 **(16)**	**251** (84)
Follow-up(ff-up)	1	100	17 **(18)**	**83** (92)
	2	140	23 **(17)**	**117** (83)
Total at ff-up	1 & 2	240	40 **(17)**	**200** (83)
Loss of ff-up (%)	1	21 **(17.5)**		
	2	36 **(20.2)**		
	1 & 2	**57** (19.1)		

3.2 Age distribution

The mean age of male and female patients in both groups was 34.7 years and 32.8 years respectively which was not statistically significant at a 5% level ($p>0.05$). Group 2 had more patients both at baseline and at follow-up and it ended up with a higher drop out rate. The overall drop out rate for both groups was 19.7%.

Table 3.2: Number and percentage of subjects by age group

Age group	Frequency	Percent
20-24	21	7.02
25-29	85	28.43
30-34	87	29.10
35-39	51	17.06
40-45	29	9.70
> 45	**26**	8.70

Approximately 60% of the patients were within the age group 25 to 34 years and 17% were within the age group 35 to 39 years. The three age groups 20 to 24 years, 40 to 45 years and above 45 years each constituted less than 10% of the sample (Table 3.2).

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3.3 Distribution by treatment groups

Table 3.3: Baseline demographic and clinical parameters of the patients selected for the trial

	Group 1	**Group 2**
	n = 121	**n = 178**
Gender M/F ratio **(%)**	19/102 **(16/84)**	**29/149** (17/83)
Mean age(years)	32.9(SD -+6.9)	**33.3 (SD -+7.2)**
Prevalence of oral lesions	40%	**60%**
Mouth pain and discomfort	**100%**	**100%**

Table 3.3 illustrates demographic and clinical parameters as patients were randomised into the study at baseline. There were no statistically significant differences between the mean age for both groups, male to female ratio and the prevalence of mouth pain and discomfort ($p>0.05$).Group 2, with a higher sample, had a higher prevalence of oral lesions (Table 3.3 and 3.4.1).

3.4 Intra-oral Lesions

The prevalence of combined candidal lesions was 71.6% of which the highest frequency in this study sample at baseline was Pseudomembranous candidiasis at 43.2%. Erythematous candidiasis and angular cheilitis were the next commonly seen candidal lesions, each with an equal prevalence of 14.2 %.

Table 3.4: Number and percentage of oral lesions at baseline in descending order

Condition	**Baseline (n)**	%
Pseudomembranous Candidiasis	272	43.2
Atypical Ulceration	106	16.9
Erythematous Candidiasis	89	14.2
Angular Cheilitis	89	14.2
Oral Hairy Leukoplakia	25	3.9
Herpetic Ulceration	20	3.2
Apthous Ulceration	12	1.9
Melanotic Hyperpigmentation	12	1.9
Leukoplakia	4	0.63
Total	629	100.03

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3.4.1 Intraoral lesions according to groups

Table 3.4.1 illustrate the number of conditions diagnosed at baseline and at a follow-up visit in patients in both Groups 1 and 2. Most of the patients had more than one oral lesion. The number of lesions decreased in both groups however, Group 2 demonstrated a greatest reduction because only 27% of total lesions were present at follow-up compared to Group 1 where 60% of the lesions were present at follow-up visit (p=0.03). Thus, patients in Group 2 demonstrated 73% reduction as opposed to Group 1 patients who showed 40% reduction in prevalence of intraoral lesions (Table 3.4.1).

Table 3.4.1: Number of oral lesions in descending order per visit in Groups 1 and 2

Condition	**Group 1**		Group 2	
	Baseline n=100	**Follow-up n=100**	**Baseline n=140**	Follow-up n=140
Pseudomembranous Candidiasis	97	42	122	**32**
Angular cheilitis	23	21	49	**11**
Atypical Ulceration	39	22	57	**14**
Erythematous Candidiasis	29	27	44	**14**
Oral hairy leukoplakia	3	2	9	**3**
Herpetic ulceration	4	3	9	**2**
Leukoplakia	1	0	3	**0**
Melanotic Hyperpigmentation	2	2	6	**5**
Apthous Ulceration	4	2	4	**1**
Total	202	121 (60%)	303	82 (27%)

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3.4.1.1 Mouth pain and/or discomfort

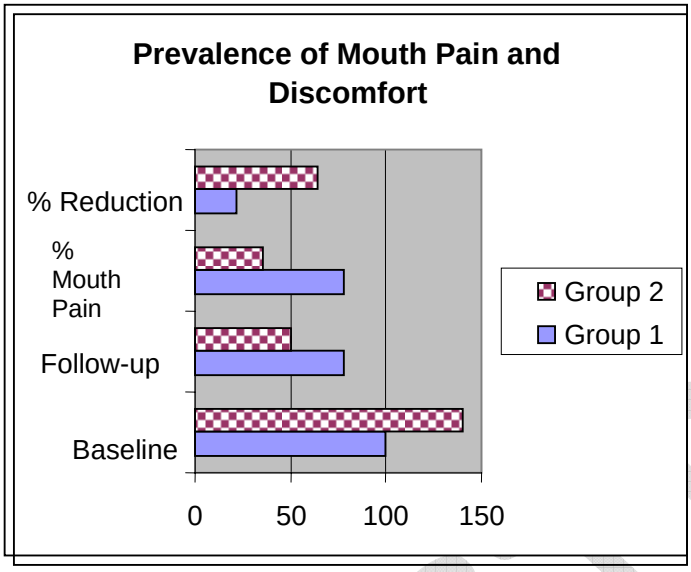


Figure 3.1 The prevalence of mouth pain and/or discomfort in both groups at baseline and follow-up visits.

At baseline all the patients reported mouth pain and/or discomfort (100 in Group 1 and 140 in Group 2). At a follow-up visit, 78 patients in Group 1 still reported feeling mouth pain and discomfort as compared to those in Group 2 where only 50 patients reported feeling mouth pain and discomfort. Therefore, Group 2 reported 64% reduction in mouth pain and discomfort (only 36% had mouth pain and discomfort at a follow-up visit) compared to Group 1 patients who reported 22% reduction in mouth pain and discomfort where 78% of patients reported mouth pain and discomfort at a follow-up visit (Fig 3.1).

3.5 Results of OHIP questionnaire by treatment group

The analysis of the OHIP data included investigation of each subscale and it is presented independently. The OHIP scores for each subscale for each individual in both Groups (1 and 2) at baseline were compared with the OHIP scores for each subscale in the same individual at follow-up visit. Repeated measures of analysis of variance (ANOVA) with Bonferroni post-hoc tests were done to compare both groups over the period of four weeks (from baseline to follow-up).

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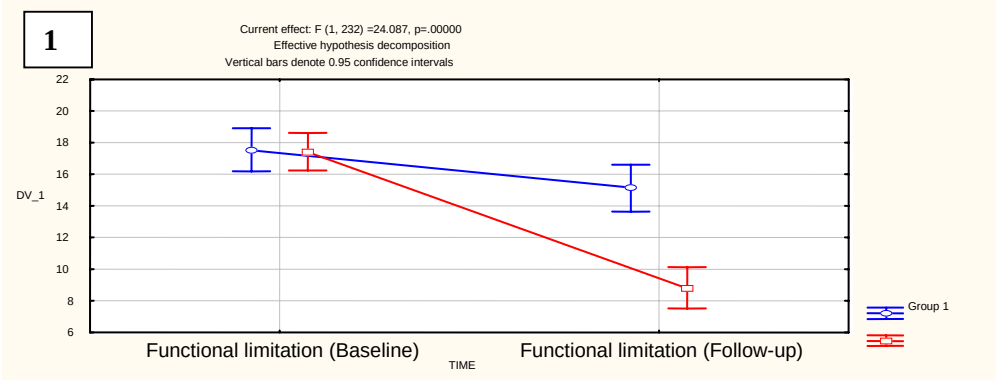
3.5.1 OHIP Subscales Results

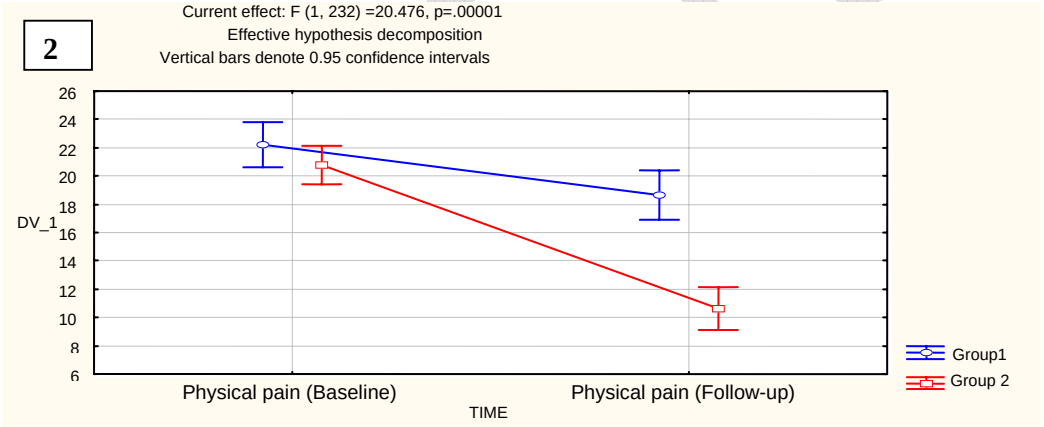
Table 3.5 and Figure 3.1 illustrate the differences between the OHIP scores at baseline and follow-up visits in both groups for all subscales. There were statistical significant differences between OHIP scores of patients in Groups 2 on all the subscales from baseline to follow-up ($p<0.00$). This means Andolex-C® mouth rinse in combination with tooth brushing and oral hygiene instruction had a positive impact on oral-health-related quality of life. No significant difference was found for patients in Group 1 from baseline to follow-up ($p =1.00$) on all subscales.

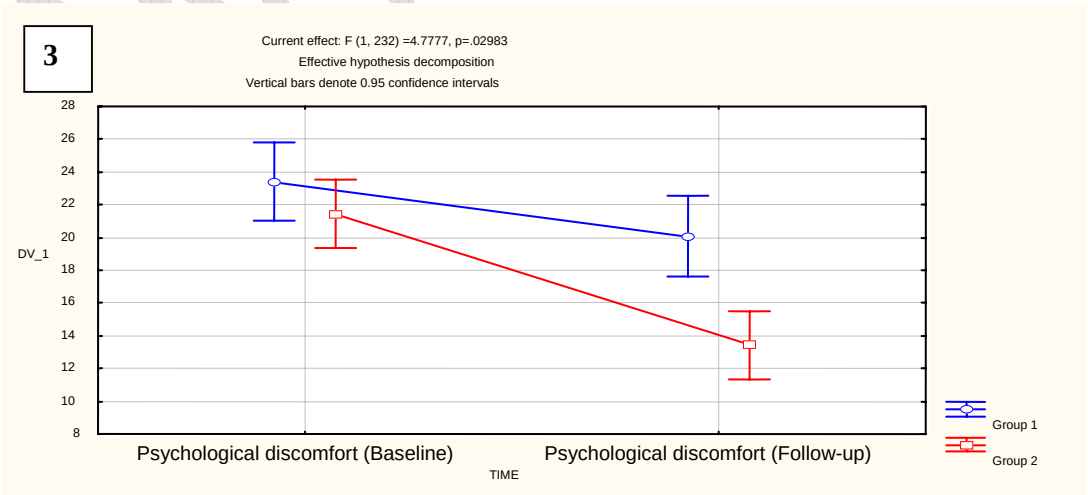
Table 3.5: Comparison of the OHIP Scores for Groups 1 and 2 at Baseline and Follow-up visits for all OHIP Subscales

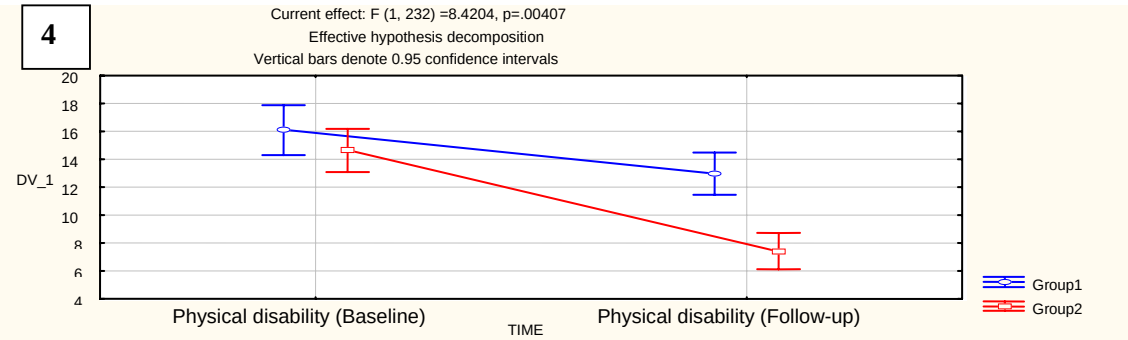
Group 1(Routine Standard Care)				**2 (Andolex-C® Mouth Rinse)**			
Subscale	**OHIP Score Baseline**	**OHIP Score Follow-up**	**p-value**	**Subscale**	**OHIP score Baseline**	**OHIP Score Follow-up**	**p-value**
Functional Limitation	17.54	15.12	1.00	Functional Limitation	17.42	8.81	**<0.00**
Physical Pain	22.22	18.62	1.00	Physical Pain	20.75	10.61	**<0.00**
Psychological Discomfort	23.41	20.07	1.00	Psychological Discomfort	21.44	13.42	**<0.00**
Physical Disability	16.12	12.95	1.00	Physical Disability	14.65	7.42	**<0.00**
Psychological Disability	19.03	15.36	1.00	Psychological Disability	18.31	10.55	**<0.00**
Social Disability	14.50	15.36	1.00	Social Disability	12.98	8.85	**<0.00**
Handicap	16.43	15..36	1.00	Handicap	14.53	8.54	**<0.00**

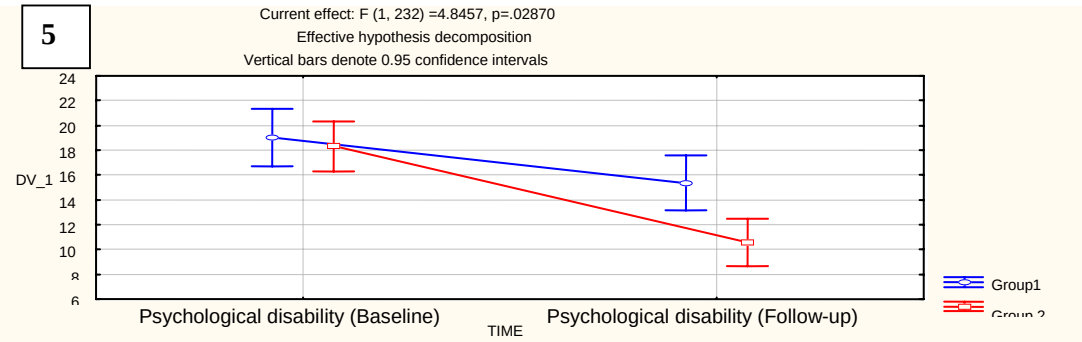
Figure 3.2 Diagrams 1-7 showing OHIP scores for Groups 1 & 2at baseline and follow-up visits for all OHIP subscales

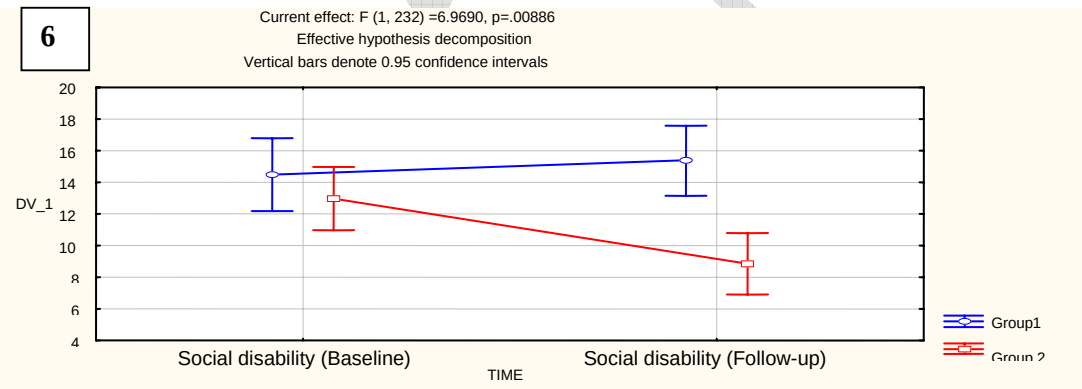


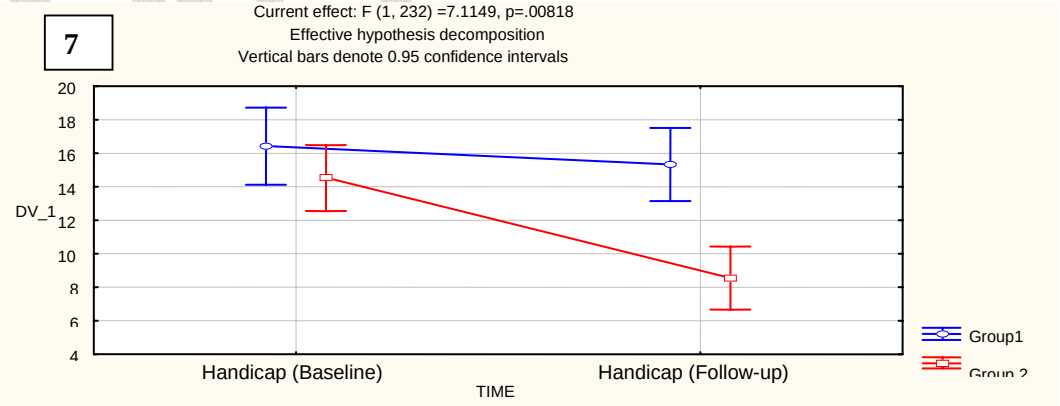












The intervention which included Andolex-C® mouth rinse, toothbrushing and oral hygiene instructions (Group 2) had a positive impact on all subscales and improved quality of life of patients when the Oral Health Impact Profile index was used.

Chapter 4: Discussion

The study sought to assess the effectiveness of Andolex-C® mouth rinse on oral palliation in HIV-infected patients. The effectiveness of Andolex-C® mouth rinse was assessed by determining the physical, functional, psychological and social impact of mouth pain and discomfort on the quality of life in HIV-infected patients using the Oral Health Impact Profile index.

A review of the literature has indicated that intervention studies which assessed an intervention for oral palliation and its effect on oral-health-related quality of life in HIV-infected patients has not been done before. Most of the published studies in oral health and quality of life investigated the different aspects of oral diseases. Llewellyn and Warnakulasuriya (2003) did a comparative study between the quality of life of the patients attending an oral medicine clinic and that of the general population, without any intervention. Other studies were descriptive and investigated oral-health-related quality of life and oral lesions in HIV also without intervention (Coates, 1996; Yengopal, 2004; and Bajomo, 2004).

Nittayanata et al., (2004) carried out a randomised controlled trial on HIV patients using chlorhexidine mouth rinse. The Nittayanata (2004) study differed from this one in that the intervention was different (Chlorhexidine mouth rinse), the sample size was smaller (n=35), and the outcome measure was not quality of life.

In a study by Hilton et al., (2004), a behavioural intervention programme was evaluated through a randomised controlled trial. The aim of the trial was to evaluate the efficacy of the Candidiasis self-help regimen consisting of repeated instruction and training on oral hygiene procedures, diet modifications and training in recognition of oral candidiasis. The participants were adults with oral candidiasis responsive to antifungal agents who presented to the San Francisco Stomatology Clinic (USA) between 1997 and 2000. At 2-3 weeks of follow-up visits, a dentist "examiner", masked to group assignment, quizzed participants as to the presence of candidiasis, and assessed candidiasis status. A second, unmasked dentist "instructor" then

delivered the program to intervention participants. Participants recorded dietary and oral hygiene practices in 24-h recall diaries: intervention participants at each visit and controls at initial and final visits. The candidiasis recurrence rates at 6 months were 78% among intervention compared to 88% among control participants. Performing oral hygiene after meals/snacks showed the largest relative improvement: intervention-control difference in proportion of meals/snacks affected was 24% (95% CI -1 to 48%). Self-diagnoses of candidiasis were inaccurate, possibly because of mild episodes. The authors concluded that there was weak evidence that oral hygiene instruction from health care professionals reduced candidiasis recurrence among HIV positive patients. In this study, patients who received professional oral hygiene instructions and toothbrushing only (standard routine care) reported no improvement in prevalence of oral lesions and in quality of life measures assessed using OHIP.

4.1 Gender and age distribution

The majority of patients were female, both at baseline and follow-up visits and there was a constant ratio of female to male patients at both visits (Table 3.1). The predominance of women was mainly due to the fact that for the past decade the Perinatal HIV Research Unit has focused on women and children. The mean age of females and males of 32.8 years and 34.7 years respectively was almost similar to the age range of the majority of HIV-infected patients in South Africa, who are between 15 and 49 years old (UNAIDS/WHO, 2004).

4.2 Intraoral lesions

The majority of intraoral lesions seen were candidal lesions (Table 3.4) which is comparable to other studies which indicate that oral candidiasis was always present as an oral manifestation of HIV/AIDS and which also had the highest prevalence (Arendorf et al., 1998; Anteyi et al., 2003; Kerdpon et al., 2004; Yengopal, 2004; Bajomo, 2004; Chattopadhyay et al., 2005).

Oral hairy leukoplakia (OHL) had a very low prevalence in this cohort but some studies have reported a very high prevalence of OHL in developed countries and Northern Thailand (Axell et al., 1993; Kerdpon et al. 2004).This could be related to non-standardised diagnostic methods being used in the different studies but a more

likely explanation could be the positive relationship between males and sexual orientation and OHL (Holmes & Stephen, 2002). In a study carried out in Northern Thailand, sex between males was a common practice, hence the higher prevalence rates. In this South African study the low prevalence of OHL (2.38 %) could be due to the low numbers of male patients. Also , the predominant mode of transmission of HIV in developing countries including South Africa is heterosexual, thus accounting for the lower rates.

The prevalence of self-reported mouth pain and discomfort from the total cohort of 521 patients who were initially examined was 57%. This prevalence is higher than that reported in a hospice in Soweto, Johannesburg, where mouth pain was the second most common symptom (50.5%) experienced by the AIDS patients (Norval, 2004) and it was also higher than that reported in a large multicenter study of persons living with HIV/AIDs in Canada, where mouth pain was reported by 33% of patients (MacDonald and Doyle, 1999). There is a perception that palliation should only be directed at patients in the terminal stages of HIV infection where the emphasis is on making the patient comfortable so that they can die with dignity. However, many of the ambulatory patients in this study were still functioning in society (i.e. they were not bed-ridden nor hospitalised and were able to travel to the clinic) but were significantly affected by mouth pain and/or discomfort as measured by the OHIP instrument. This implies that interventions for the management of mouth pain and discomfort are essential in the overall care of HIV patients as these symptoms have been shown to significantly affect the oral health related quality of life. Twycross, (1999) reported that palliative care should start concurrently with the treatment for the underlying conditions and should not be left for end-of-life care only. Oral palliation with interventions such as Andolex C® can thus be considered for reducing mouth pain and discomfort in all HIV patients who report these symptoms.

There was a significant reduction in mouth pain and/or discomfort and prevalence of oral lesions experienced by patients who used Andolex C® mouth rinse. This reduction in mouth pain and/or discomfort could be attributed to the active ingredients of the mouth rinse which have been shown to reduce pain and inflammation,

ulceration and control the candidal lesions (Addy et al., 1983; Matthew et al., 1987; Arendorf et al., 1996; Edres et al., Turnbull, 1995; Quane et al., 1998).

4.3 Treatment package and Oral Health Impact Profile (OHIP)

OHIP is a patient-based instrument of quality of life and it has been widely used in different studies in HIV-positive patients to demonstrate its sensitivity in highlighting the impact oral diseases on quality of life (Yengopal 2004; Bajomo, 2004). In the present study, the different seven subscales of OHIP had different impact for both intervention groups.

The group without Andolex-C® mouth rinse (Group 1) showed no improvement in oral-health-related quality of life whereas those who used Andolex-C® mouth rinse (Group 2) reported significant improvement.

Benzydamine hydrochloride in Andolex-C® mouth rinse has been found to reduce oedema and interfere with the inflammatory process, because of its analgesic properties (Quane et al., 1998). It is also known to improve oral mucosal health in the immunocompromised patient (Arendorf et al., 1996) and was preferred by patients with aphthous ulceration because of its ability to reduce pain (Matthews et al., 1987; Edres et al., 1997).The combination of chlorhexidine and benzydamine chloride in Andolex-C® mouth rinse proved to be beneficial to the patients in controlling mouth pain. This is in agreement with what other studies have demonstrated (Matthews et al., 1987; Arendorf et al., 1996; Edres et al., 1997; and Quane et al., 1998).

Although Andolex C® mouth rinse showed a significant improvement in the oral-health-related quality of life for all of the seven subscales in the OHIP instrument, the mouth rinse had the greatest impact on the physical pain subscale (51%) followed by functional limitation (50.6%). The social disability and handicap subscales had the least impact. These findings were expected as subscales that affect individuals personally (physical pain, functional limitation) are of greater importance than subscales that reflect social dynamics. Similar findings were reported by Yengopal (2004).

The symptoms that are caused by oral diseases and disorders form the current measures of disease and are known as the indicators of oral-health-related quality of life (Locker et al., 2002). The authors suggest that when it comes to intervention studies, clinical trials or clinical practice, investigators should include subjective outcome measures (along with clinical outcome measures) such as quality of life indicators as these are important to patients.

Patient-based outcomes provide subjective input on how pain and discomfort are experienced and their association with poor quality of life (Locker et al., 2002).It was evident in the study that removal or reduction of discomfort and mouth pain by Andolex-C® mouth rinse improved the oral-health-related quality of life of patients. Assessing impact by means of input from clinical parameters to assess biological and physiological factors alone is not enough (Wilson & Cleary, 1995). Subjective quantification of how pain and discomfort are felt by patients is essential and could result in advocacy and promotion of treatment(Wilson & Cleary, 1995).

Yengopal and Chikte, (2003) support the view that decisions on choice of treatment must be based on current evidence, clinical judgement, and patient input. This study provides patient-based inputs that suggests that Andolex-C® mouth rinse had a positive impact on oral-health-related quality of life and can therefore be recommended for mouth pain and/or discomfort.

The MacDonald & Doyle study (1999), suggested that when dealing with the prevalence and management of mouth pain, the palliative care team should strive to maintain and improve the patient's oral hygiene and institute symptomatic control rapidly to decrease incidence of loss of function and thus improve the patient's quality of life.

Oral care and treatment protocols in HIV have recommended several effective antifungals (clotrimazole, fluconazole, itraconazole) for outpatient treatment of oropharyngeal candidiasis (Shirlaw et al., 2002). Palliative intervention should be administered in conjunction with curative intervention in order to provide a total

package of care to patients (Twycross, 1999). Andolex-C® mouth rinse has been proven to be effective for a broader range of symptoms common in HIV-infected patients, including mouth pain, ulcerations, and general mucosal health (Matthews et al., 1987; and Edres et al., 1997). This finding, in effect, makes Andolex- C® mouth rinse viable as a oral palliative regimen as it has multiple effects.

With the current and future roll out of antiretrovirals (ARVs), the oral lesions that result in pain will be reduced (Schmidt-Wethausen et al. 2000, Scully and Diz Doip, 2001). However, palliative interventions that reduce pain and discomfort will still be important especially as tens of thousands of patients will suffer mouth pain and discomfort before they are eligible for ARVs, or may not access ARVs or will still suffer mouth pain and discomfort whilst receiving ARVs.

The assessment of an individual's general quality of life and quality of life related to health has taken on greater prominence in recent decades. This is because of the recognition of the need to move beyond simply conceptualising and measuring health as the lack of disease to include the measurement of how health affects quality of life (Gift, Atchison & Dayton, 1997).

Quality of life is "a multi-dimensional concept referring to a person's total well-being including the psychological, social and physical health status" (Schron & Schumaker, 1992, p.61). Disease, injury and treatment influences impairments, functional states, perceptions and social opportunities and assigned to life. The best measure of health status is, therefore, a combined measure of morbidity, mortality, and the impact they have on quality of life. Using a quality-of-life measure to assess the impact of an intervention is, therefore, not only reliable but also introduces the dimension of patient-based input, which supplements and complements clinical outcomes.

4.4 Response to change

OHIP can be used to measure change in quality of life and it is important to consider improvements in quality of life so that the aspects of oral health treatment that provide the greatest benefit can be captured. Andolex-C® mouth rinse provided improvement on all OHIP subscales namely: functional limitation; physical pain; psychological

WiSTD

discomfort; physical disability; psychological disability; social disability; and handicap in this particular study.

The results suggest that quality of life as an indicator of health outcomes is sensitive to the impact of treatment, and that differences are evident by type of treatment. Assessment of change both at an individual level and a societal level is central to health care planning.

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4.5 Conclusion and Recommendation

In conclusion, the group with Andolex-C® mouth rinse (Group 2) showed improvement in oral-health-related-quality of life compared to the one without. The patients in Group 2 demonstrated a greatest reduction in oral lesions (74%) compared to Group 1 (41% reduction) who did not receive Andolex-C® mouth rinse. Andolex-C® mouth rinse significantly reduced the pain and/or discomfort experienced and the number of oral lesions present in the mouth, and hence greatly improved the oral health-related-quality of life.

In the total management care of HIV-infected patients, Andolex-C® mouth rinse in combination with proper oral care and routine hygiene habits is recommended for use by HIV-infected patients who have mouth pain and discomfort. It can be useful in primary health care, home-based care and any setting where oral palliation is required, and could be less costly because of its multiple effects.

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Appendix I

Record No :
Group :

ORAL HEALTH IMPACT PROFILE QUESTIONNAIRE

Dimension	Weight	Question	Response
FL	1.253	1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?	
FL	1.036	2. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	
FL	0.747	3. Have you noticed a tooth which doesn't look right?	
FL	1.059	4. Have you felt that your appearance has been affected because of problems with your teeth, mouth or dentures?	
FL	1.154	5. Have you felt that your breath has been stale because of problems with your teeth, mouth or dentures?	
FL	0.931	6. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	
FL	1.181	7. Have you had food catching in your teeth or dentures?	
FL	1.168	8. Have you felt that your digestion has worsened because of problems with your teeth, mouth or dentures?	
P1	1.213	9. Have you had painful aching in your mouth?	
P1	0.937	10. Have you had a sore jaw?	
P1	1.084	11. Have you had headaches because of problems with teeth, mouth or dentures?	
P1	1.053	12. Have you had sensitive teeth for e.g., due to hot or cold food or drinks?	
P1	1.361	13. Have you had toothache?	
P1	1.088	14. Have you had painful gums?	
P1	0.998	15. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	
P1	1.264	16. Have you had sore spots in your mouth?	

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FL	1.472	17. Have you felt that your dentures have not been fitting properly?	
P1	1.002	18. Have you had uncomfortable dentures?	
P2	2.006	19. Have you been worried by dental problems?	
P2	1.902	20. Have you been self conscious because of your teeth, mouth or dentures?	
P2	2.252	21. Have dental problems made you miserable?	
P2	1.815	22. Have you felt uncomfortable about the appearance of your teeth, mouth or dentures?	
P2	2.025	23. Have you felt tense because of problems with your teeth, mouth or dentures?	
D1	1.109	24. Has your speech been unclear because of problems with your teeth, mouth or dentures?	
D1	1.111	25. Have people misunderstood some of your words because of problems with your teeth, mouth or dentures?	
D1	1.051	26. Have you felt that there has been less flavor in your food because of problems with your teeth, mouth or dentures?	
D1	1.0068	27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth or dentures?	
D1	1.266	28. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	
D1	1.022	29. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	
D1	1.351	30. Have you been unable to eat with your dentures because of problems with them?	
D1	1.070	31. Have you avoided smiling because of problems with your teeth, mouth or dentures?	
D1	0.952	32. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	
D2	1.950	33. Has your sleep been interrupted because of problems with your teeth, mouth or dentures?	
D2	1.393	34. Have you been upset because of problems with your teeth, mouth or dentures?	
D2	1.646	35. Have you found it difficult to relax because or problems with your teeth, mouth or dentures?	
D2	1.936	36. Have you felt depressed because of problems with your teeth, mouth or dentures?	

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D2	1.638	37. Has your concentration been affected because of problems with your teeth, mouth or dentures?	
D2	1.437	38. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	
D3	1.572	39. Have you avoided going out because of problems with your teeth, mouth or dentures?	
D3	2.555	40. Have you been less tolerant of your partner or family because of problems your teeth, mouth or dentures?	
D3	1.832	41. Have you had trouble getting along with other people because of problems with your teeth, mouth or dentures?	
D3	2.236	42. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	
D3	1.805	43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	
H	2.112	44. Have you felt that your general health has worsened because of problems with your teeth, mouth or dentures?	
H	1.420	45. Have you suffered any financial loss because of problems with your teeth, mouth or dentures?	
H	1.545	46. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?	
H	1.567	47. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	
H	1.879	48. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	
H	1.476	49. Have you been unable to work to your full capacity because of problems with your teeth, mouth or dentures?	

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KEY
FL = Functional limitation
P1 = Physical pain
P2 = Psychological discomfort
D1 = Physical disability
D2 = Psychological disability
D3 = Social disability
H= Handicap

Response categories for all questions are:

4 = Very often
3 = Fairly often
2 = Occasionally
1 = Hardly ever
0 = Never/ Don't know

KEY
FL = Functional limitation
P1 = Physical pain
P2 = Psychological discomfort
D1 = Physical disability
D2 = Psychological disability
D3 = Social disability
H= Handicap

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Appendix II

Clinical Examination Record Sheet

CONDITION	**LOCATION**
1 No abnormal condition	11 Upper lip
2 Pseudomembranous Candidiasis	12 Lower lip
3 Erythematous Candidiasis	13 Mucosa of the upper lip
4 Hyperplastic Candidiasis	14 Mucosa of the lower lip
5 Angular Cheilitis	15 Mucosa around the corner on R side
6 Herpetic Ulceration	16 Mucosa around the corner on L side
7 Apthous Ulceration	17 Cheek mucosa on R side of patient
8 Infective (TB, STDs) Ulceration	18 Cheek mucosa on L side of patient
9 Atypical Ulceration	19 Mucosa of upper jaw, bet lip/cheek & gums
10 Erythema Multiforme	20 Mucosa of lower jaw, bet lip/cheek & gums
11 Oral Hairy Leukoplakia	21 Mucosa of gums of upper teeth
12 Kaposi's Sarcoma	22 Mucosa of gums of lower teeth
13 Non-Hodgkin's lymphoma	23 Top surface of tongue
14 HPV - related lesions	24 Sides of tongue
15 Leukoplakia	25 Under surface of tongue
16 Melanotic hyperpigmentation	26 Mucosa bet undersurface of tongue & gums of L teeth
	27 Mucosa of hard palate
	28 Mucosa of soft palate
	29 Mucosa behind last molar of U & L jaws

Other
Mouth Pain/discomfort or inflammation
……
……
……

CONDITION	LOCATION

WitsSpace

Appendix III

HIV Oral Health Status Data Capture Sheet

Date of examination: | | | | | | | | |

1. Name ……

2. Record Number:……

3.Address……

……

……

……

4. Telephone (Home)…… **(Work)** ……

(Cell)……..

5. Date of Birth (YYYY/MM/DAY):

6. Gender: .....

7. Extra-Oral Examination

7.	Normal Extra-Oral Appearance	**Y**	**N**
7.1	Ulceration (head, neck, limbs)	**Y**	**N**
7.2	Ulceration (nose, cheeks, chin)	**Y**	**N**
7.3	Ulceration (commissures)	**Y**	**N**
7.4	Ulceration (vermilion border)	**Y**	**N**
7.5	Generalised lymphadenopathy (head, neck)	**Y**	**N**
7.6	Molluscum contagiosum	**Y**	**N**
7.7	Other (specify)	**Y**	**N**

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Appendix IV

UNIVERSITY OF WITWATERSRAND: **SCHOOL OF ORAL HEALTH SCIENCES**

INFORMED CONSENT FOR ORAL EXAMINATION

Dear .....…….....

My name is Dr Y Malele. I am a dentist from the School of Public Health: Division of Public Oral Health, University of Witwatersrand. We will be working with the management team at this clinic whereby we see all the patients that are HIV positive. HIV positive patients often have lots of problems in their mouths, e.g., they have white patches on their tongue, red patches on their palate, sores in their mouths, dry mouth and rotten teeth. Our mission is to examine your mouth, tell you what the problems are, provide you with some pain- relieving treatment and refer you to the relevant clinic if we cannot manage your problem. We also record our findings in your file, write notes to your doctor to inform him/her of our findings and request him/her to provide you with medication that we do not have with us but is available at the clinic. We also provide advice on any oral health problem that you may have and methods to prevent the reoccurrence of these problems. In essence, we examine the mouth and the medical doctor examines the rest of your body so that you get full management for your condition.

Further to the above, we will ask you a number of questions relating to any oral problems that you may have experienced in the past month. The aim here is to try and establish how these problems have affected the quality of your life. I will ask you a set of standard questions that will require you to give a standard response (never or don't know, hardly ever, occasionally, fairly often, very often).

The entire procedure (examination and interview) will take about 40 minutes. You might feel some discomfort during the examination, but you will feel no pain. If we require photographs, we will only take photographs of your teeth and mouth and no-one will be able to see your face on the photographs or recognise you. All information obtained and all the information you give us about yourself will be strictly confidential. You will not be identified by name we will only record the number on the form.

You are completely free to take part or not to take part in the study. If you decide that you do not want to be part of the study, this will not be held against you.

If you would like to take part in the study, please sign the form below to allow us to proceed with the oral examination. If you would like to withdraw from the study at any point or for any reason, please feel free to do so and no questions will be asked.

If you have any questions or queries or would like more information about the study please contact Dr Y Malele on telephone number (011) 7172631; fax (011) 7172625; e-mail maleley@sph.wits.ac.za or after hours on (011) 4758631.

Thank you for your cooperation

Yours sincerely

Dr Y Malele

I agree to participate in the study.

Name: ....
(in block letters) (Signature)

Date:…….....

Appendix V

[Copy ethical clearance certificate]

WitsETD