The measurement of procedural burn pain and anxiety in paediatric burns: *The new BOPAS method.*

by

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"I often say that when you can measure what you are speaking about in numbers, you know something about it, but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind, it may be the beginning of knowledge, but you have scarcely in your thoughts advanced to the state of science, whatever the matter might be."

(Lord Kelvin, quoted in Thomas 1983)

[1]. Thomas L. Late Night Thoughts on Listening to Mahler's Night Symphony. New York, Viking 1983: 143-145.

I DEDICATE THIS MANUSCRIPT TO MY FATHER,
WHO TAUGHT ME TO DREAM THE IMPOSSIBLE DREAM.

ABSTRACT

The assessment of pain and anxiety in South Africa is complicated by language barriers, cultural differences, socio-economic difficulties and delayed cognitive development. The high number of paediatric burn injuries (annually 2000) treated at the Red Cross War Memorial Children's Hospital, the need to accurately assess pain and drug efficacy and the current lack of specifically designed methods to do so, led to the development of the Burn Observational Pain and Anxiety Scale (BOPAS). This scale is believed to be the first of its kind and was designed to measure both pain and anxiety in burned children.

The aim of this study was:

- To develop an observational pain and anxiety scale that can overcome language barriers by excluding patient involvement in the assessment process.
- To develop a scale that can differentiate between pain and anxiety during wound care procedures.
- To develop a method that facilitates the translation of nominal information into numerical data.
- To develop a scale that can evaluate drug and dose efficacy.

A total of 105 children, (M = 65, F = 40) aged 2–12 (average age 6.8 years), admitted for minor to moderate burn injuries to the Burns Unit of the Red Cross War Memorial Children's Hospital, were included in the sample. Five different consecutive studies varying between explorative and quasi-experimental were conducted to determine different levels of validity and reliability.

Study 1 (Construct validity and reliability): Involved the video graphing of burned children during debridement procedures and the assessment of pain and anxiety by two independent observers. The aim was to determine whether the BOPAS is able to differentiate between pain and anxiety indicators.

Studies 2, 3 and 4 (concurrent and content validity): Were conducted by including live pain and anxiety observations and by comparing the BOPAS with another psychometric measurement scale, the Children's Hospital of Eastern Ontario's Pain Scale (CHEOPS) as well as with physiological measurements (heart rate and respiratory rate). The BOPAS's ability to evaluate drug efficacy was also determined.

Study 5: Further tested the reliability of the BOPAS by evaluating the performance of 44 health professionals in the application of the BOPAS after two different training sessions.

Study results have indicated that the BOPAS has fulfilled the criteria for pain assessment: reliability and validity. Both construct and concurrent validity was established and the scale's sensitivity to changes in the pharmacological approach determined. Inter rater reliability was high in both the video observations (r_{xy} = .98, p<.001) and live observations (r_{xy} = 91, p<.001). A higher incidence of anxiety than pain was determined. The difference between pain and anxiety scores (construct validity) was statistically significant from zero: $t_{(10)}$ = .67, p = .02. The relationship between the BOPAS and the CHEOPS (concurrent validity) was statistically significant: r_{xy} = .87,p<.01.

In summary: The Burn Observational Pain and Anxiety Scale is a reliable procedural burn pain and anxiety measurement tool.

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ABBREVIATIONS:

BOPAS	Burn Observational Pain and Anxiety Scale
CHEOPS	Children's Hospital of Eastern Ontario's Pain Scale
DSM IV	Diagnostic and Statistical Manual of Mental Disease
IASP	International Association for the Study of Pain
OSBD	Observational Scale of Behavioural Distress
PCA	Patient Control Analgesia
PBRS	Procedural Behavioural Rating Scale
PBCL	Procedural Behavioural Check List
PCA	Principal Component Analysis
TBSA	Total Body Surface Area
VAS	Visual Analogue Scale

DEFINITIONS:

Pain: Is the unpleasant and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Anxiety: In the context of this dissertation, anxiety means the fear and agitated behaviour often exhibited by children in pain; it is the emotion of fear or apprehension. It is associated with negative thoughts about the future, behaviours such as avoidance and physical symptoms such as a dry mouth, nausea, dizziness and palpitations.

Validity: Refers to the extent to which the results of a procedure serve the use for which they were intended.

Content Validity: Focused on the adequacy of sampling and addresses the question of how representative the items on the scale are of the domain of the construct (pain and anxiety). The objective is to determine how much each item on the scale contributes to the overall score. Content validity in the assessment process is established by ensuring that the full range of information relevant to the concept being measured is represented on the instrument.

Construct validity: Is considered to be the most complex and difficult validity to establish. To demonstrate construct validity, measurements of pain intensity should correspond with the theoretical understanding of pain intensity in specific situations such as procedural burn pain.

Concurrent Validity: Forms part of criterion validity and is related to the timing of the correlation of measures. Concurrent validity uses the new and standard measures at the same point in time.

Reliability: Is assessed by showing that when the same phenomenon is measured repeatedly, the same score is obtained, and by demonstrating that when two different raters measure the same phenomenon with an instrument, they obtain the same scores.

LIST OF DRUGS

Common pharmaceutical agents according to generic and brand names:

Generic Name:	**Brand Name:**
Acetaminophen / Paracetamol	Panado® / Tylenol®
Alprozalam	Xanor®
Amitriptyline HCL	Endep®, Elavil®, Tryptanol®,
Aspirin	Disprin®,
Buprenorphine	Temgesic®,
Butorphanol Tartrate	Stadol NS, IMI, IV
Codeine Phosphate	Codeine Phosphate®,
Diazepam	Valium®,
Dihydorcodeine	DF-118®
Dextropropoxyphene	Doloxene, Doxyfene
Fentanyl (oral)	Durogesic®,
Fentanyl Citrate	Sublimaze
Hydromorphone	Dilaudid
Ibuprofen	Ibuprofen®, Brufen®
Ketamine HCL	Ketalar®, Brevinase
Lorazepam	Ativan®,
Methadone	Physeptone®,
Mefenamic Acid	Ponstan®
Midazolam	Dormicum®
Meperidene HCL	Pethidine®,
Morphine Sulfate	Morphine Sulfate®, MS Continus®
Nalbupine HCL	Nubain®
Nitrous Oxide	Nitrous Oxide
Oxycodone	Percodan , Percocet
Pentazocine HCL	Sosenol®
Panado Codeine	Dolorol Forte®
Paracetamol + Codeine + Promethazine	Stopayne Syrup
Paracetamol + Codeine + Ibuprofen	Myprodol®
Tilidene HCL	Valoron®

CHAPTER 1

Introduction

1.1 Introduction:

Paediatric burn injury is a world wide phenomenon, with incidences reported in both developed (i.e. Canada[1], France[2], United States[3]) and developing countries (i.e. India[4], Nigeria[5], South Africa[6]). Approximately 1 million paediatric burn injuries occur each year in the United States alone. The prevalence of burn injuries is not well documented in South Africa.[6] However, an estimated 2000 children aged 13 years and younger are treated each year on an in- and out- patient basis at the Red Cross War Memorial Children's Hospital in Cape Town.[6,7,8] This burn unit serves as the only paediatric burn facility for the Metropole and regional area.

The management of these injuries presents many challenges to the victims, their families and those involved in treatment.[9,10] In addition, burn injuries are also notorious for the intense pain associated with the injury and subsequent treatment.[11,12] Three types of burn pain have been identified; background pain (associated with the injury), breakthrough pain (experienced between procedures or when at rest) and procedural pain (experienced during wound care procedures, surgery or physiotherapy),.[13] Burn survivors have singled out procedural pain as being the most intense and painful experience, while nurses experienced in burn care described burn pain management as being equally as important as the treatment of the burn injury.[14]

The emotional and physiological consequences of untreated burn pain are well known to those responsible for burn care.[15] Prolonged untreated pain can lead to long-term psychological and psychiatric disorders such as post-traumatic stress[16] as well as lengthy hospitalisation[17] or even death.[18] However, despite recognition of the importance attached to paediatric burn pain, myths and misconceptions still exist contributing to the inadequate management of paediatric burn pain.[19] Information published in 1982 described the inadequate management of both adult and paediatric burn pain in 51 American burn units and hence the need for re-evaluation of existing analgesic practices.[20]

Since then, vast improvements have been instituted in the arena of paediatric procedural burn pain management.[21] Burn units have now adopted a variety of therapeutic strategies to address pain during the three stages of burn treatment, i.e. the emergency phase, acute phase and rehabilitation phase.[21,22] Pharmacological methods of pain management, which include the combined use of opioids and non-opioid analgesics, have become the mainstay of therapy.[23] In addition, supplementary therapies such as relaxation therapy, hypnosis and distraction were included to enhance the efficacy of the prescribed pharmacological agents.[24]

Furthermore, the co-existing relationship between burn pain and anxiety, negatively influencing each other, were also recognised.[25] In an attempt to provide for effective analgesia and anxiolysis, many burn units have now included benzodiazepines and anti-depressants in their pharmacological treatment plan.[26]

Although the individual characteristics of the recommended analgesic and anxiolytic agents are well known, the efficacy of both the pharmacological and non-pharmacological approach to the treatment of procedural burn pain and anxiety has not yet been fully evaluated. This is partly due to the impact burn injuries have on the pharmacokinetics and pharmacodynamics of analgesic and anxiolytic agents.[22,26] The lack of appropriate burn pain assessment instruments further contributes to the inability to evaluate treatment efficacy.[24] However, despite being recognised in the literature[27], alterations in drug characteristics and their effect on burn patients do not fall within the scope of this study. Instead, emphasis will be placed on the assessment of procedural pain and anxiety during wound care (dressing change) procedures.

One of the biggest problems in burn pain assessment is the lack of objective measurement techniques specifically designed to measure procedural pain and anxiety in the paediatric population. Despite literary recommendations, the use of existing self–report and observational assessment methods is ineffective in burn pain assessment due to methodological and conceptual deficiencies. For example, clinicians, in an attempt to assess paediatric burn pain, must currently make use of assessment methods designed for other types of pain (e.g. post - operative pain and cancer procedural pain), with the assumption that these methods are valid and reliable indicators of burn pain. Also, existing pain assessment methods are unable to differentiate clearly between pain and anxiety. Pain (a physiological reaction) and anxiety (an emotion) require different pharmacological treatment approaches (e.g. analgesic and anxiolytic agents) and therefore, an inability to differentiate between these two constructs could lead to ineffective pain management.

These deficiencies and in particular, the lack of validity, reliability and insight in how to define an overall representative score when using existing methods, led to the development of a new assessment technique, the Burn Observational Pain and Anxiety Scale (BOPAS) by the author of this dissertation. The development of this method was also the direct result of the author's involvement in a pharmaceutical trial in which paediatric burn pain was measured by a conventional observational pain assessment method. Study results have led to the conclusion that behaviour thought of as pain was indeed behaviour indicative of anxiety.

The Burn Observational Pain and Anxiety Scale was specifically designed to measure procedural burn pain and anxiety in children aged 2–12 years. In contrast to existing pain assessment methods, the Burn Observational Pain and Anxiety Scale's ability to provide for

separate but concurrent assessment of pain and anxiety during wound care procedures, allows for the evaluation of drug efficacy and subsequent improved pain management.
In line with specifications from the literature,[28] the validity and reliability of the BOPAS was determined in a series of five experiments by the author of this dissertation. Validity in general, is established by ensuring that the full range of information important to the concept being measured, is represented on the instrument and by demonstrating that the scores on the instrument correlate highly with an independent, valid and reliable criterion. Validity is also confirmed by the measure's ability to provide data which corresponds to a pre-specified conceptualisation of the aspect being evaluated.[29] Reliability is assessed by demonstrating that when the same aspects are measured repeatedly, the same score is obtained and that this will occur if two different raters measure the same aspects.[30]

In contrast to existing pain assessment methods, the BOPAS showed reliability and validity on three levels: i.e. construct, content and concurrent validity. Results have shown that the BOPAS was able to discriminate between pain and anxiety indicators in live observations as well as video-taped procedures. Subsequent experiments have validated the BOPAS's claim to construct validity in confirming the measurement of two different constructs, pain and anxiety. Concurrent validity was determined by a comparison of the BOPAS with the Children's Hospital of Eastern Ontario's Pain Scale (CHEOPS)[31]. Results have supported the BOPAS's claim to content validity via the method's ability to differentiate more consistently between pain and anxiety than other observational pain assessment methods such as the CHEOPS, which was designed to measure pain only.

Self-report methods such as the Faces Scales and Visual Analogue Scales have established only content validity with questionable reliability amongst the overall paediatric population, where age and cognitive development impact on applicability.[32] Furthermore, observational scales such as the CHEOPS have indicated low construct validity with reliability being questioned as a result of limited information on quantification.[33] In addition, the Pain Behavioural Rating Scale (PBRS) showed no indication of validity, whereas the Observational Scale of Behavioural Distress (OSBD) showed sensitivity for only concurrent validity.[19 31] The reviewed literature offered no support for existing pain assessment methods in terms of validity and reliability in the assessment of paediatric burn pain.

Pain assessment methods do not only have to be valid and reliable, they also have to provide sufficient information regarding data quantification. The BOPAS, unlike methods such as the CHEOPS, PBRS and OSBD, was designed to facilitate the translation of pain ***and*** anxiety scores into numerical data.

The development of the Burn Observational Pain and Anxiety Scale and the reasons that led to the development of this scale, are presented in this manuscript. The literature reviewed in

Chapters 2, 3 and 4, has the aim to provide an introduction to the unique origin of burn pain and the necessity for adequate pain management. More importantly, a review of current pain assessment methods and the deficiencies that rendered them inadequate for burn pain assessment is provided.

In Chapter 2, the dual origin of burn pain, from both the injury and its treatment, is discussed. This is followed by considerations on the importance of burn pain management and the reasons for, and consequences of, inadequate pain relief.

Chapter 3 describes the management of procedural burn pain from a mainly South African perspective. It discusses the pharmacological management of both procedural burn pain and anxiety and in addition, the use of supplementary therapies.

Chapter 4 provides a literature overview of the existing pain assessment methods recommended in the assessment of paediatric procedural burn pain. Emphasis is placed on the methodological and conceptual deficiencies that rendered these methods unsuitable for paediatric burn pain assessment.

Following the literature review, is the methodology and study results as well as discussion of these results.

Chapter 5 is divided into two parts, with part 1 discussing the methodology that led to the development of the BOPAS, and part 2, the study results. Each of the 5 experiments included in the study is individually discussed in terms of methodology and results. Chapter 6 follows with a discussion and conclusion of the results discussed in Chapter 5.

This study had as its goal, the development of a valid and reliable measurement scale that could contribute to the management of procedural burn pain and anxiety in children. The following factors were however not addressed in the methodology of this dissertation; pain and anxiety scores before and after procedures, as well as scores before and after the administration of analgesia and anxiolytic agents.

The value of the new method, the BOPAS, lies in its ability to assess procedural burn pain and anxiety in children aged 2–12 years without involving the patient in the assessment process. However, the current trend in paediatric medicine, and in accordance with the United Nations Convention of the Rights of the child, is to take the child's views and feelings into account during decision-making processes. Where possible, this was always followed in the process of burn pain assessment. The BOPAS method was specifically designed to not discriminate between the verbal and non-verbal patient population. The author believes that the exclusion of verbal involvement can be seen as strength, rather than a weakness. In this

the BOPAS scale focus primarily on the non-verbal or body language of pain, believed to be universal.

It also has as an added value, the ability to assess drug efficacy and as such could contribute to protocol formulation. As a result, issues that have prevented the assessment of procedural burn pain in children can now be overcome. The BOPAS is an answer to problems in paediatric pain assessment that directly relates to language barriers and cultural diversity. This new method can be used universally in burn units around the world.

CHAPTER 2

The Causative Origin of Burn Pain

2.1 Introduction

Burns are often considered to be one of the most severe forms of trauma[34] for not only do these injuries provide health professionals with tremendous management challenges, they also have devastating physical and psychological consequences for the patient. Burn injuries are known for their intense pain, their damaging effect on the skin and their adverse impact on the psychosocial functioning of the burn survivor.[35]

Paediatric burn injuries are universal phenomena, occurring in developed as well as developing countries. For example, an estimated 1 million children are treated for burn injuries in the United States each year,[3] whilst at the Red Cross Children's Hospital in Cape Town, an average of 2000 children aged 13 and younger are treated on an in– and out-patient basis for thermal injuries annually.[8]

One of the challenges facing health professionals is the fact that most burned patients are subjected to an extended healing process.[34] Extended follow up in a multi-disciplinary context is needed for a long time after the actual burn wound has healed. The healing process is also associated with intense pain originating predominantly from two sources - the actual injury itself[36] and the treatment process of that injury[37].

Burn injuries differ from other forms of trauma. For example, burn survivors are usually fully conscious at the time of admission to a hospital or burn unit. Burn injuries often deteriorate at the beginning of treatment before improvement occurs. Burn treatment often involves repeated painful procedures as part of the overall treatment protocol.[38] The nature of burn pain is also different when compared to other types of pain. It is incorrect to think of it as merely the body's reaction to injury and tissue damage and as a result, the amount of tissue damage will correlate with the intensity of the pain experienced.[39, 40] Burned patients might experience little or no pain during the first few hours post burn. It is only thereafter that pain influenced by factors such as the depth of the burn injury, the treatment given and patient characteristics (such as age, sex, previous pain experiences and cultural background), will occur.[41]

There is reason to believe that pain can affect the healing process in the treatment of burn injuries.[15] During the emergency and acute phases of treatment, the focus is often on the somatic aspects of the patient and wound management, with very little attention paid to pain treatment. As a result of not addressing this issue, pain can have physiological and psychological effects on the patient.[42] Pain treatment is essential in burned children.[15] The

fact that the pain suffered by paediatric burn patients is often not treated can be attributed to a number of prevailing myths and misconceptions.[21] This chapter will focus on the need to treat procedural burn pain (i.e. pain caused by wound management) in children.

2.2. The burn injury:

According to Red Cross War Memorial Children's Hospital statistics, burn injuries are predominantly caused by exposure to flames (15%), hot liquids (80%), contact with hot objects, fatty substances or caustic chemicals (4.5%), or contact with an electrical current (0.5%).[35] Skin damage will occur as a result of exposure to these sources, whereas factors such as temperature, heat content and duration of contact are responsible for the depth, size and severity of the injury.[43]

2.2.1 Classification:

Burn wounds can be classified according to depth, as being superficial (first degree), partial thickness (second degree) or full thickness (third degree) burn injuries. [13] Figure 2.1 describes the anatomical structures of the skin while Figure 2.2 will explain the classification of burn injuries according to depth, and Tables 2.1a,b and c discuss the characteristics of burn injuries according to classification by depth.

Figure 2.1 SKIN ANATOMY (Feller et al 1977)[45]

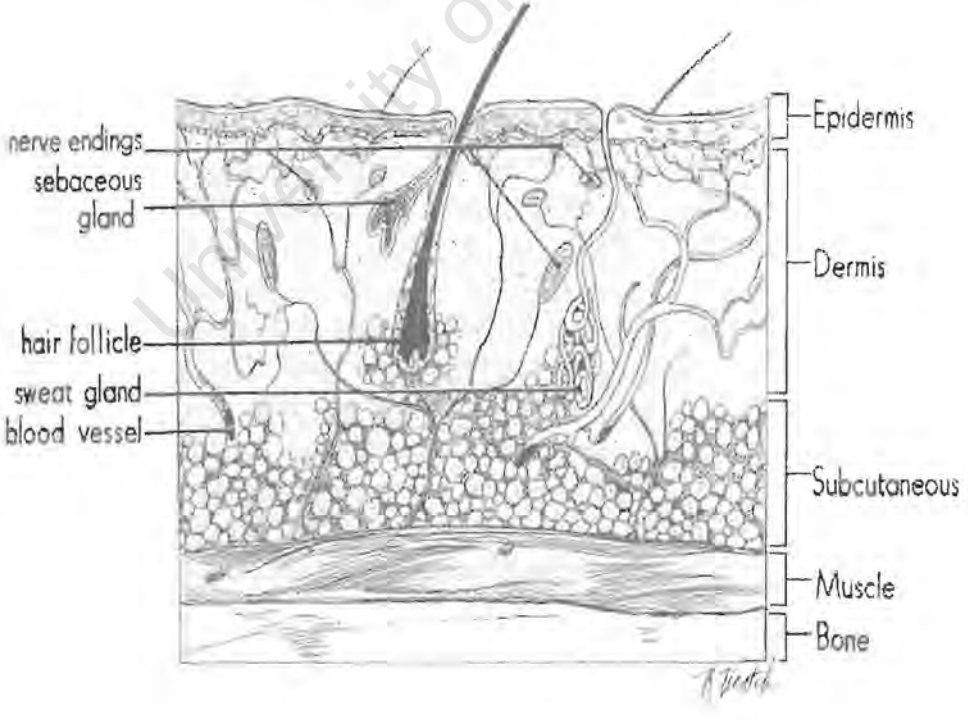
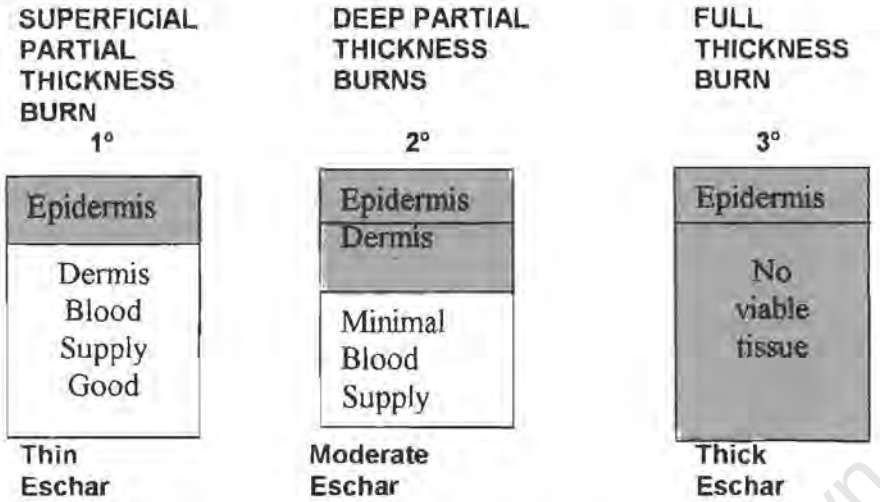


Figure 2.2

CLASSIFICATION OF BURN INJURIES ACCORDING TO DEPTH



i) Superficial burns (Table 2.1a) only involves the epidermis, leaving the deeper layers intact. The epidermis is the outer avascular layer of the skin, which consists of layers of epithelial cells.[44,45] Despite the limited amount of damage incurred, superficial burns produce both mild pain and discomfort.[13] Superficial burns are normally caused by sunlight or short exposure to a heat source and will heal within days with normal skin functions intact and no permanent scarring.[13,43]

Table 2.1a

Burn classification by depth: Superficial / first degree burns

Anatomy involved	Clinical findings	Cause	Healing
Epidermis Basal membrane Intact	Erythema Painful	Sun exposure Short exposure to heat source	3-6 days No scar

(Adapted from Latarjet (1995)[13]

ii) Partial thickness burn wounds (Table 2.1b) are classified as being either superficial or deep second degree burns with the experience of pain varying according to the amount of destruction to the dermis. In superficial partial thickness burn injuries, all of the epidermis and superficial layers of the dermis are destroyed. These injuries are normally very painful due to the exposure and damage to nerve endings in the mid and superficial dermis. The acute inflammatory response will further compound the intense pain. Superficial partial thickness injuries are normally the result of direct contact with hot liquids or flames. These injuries will heal spontaneously in 10-15 days with minimal damage to the skin. [13,43] (Table 2.1(b))

Table 2.1 b

Burn classification by depth: partial thickness burn wounds

Anatomy involved	Clinical findings	Cause	Healing
Epidermis and superficial dermis involved	Erythema Blisters Painful	Immersion scalds Short exposure to heat source	10 – 15 days. Permanent scarring.

(Adapted from Laterjet 1995)[13]

Deep partial thickness burn injuries (Table 2.1.c) are more serious and are treated as full thickness or third degree burns. In these injuries, most of the dermis is destroyed but remnants of the hair follicles, sweat glands and sebaceous glands are spared from where epithialization of the burn can occur. Deep partial thickness injuries are caused by direct contact with the heat source that in the process, destroyed the nerve endings, leaving them partly insensate.[38] Deep partially thick burn wounds might produce no or little pain in response to a sharp stimulus such as a pinprick, yet, in response to the inflammatory process, could cause a deep aching sensation of pain. Spontaneous healing can occur within 3 – 4 weeks post burn, leaving moderate to severe damage to the skin.[13,22]

Table 2.1c

Burn classification by depth: Deep partial thickness burns.

Anatomy involved	Clinical Findings	Cause	Healing
Epidermis and greater part of dermis destroyed	Erythema Blisters Little immediate pain	Immersion scalding Direct exposure to flames.	3-4 weeks and may require skin graft. Permanent scarring.

(Adapted from Latarjet (1995) [13]

iii) Third degree burns (Table 2.1.d) are characterised by the total destruction of the epidermis and dermis and are caused by prolonged exposure to the heat source.[43] Initially, little or no sensation is present in these injuries, although the patient may complain of a sharp pressurised type of pain in the wound area. Sharp sensations of pain will be experienced once the devitalised tissue is replaced by granulation tissue or with secondary infection.[22]

Table 2.1d

Burn classification by depth: Full thickness third degree burns

Anatomy involved	Clinical Findings	Cause	Healing
Total destruction of skin May involve deeper tissues, sub-cutaneous fat, muscle, tendons, & bone	No blistering No initial sensation but painful at later stage	Prolonged exposure to heat, water, flames, chemicals, hot liquids and electricity	Needs grafting Will only heal from edges. Extensive scarring.

(Adapted from Laterjet 1995)[13]

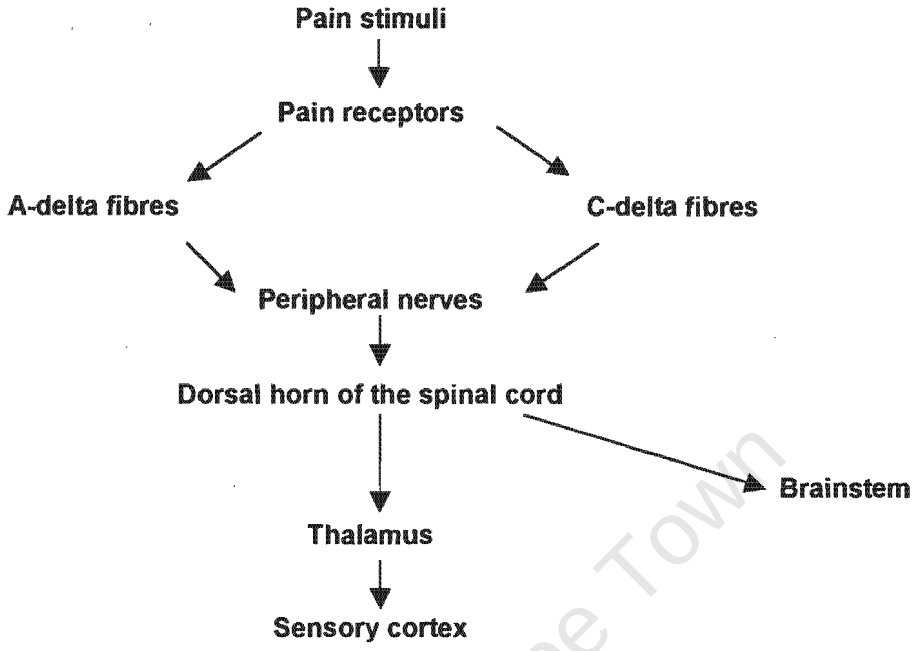
2.2.2 Causation of burn pain

There are different theories regarding the nature of pain. ***The specificity theory***[47] (pain is like vision or hearing, a specific modality with its own central and peripheral application), ***the pattern theory*** (which proposes that the nerve impulse pattern for pain is produced by the stimulation of non-specific pain receptors)[47] and the most accepted theory, ***the gate control theory***[46,47] The neuro-physiological transmission of burn pain as explained by Melzack and Wall's Gate Control theory, proposes the existence of a "neural gate" in the dorsal horn of the spinal cord.[47] Pain sensation is transmitted to this "neural gate" in the dorsal horn and, if the gate is open, the impulse will be transmitted to the brain where it is then recognised as pain. If the gate is "closed", no signal is transmitted to the brain and no pain sensation is experienced. The gate control theory supports the idea that sensory and cognitive processes are also able to open or shut the "gate". Anxiety and depression have been shown to increase rather than decrease pain perception. The gate control theory thus acknowledges the fact that anxiety is a component of burn pain.[40]

Pain, under normal circumstances, is the result of the stimulation of the peripheral receptors that transmit impulses through the pathways to the brain.[48] There are two types of pain receptors: the myelinated A-Delta fibres whose stimulation could produce a rapid sharp localised pain that serves to activate withdrawal reflexes and the non-myelinated C-fibres which primarily respond to mechanical, thermal or chemical insults.[49] Pain impulses are transmitted slowly along the non-myelinated C-fibres, producing dull, aching and poorly localised pain sensation with a slower onset. Nerve fibres from the myelinated A-Delta and non-myelinated C-fibres end in the dorsal root of the spinal cord, before transmission by ascending pathways to the brain.[47] The transmission of pain is illustrated in Table 2.2.

Table 2.2

The transmission of pain



Adapted from Bruce et al (1997)[49]

Initial burn pain is the result of the larger diameter A-Delta fibres that are thought to transmit "first pain" sensations, i.e. the immediate stinging, sharp and well localised pain sensation that accompanies the injury. The more diverse burning localised pain that follows seconds later is related to the smaller diameter C-Fibres.[49] Meyer et al (1981)[50] have studied the mechanisms of pain in reaction to burn injuries to the hand, using both animal and human subjects. Study results indicated that burn injuries contributed to an increase in the sensitivity of the A-Fibres, a decrease in the sensitivity of the C-Fibres and hyperalgesia in human subjects. Findings also indicated that the A-Fibres were responsible for the hyperalgesia related to burn injuries, instead of the C-Fibres as was originally thought.[18 50,

Peripheral changes can amplify activity within the spinal cord and can led to persistent input into the Central Nervous System. From this two observations can be made: the first is that low-threshold stimulus response in infants can, due to the activating of C-Fibres lead to marked and prolonged increase in the flexion withdrawal reflex. Secondly, the repetition of constant-intensity C-Fibre stimulus could induce wind-up, and dramatically increase the number and duration of responses of certain dorsal horn neurons.

Wind-up can increase these responses and can continue even after the cessation of peripheral input. Wind-up is furthermore sensitive to a wide range of NMDA receptor antagonists and channel blockers. This spinal event is thus thought to be crucial to central

hypersensitivity or central hyperalgesia, because the NMDA receptor switches a low level of pain related activity to a high level without any change in the input arriving in the peripheral nerves. Ketamine at analgesic doses is an effective NMDA receptor-channel blocker.

Studies in the neurophysiology of pain have revealed remarkable plasticity of dorsal horn neurons. Neural plasticity can be defined as the ability of neural circuits to undergo changes in function or organisations due to previous activity. Following a peripheral nerve injury, anatomical and nerve-chemical changes can occur within the dorsal horn of the Central Nervous System (CNS). Sensitisation of neurons can occur within the dorsal horn following peripheral tissue damage and is characterized by increased spontaneous activity of the dorsal horn neurons, decreased thresholds and increased responsibility to afferent output, and cell death in the spinal dorsal horn.[51]

Burn pain in these injuries are the result of the liberation of chemical substances such as histamine, serotonin, prostaglandins, norepinephrine and substance P, a peripheral pain transmitter released in the area of the burn wound.[19] Burn pain is further compounded by a phenomenon known as hyperalgesia, which refers to the lowering of the pain threshold to the level where even minor stimuli can increase the pain experience.[52] Hyperalgesia is a phenomenon commonly encountered among burn patients and can be defined as an increased response to a stimulus, which is primarily painful.[35]

Two zones of hyperalgesia can be described: an inner zone of primary hyperalgesia which is characterized by lowered pain thresholds and enhanced pain responses, and the surrounding secondary hyperalgesia zone which in turn is indicative of lowered pain thresholds and enhanced pain responses to mechanical stimulation. Primary hyperalgesia is caused by a combination of the sensitisation of peripheral receptors and central neurons, whereas secondary hyperalgesia results from central neuron sensitisation alone. Heat hyperalgesia within the primary area of hyperalgesia can be reduced by IV Ketamine, whereas the area of secondary hyperalgesia is reduced by IV Ketamine, epidural morphine and subcutaneous lidocaine.[53]

2.2.3 Pain associated with wound healing

A large part of the pain attributed to burn wounds originates from procedures involved in the management of these injuries.[37] It is often incorrectly assumed that wound care is the only painful procedure involved in burn management. Other procedures such as nursing care, debridement, surgery and physiotherapy could also contribute to the pain experience[54]. An example of one paediatric patient's procedural experiences in the burns unit of the Red Cross Children's Hospital is described in Table 2.3. High levels of pain inflicted repeatedly during hospitalisation are associated with these procedures, and many patients have described procedural burn pain as worse than the actual injury itself.[54]

Table 2.3

Painful and uncomfortable procedures: 1 patient age 2 (25% TBSA) over 8 hour period.

Time	Procedure	Patient response
08:00	Nursing observations. (blood pressure, pulse, temperature.)	No crying
08:30	Administration of drugs as boarded (Analgesia, vitamin supplements & antibiotics)	No crying
08:35	Feeds as boarded	No crying
09:15	Physiotherapy: Suction therapy for chest infection.	Crying & resisting
10:00	Ward round; examination by registrar.	Anxiety & resisting
10:15	NJ Tube removed. IV line inserted.	Anxiety & resisting & crying
10:30	Change of dressings Check urine catheter Pus swab	Anxiety, crying & resisting
11:15	Occupational therapy: Axilla splinting. Manipulation of burnt area.	Crying & resisting
12:00	Lunch feeds	No crying
13:20	Milk feed	No crying
14:20	Bloods taken, Blood gasses.	Anxiety, crying & resisting
15:30	NG Tube inserted	Anxiety, crying & resisting

The burned patient's pain experiences are influenced by the daily procedural activities and may vary considerably during the three stages of burn care. The first stage of burn care, ***the emergency phase,*** covers the first 72 hours post-burn during which all efforts are concentrated on resuscitation and the achievement of ventilatory and haemodynamic stability.[55,56] Pain during this phase is due to two reasons, direct trauma to the skin and surrounding tissue as a result of the burn injury and medical care involving painful procedures such as intubation, venous catheterization and wound care.[40]

Following the emergent phase is the much longer ***acute stage*** that will continue until complete skin coverage of the burn site has occurred. This phase has the highest mortality rate and is the most painful, with the patient not only acutely ill but also in an acute and chronic state of pain.[12] Superficial burn injuries should recover spontaneously. However, the more serious partial and full thickness burn wounds require painful surgical interventions such as excision, grafting and, subsequently, equally painful wound care and therapeutic rehabilitation procedures such as the active or passive stretching of the patient's scar tissue.[22] The acute phase is only completed once the burn wounds are covered with either autografts (skin taken from the patient's own body) or allografts (skin obtained from a donor).[57]

The rehabilitation stage, the third phase of wound management, involves the physical and emotional rehabilitation of the child and only ends when this has been achieved. A healed burn is seldom painless; the physical discomfort could be attributed to the itching and tingling sensations experienced in recently healed burned wounds. These sensations are thought of as equal in discomfort to the pain experienced in the first two phases of treatment and will subside over time as the scar tissue matures.[45]

Anxiety and thermal injury: Another issue involved in the experience of burn pain is that of anxiety, as it is widely assumed that burned patients have increased levels of anxiety. Anxiety can be defined as the emotion of fear, apprehension or dread, and is associated with negative thoughts about the future, anti social behaviour and physical symptoms.[58] Anxiety in burn patients is related to the patient's anticipation of painful procedures and expectations around the outcome of burn treatment. Anticipatory anxiety related to painful procedures could intensify the pain experience and increased pain could in turn lead to further increases in anxiety.[59] Anxiety will be further discussed in Chapter 4.

2.3 Why treat pain in burned patients?

Pain caused by burn injuries and its subsequent treatment, is an area of great concern for health professionals, not only to eliminate or reduce suffering, but also to counteract the negative physiological and psychological consequences.[34]

2.3.1 Physiological consequences of unrelieved burn pain:

Several physiological reactions follow on a burn injury. Evidence has suggested that untreated pain could adversely affect morbidity and mortality in burned patients.[60,61] Activation of the neuro-endocrine responses will occur in response to pain. The neural afferent pain stimuli pain, as a result of trauma could increase the complex, interconnected group of neuro-endocrine stress responses that disrupt the body's metabolic, autonomic and thermo-regulating functions.[60] These responses may accelerate various metabolic, cardiovascular, haematological and infectious complications, which in some cases could lead to multiple organ failure.[62] In this regard, the suppression of stress responses in adult patients through the use of opiods, is associated with a significant reduction in post-operative morbidity and mortality.[18]

The physiological responses to unrelieved pain might be indicated by an increase in blood pressure, heart rate and respiratory rate, as well as dilated pupils and perspiration.[63] Subsequently, severe uncontrolled pain can result in marked catecholamine release that can result in ischaemia and cardiac arrhythmias. Animal studies have indicated that pain and stress could inhibit immune functions; uncontrolled pain further compromises the ability of burned patients to withstand infection[64,65], a complication that could result in death. The rate at which the local circulation can supply oxygen to injured body tissues is determined by the

autonomic nervous system and can lead to peripheral vasoconstriction, which adversely affects wound healing.[66]

Pain perception, however, is not only physiological in nature, it also involves a psychological factor.[15,42] Following is a discussion of the psychological reaction to untreated or unrelieved burn pain.

2.3.2 Psychological reaction to unrelieved pain.

Insufficient burn pain management could result in the patient losing confidence in the medical team. However, untreated pain can have a more serious effect. It can cause the development of psychological (e.g. anxiety, withdrawal and regression) and psychiatric disorders (e.g. depression, delirium or maladaptive behaviour), which in turn could complicate burn wound healing and management.[15,16,42]

Severe pain can cause a number of behavioural changes including withdrawal from interpersonal contact, self-absorption, or increased sensitivity to external stimuli such as light. In addition, burned patients often express pain via emotions such as anger, resentment, depression, helplessness and feelings of loss. Although these facts are based on adult responses, it is believed that children have similar experiences.[67].

Literature[68 69 70] has confirmed that the psychological results of untreated pain have the ability to exacerbate the pain experience, which can often be displayed in behavioural changes. Some of these are:

> **Withdrawal:** This reaction is more prominent during the acute phase of burn management, where the preoccupation with pain during dressing changes, surgery and other types of procedures, takes up most of the patient's physical and psychological energy. Withdrawal in response to burn treatment and pain is often mistaken for depression, as the patient appears to have lost all interest in external events, family and friends. As the patient's condition improves, so will his/her emotional state.[68]
>
> **Regression:** Hospitalised children often display regression, a behaviour that is also a common occurrence in burned children as a result of their daily exposure to pain. Regression can be defined as retreating into past levels of behaviour where the person could feel more comfortable and as such more able to cope with the stress, fear and anxiety associated with hospitalisation. In burned children, regression can also manifest in temper tantrums, assertiveness and crying.[68 69]

Anger and hostility: This type of behaviour is often displayed as part of the grief response that occurs when the patients are faced with the loss of body image and separation from parents and siblings.[68] Anger and hostility can also occur as a result of long-term exposure to uncontrolled pain and is often mistaken for depression.[70]

Thus, in addition to the physiological consequences of untreated pain[71], psychological responses, not only influence the pain experience, but also, the long-term emotional health and well-being of the burn survivor. Despite the fact that these consequences are well known and well described in the literature, paediatric burn pain is often inadequately managed. There are a number of reasons for this, including the inability to measure pain accurately and the still existing myths and misconceptions often found amongst health professionals. Some of the reasons that cause inadequate management of paediatric pain will be discussed in the following section.

2.4 Obstacles in adequate pain relief:

Inadequate pain relief might occur as a result of the under-prescription and/or incorrect administration of medication for fear of addiction. A clear understanding of addiction, tolerance and physical dependence is needed to diminish this fear. Myths and misconceptions amongst staff members can impact negatively on the quality of pain management in children[16]. One of the most widely encountered myths today, is the belief that because children's nervous systems are immature, they are unable to experience and understand pain the same way adults do.[71] This assumption is totally inaccurate as was indicated by Ananad et al (1987) [72] who determined that a foetus, by the end of the second trimester of gestation, already possesses the anatomical and neurochemical capabilities to experience discomfort and pain. It was also determined that at six months of age, children will not only anticipate pain but will try to avoid it.[73] In fact, evidence supports the belief that neonates feel pain while some evidence suggests that younger children are even more sensitive to pain than older children.[74] These studies clearly show that children at very early stages of life both experience pain and communicate pain experiences.

Another myth that has since been dispelled is that paediatric pain cannot be measured accurately because of paediatric patients' inability to verbalise their pain feelings, and because of their immature cognitive development.[75] In fact, paediatric pain can be accurately measured through a variety of physiological, self-report and observational measures.

A further inaccurate myth or misconception is the assumption that children metabolise opiods differently to adults and that it is therefore dangerous to use these pharmacological agents in children.[76] In an attempt to investigate this assumption, Eland (1990)[77] conducted a study on the respiratory side effects involving 3 263 children in which it was found that only 3 patients experienced any significant respiratory compromise.

Despite the overwhelming evidence attesting to the inaccuracies of these misconceptions[78], some still believe that children have no memory of pain, that pain produces no harmful effects[79] and that children can easily become addicted to narcotics and other pharmacological agents.[77] Although these arguments have all proven to be inaccurate, they are still used by health professionals to rationalise inadequate pain treatment.

2.5 Discussion:

Burn injuries occur on a global level[1,2,4,5] and as such, present health professionals with continuous management problems,[3] one of which is the management of pain.[26] The intense pain experienced by burned patients is not only a result of the actual injury and associated tissue damage,[13] but also due to management procedures.[22,40,57] The initial experience of burn pain varies according to the amount of damage to the anatomical structures of the skin.[16] Superficial to partial thickness wounds can produce severe pain[13,22,43], while the more serious full thickness wounds often display an initial lack of sensation due to severe structural damage to the skin.[13,22] Burn care is synonymous with repetitive pain, as patients are subjected to painful procedures such as wound care, surgery and physiotherapy, on a daily basis. Even a healed burn is seldom painless, with patients still experiencing physical discomfort in the rehabilitation phase of management.[54]

Until recently, the treatment of pain was an underdeveloped area, as pain was often seen as a side effect of the underlying condition and was not recognised for the negative implications it could have on the patient.[71] However, health professionals are now fully aware of the physiological and with regard to burn patients, the potentially lethal impact of untreated pain in burn patients.[16,64] The psychological (withdrawal, regression and anger) and psychiatric consequences (depression and post-traumatic stress) of pain are also recognised as demonstrating a need to treat pain.[16]

Although the necessity to treat pain has been recognised in numerous scientific articles,[15,19,24,34,42] prevailing myths and misconceptions are associated with the persistent inadequate pain management practices.[72,73,74,75,76] In spite of contradictory evidence, many health professionals still defend their inappropriate pain management practices on the principle that children, due to immature neurological development, do not feel pain the same way as adults do.[71]

In conclusion, pain affects the healing process and when left untreated, may have both physiological and psychological consequences for the patient. The necessity to recognise and treat procedural burn pain is therefore undisputed.

CHAPTER 3

The Management of Procedural Burn Pain

3.1 Introduction

The previous chapter discussed the validity of burn pain, with pain now an acknowledged problem in burn management.[22] While the traditional approach to pain management is still found in drug therapy,[23] in addition, supplementary therapies can enhance pain relief. However, the effective management of burn pain raises a number of issues. Although it is an accepted fact that pharmacological agents will have an effect on pain, the efficacy of these drugs in terms of the individual's pain experience, is difficult to evaluate.[19] A number of factors such as a young child's inability to communicate pain, or preconceived misconceptions, could influence the decision on the need to provide pain relief, the choice of analgesic agents and drug doses.[71,72]

In addition to the inclusion of pharmacological agents, the overall management of burn pain requires a comprehensive pain assessment approach. The ability to assess pain accurately will enable clinicians to determine not only the necessity for treatment, but also the efficacy of the chosen drug approach. Comprehensive pain management strategies could be severely compromised by the lack of a framework in which to evaluate drug effectiveness.

This chapter will focus on the management of procedural burn pain in children and will include a discussion on the pharmacological management of pain and the use of supplementary therapies.

3.2 Fundamental considerations for pain management:

Burned children are inevitable treated in a specific milieu or context, which can vary from anxiety and distrust to a positive and therapeutic milieu. Paediatric burn pain management requires in addition to pharmacological and supplementary therapies, specific attitudes, techniques and principles. Some of these are:

- The subjective nature of pain. The International Association for the Study of Pain in their definition of pain placed great emphasis on its subjective nature. Children's self-report of pain should therefore never be underestimated, ignored or minimised.
- Painful procedures and treatment should be anticipated, measured and managed. Routine pain measurement is therefore advised.
- Pain prevention is better than pain management.
- Parents should be encouraged to accompany children undergoing painful procedures. In this regard, parents should be given specific instructions on what they could do to help their children during procedures.

- In addition, children should be given developmentally appropriate explanations as to what they can expect during a procedure. Explanations should be honest and geared to the level of the child.

Non-pharmacological approaches should always be integrated with pharmacological modalities. The paediatric burn patient requires all considerations pertaining to injured or traumatised children with regard to the environment, caregivers and treatment.[31]

3.3 The pharmacological management of procedural burn pain.

The mainstay management of burn pain is drug therapy,[22,23] although several principles should be adhered to when planning drug intervention. For instance, the chosen drug approach should not cause more pain and anxiety than what it is intended to relieve, (e.g. painful intra-muscular injections).[76] Pain relief should also be as constant as possible, providing for both pain intensity and the patient's psychological status.[80] Additionally, the severity of pain should be anticipated and treated before onset, thus ensuring a drug approach that is appropriate for the degree of pain experienced.[81] Jaffe (1993), in support of the constant effective management of pain, has argued that the patient's need for pain relief is indicative of poor pain management: *"as it relied on acting when things were already bad".* It is advisable to prevent the onset of pain rather than to try and manage already existing pain.[82]

The reviewed literature has recommended a variety of therapeutic strategies to manage procedural pain during the three stages of burn treatment. Following is a discussion of the pharmacological agents used during:

The emergency or resuscitation phase (0–72 hours post burn).
The acute phase (72 hours – 3-5 weeks, until wound closure is achieved).
The rehabilitation phase (from wound closure to scar maturity).[57,83,84]

In addition, Table 3.1 will discuss the protocol considerations for burn pain management as suggested by Marvin et al (1996)[22] The administration routes recommended are intra-muscular (IM), intravenous (IV), intravenous bolus (IVB), intravenous continuous infusion (IVCI), patient administered analgesia (PCA) and oral administration (PO).

In this dissertation, generic terminology is interchanged with brand names to facilitate the understanding by health professionals.

Table 3.1

Pharmacological therapies for procedural burn pain relief.

Emergency Phase	Acute Phase	Rehabilitation Phase
Morphine (IVB, IVCI)	Morphine (IVB, IVCI, PCA)	Non-steroidal anti –
Meperidine (IVB)	Fentanyl (IVB, IM)	inflammatory drugs
Ketamine (IV)	Ketamine (IV, IM)	with or without narcotics
Fentanyl (IVB, IVCI)	Meperidine (IVB, IM)	(e.g. Ibuprofen)
Valoron (Tilidene)	Codeine (PO)	
	Ibuprofen (PO)	
		Antidepressants
Anxiolytics:	**Anxiolytics**	(e.g. Amitryptaline)
Midazolam (IV,IVCI,PO)	Midazolam(IV, IVCI, PO)	
Lorazepam (IV)(Ativan)	Lorazepam (PO) Ativan	Diazepam (PO) Valium
Diazepam (IV) (Valium)	Alprazolam (PO) Xanax	(Dormicum)
	Midazolam (PO) Dormicum	

(Adapted from Marvin et al (1996)[22]

3.3.1 The emergency or resuscitation phase:

For the purpose of this dissertation only, in terms of pain management, the emergency phase applies to patients with burn injuries greater than 10% of the total body surface area burned. Intravenous drug administration (IV) is the preferred method during this phase, due to potential problems in drug absorption from subcutaneous, intramuscular or enteral routes during the emergent hypoperfusion phase.[41,85,86]

The burned patient usually undergoes two distinct metabolic changes, one of which could affect pain management in the first 48 hours post burn. During this phase, blood flow to the organs and tissues is decreased due to hypovolaemia, depressed myocardial function and increased blood viscosity. As a result, drugs administered during this phase will have delayed absorption if administered other than intravenously. Decreased peak concentrations and bio-availability will also occur, leading to the rapid uptake of drugs and elevated systemic drug delivery. The same metabolic change, however, might not occur in the following phase.[26] Morphine, administered in intravenous bolus (IVB) and intravenous continuous infusion (IVCI), is the most accepted approach to pain relief during this phase.[11,41,87]

Marvin (1996)[83] and Osgood (1989)[84] have suggested the use of Fentanyl in cases of severe procedural pain, as it has the advantage of being shorter acting and as such avoids over-sedation. Other literature sources have recommended the use of other anaesthetic agents such as Ketamine and Nitrous Oxide to relieve pain.[11 ,19 ,83,] However, the potential side effects of both these agents may be problematic.[85]

At the Red Cross Children's Hospital, Valoron (Tilidene) drops are the preferred alternative drug of choice for pain management during the emergency phase, and is administered at 0.5 – 1mg/kg dose.[85]

3.3.2 The acute phase:

The choice of pharmacological agents to manage procedural pain in this phase can include a combination of orally administered opioids (e.g. Morphine, Codeine Phosphate), non opioids (e.g. Paracetamol, Ibuprofen) and, where necessary, anaesthetic agents (e.g. Ketamine) as long as there are no side effects from the use of these agents.[22 86]

Marvin (1996)[22] suggested the use of oral hydromorphine (Dilaudid) for the relief of moderate to severe procedural pain caused by surgical interventions, wound care and physiotherapy. Other sources have recommended the use of pharmacological agents such as Morphine, Fentanyl and Meperidine HCL (Pethidine).[11,13,85] as well as a combination of opioids (e.g. Codeine Phosphate) and non-opioids (e.g. Ibuprofen, Paracetamol).[22,85]

3.3.3 The rehabilitation phase:

Many patients complain of an aching type of pain similar to that of arthritis during this phase. Non-steroidal and mild narcotics might be described for pain relief during the rehabilitation phase.[22] The suggested analgesic agents might be supplemented by the use of low-dose antidepressants such as Amitriptyline HCL.[88]

Anxiety in response to procedural pain is treated in all three of these phases with anxiolytic agents such as Midazolam, Lorazepam or Diazepam.[22, 85,]

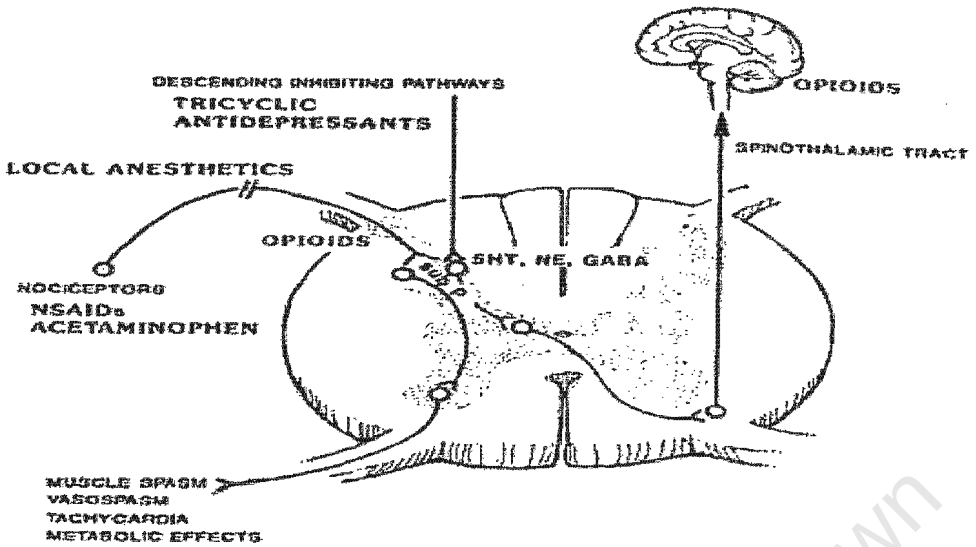
3.3.4 Individual drug characteristics.

The pharmacological treatment of paediatric burn pain predominantly involves administering non-opioid analgesics (e.g. Aspirin, Paracetamol and non-steroidal anti-inflammatory agents), weak opioid analgesics (e.g. Codeine Phosphate), strong opioid analgesics (e.g. Morphine Sulfate, Fentanyl, Meperidene HCL and Oxycodone), tricyclic antidepressants and benzodiazepines (e.g. Midazolam).[22,85] Combinations of these suggested therapeutic modalities can often provide an enhanced management effect and reduce the incidence of side effects from any one agent, an effect which when described in this context is called multimodal analgesia.[22]

The following figure (Figure 3.1) highlights pain pathways and the site of impact for the various analgesic agents.

Figure 3.1

Pain pathways and sites of action for analgesics



(Adapted from Majacher et all 1992)[81]

Described below are the drugs or groups of drugs generally used in the treatment of paediatric burn pain, with emphasis on the protocol followed at the Red Cross Children's Hospital. (Table 3.2 and Appendix 1) For example, drugs such as Oxycodone (Percocet), Hydromorphine (Dilaudid) and Nalbuphine (Nubain) have been suggested by the literature for the treatment of paediatric burn pain,[81] but are not widely used in South African state hospitals where budgetary constraints often dictate the availability of pharmacological agents.

Table 3.2

The Red Cross Children's Hospital procedural pain protocol.

Pharmacological Agent		Dose
Benzodaizepine	Midazolam	0.25 – 0.5 mg/kg orally
Weak and non opiod analgesia-	Paracetamol and Codeine *	1ml/kg orally
NSAID's	Mefenamic Acid	6.5 mg/kg orally
NSAID's	Ibuprofen	5 – 6 mg/kg orally
Stong opioid analgesia	Tilidene HCL drops	1 mg/kg (2.5mg/drop)
Strong opiod analgesia	Morphine Sulfate	Intravenous bolus: 25–100 mcg/kg dose 3- 4 hourly (slow injection over minute.) Intravenous infusion: 10 – 40 mcg/kg/hr PO: 0.3mg/kg/dose 4 hour

* (each 1ml = 20mg paracetamol + 1mg Codeine). (Thomas 2000)[88]

The pharmacological management of burn pain could be further challenged by issues related to drug metabolism, in that patients can develop tachyphylaxis, especially in the use of Ketamine HCL where the drug requirements might be much higher in comparison to other children with the same height and weight.[89] The correct dose for analgesics and anxiolytic agents is "that which is enough to have the effect required".[85]

3.3.4.1 Non-opioid analgesics:

Non–opioid analgesics may include drugs such as Aspirin, Paracetamol and Nonsteroidal anti-inflammatories.[85,] These drugs (NSAID's) are popular in the treatment of mild or moderate burn pain and, in combination with opioids, are used to manage moderate to severe burn pain.[85,90] Dependence and tolerance are not problems associated with non-opioid analgesics, but drug dose increases might lead to an efficacy ceiling effect.[82]

Aspirin: (dose 10mg/kg orally, 4 hourly)[85]

The use of the drug Aspirin is limited, either alone or in combination with Codeine Phosphate where it has the British Pharmacopaeia approved name of Cocodaprin.[76] Aspirin is suitable for the treatment of pain, fever, inflammation and the prevention of myocardial infarction and stroke.[80] It is, however, not a favoured drug in the treatment of paediatric pain due to the possible complications mentioned above, as well as due to side effects such as gastro-intestinal disturbances (i.e. nausea, dyspepsia and vomiting) and the possible irritation of the gastric mucosa which could result in erosion, ulceration, haematemesis and malaena. [88,90,91] To emphasise this point, Reye's Syndrome as reported in 1963 has resulted in the minimal use of Aspirin in children, and it is not indicated for use in babies and young children.[80]

Paracetamol / Acetaminophen

Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties, but does not possess any anti-inflammatory activity.[88] It is popular in the treatment of minor to moderate pain and fever in children. Adverse effects are rare, although rashes and blood disorders can occur.[92] An overdose of Paracetamol could result in severe liver damage and in some instances, acute renal tubular necrosis. Paracetamol should be given with care to patients with impaired liver or kidney function.[82] The following table will discuss the oral dosage of children younger than 12 years:

Table 3.3

Suggested Paracetamol doses in children < 13 years of age.

Dose recommendations at the Red Cross Children's Hospital:

***Oral: Loading dose*: 20mg/kg** **Maintenance: 15mg/kg (4 – 6 hourly)**
***Rectal: Loading dose*: 40mg/kg** **Maintenance: 30mg/kg (8 hourly)**
***Maximum TOTAL daily dose*:** **Neonates: 60mg/kg/24 hours** **Others: 90mg/kg/24hours.**

(Thomas 2000)[88]
(Anderson 1998)[92]

Paracetamol is absorbed in the gastro-intestinal tract with peak plasma concentrations occurring about 10–60 minutes after oral administration. The elimination half-life of Paracetamol varies from about 1–3 hours. The drug is metabolised in the liver and excreted in the urine.[93] Combination drugs inclusive of Paracetamol are: Stopayne, Myprodol, and Panadeine (the latter is a combination of Paracetamol and Codeine Phosphate used at the Red Cross Children's Hospital).[88]

Non steroidal anti–inflammatories (NSAID's):

Non steroidal anti–inflammatory drugs are used to relieve mild to moderate pain as well as fever and inflammation.[94] Most NSAID's have a greater analgesic effect than Aspirin or Paracetamol when used in a single dose, however, adverse effects can limit their usefulness.[80] The most common side effects that may occur during NSAID administration are gastro-intestinal disturbances (e.g. bleeding and peptic ulcers)[95], nephrotoxicity (e.g. interstitial nephritis and renal failure)[96], central nervous system related side effects (e.g. headaches, dizziness, nervousness, and tinnitus)[97] and adverse haematological effects[98] (e.g. anaemia, cosinophilia and thrombocytopaenia). Other side effects might occur due to interactions with other pharmacological agents. Non-steroidal anti-inflammatory agents are protein bound and may thus displace other drugs from protein, resulting in increased levels of the other drug, for example when using Warfarin. Many of the side effects of non-steroidal anti–inflammatories appear to be due to their inhibitory action on cyclo-oxygenases which are involved in the biosynthesis of prostaglandins.[41,86]

Ibuprofen, a propionic acid derivative, is a non-steroidal anti-inflammatory drug often prescribed in combination with opioids for the management of burn pain.[99]

Table 3.4

Dose recommendations for Ibuprofen.

***United Kingdom*:**
20mg/kg body weight daily in divided doses
***United States of America*:**
every 4 – 6 hours with a maximum dose of 40 mg/kg body weight *
Dose recommendations at the Red Cross Children's Hospital:
5 – 6 mg/kg/dose orally, given 8 hourly.
(maximum dose 20mg/kg/day)**

*(Jaffe 1993)[82]

** (Thomas 2000)[88]

Ibuprofen is absorbed from the gastro-intestinal tract with peak plasma concentrations occurring 1–2 hours after ingestion. This drug has a plasma half - life of about 2 hours and is rapidly excreted in the urine.[26] A study into the Pharmacokinetics of Ibuprofen have suggested a half life variation of 1.4 - 1.5 hours depending on the route of administration (e.g. tube feeding: $t_{1/2}$ = 1.4 hours, oral administration: $t_{1/2}$ = 1.5 hours.) and/or the presence of solid food.[81]

Mefanamic Acid is a non–steroidal anti–inflammatory drug often used as a replacement for Ibuprofen at the Red Cross Children's Hospital.[85] The recommended dose of this drug is 5–6mg/kg/dose 4 hourly. Caution should be taken during administration to patients with renal dysfunction, hypovolaemia, gastric irritation, bleeding problems, broncho-constrictive diseases and closed head injuries.[41,86]

3.3.4.2 Weak opioid analgesics:

Weak opioids such as Codeine Phosphate[87], Dextropropoxyphene and Dihydrocodeine[100] are often administered in combination with non–opioid analgesics in the management of moderate, or moderate to severe opioid sensitive pain.[104] Codeine Phosphate is the drug of choice commonly used at the Red Cross Children's Hospital.[80]

Codeine Phosphate: is an opium alkaloid with activity similar to, but weaker than, morphine as it has relatively milder sedative effects.[80] This oral administration of Codeine Phosphate in the treatment of mild to moderate pain should provide effective analgesia. Dependence similar to that found in Morphine Sulfate may be the result of prolonged use of high doses of Codeine Phosphate, but it produces less dependence and euphoria than Morphine Sulfate.[80] Codeine Phosphate, like Morphine Sulfate, has a dose related histamine releasing effect, and

anaphylactic reactions might follow intravenous administration. In small doses, Codeine is less likely than Morphine Sulfate to produce adverse effects. However, excitement and convulsions may follow large doses of Codeine Phosphate.[80] Von Mühlendahl (1976)[101] surveyed the results of Codeine Phosphate intoxication in 430 children aged 1–6 years. Symptoms such as somnolence, rashes, vomiting, itching and ataxia were associated with Codeine Phosphate intoxication. Codeine Phosphate is contraindicated for intravenous administration as well as intra-muscular injections and should only be administered orally or rectally. [88]

Codeine phosphate is absorbed from the gastro-intestinal tract and rectal absorption was also reported. Ingestion of Codeine phosphate produces peak plasma–Codeine Phosphate concentrations in about one hour.[102] This drug is excreted almost entirely by the kidneys, mainly as conjugates with glucuronic acid. The plasma half-life has been reported to be between 3–4 hours after oral administration or intra muscular injection.[103]

Table 3.5

Dose recommendations for Codeine Phosphate

30 - 60 mg 4 hourly to a maximum of 240 mg daily.
Children aged 1 – 12 years, 500 µg/kg body weight 4- 6 times daily.
(Doses are similar for both oral administration and intra muscular injections) *
Dose recommendations used at the Red Cross Children's Hospital
0.5 mg – 1mg/kg/dose 4 – 6 hourly. **

*(Martindale 1972-1996)[80]

**(Thomas 2000)[88]

Codeine Phosphate with Aspirin or Paracetamol is also known as Co-codaprin or Co codamol.[80]

3.3.4.3 Strong opioid analgesics: (e.g. Morphine Sulfate, Methadone, Fentanyl, and Hydromorphine).

Strong opioids include antagonists such as Morphine Sulfate, Diamorphine, Hydromorphine, Pethidine (Meperidene HCL), Oxycodone and Fentanyl and partial agents such as Buprenorphine, as well as mixed agonist – antagonists such as Pentazocine HCL, Butorphanol Tartrate and Nalbuphine HCL.[80]

Strong opioids are mainly used in the treatment of severe acute opioid sensitive pain and chronic opioid sensitive cancer pain.[104] The most general side effects are nausea, vomiting, constipation and drowsiness, while large doses could cause respiratory depression.[80,85]

Morphine Sulfate: is used for the control of moderate to severe pain. Morphine Sulfate dependence and tolerance is not a problem if used correctly for the relief of opioid sensitive pain. Adverse effects may include gastro–intestinal disturbances, constipation and respiratory depression.[105]

Morphine Sulfate is well absorbed from the gastro–intestinal tract but has poor oral bio-availability[80] since this drug undergoes extensive first pass metabolism in the liver and gut.[106] Morphine is readily absorbed into the blood after intra-muscular injection, and crosses the blood–brain barrier less readily than Diamorphine, a lipid soluble drug.[80] Mean plasma elimination half-lives of 1.7 hours for Morphine and 2.4–6.7 hours for Morphine-3-glucuronide have been reported.

Perry et al (1983)[107] have studied the Pharmacokinetics of Morphine in burned patients and found no significant changes when compared to the normal uptake of Morphine in the system. Their findings have indicated that the $t_{½\alpha}$ (apparent distribution of half life in minutes) was 4.3 ± 3.4 (SD) in burned patients in comparison to the $t_{1/2\alpha}$ 1.7 ± 1.2 in normal patients and that the $t_{/2\beta}$ (apparent elimination half life in minutes) was 98.8 ± 20.8 (SD) in burned patients in comparison to the 176.8 ± 70.3 in normal patients.[22] Up to 10% of a dose of Morphine may be excreted through the bile duct into the faeces; the rest is excreted in urine. [80 105]

The Pharmacokinetics of Morphine Sulfate in children are similar to those in adults[108], in each case elimination half-life of about 2 hours has been reported[109]. The following table will discuss the dose recommendations for Morphine Sulfate administration.

Table 3.6

Dose recommendations for Morphine Sulfate

Children >1 month of age – 15 mcg/kg body weight 4 hourly *
Dose recommendations at the Red Cross Children's Hospital
Intravenous bolus: 25 – 100mcg/kg/dose 3- 4 hourly (slow injection over a minute.)
Intravenous infusion: 10 – 40 mcg/kg/hr
PO: 0.3mg/kg/dose 4 hourly **

* (Martindale 1972 – 1996)[80]

**(Thomas 2000)[88]

Hydromorphine is a potent derivative of Morphine and is seven times as potent as Morphine.[80,110] This drug is noted for its rapid onset and duration action of 4–6 hours.[105] In the management of procedural burn pain, Hydromorphine serves as an effective first–line back up

to Morphine and Fentanyl[24] although it produces less sedation and nausea than Morphine.[105] Intravenous infusion, is the preferred route of administration at a dosage of 5–15 µg/kg, although it can also be given orally or subcutaneously.[24]

Methadone is a long-acting synthetic opioid found to be three times as potent as Morphine. It has excellent bioavailability after oral intake.[24] This drug is also an excellent weaning tool after a long course of intravenous opioids.[111] An initial loading dose of 0.1–0.2 mg/kg to be titrated in 0.5mg/kg increments every 10–15 minutes until analgesia is achieved is recommended.[24]

Fentanyl Citrate is a synthetic opioid, related to Pethidine(Meperidene HCL) and with similar properties to Morphine.[80] It is fast acting after a single dose and has a relatively long elimination half - life of about 4 hours because of rapid redistribution in the body.[22 24 ,105,] Fentanyl is an anaesthetic agent, usually administered intravenously at 0.5–1.0 µg/kg/hour.[112] A side, effect respiratory depression, may occur.[113] Linneman et al (2000)[114] have studied the effects of Fentanyl during wound care procedures in 55 burned patients aged 9 months to 75 years. While transient respiratory depression occurred in 17 (33%) of these patients, none needed intubation or additional supplementary oxygen after the conclusion of the procedure. Fentanyl and some of its derivates (e.g. Alfentanyl, Sufentanil and Lofentanil) are considered to be useful in the treatment of procedural burn pain.[24]

Tilidine_HCL is an opioid often used for the management of procedural burn pain at the Red Cross Children's Hospital. It is an orally absorbed synthetic narcotic analgesic and as such has the same side–effects and contra-indications as other opioid preparations. It is indicated for acute as well as moderate to severe pain and can be given concurrently with Paracetamol, alternating 3 hourly (each drug given 6 hourly but alternating 3 hourly). The prescribed dosage of 1 drop/year of age can lead to under dosing as the correct dose is 1mg/kg/dose, 6–8 hourly. Each drop is equal to 2.5 mg Valoron.[85]

3.3.4.4 Benzodiazepines (e.g. Midazolam, Lorazepam and Diazepam)

Patients frequently have a high degree of anxiety associated with the painful procedure they are undergoing, which may exacerbate the pain experience.[115] Choinière (1989)[116] found that high levels of anxiety or depression were not necessarily associated with higher pain scores in adult patients during therapeutic procedures, although findings have indicated that anxious patients will report more pain at rest. Charlton (1983)[117] on the other hand described a significant relationship between the pain and anxiety associated with burn procedures. Anxiolytic agents are often used either alone or in combination with opioids for pain relief. Midazolam and Diazepam are the drugs of choice in the relief of procedural induced anxiety.[24,118]

Plasma protein concentrations are often decreased in burn injuries. As a result the plasma binding ability of drugs such as Benzodiazepines is decreased, which increases the amount of unbound drug[119] and can influence the volume of distribution and clearance of these drugs.[26]

Midazolam: is a benzodiazepine used as a pre-medication and sedative in surgical and other procedures. It is a short acting drug with two distinct characteristics, that of anxiolysis and antegrade amnesia.[120] It is also an anti-convulsant and muscle relaxant. [24 80,] Midazolam is rapidly absorbed, with peak plasma concentrations being achieved within 20–60 minutes of intake.[24] Extensive first -pass metabolism results in a low systemic bioavailability after oral administration.[121] Midazolam has a short elimination half -life of about two hours although this is prolonged in neonates, those with liver disorders and the elderly.[80] Midazolam as an anxiolytic agent is administered orally at 0.25-0.5 mg/kg/dose at the Red Cross Children's Hospital.[85]

Sheridan et al (1994)[89] evaluated the safety and efficacy of Midazolam infusions in burned paediatric patients who were undergoing mechanical ventilation. This study was inclusive of 24 acutely burned children requiring mechanical ventilation, aged 7 months to 12 years. Findings indicated that Midazolam, when titrated to achieve diminished narcotic requirement, could result in decreased anxiety and better tolerance of wound care procedures. Only two trial patients experienced reversible neurological abnormalities attributed to the Midazolam infusion.

Other useful anaesthetic agents that can provide effective procedural burn pain relief are:

Ketamine HCL: provides effective sedation, analgesic and amnesic properties for burned children and has been used intravenously with good results. When administered intravenously at doses of 0.25–0.5 mg/kg, Ketamine HCL will provide intense analgesia.[88] Humphries and colleagues (1997)[89] included 19 burned paediatric patients in a study testing the results of oral Ketamine HCL on procedural burn pain. Their findings demonstrated a more than 400% reduction in pain and an improved sedation rate of almost 360%. Ketamine HCL has a hallucinatory quality, with patients describing vivid dreams, auditory and visual illusions.[122,123] Dose recommendations are as follows: intravenous doses should be administered at 0.25–0.5 mg/kg/dose, intra-muscular at 2–4 mg/kg/dose and orally at 5–6 mg/kg/dose.[88]

Diazepam: is a slower–onset benzodiazepine with a longer duration of action.[24,124] the elimination half-life is 10–20 hours. It has the same action as Midazolam in that it can be administered by intermittent doses rather than constant infusion.[125] Midazolam and Lorazepam have replaced diazepam; although it's clinical value lies in its ability to treat

muscle spasm. This drug can also be used as an oral pre-medication and as a weaning agent for patients that have been on long term infusions of benzodiazepines.[122]

3.3.4.5 Antidepressants

Antidepressants have been advocated in the treatment of chronic pain or where pain is accompanied by significant depression, unresponsiveness, sleep difficulties or panic disorders.[126] There is little value in using antidepressants in the early phase of burn injury treatment, as side effects (e.g. cardiovascular complications) can compromise the stability of the patient.[41]

Low doses of Amphetamine, Ritalin or Trycyclic antidepressants, however, have been shown to enhance opioid induced analgesia and as such reduce the need for analgesia.[41] The effects of these drugs can have positive results such as the enhancement of energy levels and subsequent decrease of fatigue and suicidal thoughts.[122]

3.4 Patient controlled analgesia (PCA):

The principle of patient-controlled analgesia was developed during the mid 1970's and early 1980's with the development of devices such as the Demand Dropmaster[127] Demanalg[128], Cardiff Palliater and the On Demand Analgesic Computer[129]. Observations made from early studies confirmed that patients could titrate their own analgesia better than ward staff; that patients' pain requirements differ and that patients are capable of using these devices correctly.[128] Since the development of these early devices, patient-controlled-analgesia has become an accepted form of opioid administration, deemed suitable for all forms of pain. [129] [130]

The use of patient-controlled-analgesia has become popular for use in children despite initial fears that they would not be responsible enough to control their own opiate therapy. Concerns, however, still remain with regard to the use of patient-controlled-analgesia in young children, as it was found that children younger than 6 years of age often could not cope with this technique.[131]

Numerous studies and research reports have substantiated the efficacy of patient-controlled-analgesia in non-burned patients; few however, have reported on its use in burned patients. Choiniere et al (1992)[132] assessed the efficacy and safety of patient-controlled-analgesia in 24 adult burn patients, and their results indicated that patient-controlled–analgesia is a safe, effective and improved method for controlling burn pain. The possible inclusion of this form of analgesia in paediatric burn pain management should therefore not be excluded although its effectiveness in this regard has not yet been fully determined in the South African context.

Pain relief should be a nursing priority for although nurses do not prescribe analgesics, they are responsible for administering them. The use of PCA (patient controlled analgesia) or NCA (nurse controlled analgesia) medication regimes are recommended for the control of background pain, donor site pain and post operative pain and are far more superior than the PRN (as needed) method. For this purpose, low dose Ketamine infusions, local anaesthesia techniques and slow release morphine infusions are recommended.[133]

3.5 The non - pharmacological management of pain.

Although pain commences with the transmission of nociceptive signals, burn pain cannot be explained by the degree of tissue damage alone, as a merger of physical sensations and cultural, psychological and social factors produces pain.[24] Pain management should therefore include, in tandem with the pharmacological approach, non-pharmacological therapies.[24,133] The efficacy of both pharmacological and non-pharmacological therapies needs to be evaluated. However, this dissertation will focus only on the efficacy of the drug therapy and the measurement techniques used to assess procedural burn pain.

Some of the existing supplementary therapies are:

3.5.1 Hypnosis [22,41,135]

3.5.2 Visual Imagery [134]

3.5.3 Relaxation [138]

3.5.4 Distraction [22,139]

3.5.5 Touch therapy[142]

3.5.1 Hypnosis:

Hypnosis is frequently used as a supplementary therapy for the treatment of pain in burned patients,[41] although conflicting reports as to its effectiveness for use in burned children exist.[22] Wallace (1987)[135] has reported positive results on the use of hypnosis in a British burn unit. Data obtained from a single case study described obtaining good control of background pain and partial control of procedural burn pain. Van der Does et al (1988)[136] described a study in a Dutch Burn unit where the pain levels (which were based on patient self-report in 3 adult patients) were reduced by 50–64%, and in one patient increased by 52%. A 30% overall mean reduction in anxiety was also reported, which again was based on the patients' verbal description of their anxiety. The validity of these measurements could however be questioned.

Patterson et al (1987)[137], in a review article, questioned the effectiveness and cost effectiveness of hypnosis in burn pain management. Conclusions from this review indicated that hypnosis can be used as an effective supplementary pain therapy, although cost-effectiveness was a concern.

In general, hypnosis could be utilised with great success, provided that a skilled hypnotist is available[22] Although found to be useful in the reduction of burn pain and anxiety, hypnosis could not be implemented at the Red Cross Children's Hospital, due to existing language barriers.

3.5.2 Visual imagery:

Visual imagery techniques focus the child's attention towards imaginary situations. These techniques might include imaginary stories, an imaginary trip to a favourite place, or the use of imaginary "pain switches" and the use of imaginary gloves. Visual imagery is non-invasive and very effective in a supplementary capacity to analgesic therapy.[134]

3.5.3 Muscle relaxation:

Muscle relaxation is a well-known technique for reducing anxiety and pain in children. Several forms of muscle relaxation exist, for example, tension relaxation, suggestion relaxation, mini relaxation and differential relaxation.[19]

In the implementation of muscle relaxation, instructions are given to patients to tighten a muscle group for 5–10 seconds, to notice the feeling of tension in the muscle and to release the tension by relaxing the muscle group. These suggestions are often accompanied by suggestions of relaxation and images of relaxing situations.[138]

3.5.4 Distraction:

Distraction is an intervention tool that attempts to re-focus attention away from pain to a pleasant sensory stimulus. Distraction is used in combination with auditory and visual stimuli with the aim of distracting the patient's awareness of pain and of increasing pain tolerance.[19,139]

Kelly et al (1984)[140] has evaluated the efficacy of distraction and behavioural feedback in 2 paediatric burn victims during procedural burn treatment. The distraction technique in this study was inclusive of the viewing of cartoons and the rewarding of positive behaviour. Pain, fear and the willingness to co-operate were measured according to the mothers' evaluation of their presence and the therapist's assessment of their severity. Study findings showed a 40% reduction of pain frequency during burn wound procedures.

3.5.5 Touch therapy/Massage therapy.

Massage therapy has been associated with reduced pain in fibromalgia as well as reduced anxiety and depression and improved sleep patterns in psychiatric patients. It was also found that massage therapy could reduce stress hormones such as cortisol and norepinephrine.[141] Consistent with these findings, it could be expected that massage therapy could reduce pain,

anxiety and depression in burned patients. However, only one study in this regard was found in the literature. Field et al (1998)[142] reported on a study involving 28 adult patients receiving massage therapy before wound care procedures. Findings indicated a decrease in state of anxiety, cortisol levels and pain.

3.6 Conclusion:

The treatment of procedural burn pain is found in a combination of both pharmacological agents [22,23] and supplementary therapies.[24] A number of pharmacological options exists in procedural burn pain management[76,85,83,] although it is important to note that there are "no set formulas" for achieving analgesic and anxiolytic sedation. Whatever approach to pain management is selected, it has to include a combination of analgesic (non-opioids and opioids) and anxiolytic agents, for both pain and anxiety co-exist in the experience of burn pain.[115]

The inclusion of supplementary therapies such as hypnosis[135], muscle relaxation[20] and touch therapy[141] provides for a more holistic approach to burn pain and anxiety management. However, despite the recommended use of these therapies, issues such as validity, the need for specific training and financial constraints make the general implementation of these methods impractical. Supplementary therapies could never replace the pharmacological approach to pain management, but could enhance drug efficacy.

CHAPTER 4

Paediatric Burn Pain Assessment.

4.1 Introduction:

I cannot assess,
Therefore I cannot manage

Ruth Graunau, 9th world congress on pain, Vienna 1999

With this opening remark at her presentation at the World Congress on Pain in 1999, Ruth Granau underlined the importance of assessment in the management of pain, and tried to convince her audience that without pain assessment, adequate pain management is impossible.

Pain management, now an accepted part of burn care, predominantly involves the use of pharmacological agents (as was described in the previous chapter), although supplementary non-pharmacological therapies are also used.[24] However, without the ability to assess pain, the effectiveness of management cannot be measured and clinical goals cannot be reached. A major problem experienced in pain management does not originate from the availability of various pharmacological and supplementary therapies, but in the inability to measure their effectiveness.

Due to the lack of an existing framework in which to measure drug efficiency, clinicians must make use of measurement techniques designed for other types of pain when assessing procedural burn pain, for example, those used in post-operative pain and procedural cancer pain assessment. Unfortunately, conceptual and methodological constraints affect the adequacy of these measurements.

This section will discuss the importance of pain measurement and the methods currently employed in procedural burn pain assessment.

4.2 Importance of assessing procedural pain in burned children:

The literature emphasises the need for a comprehensive pain assessment approach: i.e. a measurement technique that can evaluate pain intensity[19] and obtain information regarding individual pain experiences[143] and drug efficacy.[28] It is accepted that the use of analgesic and anxiolytic agents alone, is inadequate in the overall management of burn pain. Following are a number of reasons attesting to the importance of burn pain assessment identified in the literature:

- To determine individual pain experiences during inpatient treatment as a scarcity of information of this nature exists.[144]

- To evaluate pain management guidelines and subsequent adjustments.[145]
- To determine appropriate measurement techniques and application criteria.[146]
- To determine factors that could influence the experience of burn pain (e.g. previous pain experiences, cognitive development and anticipatory anxiety)[147]
- To determine the need for, the adequacy of pharmacological interventions and subsequent supplementary therapies.[148]
- To determine pain intensity.[19]

4.3 Current measurement techniques used in paediatric burn pain assessment.

A variety of instruments to measure pain and anxiety in infants and children have been developed over the past two decades. None of these were specifically designed for the measurement of procedural burn pain. Only a few of the existing measurement techniques combined the assessment of nociceptive (pain) and emotional (anxiety and fear) stimuli, with none of these methods being found appropriate for children across all developmental levels.[24]

Discussion of the measurement techniques currently in use for burn pain measurement follows (Table 4.1) as well as their deficiencies in this context. The techniques to be discussed are characterised by (1) physiological and (2) psychological aspects. The psychological aspect of pain measurement is far more complex than the physiological approach as it involves both subjective and objective measurement strategies.

Pain measurement techniques designed for neonates and adolescents were omitted from this discussion. Specific techniques are utilised for different age groups.

Table 4.1

Recommended clinical pain measurement tools for burned children

Physiological Measurement	**Psychological Measurement**	
Heart rate	**Subjective measures**	**Objective measures**
Blood pressure	**Self report scales**	**Observational methods**
Respiratory rate	-Visual analogue	CHEOPS *
	- Numerical scale	Observer Pain Scale *
	- Faces scale	PBRS scale *
	- Word Graphic scale	OSBD scale *
	- Pain Thermometers	PBLC *

(Adapted from Marvin 1996)[22]

- See text.

4.3.1 Physiological measures.

Physiological parameters such as heart rate,[149] blood pressure[150] and respiratory rate[63,151] are associated with changes during painful experiences and are relatively easily quantified. Although other physiological measures also exist, the above-mentioned are predominantly used and will be discussed below.

Heart rate generally increases with pain[152], although it would appear that physiologically, in response to pain, the heart rate first decreases and then increases.[153] Studies have also suggested a heart rate decrease in response to the use of analgesics, as was demonstrated in the changes found in a study looking at the heart rate during infant circumcision.[154] Changes in heart rate have also been found in relation to other measures designed to calm, soothe or distract the patient during painful procedures.[155] Heart rate as a pain indicator can be measured in two ways: it is either calculated as the number of beats occurring in a given time frame, (e.g. beats per minute at intervals ranging from one second to 90 seconds), or it can be described in terms of the time between successive beats.[156]

Respiratory rate is usually defined as the number of breaths taken in a given period and can be measured by direct observation or through mechanical cardio-respiratory monitoring.[157] An increase in respiratory rate is often associated with pain[158], although some studies have indicated a decrease in respiratory rate in association with pain.[151]

Blood pressure is described in terms of the force of blood against the walls of the blood vessels, and could be measured by either using a sphygmomanometer at the brachial artery, a laser Doppler, an intra-arterial catheter or a strain transducer.[150] An increase in blood pressure has been noted during and directly after painful episodes.[159]

Physiological pain measurements turned out to be less efficient than originally anticipated. These measurements appear to be able to identify pain, but not to differentiate between different levels of pain.[63] Physiological measurements also lack the ability to discriminate between pain and other forms of stress to the body such as anxiety or fear.[24] The ability of physiological measurements to measure pain could also be influenced by the impact of certain pharmacological agents on the system, which could affect their accuracy as pain measurement techniques.[63]

There is a general agreement that these methods show promise as indicators of pain but that they should, in this context, be used in conjunction with other measures such as self–report or behaviour observations.[153]

Below is presented firstly a list and then a short summary of the most commonly used self – report and behavioural scales. The methodological and psychometric properties are discussed subsequently.

4.3.2 Self-report measures.

Self-report measures are considered to be the most acceptable pain measurement technique.[160] These measures rely on children reporting their own subjective experiences and are consistent with the International Association for the Study of Pain's definition of pain which emphasis the subjectivity of pain.[161] In response to self- report, children communicate their pain by using words, numbers, pictures or mechanical devices to indicate how they feel.[162] Thus, self-report measures address the patient's own experience of pain.

Below is a description of the self-report measures used in the field and considered to be applicable in procedural burn pain assessment.

Figure 4.1

Faces scales

0 1 2 3 4

These scales provide the patient with a series of facial expressions depicting different values of pain. In the implementation of this scale, the child is requested to choose the face that most closely resembles the intensity of their pain experience.[149] Examples of these are the Faces scale[163] and Oucher scale[143]. The Oucher Scale normally consists of either 9 faces that vary in levels of overt distress expressed. These scales are normally presented in random order with three faces displayed in each of the three rows on an 8x11 inch page. Numerical values are often assigned to the faces, reflecting their rank in order within the series, for example 1–7. However, these numbers do not correspond to the perceived level of pain depicted from the child's perspective.[160]

Recent studies involving the faces scale revealed certain contradictions in its application, although validity and reliability were not recommended. The Faces Scale was originally used in a horizontal form with happy and sad faces placed from left to right. Criticism based on the suggestion that the horizontal left to right fashion might cause participant bias, led to changing this scale into a circular format. However, subsequent studies have revealed that the circular format contributed to participant confusion.[164]

The recently developed Facial Affective Scale was specifically developed to assess the child's feelings in relation to pain. This scale consists of a set of nine faces that vary in the level of distress they express: for example, from most pleasant feeling to most unpleasant feeling. Evidence of reliability and validity were found when used in conjunction with the vertically formatted Coloured Analogue Scale.

Although facial expression scales were found to be developmentally appropriate and appealing to children, original scales included 7 to 9 faces which might have presented young children with to many options. Evidence suggested that young children have difficulty with more than four or five choices. Alternatives are currently explored in the newly formatted Faces Pain Scale that will involve the use of one single face whose expression could be manually manipulated by the participant.[162]

In the implementation of the Oucher scale, children are asked to choose from 6 photographs of a child, depicting various levels of pain intensity.[143] The photographs are positioned at regular intervals on a 0–100 vertical numerical scale. These scales are not applicable to children younger than 5 years as it was found that they present the younger child with too many options, leading to confusion. In their ability to measure pain, they tend to reflect the overall severity of the pain experience, instead of a single dimension.[143,162]

Visual analogue scales:

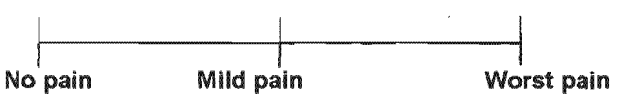
Older children's cognitive development allows for more abstract thinking, making these scales more applicable to children 5 years of age and older[22] A Visual Analogue scale is basically a horizontal or vertical line with verbal or facial anchors on a continuum of pain intensity, which in its application is presented to the child, who is then asked to indicate on the line, his/her level of pain.[165, 166] Visual Analogue scales were described as developmentally appropriate, and according to Thompson et al (1986)[167] did provide reliable measures of children's pain perception when compared with parental estimates, ($r = 0.72, P < 0.001$).

Word Graphic Scale: (Fig. 4.2)

There are also other types of visual analogue scales such as the Word Graphic scale and the Numerical Rating scale. The Word Graphic scale, usually recommended for children aged 8–17 years, consist of a series of words (e.g. no pain, mild pain, moderate pain and severe pain) on a continuum. In the application of this scale, the child is asked to select the word on the continuum that resembles the level of pain he/she is experiencing.[32]

Figure 4.2

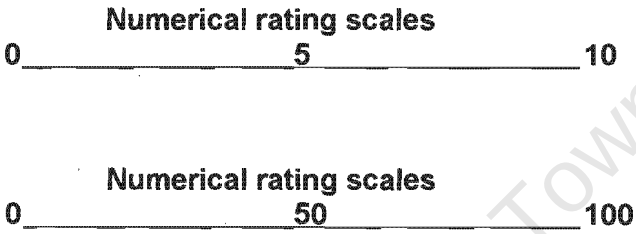
Word Graphic Scale



Numerical rating scales: (Fig 4.3)

Numerical scales were developed on the same principle as the Visual Analogue Scales in that they have numerical anchors at each end of the line. In their application to pain measurement, they were found to be too difficult for use with young school age children. However, older children respond well to this scale on which pain can be rated on a continuum from 0–5, 0–10 or 0–100. It is important to remember that the intervals on the continuum might not be equal from a child's perspective and that a change from 2–4 might not be the same as a change from 8–10.[168,169,170]

Figure 4.3



Pain thermometers.

Pain thermometers consist of a vertical or horizontal line graduated as 0–10 or 0–100. Zero as indicated in these scales is often designated as indicating "no hurt" while the number at the endpoint is designated as "most hurt of all". Children in the implementation of these scales will be asked to point to the level on the pain thermometer that indicates their pain.[163]

In summary: Bieri et al (1990)[163] have evaluated the ratio scale properties of the Faces scales. Twenty eight children (average age 6.8 years) were included in a study where children were asked to place the 7 faces in the Faces scale in order from the most to the least painful, or to indicate which of the faces have indicated the most pain. According to findings obtained, children agree on the rank order of the faces as a measure of pain severity – an indication of content validity. No specific values were provided. Reliability was determined by instructing 35 children (average age 6.7 years) to rate a recent painful event by means of the Faces scale with minimal aid of the instructor. This test was repeated two weeks later when the children were asked to recall the same personal pain experience and again to rate it on the Faces scale. Results yielded a rank correlation coefficient of 0.79, and it was concluded that pain scores were adequately reproducible over time. However, the validation of facial self-report measures in terms of children's pain and distress from a child's perspective are not yet established.[165,171] A literature review[162] has indicated that no currently available self-report pain scale meets all the criteria required for reliability and validity.

Although considerable effort has been invested in developing self–report scales and subsequent psychometric properties,[160,171] no indications in the literature were found attesting to the validity[139] and reliability of these scales when applied to procedural burn pain assessment.[24] Burn pain is different from other sources of pain such as, for instance, post-operative pain.[38] Burn pain is more complex as various types of burn pain exist (e.g. procedural, background and breakthrough).[39] It also has multiple origins (e.g. wound care procedures, surgery and physiotherapy) and is repetitive in the patient's daily exposure to painful procedures. [19,145] In terms of pain assessment, the traumatic circumstances under which the burn injury occurred, painful treatment[39], separation anxiety and regression[68], could all influence the child's ability to accurately portray his/her pain and as such the use of self-report measures.[24]

Pain assessment is problematic when verbal fluency and cognitive development may limit a child's ability to communicate pain. For example, Goodenough (1997)[168] reported a significant difficulty in 3–4 year olds understanding the requirements of Visual analogue measurements. The ability of children aged 3- 4 years to evaluate current pain by matching it to previous pain experiences and then representing its severity or intensity on a visual analogue scale is a difficult task that requires a certain level of abstractionism and is therefore limited in its success.[33] Clinicians seem to assume that the child has the ability to translate his own concept of pain into a point on a line when using a Visual analogue scale to measure pain.[30,172,173] Paediatric patients might also lack the cognitive ability to use scales such as the Visual analogue scales or Numerical scales as they need understanding of the numerical values attributed to minor, moderate and severe pain.

Children's verbal descriptions of their pain may also be biased.[24] Hospitalised children may be influenced to answer questions regarding their pain experiences in a socially desirable way,[19] may distort answers either to obtain analgesics more promptly from the nursing staff, or alternatively to try and avoid painful or unpleasant analgesic administration.[169]

The implementation of the Faces scale is furthermore complicated by children's inability to distinguish between pain and other forms of distress (e.g. anxiety and fear).[163] Children might select the face that indicates their mood rather than their level of pain. This was supported by the author's experience at the Red Cross Hospital, where burned children tended to evaluate their emotions instead of pain. Although developmentally appropriate for young children, Faces scales might present children with too many options, which could affect applicability.[156]

4.3.3 Behavioural Observational Scales.

Behavioural measures in children usually involve the observing and recording of pain by a trained observer and the implementation of behavioural scales.[174] A number of behavioural scales, designed to measure pain by providing standardised instructions and guidelines for

observing behaviours, have been designed. The behavioural observational scales described above are inclusive of more of less similar behavioural indicators, for example, verbal cues, facial cues, body cues. The assumption could therefore be made that behavioural pain indicators are universal.[174]

The following behavioural observational scales were identified by the reviewed literature as being useful in the measurement of procedural burn pain in children.[22,67,174]

The Observer Scale: Although easy to implement, it has not been validated and appears to be insensitive for anxiety and fear.[22] The Observer pain scale (Table 4.2) categorises overall pain behaviours on a scale of 1–5. During the implementation of the Observer Pain Scale, pain behaviour is observed and categorised on a 5 point Likert scale varying in severity. [175]

Table 4.2

The Observer Pain Scale

Score	Description
1	Laughing, euphoria
2	Happy, content, smiling, playing
3	Neutral (asleep)
4	Mild – moderate pain: expresses pain, vocalises pain, wrinkles brow, but can be distracted
5	Moderate – severe pain: expresses severe pain, crying inconsolably, screaming, hysteria, sobbing. . [175]

Gracely et al 1978[175]

The CHEOPS [22 176] (Children's Hospital of Eastern Ontario's Pain Scale), initially developed to measure post operative pain in children aged 2 – 6 years, is the most widely used scale of all existing behavioural scales. The implementation of this scale consists of the rating of 6 behaviours (crying, facial expression, verbal pain expression, torso movement, touch behaviour and torso position) at 30-second intervals by a trained observer. Numerical values are assigned to the observed behaviour on a 0 = positive, 1 = neutral or no pain, 2 = mild to moderate pain and 3 = behaviour indicative of severe pain, basis. [176]

In the measurement of procedural burn pain, the CHEOPS is consistently more acceptable than any of the other observational scales despite being a postoperative assessment scale. . Initially in the development of this scale, inter-rater reliability was reported to be between 90–99.5%.[176] Despite this high inter rater reliability, validity, when compared with self-report measures, was reported to be low.[169] Although this scale is considered to be

psychometrically sound on the level of face validity and relatively easy to implement[24], in the measurement of procedural burn pain, lacked the ability to discriminate between pain and anxiety or fear. Support for criterion validity and reliability[177] is difficult to produce due to the lack of, in particular, the key to quantification, and as result can impact on the reproducibility of the CHEOPS.

The following table is an illustration of the CHEOPS as described above.

Table 4.3

The CHEOPS

CRY:	No cry, Moaning, Scream
FACIAL	Composed, Grimace, Smiling
CHILD VERBAL	None, Other complaints, Pain Complaints, Both complaints, Positive statements
TORSO	Neutral, Shifting, Shivering, Upright, Restrained
TOUCH:	Not touching, Reach, Touch, Grab, Restrained
LEGS:	Neutral, Squirming, Drawn up, Standing, Restrained

(Adapted McGrath et al 1985)[176]

The Procedural Behavioural Scale (PBRS),[169 170] was originally developed for the combined measurement of both pain and anxiety in paediatric oncology patients, specifically those children undergoing bone marrow aspirations and lumbar puncture procedures,[178] aged 8 months to 17 years. In implementation, the scale records the occurrence of 11 behaviours during 3 time periods within the medical procedure.[169 179] Behaviour indicators as implemented by this scale were: crying, screaming, physical restraint, request for emotional support, verbal resistance, muscular rigidity, verbal pain expression, flailing, nervous behaviour and information seeking. Inter rater reliability for the PBRS: 0.80 - 0.90.[179]

The Observational Scale of Behavioural Distress (OSBD)[169 170] uses the same 11 behaviours as the PBRS but with methodological differences. Behaviours were recorded continuously at 15-second intervals throughout the bone marrow aspiration and lumbar puncture procedures.[57 180] Behaviours in both scales are weighted according to the amount of distress they represent, with pain intensity ratings varying along a 1 – 4 point scale, with 4 indicating maximal pain and anxiety. A final pain score was obtained by averaging the distress levels associated with observed behaviour. The term "behavioural distress" in this context refers to both anxiety and pain, because of the difficulty in differentiating between the two.[169 181] Only the OSBD showed evidence of concurrent validity and reliability: 0.80 - 0.91.)[179]

The Procedure Behavioural Checklist (PBCL):[57] was based on the Procedural Behavioural Scale (PBRS)[170] and consists of an 8-item checklist of pain behaviour exhibited by children

during painful cancer procedures. The PBCL, was presented as a 5 point Likert scale. The following behavioural indicators were included in the PBCL: muscle tension, screaming, crying, the use of restraint, verbalised pain, verbalised anxiety, verbal stalling of a procedure and physical resistance.[168] These indicators are similar to those used in other behavioural observational scales, for example; the CHEOPS[176], the PBRS[170] and OSBD[170]. Study findings on the implementation of the PBLC indicated that this scale corresponded more strongly with ratings of anxiety than pain. The inter rater reliability on the implementation of this scale on the pain ratings of 22 patients was 84%. It was suggested, during a critical evaluation of this scale, that anxiety and pain should be assessed separately, and not be jointly assumed according to the numerical value attached to observed behaviour. [182]

Problems in the implementation of existing observational scales in procedural burn pain assessment:

Although some of these scales indicated sensitivity for both pain and emotional distress (i.e. OSBD), complications in their implementation rendered them ineffective for use in procedural burn pain assessment. For example, the number of behavioural indicators that needed to be recorded during the suggested time intervals complicated their use in procedural burn pain assessment. Furthermore, the implementation of these methods appears to be time consuming.

4.4 Empirical data regarding procedural burn pain assessment in paediatric patients.

The following discussion focuses on reviews and reports on pain measurement techniques used in the assessment of procedural burn pain.

Foertsch et al (1998)[181] used the Observational Scale of Behavioural Distress (OSBD), the Faces scale and a Visual analogue scale to study the impact of social support and distraction on procedural burn pain in 23 children aged 3 – 12 years. Subjects were videotaped during procedures and observations were made from these tapes. Findings have indicated that most of the three year olds and some of the four year olds were unable to understand the implementation of the Faces scale, thus rendering it unsuitable for implementation in that particular study. The effectiveness of the OSBD as an observational measurement technique was also questioned by the study results. Older children exhibited a lower range of behaviours and scores as indicated on the OSBD, thereby questioning the use of observational scales in children older than 10 years of age. It was argued that older children might not display pain in observable ways.

Atchison et al (1991)[183] studied pain levels before, during and after wound care procedures in acutely burned children. This study included 48 children aged 7 – 17 years. A Pain Thermometer, a type of visual analogue scale, was used to assess subjective pain

responses. Although findings supported the sensitivity of this technique in the assessment of procedural burn pain, methodological and conceptual weaknesses were noted in the study. Firstly, the practicality of the study method was questioned, as well as the participants' ability to provide accurate and unbiased information regarding the intensity of their pain experiences. In the study, participants were asked to provide pain scores prior to a wound care procedure, at 1-minute intervals during the procedure and again post procedure. Furthermore no differentiation was made between pain and anxiety.

Doctor (1994)[184] reported on the assessment of young children's behavioural responses to painful burn care procedures with and without a parent present, and the impact of parental support on the child's ability to cope. Twenty-eight 3-year old children were included in this study, with pain observations made by implementing a Behavioural Checklist and a Global Assessment Scale. The latter was not recommended by the reviewed literature as a measurement for burn pain. These scales were designed to measure pain, anxiety and distress in children. The mean scores of the Behaviour Checklist indicated a slight increase in body and verbal cues during wound care procedures. However, the psychometric properties of the Behavioural Rating Scale and Global Assessment Scale are unknown.

Gordon et al (1998)[146] surveyed 159 burn centres in the United States of America to determine the procedural pain measurement technique of choice. Their findings indicated that 67% of the responding burn centres preferred the Visual Analogue scales as their pain measurement technique, while patients indicated their preference for the Faces scale.

These studies provided some insight into the most common pain measurement techniques used in procedural burn pain assessment. Although the psychometric properties of observational and self–report measures used in these studies are assumed, they seem inconclusive about the level of validity and were not evaluated specifically for burn pain measurement.

4.5 The role of anxiety in procedural burn pain

The previous discussion focussed on pain measurement techniques and their methodological and conceptual flaws with particular reference to the phenomenon of anxiety. The reviewed literature underlined the need to recognise anxiety as an emotion that alters effective pain management.[26] Although pain and anxiety seem interrelated, they are viewed as two different phenomena in reference to burn pain management, with pain being a physical experience and anxiety, a state of emotional arousal.[185]

The relationship between pain and anxiety has been the subject of substantial experimental investigation and speculation.[186 187 188 189] This is mainly due to the many common features shared by anxiety and pain. Both have been described in terms of similar physiological

changes (e.g. respiratory rate and cardiac arousal), verbal and non–verbal complaints (e.g. moaning and crying), and behavioural similarities (facial tenseness, visual movements).[185] Clearly these common features fail to differentiate between pain and anxiety. Recent insights have emphasised the need to differentiate between the two and for the use of individual methods of assessment and treatment interventions, (e.g. analgesic and anxiolytic agents).[182] Initially, pain was not assumed to impact on anxiety levels. Literature from the mid 1970's stated that increased anxiety exacerbated pain intensity.[188 189] Thus, consistent with the traditional view of the relationship between pain and anxiety, pain management did not require a differentiation between pain as a somatic state and anxiety as an emotion.

Contradicting evidence, however, bears testimony to the fact that the relationship between pain and anxiety is more complicated. A recent publication reported a lack of empirical evidence and clinical consensus on the causal relationship between anxiety and pain intensity.[24] This relationship is not as linear as was originally assumed since the levels of anxiety may vary according to the intensity of the pain experience. Rhudy et al[25] explained the lack of consensus on the effect of anxiety on pain as the inability to distinguish between fear and anxiety. According to these authors, fear and anxiety can have different effects on pain. Moderate levels of pain and anxiety will increase pain perception, while more intense fear and anxiety will attenuate the perception of pain. In contrast, Weisenberg et al,[190] found pain intensity will increase when anxiety and fear is related to the pain inducing event. Pain inhibition will thus occur when pain and anxiety are unrelated to the pain-inducing event.

Anxiety is furthermore interrelated to the anticipation of pain.[186] Additionally, three independent types of anxiety might present themselves in burned patients, of which only one is directly related to the pain experienced. The first is trait anxiety, i.e. anxiety already present in the pre-burn personality of the patient; the second type is anxiety associated with post traumatic stress, a disorder observed in at least 25% of all burned patients; and lastly, anxiety related to the anticipation of pain.[191] Yet, however complex the relationship between pain and anxiety is for many patients, the experience of pain is universally reduced when anxiety is controlled.[192 193]

Anxiety is therefore viewed as a phenomenon directly related to the emotional state of burned patients, but particularly to the anxiety related to procedural pain, and is thus a part of the management of burn injuries. This understanding of anxiety differs from the understanding used in the field of clinical psychology; a difference illustrated in the use of the DSM IV (diagnostic and statistical manual of mental disorders).[194]

Historically, anxiety disorders have been conceptualised as a non-specific class of childhood emotional or neurotic disorders including depressive, hysterical and obsessional disorders. Today, the field has shifted to greater diagnostic refinement.[195] The DSM IV includes anxiety

as a symptom in a wide spectrum of anxiety disorders such as Panic Attacks, Obsessive – Compulsive Disorders, Post Traumatic Stress Disorders, Acute Stress Disorders, General Anxiety Disorders, and Anxiety Disorders caused by a general medical condition. The latter is of relevance to this study as it was defined as "*being characterised by prominent symptoms of anxiety that are judged to be direct physiological consequences of a general medical condition*". [196]

The phrase "pain and distress" is often used in the literature[24 25 190] and by researchers to describe pain and pain-related fear and anxiety, as well as the agitated behaviour often displayed by children in pain.[197] This phrase acknowledges the fact that the pain experience consists of affective, emotional and sensory aspects and that although pain related distress is highly correlated with pain intensity, the measurement of distress may reflect other emotional reactions (e.g. stress and fear) as well.[197 198] Taal and Faber (1997)[199] have distinguished between general anxiety as described by the DSM IV and pain induced anxiety by stating that: "*since the anxiety of the burned patient is clearly situational specific, it's operation description and assessment separately from related concepts such as general anxiety and related neuroticism, seems appropriate.*"

Seen from this point of view, it is clear that pain and anxiety are different sensations that can affect the emotional and physical states of the burned patient.[193] In this study the phenomenon of anxiety will be approached as described by Taal and colleagues.

4.5.1 Instruments used in the assessment of paediatric anxiety.

It is often difficult to differentiate between pain and anxiety especially in children as assessment discrepancies might occur. For example, staff members might attribute emotional distress to either pain or anxiety. Children might not even be aware that they are anxious or might lack the verbal indicators to suggest that they are.[24] As was discussed previously, emotional distress (anxiety), being part of the pain experience, is an important aspect in the management of pain in burned children.[200] The ability to measure the degree of anxiety during wound care procedures could review the need for the additional management of anxiety, which in turn could result in more effective pain management.[201] Below is a review of studies in which paediatric anxiety measurement were either used or developed.

McGrath (1990)[160] developed the Pain Affect Faces Scale that allows children to choose from a selection of facial drawings, the face that best represents their feelings in relation to their pain. In the implementation of this scale, the child is asked to choose between faces ranging from: "the happiest feeling possible" to the "saddest feeling possible". In this, the accurate assessment of paediatric anxiety will depend on the child's ability to understand distress in such depth that they will be able to depict those feelings.

Chambers et al (1996)[202] developed the Emotional Reactions Checklist where burned children, in the implementation of this measurement tool, must respond to questions about how happy, sad, angry, calm, relaxed, scared or nervous and worried they feel. The accurate implementation of this measurement technique depends on the child's ability to translate fear and feelings of anxiety and apprehension into words and on their ability to select the appropriate word descriptors portraying these feelings.

Sheridan et al (1997)[203] developed analgesic guidelines for effective pain and anxiety management in burned children. Their study described the implementation of a discomfort scale to measure drug efficacy in the management of pain and anxiety in 125 burned children. The presence of pain and anxiety were rated on a 5 point Likert scale with the following indications: 1 = overmedicated, 2 = comfortable but arousable, 3 = some pain / some anxiety with no additional medication required, 4 = pain and anxiety present and require additional medication and 5 = unacceptable pain and anxiety. Although the researchers in this study admitted the discrepancies found in subjective scoring, they still believed that their scoring system, based on the practical judgement of professional nurses, outweighed the potential problems associated with subjectivity amongst clinicians.

No evidence was found in the reviewed literature attesting to the use of the Pain Anxiety Symptoms Scale (PASS) a self-report scale, in the paediatric burn population.[205] The PASS, developed by McCracken and colleagues (1992)[204] was developed to assess the fear of pain in adult patients. Efforts to validate this scale were confined to examining the association between the PASS and other self-report scales such as the Beck Depression Inventory and the Spielberger State-Trait Anxiety Inventory in 98 adult male patients. Items included in the PASS were somatic anxiety, cognitive anxiety, fear and escape or avoidance behaviour.[205]

As was the case with the use of self-report scales in pain measurement, certain methodological inadequacies were found in the use of self-report measures in the measurement of anxiety. For example, children, in implementing these scales, might not be aware of their feelings of anxiety, or might not have the verbal descriptors to describe anxiety, or might give inaccurate descriptions of their anxiety due to defensiveness or social pressure.

In addition, the observational measurement of anxiety has clear advantages over other types of anxiety measures such as self-report, with only relatively minor disadvantages. Some of the advantages are that observations are not based on assumptions about the cognitive ability of the patient to understand measurement requirements, that behaviour ratings are more unobtrusive (unlike, for example, physiological assessments) and that clinicians do not require the same training necessary for the use of self-report scales.[206] Observer bias and a low level of inter-rater disagreement were named as some of the disadvantages found in

observational measurements.[24] However, clearly defined behaviour categories and increased training should reduce low inter-rater agreement.

4.6 Discussion:

Adequate management of procedural burn pain is threatened by lack of insight into the efficacy of the drugs prescribed in the treatment of such pain. The literature emphasises the need to measure the efficacy of drugs[28] to improve the treatment and healing of burn wounds, to determine the pharmacological approach[148] and individual pain needs[143], and to provide subsequent pharmacological adjustments where needed.[148]

Although a variety of pain measurement techniques exist, none was specifically designed for the measurement of procedural burn pain.[24] Clinicians, when attempting to measure procedural burn pain, had to use methods designed for other types of pain (e.g. post - operative pain[176] and cancer procedures[180]). In this regard the literature suggested the use of self–report measures (e.g. visual analogue scales, numeric and word graphic scales and the Faces scales) and observational assessment measures such as the CHEOPS and the OSBD, in combination with physiological measurements such as heart rate, pulse and blood pressure.[22]

However, these methods are methodologically and conceptually flawed. [140] [171] In terms of self–report, physiological and observational measures, methodological deficiencies[33] [160] exist in implementation as well as in proving validity and reliability.[30] [171] Self-report measures require sophisticated cognitive abilities and insight, as well as verbal compliance from sick children.[19] Measures such as the Faces scales or Visual analogue scales were not specifically tested on burned children[24] and the impact of factors such as regression, separation anxiety and burn trauma on the child's ability to report his/her pain were never determined. Pain is also an abstract concept, which may be meaningless to children in the pre-abstract stage of cognitive development.[156] In this context, children's cognitive development and hence their ability to conceptualise pain and illness might affect their understanding of the meaning of pain.[168] Physiological measurements, although able to measure pain, are unable to discriminate between different levels of pain and are questionable in terms of the practicalities of implementation. [63]

The reliability of most measures was tested by showing that the same scores were obtained when either the same phenomena were measured repeatedly, and or when two different raters measured the same phenomena with the same instrument.[30] For self-report measures, none of these methods was reliable in this context due to a scarcity of psychometric values. Pain is a state that can vary dramatically over short periods of time. It is therefore not expected to be the same when measured at different points in time.[30]

Although some of the measures were found to be reliable and valid for what they were designed to measure, their ability to measure burn pain adequately was either not at all or insufficiently determined.[24] Where observational assessment methods such as the OSBD[169] [180]and the PBRS[169] [170] were found to be reliable, only the OSBD[179] and the CHEOPS[176] showed evidence of concurrent validity. Content validity in the assessment process is established by ensuring that the items on the instrument of measurement represent the full range of information important to the concept being measured.[186] Both the Faces scales[163] and the Visual analogue scales[162] have established content validity, although criterion and construct validity is more difficult to recognise. For example, to be able to demonstrate construct validity, measurements of pain intensity should at least correspond with the clinician's theoretical understanding of pain intensity in specific situations such as procedural burn pain. Physiological measurements in this regard, also lack validity, specificity, sensitivity and practicality.[175]

A number of studies used these instruments in the assessment of procedural burn pain but it would appear that they were insufficiently described and that their psychometric soundness as methods in the case of burn pain assessment was assumed rather than tested. For example, the CHEOPS, an instrument widely used in burn pain assessment, was originally designed with the aim of measuring short acute post-operative pain in children aged 2 – 6 years of age.[166]

Conceptual problems were also identified in the implementation of these methods. The majority of these instruments failed to differentiate between the sensations of procedural burn pain and anxiety. Instead, a few techniques measure anxiety[160] [202] [203] only while most measure only pain.[143] [160] [163] [176]179

Anxiety measures made use of mostly verbal descriptors of anxiety [160] [202], thus rendering them inapplicable for use with children who lack the prescribed anxiety indicators in their vocabulary. In essence, the same methodological and conceptual problems found in the implementation of the previously described pain measures, could apply to the anxiety measures.

In conclusion, the need to measure the effectiveness of the pharmacological approach and the discussed criticism of the available pain and anxiety measures, underlined the necessity to develop a more appropriate measurement technique that is valid: reliable, practical, able to discriminate between procedural burn pain and anxiety and has the ability to measure drug efficacy.

CHAPTER 5

The Burn Observational Pain and Anxiety Scale for Burned Children.

Part 1: Methodology

5.1 Introduction

The aim of the study was to determine the validity and reliability of the Burn Observational Pain and Anxiety Scale for burned children, the BOPAS, a measurement scale developed in response to the need for appropriate measures, as was discussed in the previous chapters. The study was also aimed to determine the clinical practicality of the BOPAS technique in terms of the ease and accuracy with which this method could be implemented.

The BOPAS is specifically designed to measure pain and anxiety during wound care procedures. These procedures occur on a daily basis during which dressings are removed, the wounds cleaned, anti-microbial creams applied and recovered with new dressings.

The wound care procedures consist of three observable stages; dressings off, debridement and new dressings on. The BOPAS uses the three stages with a number of observation units that are referred to as categories in each stage. Six pain and anxiety indicators are evaluated per stage: crying, facial expression, verbal indicators, body movement, touch /hand and leg movement. These indicators are also referred to as variables. Various measures use two or more of these indicators to assess pain in children.[28] The Children's Hospital of Eastern Ontario's Pain Scale, the CHEOPS[174] in particular, provided substantial qualitative support for considering these indicators as representative when observing pain.

5.2 The history of the BOPAS scale:

The development of the BOPAS originated from a double blind pharmaceutical trial[207] which was conducted by the author in August 1994 – August 1995 in the burn outpatient clinic of the Red Cross War Memorial Children's Hospital. The aim of this study was to evaluate the efficacy of Myprodol in the management of procedural burn pain. This study included 150 children aged 2–12 years referred to the outpatient clinic with recent minor burn injuries. Participants in this study were divided into two groups. Group 1 (n = 75) received the trial medication, a cherry flavoured analgesic suspension. Group 2 (n = 75) received the placebo cherry flavoured suspension, which had no analgesic properties. Two trained observers, the author of this dissertation and a medical practitioner, scored with the aid of video recordings, the pain behaviour of each individual patient during wound care procedures. The Children's

Hospital of Eastern Ontario's Pain Scale (CHEOPS) was used during these observations. Raw data scores and statistical data were independently assessed and analysed.

Study results revealed the following:
From the time of admission to the removal of the dressing, the mean total pain score increased by 2.3 (median 2.0) from 1.0 (median 1.0) to 3.3 (median 3.0) and by 2.9 (median 2.0) from 0.9 (median 1.0) to 3.8 (median 3.0) in the Myprodol and placebo groups respectively. This resulted in a mean difference of –0.6 (median 0.0) in the change between the two treatment groups.

In Group 1, the drug treatment group, according to the CHEOPS, 77.4% of the patients indicated pain, with 22.6% indicating increased pain intensity *after* receiving the trial drug. The placebo group, (Group 2) showed a decline in pain intensity -thus an improvement- 64.1% indicating no change in pain intensity and in 34.4%, pain intensity apparently increasing.

In explaining the results, it was concluded that while patients in Group 1 might have been effectively treated for pain, observed behaviour indicators indicating pain, could in fact, have been indicative of procedural pain or pain induced anxiety, rather than pain as was assumed. Observations from the placebo group could have been similarly affected. A further conclusion was that the measurement technique, the CHEOPS, was therefore insensitive for the measurement of procedural burn pain and anxiety and as such could not effectively evaluate the drug's efficacy. **This study led to the recognition of the need for a pain assessment method designed specifically for the measurement of procedural burn pain and anxiety in paediatric patients.** An additional consequence of this study was the development of the BOPAS, which was preceded by the observation of 250 wound care procedures in the Burns Unit of the Red Cross War Memorial Children's Hospital.

5.3 Material: The BOPAS measurement scale

The development of the BOPAS measurement scale was primarily a response to the validity and reliability of existing observational behavioural scales as well as the ability to measure anxiety as a separate construct. Furthermore, it was an attempt to improve and formalise the obtaining of an overall score. The hidden factors in the composition of an overall pain score when using many different pain assessment methods, not only complicates duplication of these methods but also, the evaluation of their reliability and higher levels of validity. As a consequence, the use of these methods to evaluate the efficacy of the pharmacological approach to the management of pain and anxiety treatment was questioned. The BOPAS uses the same indicators as other behaviour scales such as the Procedural Behaviour Rating Scale (PBRS),[170 172 178] the Observational Scale of Behavioural Distress (OSBD)[169 170 180] and the most well known scale, the Children's Hospital of Eastern Ontario's Pain Scale

(CHEOPS).[176] However the units of observation in the BOPAS vary specifically to accommodate the measurement of anxiety. Additionally, the BOPAS is aimed at an older age group (2–12 years) and is focussed on 'repetitive pain and anxiety' sensations present at every wound care procedure during the admission period. Younger children display different pain indicators than older children, hence, the exclusion of children younger than 2 years of age.

The following revisions on the pain indicators in the CHEOPS[176] were included in the BOPAS:

(a) Changes in the categories of some of the indicators, e.g. in the category leg movement, the pulling up or pushing forward of the feet, was based on pilot studies of inter alia a pharmaceutical trial. Additional changes were made:

(i) "Facial expression" to include an additional two categories, facial contortion and frozen watchfulness,

(ii) "Verbal expression": to include "not verbal" referring to a child too young to verbally express pain, or unable to express pain due to cultural reasons or due to a facial injury with its accompanying oedema. "Both complaints", as included in the CHEOPS, was excluded from the BOPAS.

(iii) "Touch\hand" behaviour changed with the inclusion of three more categories; trembling, hands balled in a fist and guarding.

(iv) in "body position", tone category, standing, was excluded.

(v) In "body movement" the "upright" as was used in the CHEOPS, was excluded in the BOPAS.

(vi) The evaluation of pain differed from the CHEOPS, firstly, because the literature description of the CHEOPS [2] was unclear about its rating scale and secondly, because the CHEOPS does not differentiate between pain and anxiety.

(b) In the CHEOPS, a value of zero refers to a positive statement or facial expression. The BOPAS scale uses the value (1) to indicate anxiety, whereas the values 2 (two) or 3 (three) indicate pain. The relationship between these values is treated nominally: scores with the values of 1 distinguish anxiety from pain. The difference between a "2" and a "3" in the pain rating is only for observational purposes. Experience showed the need for observers to differentiate between extreme pain levels. The differentiation merely improves the reliability of the observation. Thus, a category indicator could have only one of the following 5 scores or pair of scores, 1-2, 1-3, 1, 2, or 3. In the calculation of pain and anxiety levels, this differentiation is of no importance since the overall score is based on the occurrence of pain and anxiety sensations. Numerical values in the CHEOPS are used to discriminate between the differing intensities of the observed pain behaviour.

(c) In contrast to the CHEOPS, the BOPAS distinguishes three stages in wound management: the removal of bandages, hydrotherapy and cleansing and the re-applying of bandages. In each stage different behavioural categories are observed.

(d) The CHEOPS only observes behaviour indicative of post-operative pain[176], in contrast to the BOPAS where both pain and anxiety are observed. Pain is only scored when observed behaviour occurs in response to definite observable pain inflicted on the child. For example, during wound care procedures, touching the wound or the pulling of bandages stuck to the wound produces pain.

(e) The CHEOPS in its initial development continuously rated post-operative pain behaviour at 5 second observational and 25 second recording intervals[176]. This is in contrast to the BOPAS where indicators of pain and anxiety are only positively identified and accordingly scored when present for 15 seconds or more. This provided for a uniform time interval for the observation of pain and anxiety indicators.

The scoring method for the BOPAS was devised to facilitate the translation of nominal information into numerical data. The total anxiety score was calculated by taking the sum of all the '1' (one) ratings. The total pain score was calculated by summarising the occurrence of all '2' and '3' (two and three) ratings. Overall pain and anxiety scores were calculated by dividing each total score by the number of categories (n = 84). Multiplication of this ratio by 100 gives the percentage of anxiety and the percentage of pain per patient. The mathematical formula to calculate overall scores is:

$$\frac{\sum(n)\,\text{observations}}{(n)\,\text{categories}} \times 100$$

5.4 Procedure:

The protocol of observation is as follows. Prior to the procedure children were medicated with a combination of non–opioid, opioid and anxiolytic agents according to ward protocol. (Appendix .1.) A certain degree of analgesia and anxiolysis prior to the procedure was thus achieved. The time interval between drug administration and pain evaluation could not be controlled. The standard observation form of the BOPAS used during observations is presented in Appendix 2. Observed pain behaviours were identified and scored separately during the three stages of the wound care procedure. Behaviour indicative of pain or anxiety is scored only once per stage, and only when observed for a minimum of 15 seconds. Scores are calculated according to the above-explained method: anxiety and pain were rated on a three-point scale only, to facilitate the observation and rating task. They were treated independently and nominally. Thus, only the frequency of a score was used to evaluate either pain or anxiety by means of the indicators.

5.5 Design:

Behaviour indicative of pain and anxiety was observed and evaluated by using the observation categories in the BOPAS during the wound care procedure. All evaluations took place in the Burns Unit of the Red Cross Children's Hospital. In addition to live observations, video recordings were also made during the wound care procedure. This allowed a set of comparisons to reveal insights into the accuracy of the evaluation and the reliability of the evaluation method: The analysis of video taped material allows a thorough evaluation of the observed situation and a study of a more controlled design. Video taped material was subsequently used to train volunteer users in the BOPAS.

Five studies varying between explorative and quasi-experimental were conducted. The studies were designed to establish different levels of validity and reliability. The relationship between the BOPAS and the CHEOPS and the physiological measurements of respiration and heart rate was investigated as well as the instrument's ability to measure and differentiate between pain and anxiety and to evaluate the efficacy of the pharmacological treatment of pain and anxiety. A series of experiments was conducted to determine the BOPAS's construct and concurrent validity. The remaining series was conducted to demonstrate the reliability of the BOPAS as an instrument, with a standard set of observation units and a key to calculate the overall percentage of pain and anxiety with a test that is practical and easy to apply after a short training period by nursing staff and students.

Validity was analysed at three levels: content, construct and concurrent validity. Content validity was established by using similar indicators to measure pain and anxiety as those used by a variety of other composite scales and in particular the CHEOPS.[28 174] The fundamental difference between the BOPAS and the CHEOPS is found rather in the application of the indicators to evaluate pain and anxiety sensations separately, than in the definition of the indicators. Thus, the representivity of the indicators (items of the scale) was derived from established content validity of similar measurement instruments such as the CHEOPS, the OSBD and PBRS. (See Chapter 4) Construct validity is confirmed by showing the BOPAS's ability to differentiate significantly between the perception of pain and the perception of anxiety. Concurrent validity is established by demonstrating that BOPAS is statistically significant in comparison to other pain and anxiety measurement instruments and criteria.

Reliability was analysed by evaluating the consistency in observations over time, the intra-rater and the inter-rater reliability between observers,. In addition, the intra-and inter-rater reliability was evaluated under different conditions: the evaluation of participant observation versus the evaluation of videotaped and pre-selected events. Finally, the reliability of the training method in the BOPAS was examined by analysing the inter-and intra-rater reliability of subjects exposed to a condensed training period versus the normal one-hour training period.

The following definitions are used: The six pain and anxiety indicators, crying, facial expression, verbal indicators, touch, body (torso) and leg & feet, are interchangeable and referred to as ***'variables'*** or ***'indicators'***. The three sections in the observation procedure are referred to as dressing ***'stages'***. The observation units within each stage are referred to as observation ***'categories'***.

Prior to the presentation of the results of each study, the specific material, design, subjects and procedure of that study are presented.

5.6 Subjects:

In total, 108 patients aged 2–12 years, admitted to the burns unit of the Red Cross Children's Hospital were included in the study. Burn injuries included in the study were minor to moderate, ranging from a 4–35% total body surface area burned. Patients with severe burns or those requiring intensive care were excluded from the study as their wound care procedures were done under general anaesthesia. Only recent burn injuries were included in the study. Behaviour observations were collected during the first wound care procedure post admission, or in the case of one experiment over the first three days post admission.

5.7 Observers:

All assessments from live observations and from video-material of procedural pain and anxiety were performed independently by two trained observers (the author of this study and a health psychologist). The second observer was extensively trained in the implementation of the BOPAS over a period of three months prior to the study. In addition to and dependent on the aim of the study, more observers were trained and instructed in order to assess procedural pain and anxiety independently both in live observations and from video material.

5.8 Ethics:

Informed consent (Appendix 3) was obtained from the parents and caregivers of each child in a written form where possible or else, orally and telephonically. Consent for inclusion in the study and videographing of patients was obtained during patient admissions or as soon as possible afterwards. The obtaining of consent formed part of the parental interviews conducted during the assessment process.

Following is a discussion of the methodology and results of each individual experiment.

Part II: Methodology and Results:

Study 1: Construct validity.

This study was conducted to determine whether the BOPAS is able to differentiate significantly between anxiety and pain observations.

Sample

Fifty-nine patients (38 boys and 21 girls) between the ages of 2 and 11 years, with an average age of 6 years, who were admitted to the burns unit of the Red Cross Children's Hospital, served as subjects. The average total body surface area burned was 21%, ranging from 8% to 35% TBSA burned.

Method

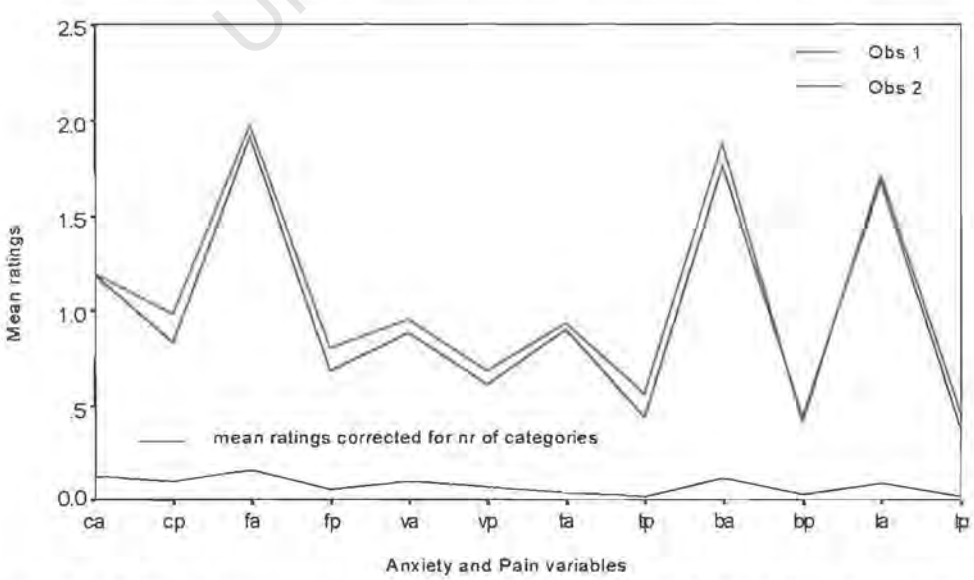
Procedural burn pain and anxiety was assessed with the BOPAS during wound care procedures (dressing changes). The wound-care procedures were video taped. Two observers independently assessed anxiety and pain levels using both live observation and videotaping. Fifty-nine videotaped dressing events were evaluated on line. In addition, twenty-one patients (boys 14, girls 7) between the ages of 2 and 10 years, who were admitted to the burns unit of the Red Cross Children's Hospital, were evaluated during live observations of the dressing procedure. The average total body surface area burned of the subjects was 8%, ranging from 4% to 12%.

Results

Preliminary analysis in which the mean ratings per indicator (variable) were calculated revealed that the ratings fluctuated per indicator and that the pain scores differed from the anxiety scores. Figure 1 presents a graphical representation of the means per indicator and per observer. The first letter of a variable name refers to the indicator and the second letter to either anxiety (a) or pain (p).

Figure 5.1

The mean anxiety and pain ratings per variable and per observer.



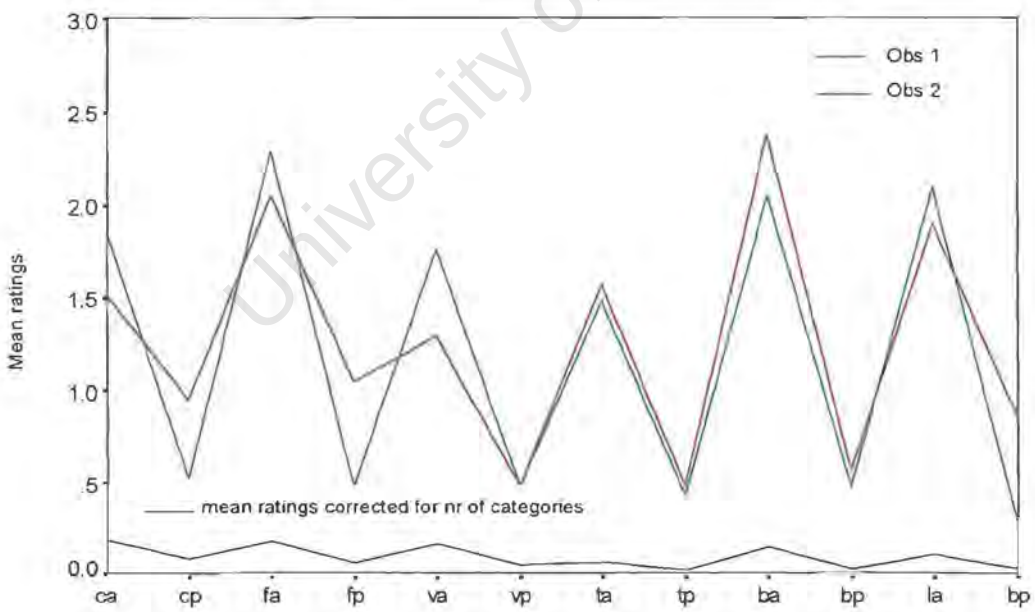
c=crying, f=facial expression, v=verbal indicator, t=touch, b=body(torso) and l=leg & feet.

The coloured lines in Figure 5.1 represent the pain and anxiety ratings from ***videotaped*** procedures by two observers. Both lines seem almost parallel and suggest a high level of inter-rater reliability. The relationship between both observers was r_{xy} =.98, p<.001. The general pattern of the ratings suggests that the patients experience relatively more anxiety than pain: for every variable, pain was observed less frequently than anxiety. Based on the results from this study, it is proposed that the higher incidence of anxiety can be linked to the pharmacokinetic and pharmacodynamic reactions of the administered analgesic and anxiolytic agents.

Figure 5.2 presents a graphical representation of the mean ratings per variable and per observer of the *participant* observations; thus, observations made in real life of 21 subjects. The figure shows the same pattern as the ratings from video shown in Figure 5.1. The relationship between both observers was r_{xy} =.91, p<.001. A slight deviation can be observed in the ratings of pain via crying and facial expression and the ratings of anxiety via verbal indicators. However, these differences, do not disturb the main pattern, which again suggests that the patients experience relatively more anxiety than pain. Thus, the BOPAS appears to be able to differentiate between anxiety and pain under videotaped as well as under live observation conditions.

Figure 5.2

The mean anxiety and pain ratings per variable and per observer.



c=crying, f=facial expression, v=verbal indicator, t=touch, b=body(torso) and l=leg & feet.

The method of observation, live or from video, indicated that neither the sensitivity of the BOPAS to differentiate between anxiety and pain, nor is the inter-rater reliability is affected.

To compare the different variables pain and anxiety accurately, ratings were corrected for the different number of observation categories. Although the number of stages was equal per indicator, the number of observation categories differed, e.g. 'Crying' was rated by three categories per stage whereas 'Touch' was rated by seven categories per stage. Thus, the ratio between the number of observations and the total number of categories gives the relative level of pain and anxiety per variable. The bottom line in the graph represents *the* ratios averaged between both observers.

As indicated by the bottom line of the graph (Figure 5.2), anxiety scores differed from pain scores. The mean anxiety score of the video-taped condition was .11 and the mean pain score was .05. The difference between anxiety and pain scores was statistically significant from zero; $t_{(10)}=2.67$, p=.02. This confirms the descriptive finding above that the BOPAS differentiates between pain and anxiety. Furthermore, anxiety was most frequently observed through the variables 'facial expression', 'crying' and 'body'. The variable 'touch' had the lowest anxiety observations with 'verbal Indicators' and 'leg and feet' in between.

A slightly different pattern was presented when pain was observed. Now, the highest observations were made through 'crying', 'facial expression' and 'verbal indicators'. In contrast, 'body', 'touch' and 'leg & feet' had the lowest pain observations. Table 5.1 presents the corresponding means presented in Figure 5.1.

Table 5.1

The mean values of anxiety and pain per variable by two raters.

Variable	Observer 1			Observer 2			Corr Averaged
	Mean	Std.Dev	Sum	Mean	Std.Dev	Sum	Mean Ratios
ca	1.20	1.16	71	1.19	1.20	70	.13
cp	.98	1.04	58	.83	1.00	49	.10
fa	1.98	1.14	117	1.92	1.13	113	.16
fp	.80	.91	47	.68	.90	40	.06
va	.95	1.02	56	.88	1.07	52	.10
vp	.68	.90	40	.61	.87	36	.07
ta	.93	.98	55	.90	.98	53	.04
tp	.56	.88	33	.44	.79	26	.02
ba	1.88	1.04	111	1.76	.92	104	.12
bp	.41	.72	24	.44	.73	26	.03
la	1.71	1.41	101	1.68	1.40	99	.09
lp	.47	.88	28	.39	.79	23	.02

A Principal Component Analysis (PCA) was thoroughly conducted to explore how the different indicators are interrelated and how they differentiate between anxiety and pain. Since the inter-rater reliability explained more than 96% of the variance and was highly significant, the observations of both observers were averaged and used as dependent variables in further analysis.

A preliminary analysis extracted three Principal Components (dimensions) with the Eigenvalues respectively of: 4.40, 2.58 and 1.13. The first dimension explained 36.6 per cent of the variance, the second 21.5 and the third 9.4 per cent, thus explaining 67.7 per cent of the total variance. Table 5.2 presents the component loadings per dimension and per variable.

The first dimension was dominated by all 'pain' variables. The second dimension was dominated only by three 'anxiety' variables; ca, fa and va. Since the 'pain' variables, cp. fp and vp have negative loadings; the relationship between pain and anxiety was reciprocal on this dimension. Finally, the 'anxiety' variables la, ba and ta defined dimension three. These variables appear to measure different aspects of anxiety from those done through the observation of 'crying, 'facial expression' and 'verbal indicators'. Thus, evaluating anxiety by 'leg & feet', 'body' and 'touch' does not seem strongly related to the evaluation of either pain or anxiety by means of the other indicators. Furthermore, the table indicates that the commonality of the observation of anxiety through 'touch' (ta) is relatively low.

Table 5.2

The component loadings and commonalities of a three dimensional Principal Component Analysis (PCA)

Variable	Dimension 1	Dimension 2	Dimension 3	Communality
ca	.069	.832	.229	.750
cp	.822	-.178	.214	.754
fa	-.363	.725	-.001	.657
fp	.859	-.324	.070	.848
va	.197	.722	.371	.697
vp	.731	-.141	.144	.576
ta	.237	.256	.513	.387
tp	.863	.170	-.085	.780
ba	.135	.057	.737	.565
bp	.868	.279	-.001	.831
la	-.197	.171	.776	.669
lp	.766	.090	.030	.596

Since the observation of anxiety through 'leg & feet', 'body' and 'touch' deviated from the general pattern, a two dimensional PCA was conducted on all the variables excluding the three deviating 'anxiety' variables. The Eigen values of dimension one and two were 4.27 and 2.11 and explained respectively 47.4 and 23.4 per cent of the variance. Hence, both dimensions together explained 71%, which is a significant improvement compared to the 67.7% of the three dimensional solution.

Table 5.3 presents the factor loadings and the commonality per variable of the two dimensional solution. The variables contributed between 57 to 84 per cent of their variance to the total fit, indicating that all variables were important. Once again, the first dimension refers to pain and the second dimension to anxiety. The high component levels and the reciprocal relationship between anxiety and pain support the assumption that these constructs are separately observable and that the measurement instrument differentiates between pain and anxiety.

Table 5.3

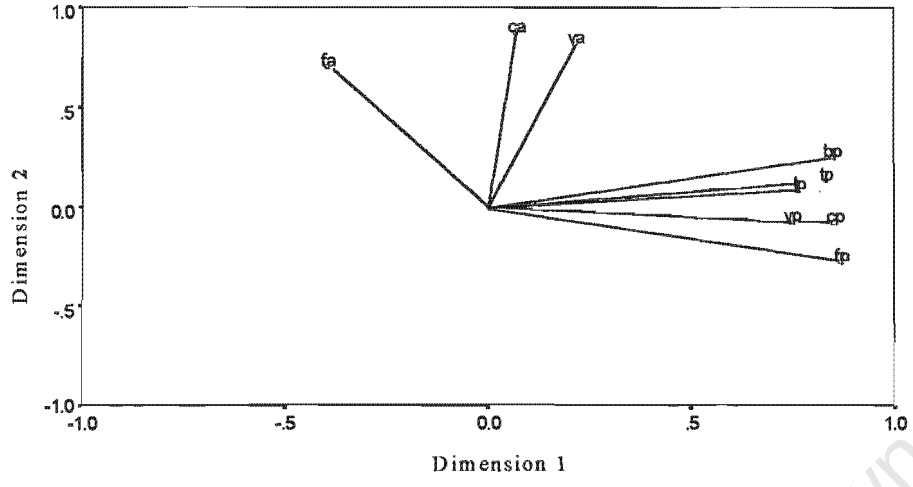
The Component loadings and commonalities of a two dimensional PCA after removal of the anxiety scores of 'touch' (ta), 'body' (ba) and 'leg & feet' (la).

Variable	Dimension 1	Dimension 2	Communality
ca	.073	.874	.770
cp	.856	-.077	.738
fa	-.392	.707	.653
fp	.873	-.278	.839
va	.217	.819	.717
vp	.751	-.076	.570
tp	.834	.133	.715
bp	.848	.249	.782
lp	.767	.085	.595

The inter-relationship between the 'anxiety' and 'pain' indicators is easier to interpret by analysing the graphical representation of the component loadings. Figure 5.3 shows how the 'anxiety' and 'pain' variables are grouped into two clusters. These clusters again confirm the assumption of two different constructs underlying the observations. Although anxiety observed through facial expression seems less strongly related to both other anxiety variables, it still is more closely related to anxiety than to pain. In contrast to 'crying' and 'verbal indicators, where pain and anxiety were almost perpendicular to each other, anxiety and pain observations through 'facial expression' were rather each other's opposite. The angle between facial anxiety ('fa') and facial pain ('fp') was moderate and suggests a negative correlation between these variables.

Figure 5.3

The graphical representation of the component loadings of the 'anxiety' and 'pain' variables.



To test whether the above results were statistically significant, a 2X2 multivariate analysis of variance (MANOVA) was conducted with the first factor both observers, the second factor anxiety and pain sensation and with the six indicators as dependent variables.

As expected, the multivariate as well as the univariate tests on the first factor showed no significant difference between both observers; with P>.50. This confirms the inter-rater reliability. The multivariate test between anxiety and pain, the second factor, was statistically significant: $F_{(6,227)}$=.53, P<.001. This implies that a linear combination of the six indicators successfully differentiates between anxiety and pain sensations. This is an insight that is of particular significance to the construction of a separate pain and anxiety impression per patient. The results of the univariate analysis are presented in Table 5.4 and show that the difference between anxiety and pain was statistically significant from zero with P<.05 .

Table 5.4

The F ratio and P values of testing the difference between the anxiety and pain ratings per variable (df 1,232).

Variable	F ratio	P value
crying	4.03	.046
facial	82.39	.000
verbal	4.62	.033
touch	12.28	.001
torso	155.94	.000
leg & feet	70.46	.000

Study 2: Concurrent validity.

Concurrent validity was evaluated by comparing the new behavioural observation instrument with:

(i) Another psychometric measurement scale, and with

(ii) Physiological measurements as well as

(iii) Examining its efficacy in detecting the effects of pharmaceutical pain and anxiety management.

Three series of studies were designed for this purpose. The first one was aimed at comparing the BOPAS with The CHEOPS. The second one was aimed at investigating the relationship between respiratory and heart rate, and procedural anxiety and pain as measured with the BOPAS. Thus, the respiratory and heart rate of each patient was measured before and after the dressing procedure. The third sub-study was designed to investigate whether the BOPAS was sufficiently sensitive to detect differences in pain and anxiety levels due to delays in medication. These delays were not experimentally manipulated but caused by external factors. Twenty-five new patients were observed over a period of three days for this purpose.

The purpose of this study was to establish concurrent validity by analysing how the BOPAS relates to the CHEOPS after transforming its two constructs, anxiety and pain, into a composite score. The overall relationship as well as the interrelationships between the indicators of both methods was investigated.

Sample

Another forty-three patients (28 boys and 15 girls) between the ages of 2 and 11 years (average age 7 years) who were admitted to the burns unit of the Red Cross Children's Hospital served as subjects. The average total body surface area burned was 15%, ranging from 6% to 27%.

Method

Procedural burn pain and anxiety during wound-care procedures was assessed with the BOPAS and with the CHEOPS from video taped material. Two observers assessed independently, the anxiety and pain levels on line from video using a "within and between subject" design. To control repetition and interference, a time-delay of a month and an interference task of new observations were used in addition to a randomisation of 59 target events amongst a total of 80 events. Observers were unaware of the design. Furthermore, respiratory and heart rates were measured before and after the wound care procedure. The purpose of these measurements is explained in the next section; 'Study 3'.

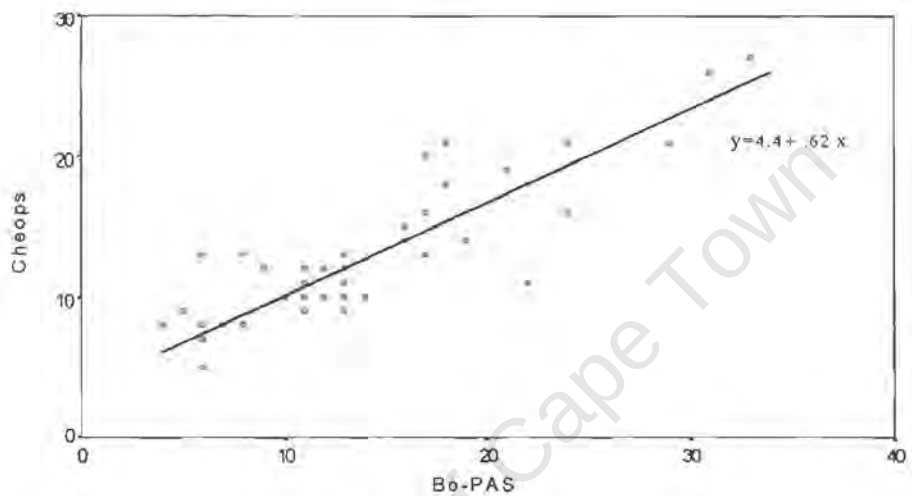
Results

A number of analyses were conducted to compare the BOPAS with the CHEOPS. Since BOPAS was designed to measure two separate constructs, pain and anxiety, a composite BOPAS score was needed to allow the comparison. In contrast, the CHEOPS scale is

conceptually an integrated anxiety and pain score. Since the analysis above allowed a linear combination between the variables, both anxiety and pain ratings of the BOPAS were summed over the six variables and transformed to a composite scale. Figure 5.4 represents the relationship between both methods: r_{xy}= .87 , p<.01 .

Figure 5.4

The relationship between the BOPAS and the CHEOPS based on their overall scores.



To examine the relationship between the indicators of both methods, first a canonical correlation was calculated. A one dimensional canonical correlation, in which a linear combination of the set of variables of the CHEOPS was correlated with a linear combination of the set of variables of the BOPAS, was R_c= .92. The canonical loadings, presented in Table 5.5, appeared similar between both methods. With both methods, only 'facial expression' seems less related to the other variables.

Table 5.5

The canonical loadings of a one-dimensional canonical correlation between the CHEOPS and the BOPAS.

	CHEOPS	BOPAS
Crying	.91	.89
Facial Expression	.39	.29
Verbal Indicators	.55	.77
Body(Torso)	.72	.79
Touch	.61	.70
Leg & Feet	.60	.61

The variance of the component loadings of the variables of the BOPAS with the exception of 'facial expression', was less than that of the CHEOPS. This suggests that the BOPAS is more consistent in measuring a combined pain and anxiety score than the CHEOPS (Table 5.6).

Table 5.6

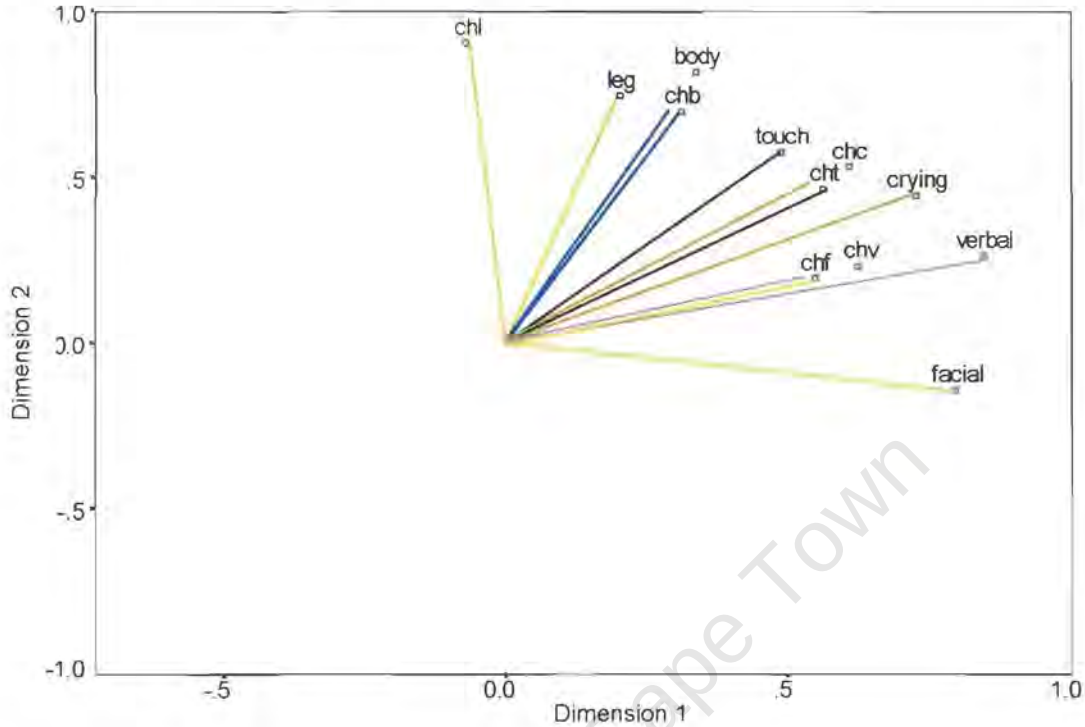
The descriptive statistics of the component loadings of the indicators of combined pain and anxiety with the exception of 'facial expression'.

Variable	Mean	Std Dev	Variance	Range	Sum	No
CHEOPS	.68	.14	.02	.36	3.39	5
BOPAS	.75	.10	.01	.28	3.76	5

A Principal Component Analysis was used to thoroughly analyse how the variables of both methods are interrelated. A two dimensional PCA with the Eigenvalues of 5.93 and 1.61 explained 63% of the total variance. Figure 5.4 shows how the variables of both methods are interrelated. The CHEOPS method is indicated by the abbreviation 'ch' followed by the first letter of the variable. For example, 'chb' stands for the CHEOPS rating of the variable 'body', whereas 'body' refers to the BOPAS rating of the same variable. To evaluate the relationship between the methods, six different colours are used to represent each variable. Figure 5.5 reveals that the same indicators of both methods are strongly associated, in particular the variables 'body' (blue), 'verbal' (purple), 'touch' (black) and 'crying' (brown).

Figure 5.5

The graphical presentation of the inter-relationship between variables and both methods.



The commonalities of variables presented in Table 5.7 again showed a pattern in which the BOPAS seems more consistent than the CHEOPS.

Table 5.7

The commonalities of the overall pain and anxiety indicators per method of observation.

Method	Variable	Commonality
CHEOPS	Crying	.66
	Facial	.35
	Verbal	.45
	Body	.59
	Touch	.54
	Leg	.83
BOPAS	Crying	.73
	Facial	.66
	Verbal	.79
	Body	.79
	Touch	.58
	Leg	.60

Since the transformed BOPAS differs only in the measurement of an overall score, (the CHEOPS gives an integrated score whereas the overall score of the BOPAS consists of the sum of separate anxiety and pain scores), a reliability test of the indicators (items) should reveal whether the BOPAS is indeed more consistent than the CHEOPS.

The results of two reliability tests confirmed the previous insights. The CHEOPS reached a Cronbach α reliability coefficient of .74 whereas the BOPAS achieved .85. A Fisher Z transformation of the coefficients demonstrated a significant difference between the coefficients at P=.06. The statistics of the reliability tests are presented in Tables 5.8 a and b.

Table 5.8a

The statistics of Cronbach α reliability test of the CHEOPS (n=43)

Items	Scale	Scale	Corrected	
	Mean if Item Deleted	Variance if Item Deleted	Item Total Correlation	Alpha if Item Deleted
Crying	10.16	14.71	.62	.71
Facial	11.47	22.11	.42	.76
Verbal	11.74	21.86	.50	.75
Body	10.72	18.30	.61	.71
Touch	11.44	16.30	.58	.72
Leg	10.74	17.58	.51	.74

Table 5.8b

The statistics of Cronbach α reliability test of the BOPAS (n=43).

Items	Scale	Scale	Corrected	
	Mean if Item Deleted	Variance if Item Deleted	Item Total Correlation	Alpha if Item Deleted
Crying	12.12	34.68	.74	.79
Facial	11.47	42.68	.42	.85
Verbal	12.70	37.55	.69	.80
Body	11.89	35.95	.72	.79
Touch	12.72	33.64	.66	.81
Leg	11.79	35.60	.52	.84

Study 3: Concurrent and Content Validity.

The purpose of this study was, as part of the concurrent validity study, to investigate how the BOPAS relates to two physiological measures, respiratory rate and heart (pulse) rate.[24] As discussed in previous chapters, these measures are considered to be associated with pain and anxiety.

Sample

Respiratory and heart (pulse) rates of the forty-three patients that served in the study presented above were measured. Twenty-eight boys and fifteen girls between the ages of 2 and 11 years (average age 7 years) who were admitted to the Burns Unit of the Red Cross Children's Hospital, served as subjects. The average total body surface area burned was 15%, range 6% to 27%.

Method

The respiratory and heart rate of each patient were measured manually before and after the wound care procedure. Procedural burn pain and anxiety during wound-care procedures were videotaped and assessed with the BOPAS and the CHEOPS, as explained in the previous study. It was hypothesised that since respiratory and heart rates are known to be associated with pain and anxiety sensations, the composite BOPAS score should be at least moderately predicted by the respiratory and heart rate values and in the same range as the CHEOPS. A number of analyses were conducted.

Results

The results of a paired test reviewing the differences between respiratory and pulse measurements pre- and post- procedure are presented in Table 5.9. No statistical significant difference was found between pre- and post respiratory rate measurement $t_{(42)}$= -.40, p=.70 and between pre- and post- pulse measurement $t_{(42)}$= -.20, p=.85. Table 5.9 represents the descriptive statistics.

Table 5.9

The descriptives of pre- and post respiratory rate measurements.

Variable	N	Mean	SD	Min	Max
Resp1	43	26.42	5.78	20	40
Resp2	43	26.84	6.45	16	48
Pulse1	43	125.53	18.25	90	178
Pulse2	43	125.12	20.77	90	172

On the basis of these results pre-and post- respiratory values were averaged to a single value per patient. Likewise the average of the pre-and post-pulse values was calculated. The Pearson product moment correlations between the physiological measures and, respectively, the BOPAS pain and anxiety composite scores and the CHEOPS scores are presented in Table 5.10.

Table 5.10

The Pearson Correlation between the physiological and behavioural measurements.

	BOPAS	CHEOPS
Respiratory	.54	.56
	P <.01	P <.01
Heart rate	.11	.22
	P = .11	P <.16

Table 5.10 shows that respiratory ratings are more strongly associated with both behavioural scales than pulse ratings. A linear regression analysis in which the composite pain and anxiety scores of the BOPAS were predicted by the respiratory values, showed a significant contribution ($p<.01$) of respiratory rates in the prediction. The model explained 30 per cent of the variance ($R_y= .54$). The regression coefficient and constant were:

$$\mathbf{BOPAS_i = .76\ resp_i - 5.88}$$

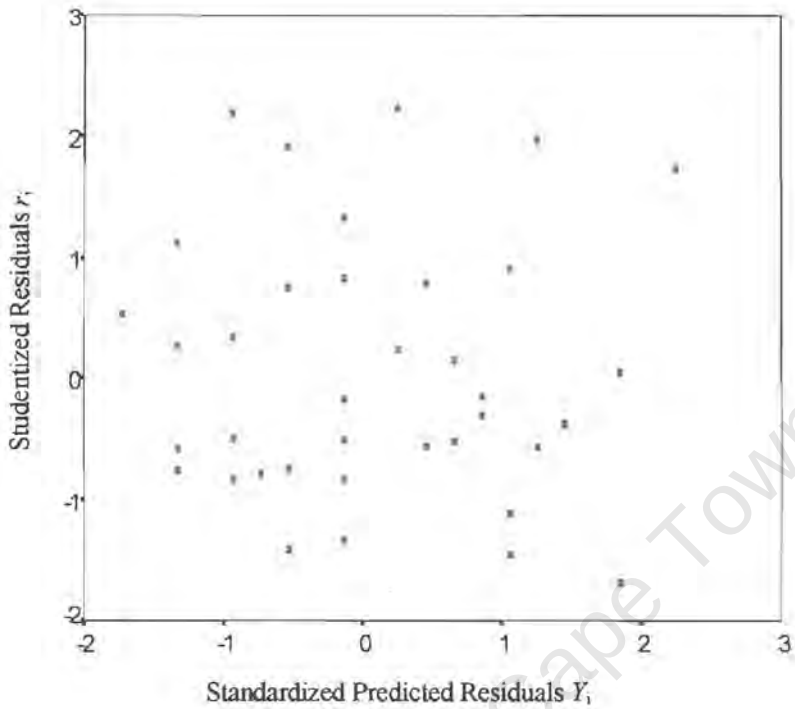
The same regression model was used to analyse the performance of the CHEOPS. Similar results to the BOPAS were found, with a minimal increase in the regression correlation: $R_y= .56$. The regression coefficient and constant were:

$$\mathbf{CHEOPS_i = .57\ resp_i - 1.75}$$

Figure 5.6 shows the 'accuracy' of the regression model:- there is no relationship between the (studentized) residuals and the (standardised) predicted residuals of the BOPAS.

Figure 5.6

The analysis of the residuals of the regression model predicting the BOPAS overall score from respiratory values.



Study 4: The ability to measure drug efficacy:

A quasi-experimental 'double blind' study was designed to investigate whether the BOPAS was sufficiently sensitive to detect differences in pain and anxiety levels due to delays in medication. It was hypothesised that if the BOPAS is a measurement of both pain and anxiety, then changes in medication (analgesics and anxiolytics) should be reflected in the scores. The delays were not experimentally manipulated but caused by external factors.

Sample

Twenty five patients (13 boys and 12 girls) between the ages of 2 and 12 years (average age 6) who were admitted to the Burns Unit of the Red Cross Children's Hospital served as subjects. The average total body surface area burned was 13%, ranging from 4% to 22%.

Method

This study included the first three wound care procedures post burn. The rationale for this has been that the majority of wounds were minor to moderate in size and that patients were discharged on day 4 or 5. To ensure continuity, the decision was made to include a three-day admission period. Two observers evaluated the pain and anxiety levels with the use of the BOPAS during wound care procedures. The study was conducted with a few fixed conditions: the time of day factor, the medication and procedural wound care protocol and the rating procedure of anxiety and pain with the BOPAS. Homogeneity of the sample was controlled by the age of the patients and by the inclusion of recent burn injuries. Participant observations were used to rate anxiety and pain levels. Medication and dosages of anxiolytics and analgesics were registered. Observers were only informed after pain and anxiety ratings about the time delays. Fluctuations in the delay between medication and burn care procedure were registered but not controlled and were due to external circumstances. The analysis was explorative and based on the distribution of the administration of the pain and anxiety drugs over time periods. Five patients were excluded from the study due to missing data.

It was assumed that drugs, reduced sensations of pain and anxiety when administrated in the prescribed period of time preceding the wound care procedure. By interacting with the healing and management process, a decrease in pain and anxiety towards a more stable level is expected in the first three days. Since deprivation of pain and anxiety treatment for experimental purposes was not possible, the first step of the analysis was aimed at showing that BOPAS is able to register a decrease of pain and anxiety during the first three days of treatment. The second step of the analysis was aimed at examining whether BOPAS is sensitive to subtle variations in pain and anxiety levels due to delayed administration of drugs after the procedure.

Step1: Figure 5. 7 show a steep drop in anxiety and pain levels over 3 days. Pain reached its baseline at the end of the second day and remained almost constant on the third day.

Anxiety levels, in contrast, continued to drop almost linearly during the three days. The corresponding descriptive statistics are presented in Table 5.11.

Figure 5.7

The relationship between anxiety and pain levels per day

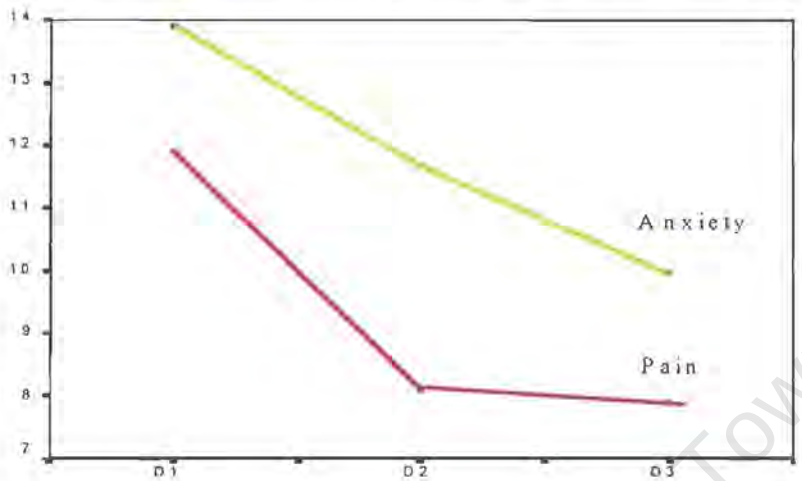


Table 5.11

The results of a descriptive analysis of the anxiety and pain levels per day.

		Mean	Std. Error	95% Confidence Interval	
Day 1	**anxiety**	13.900	1.312	11.245	16.555
	pain	11.900	1.312	9.245	14.555
Day 2	**anxiety**	11.650	.980	9.665	13.635
	pain	8.100	.980	6.115	10.085
Day 3	**anxiety**	9.950	.882	8.165	11.735
	pain	7.900	.882	6.115	9.685

A repeated measure ANOVA showed that the anxiety levels were significantly higher than the pain levels: $F_{(1,38)}=4.57$, $p < .04$. The multivariate test showed that the decrease over the days was statistically significant; $F_{(2,37)}=8.84$, $p < .01$. Univariate tests showed that pain levels remained constant between day 2 and day 3; $t_{(19)}=2.31$, $p>.10$. The difference between mean pain and anxiety levels at day 3 was not statistically significant from zero; $t_{(38)}= 1.64$, $p>.10$.

Step 2: The second step of the analysis was aimed at examining whether BOPAS was sensitive to subtle variations in pain and anxiety levels due to delayed administration of drugs after the procedure. Ethical reasons did not allow researchers to manipulate the time interval of drug administration experimentally. However, due to external factors, the timing of drug administration varied between 30 minutes to a maximum of 180 minutes before commencement of wound care procedures. According to protocol specifications (Appendix 1), drugs are most effective when administrated within a period of 60 minutes. Hence, two

categories were composed: Category one represents patients who received medication within the 60 minutes interval and Category two represents patients who received medication with an interval of more than 60 minutes. It was assumed that if the BOPAS is valid and sensitive, the effect of the delay in administration should be shown as a positive relationship between anxiety and pain levels and the delay of the drug administration.

Figure 5.8 presents the effect of the time delay on the mean *anxiety* level per day. Figure 5.9 presents the effect of the time delay on the mean *pain* level per day. Both figures show that drug administration within the 60 minute interval reduces pain and anxiety levels more effectively than after a 60 minute time interval. However, after three days, the influence of time delay on the mean anxiety levels seems to disappear. This suggests that after three days the anxiety levels related to the procedure are lower.

Figure 5.8

The effect of time delay on anxiety levels

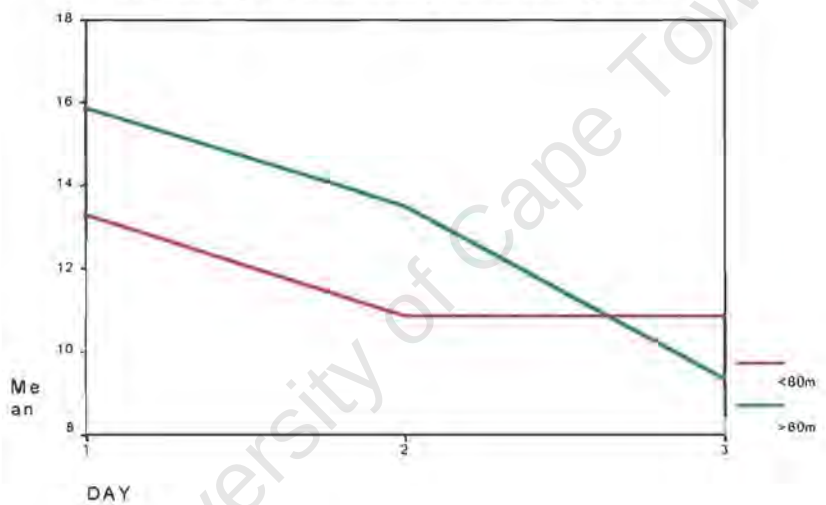
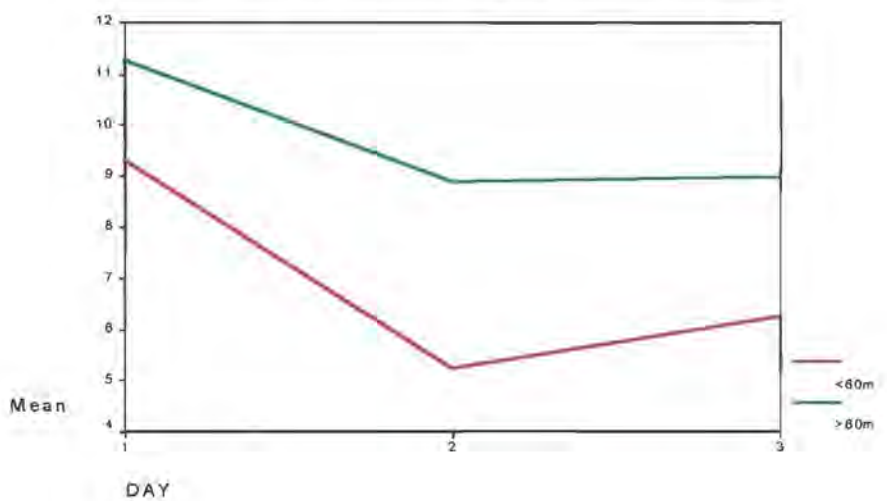


Figure 5.9

The effect of time delay on pain levels



In contrast to anxiety, the delay in the treatment of pain through medication seems almost constant over the second day.

Table 5.12 presents the corresponding results of both figures. The sample sizes and the fluctuation between-and within measurements did not allow statistical testing of the difference in time delay over days. Nevertheless, the results do show that BOPAS was sufficiently sensitive to detect the more subtle difference in pain and anxiety levels due to short - term delays in drug administrations.

Table 5.12

The mean anxiety and pain levels per time interval per day

	Day 1		Day 2		Day3	
	<60min	>60min	<60min	>60min	<60min	>60min
Anxiety	13.33 n=3	15.90 n=21	10.88 n=8	13.53 n=17	10.88 n=8	9.33 n=12
Pain	9.33 n=3	11.29 n=21	5.25 n=8	8.88 n=17	6.25 n=8	9.00 n=12

Study 5: Reliability of the BOPAS.

The results of the studies presented above suggest that the BOPAS is a potent instrument for measuring pain and anxiety during the wound care procedures of burned children between the ages of 2 and 12 years. This part of the study was aimed at demonstrating the reliability of the instrument.

The reliability of the method was already indicated in the experiments aimed at showing the validity of the BOPAS. The inter-rater reliability ranged between .91 and higher. Furthermore, it was shown that the conditions under which the BOPAS was applied, did not affect the reliability coefficient of the instrument. The inter-rater reliability in the laboratory set-up where on-line observations were made from video was r_{xy} =.96, p<.001. The inter-rater reliability in the participant observation set-up where observation was made live during the wound care procedure, was r_{xy} =.91, p<.001. These results supported the conclusion that observations from video are as representative as real life observations when BOPAS is used as designed. The following experiments were designed to evaluate the reliability of the BOPAS when using a larger group of observers. Once again, reliability was tested under two experimental conditions: a standard training in the BOPAS before applying the instrument versus a condensed 30-minute training.

The purpose of this study was to further evaluate the reliability of the BOPAS by evaluating the performance of 44 participants in the application of the BOPAS after a training session in how to utilise the instrument. Performance was analysed by means of both a reliability and an accuracy test.

Sample

Forty-four (44) volunteer health professionals served as participants of whom 30 were nursing professionals of various levels of training and experience, 4 psychology students and 10 paramedic professionals, all working at the Red Cross Children's Hospital.

Material

The 'training material' consisted of a sample of 60 patients who had been videotaped during the dressing procedures. The sample was a random compilation of videotaped material used in the studies mentioned above. The 'evaluation material' consisted of three patients previously not included, video-taped during dressing procedures. The first patient displayed a variety of anxieties, the second displayed behavioural indicators of both pain and anxiety and the third patient's behaviour appeared to be that of an almost over sedated patient. These three profiles were considered as representative for they showed explicit pain and anxiety as well as masked forms of pain and anxiety sensations. A manual of the BOPAS (see Appendix 2) was handed out as part of the training course.

Method

The first thirty-four (34) trainees were divided into 5 groups and trained for a one-hour period in the BOPAS. Training was provided by the author and the second observer and involved a formal lecture and practice in evaluating procedural pain and anxiety from video with the BOPAS. After a delay, trainees were instructed to score procedural pain and anxiety behaviour of the three evaluation patients from video.

An additional group of ten nurses with burn experience, were trained for 30 minutes only. It was assumed that, if a shorter training period is possible, more experienced and professional nurses will be required. The training consisted of a shortened version of the same lecture with illustrative material. However, trainees were not given practise in observation from video. Only two of the three evaluation videos were used (patient three was excluded). The reason was external; although evaluations from video could be interrupted, on line video evaluation is time consuming and it appeared difficult for the nursing staff to make themselves available for the time required

Results

Since the reliability of an instrument does not necessarily imply accurate use, the analysis was conducted in two steps. Firstly, the reliability of the BOPAS subjected to both training methods was analysed. Secondly, the accuracy of the scoring of the trainees was analysed.

Step1a: The reliability of the BOPAS after standard training. The reliability between the subjects (N=34) was evaluated by representing the categories of the indicators as rows and the subjects as columns. In addition, a Q analysis was conducted by means of a one-dimensional PRINCALS. PRINCALS can be regarded as a non-linear Principal Component Analysis suitable for non-metrical data.[208] In contrast to PCA, the Eigenvalues are analogous to the amount of explained variance. Responses were treated at an ordinal scale measurement and were analysed per patient, thus requiring three separate analyses. Table 5.13 presents the Eigenvalues of the analysis. The second column of the table presents the Eigenvalues with all trainees included. The third column presents the Eigenvalues after three trainees with strongly deviating answering patterns per condition were removed from the analysis.

Table 5.13

The Eigenvalues of a one dimensional PRINCALS with the trainees as variables.

	Eigenvalue n=34	Eigenvalue after removal of extremes n=31
patient 1	.80	.84
patient 2	.68	.72
patient 3	73	.77

The Eigenvalues in Table 5.13 revealed that between 72 and 84 per cent of the total variance was explained by the consistency of the ratings between the trainees; thus, the inter-correlations varied between .85 and .92, indicating a high level of inter-rater reliability.
In Table 5.14 (See Addendum), the frequencies of the ratings per condition are presented. Only patient one seemed to show severe pain. The pain ratings of patient two and three were all of a moderate level.

Step1b: The reliability of the BOPAS after condensed training. In order to evaluate whether the training period could be shortened without threatening the reliability, another ten participants (nursing professionals) were intensively trained for 30 minutes. Table 5.15 presents the Eigenvalues of the analysis in the same format as Table 5.13. In the evaluation of both patients, again three trainees produced a deviant pattern from the remaining trainees and were removed from the analysis (see the third column).

Table 5.15
The Eigenvalues of a one dimensional PRINCALS with 10 trainees as variables.

	Eigenvalue n=10	Eigenvalue after removal of extremes n=31
patient 1	.55	.75
patient 2	.48	.56

The Eigenvalues in Table 5.15 show that a short training period resulted in more variability in the responses as compared to the responses of participants with extensive training. Furthermore, the ratings of patient 2 seemed to show more variance than the ratings of patient 1. Between 56 and 75 per cent of the total variance was explained by the consistency of the ratings between the trainees, whereas, when extensively trained, 72 and 84 per cent was explained by the consistency of the ratings of patient 1 and patient 2 respectively. Although the consistency dropped, the intercorrelations were still considerable: .87 and .75 respectively. In Table 5.16, the corresponding frequencies of the ten trainees are presented per condition and rating category.

Table 5.16
The frequencies of the anxiety and pain ratings per condition for 10 trainees trained in a short training-period.

Trainee	Patient One				Patient Two			
	no pain or anxiety	anxiety	mod pain	sev pain	no pain or anxiety	anxiety	mod pain	sev pain
T1	142	14	11	1	148	11	9	0
T2	150	8	9	1	157	9	2	0
T3	144	11	12	1	160	6	2	0
T4	144	16	8	0	158	8	2	0
T5	141	14	13	0	155	6	7	0
T6	139	15	13	1	148	15	5	0
T7	145	13	9	1	152	13	3	0
T8	147	9	12	0	156	10	2	0
T9	142	13	12	1	157	7	4	0
T10	140	11	17	0	159	7	2	0

Step 2: The accuracy of the ratings. The following analysis was conducted to evaluate the accuracy of the ratings of both the 34 participants given standard training and the 10 participants given condensed training. The ratings were averaged over the valid number of subjects per patient. Thus, for each of the six variables (crying, facial, etc), a single score was calculated by taking the sum of the ratings of all subjects and dividing the sum by the number of subjects. The number of valid subjects was thirty-one for the extensive training and seven for the short training. The averaged score was then rounded and correlated with a criterion score. The criterion scores constituted the anxiety and pain ratings of the three patients by the designer of the BOPAS and the second observer from the studies above. The correlations between the averaged score of the trainees and the criterion rating per condition are presented in Table 5.17.

Table 5.17
The correlations and significance levels of the trainees with a criterion per condition to evaluate the accuracy of the trainee's ratings.

Criterion	Trainees				
	Extensive training			Condensed training	
	n=34 Patient 1	n=34 Patient 2	n=34 Patient3	n=10 patient 1	n=10 patient 2
Patient 1	.64 P= .025	-	-	.075 P= .815	-
Patient 2	-	.93 P<.01	-	-	.29 P= .364
Patient 3	-	-	.86 P<.01	-	-

From Table 5.17, it became evident that the levels of inter-rater reliability do not necessarily imply a high level of accuracy. In particular, the accuracy of the ratings of patients two and three by the extensively trained group, were highly accurate. However, the accuracy of ratings by the subjects trained for a short period of time, was poor.

In summary, the results of the five experiments discussed in this chapter have supported the Burn Observational Pain and Anxiety Scale's (BOPAS) claim to validity and reliability. In this, the method showed validity for both construct and concurrent validity. Results have shown that the BOPAS was able to discriminate between pain and anxiety indicators in live as well as videotaped procedures.

Subsequent experiments have supported the BOPAS's claim to construct validity in confirming the measurement of the two different constructs, pain and anxiety. Concurrent validity was determined by a comparison of the BOPAS and the internationally accepted Children's Hospital of Eastern Ontario's Pain Scale (CHEOPS). Results have supported the BOPAS's ability to differentiate more consistently between pain and anxiety when compared to the CHEOPS, which was designed to measure post - operative pain. As was suggested by the literature[152] [153], a physiological pain measurement (heart rate and respiratory rate) was included in the study. An analysis of the association between the physiological measurement of pain and anxiety and the two observational scales the BOPAS and the CHEOPS have revealed a stronger association with heart rate as a pain indicator.

Furthermore, the BOPAS's ability to detect changes in behavioural responses related to changes in drug administration supported the scale's ability to evaluate the efficacy of prescribed drugs. Subsequently, two or more observers were used in determining the BOPAS's reliability. Two experiments were conducted to establish inter rater reliability, first

through the use of videotaped material and subsequently using live observations. Additionally, a deeper level of reliability and accuracy was established through the evaluation of the ability and accuracy of 44 health professional volunteers in the use of the BOPAS.

Chapter 6

Discussion

Five experiments were conducted to evaluate the Burn Observational Pain and Anxiety Scale's (BOPAS) validity and reliability as an instrument to measure procedural pain and anxiety. Different levels of validity were evaluated. Content validity was preserved by applying observation units used by most well known pain rating scales, such as the PBRS[180] (Procedural Behavioural Rating Scale) and the CHEOPS[176] (Children's Hospital of Eastern Ontario's Pain Scale) as indicators of pain and anxiety behaviour. However, content validity is rather a pre-condition than a specific measurement level sufficient to claim validity of an instrument with properties to evaluate pain and anxiety and therefore, the efficacy of pain and anxiety treatments.

To evaluate the construct validity of the BOPAS, a level at which most instruments in the field of procedural and post-operative pain seem to operate, an in-depth analysis of the interrelationship between the observation units in the context of both constructs, pain and anxiety, was conducted. The results support the BOPAS' claim to be able to differentiate between procedural burn pain and anxiety while observing pain and anxiety behaviour in reaction to wound care procedures. If the BOPAS is indeed able to measure pain and anxiety as two different constructs, the hypothesis that the pain and anxiety levels of a sample of patients should not differ must be rejected. Figures 5.1 and 5.2 showed that evaluations made with the BOPAS under live conditions (participant observation) as well as under experimental conditions (evaluation of video-taped procedures) differentiate between pain and anxiety. Subsequent analysis showed that the difference between pain and anxiety was statistically significant from zero, after correction of the incongruity of the 'indicator-categories'.

The analysis furthermore revealed that the mean anxiety scores were relatively higher than the mean pain scores. One of the reasons explaining the lower incidence of pain is related to the wound care procedure used at the Red Cross Children's Hospital. Prior to wound care procedures, patients are medicated with both analgesic (Paracetamol, Codeine Phosphate and Ibuprofen) and anxiolytic (Midazolam) drugs. Burn injuries have the ability of not only enhancing the metabolic rate of patients, but also of adjusting the pharmacokinetics of prescribed drugs. This could affect the efficacy of the drugs.[99] For example, animal studies revealed an increased analgesic potency effect in animals when opioid agents are administered immediately post burn.[209] Prescribed analgesics could therefore have a greater than anticipated effect on burn pain, leading to lower pain levels when measured. In contrast to pain, anxiety was treated with the anxiolytic agent Midazolam. Midazolam is a short acting and rapidly absorbed drug, with peak plasma concentrations achieved within 20–60 minutes

of administration.[24 80] Any delay between drug administration and procedure could lead to a loss in anxiolysis and thus, higher anxiety levels.

Hence, it might be possible that the observed anxiety levels reflect more aspects of anxiety than defined by the BOPAS. Literature described three different types of anxiety: trait anxiety (anxiety related to the patient's pre-burn character), anxiety associated with post–traumatic stress (i.e. anxiety directly related to the burn injury) and anxiety related to the anticipation of pain.[25] It could be assumed that Midazolam, although effective in the treatment of pain induced anxiety, is not indicated for the treatment of anxiety from a more psychological origin.

Although the mean differences are not easily explained by present insights into the medication of procedural anxiety in particular, it is rather a property of the BOPAS to differentiate between procedural pain and anxiety than an artefact. In addition, further analysis of the breakdown of the mean differences into differences at the level of indicators supports this view. Although the results revealed two principal components, determined respectively by pain indicators and anxiety indicators, the analysis also revealed that the indicators, 'Leg/Feet', 'Body' and 'Touch' did not as accurately measure anxiety. Thus, procedural pain was accurately indicated in crying, facial expression, verbal expression and the lower pain indicators body/torso, touch and leg/feet movement.

Anxiety, however, was more accurately observed in the indicators facial expression, crying and torso/body. The results of a two dimensional analysis with only these indicators explained 71% of the total variance and revealed a significant clustering of pain indicators versus anxiety indicators as shown in Figure 5.3. The insight that body/torso, touch and leg/feet indicators are less suitable for evaluating anxiety is, in hindsight, not surprising. Firstly, the behavioural indicators included in the BOPAS were based on and derived from existing pain and anxiety observational behavioural scales. The differences between these scales are expressed in the emphasis placed on the indicators and related to the different causes of pain. For example, the Observational Scale of Behavioural Distress (OSBD)[180] and Procedural Behavioural Rating Scale (PBRS)[169] described the indicators crying, body/torso, as more representative of cancer procedural pain and anxiety, followed by verbal expression. In support, McGrath (1998)[174] revealed that the majority of observational pain behavioural scales included crying, facial changes and verbal communication of pain as well as body and limb movement to indicate behavioural distress. The CHEOPS in the measurement of pain, found the indicators crying, facial expression, torso/body and leg movement, as more indicative of post-operative pain.[63]

Secondly, the indicators, facial expression, crying and verbal expression seem more appropriate to express anxiety, for anxiety, in particular, is a more cognitive concept. These indicators are in general use to express emotion whereas the indicators leg/feet movement,

torso and touch are more related to the large motor responses to a painful stimulus. A multivariate test between pain and anxiety supported the insights provided by the results of the above analyses with statistical significance; the multivariate test as well as univariate tests varied between .001>P>.05. It is therefore concluded, that the six indicators discriminate effectively between pain and anxiety and that the BOPAS is construct valid.

Although the set of experiments referred to above served to support the construct validity of the BOPAS, an additional study was designed to establish its level of concurrent validity. Concurrent validity was evaluated by comparing the BOPAS with a representative criterion and by analysing its predictive property by evaluating its association with physiological indicators. Thus, criterion validity was examined by comparing the BOPAS with another post-operative pain assessment scale, the CHEOPS[176]. Amongst the assessment scales and despite its recognised methodological constraints, the CHEOPS is one of the most widely recommended observational scales in burn pain assessment.[22 24 160] Thus, 43 patients were evaluated with the BOPAS as well as the CHEOPS. Whereas the BOPAS is unique in its separate measurement of procedural pain and anxiety and as such, generates separate scores, the CHEOPS generates an overall pain-anxiety score.

To compare both scales, a composite score for the BOPAS was calculated. The results showed a significant association between the overall scores of r= .87 of both scales, explaining 76% of the total variance. The canonical correlation between the set of indicators of the CHEOPS and the set of indicators between the BOPAS yielded .92. Further examination of the interrelationship between indicators of both scales revealed that the indicators of both techniques grouped according to their definition. Therefore, the composite score of the BOPAS of 'body' correlated highly with that of the CHEOPS (see Figure 5.5). Furthermore, the BOPAS composite scores seemed somewhat more consistent than the CHEOPS scores (see Table 5.4). A Cronbach reliability test supported this finding. Hence, it was concluded that the BOPAS meets and in fact, improves on the present standard of scales used to measure post-operative pain.

Since pain and anxiety are sensations considered to be associated with physiological indicators, its predictive relationship with respiratory and heart rates were examined. Study findings supported the use of respiratory rate in burn pain assessment if used in conjunction with observational pain assessment scales. Although literature refers to an association between pain and anxiety and physiological measures, the results are not always as consistent. For example, the effect of analgesics could influence pain responses. The low correlation between heart rate and procedural pain could be attributed to the heart rate's unpredictable response to pain. In response to pain, heart rate will first increase[152] and then decrease, and could further decrease as a result of administered analgesic agents.[153]

It is therefore assumed that the BOPAS should at least show some level of association with respiratory and heart rates although not a strong one. In order to triangulate the comparison, the association between the CHEOPS and physiological measures was also evaluated. The results showed that the BOPAS and the CHEOPS were positively associated with respiratory measurements but not with heart rate (see Table 5.10). Both behavioural scales explained about 30 percent of the variance in the respiratory rates. Thus, both the BOPAS and the CHEOPS were almost equally and statistically significantly, positively associated with respiratory rates. Furthermore, no differences of any significance were found in the physiological measurements between the prior and post conditions. This suggests that although respiratory rates are associated with both behavioural scales, physiological measurements seemed insensitive to detect a difference between pain and anxiety during wound care procedures.

In an attempt to find support for predictive validity of the BOPAS, a quasi-experiment was conducted. If the BOPAS was not able to detect changes in pain and anxiety behaviour in response to changes over a time period of three days and in particular, subtle changes in the time interval between drug administration and the wound care procedures, the null hypothesis should be rejected and support for this level of validity be found.

Although this study was limited, (as the time delays were not experimentally manipulated due to ethical considerations), the results were significant. Figure 5.7 indicated a drop in both anxiety and pain levels over three days. Multivariate and univariate tests showed that these changes were statistically significant. However, the decrease in pain and anxiety levels, differed in their pattern. Anxiety levels dropped almost linearly over three days whereas pain levels seemed to reach a baseline on the second day and remained almost constant on the third day. The initial high levels of pain and anxiety are to be expected, since these patients were new/recent admissions and on the first of admission, were exposed to the wound care procedure for the first time. The drastic decrease in pain levels after the first day could be attributed to the efficacy of and in particular, the analgesics use, probably in combination with a reduction in anxiety. This finding is supported by Choiniere et al (1989)[116] who concluded that there was no steady decline in the daily pain scores and that a gradual reduction of pain would only be observed towards the end of hospitalisation. Anxiety was treated with an anxiolytic agent, Midazolam. The linear decrease over the three days indicates that the process of treating anxiety with Midazolam was gradual. This result could be explained by arguing that the intensity of anxiety desensitises as a consequence of the amnesic properties of Midazolam. A more elaborate discussion on the influence of aspects such as metabolic rate, nutrition and oedema on drug metabolism in the burned patient, was not indicated for this study

Ward routine at the Red Cross War Memorial Children's Hospital often increased the effects of short term delays between drug administration and wound care procedures. It was hypothesised that a time delay between the administration of drugs and the start of wound care procedures should result in different pain and anxiety levels providing the BOPAS is sufficiently sensitive. It is assumed that the elimination half-life of these drugs, their uptake into the system and the increased metabolic rate found in burned patients could influence drug efficacy.[27] Figures 5.8 and 5.9 and Table 5.12 indicate that the mean anxiety and pain levels were lower when drugs were administered within a 60 minute period of the wound care procedure, compared to the mean levels observed after a 60 or more minute delay. This pattern seemed consistent over the three days, with an exception in anxiety after the second day: anxiety levels on the third day were slightly higher within the 60 minute delay than after the 60 minute delay. The difference, however, was considerably smaller than the differences in time delay on days one and two. This suggests that the time delay becomes more critical with increasing time after burns and should be reduced to reach effective drug treatment of anxiety after the second day. Although the differences in pain and anxiety levels due to short term time delays were not tested statistically because of methodological reasons, the results of the explorative study are considered as supportive to the predictive validity of the BOPAS.

The aim of this study was to show that the BOPAS is not only a valid instrument to evaluate procedural anxiety and pain but that it is also reliable. All results discussed above were based on the observations of at least two observers. As indicated above, these observations were done under live (participant observation) as well as under experimental (from video) conditions. The results of the inter rater reliabilities ranged between $.91 < r < .96$ with a $P < .001$. These findings were substantiated by the results of a reliability and accuracy analysis of a group of 34 health workers after an intensive one-hour training in the BOPAS. Again the study was conducted such that triangulation of the results was possible. Two groups of trainees, one intensively and one shortly trained in the BOPAS, were compared on reliability and accuracy. The results of a Q-analysis of the intensively trained subjects supported the earlier findings of reliability. After the removal of three trainees who showed no variance in their observations, between 72 and 84 per cent of the variance was explained by consistency of the observations by 31 subjects. The reliability coefficients ranged between .85 and .92. If the correlation between both observers in previous experiments is considered the highest reliability, $r=.96$, then the maximum reliability with more observers is $r=.72$. Furthermore, the consistency in the evaluations dropped significantly when subjects were exposed to a shorter training period. These findings support the conclusion that the BOPAS is a reliable instrument and in the range of other observational assessment methods. Although it is not completely clear how these scales established reliability, in particular the notice of extremely high coefficients, the PBRS scale claims an inter rater reliability of .80 - .90, the OSBD scale also varied between .80 - .91[179] and the CHEOPS a varied between .96 - 99.[176]

Because of the established validity, the high reliability should result in a considerable level of accuracy. A separate analysis, in which the mean trainee scores per indicator was compared to a criterion - the evaluation score per indicator of the designer and co-observer of the BOPAS - supported this assumption, in particular for the intensively trained 31 trainees. The accuracy of the shortly trained group was poor. The correlations for the highly trained group varied between .64 and .93 and were statistically significant. A comparison with the accuracy of other techniques is unfortunately not possible, due to the lack of any study mentioning the accuracy of these techniques. On the basis of the findings presented above however, it is concluded that the BOPAS is a reliable instrument, which can be accurately used after training to evaluate procedural pain and anxiety.

It is proposed that the BOPAS should be used to establish thresholds for pharmacological and supportive therapeutic measures. Due to the pre-procedural administration of analgesics and anxiolytic agents, the presentation of a 100% or even a 50% pain/anxiety profile is highly unlikely. A 0% score is equally unlikely in the assessment of recent burn injuries as such a score (0%) could only be achieved with general anaesthesia. Therefore, a score of <10% would suggest minor pain or anxiety and would not require any adjustments to the prescribed drug regime. Percentages ranging from 10% - 25% are indicative of mild to moderate pain and anxiety. However, when above 15%, a change in drug dose and the inclusion of supplementary therapies is suggested. Moderate to severe pain could be translated in percentages ranging from 20% - 35%. Severe pain and anxiety is indicated in percentages ranging from 35% or more. Changes in the pharmacological approach and doses as well as supplementary therapy are indicated in these cases. However, this assumption as well as the interpretation of pain and anxiety scores and subsequent pharmacological intervention require further investigation and are currently based on personal experience only.

It is clear that the fine-tuning of the BOPAS does not end with this study. Further data collected through the use of the BOPAS may reveal more insights into the relevance of the categories of the indicators and the range in which procedural pain and anxiety seem to stabilise. For example, the PCA showed that the categories of the indicators body/torso, touch and leg/feet were less suitable for evaluating anxiety. If this pattern is recurrent, one might consider removing these categories or even indicators from the observation form.

Furthermore, the observed anxiety percentage was about 11% and the pain percentage about 5%. It is evident that adjustment in the number categories influences these values and that unequal removal requires weighting factors such that a comparison between relative pain and anxiety remains possible. Finally, although an instruction and training manual of the BOPAS has been designed, minor modifications might be necessary. For example, since the reliability of the trainees was high, (in particular the condition that showed an accuracy

coefficient of .64 [Patient 1]), the range in the accuracy coefficients might be positively reduced by an improvement in training.

Considering these recommendations, the sets of experiments and their results strongly support the use of the BOPAS as an instrument to evaluate procedural pain and anxiety; in the support of pain and anxiety management; and, in particular, in the evaluation of the efficacy of the medical treatment of pain and anxiety in burned children. Hopefully, burn centres around the world, for the benefit of the burned child will adopt this method.

Conclusion: The need for a more reliable method to assess procedural burn pain and anxiety in paediatric patients led to the formulation of the Burn Observational Pain and Anxiety Scale (BOPAS). This method, proven to be reliable and valid, has demonstrated the ability to differentiate between pain and anxiety indicators during wound care procedures. Additionally, the efficacy of the prescribed drug regime can be evaluated by the BOPAS, thus ensuring adequate individual pain management. In this, the BOPAS has been shown to be reliable and effective in the assessment of procedural burn pain in paediatric patients.

Addendum.

Table 5.14

The frequencies of the anxiety and pain ratings per condition for all trainees extensively trained in the new observation BO-PAS.

Trainee	Patient One				Patient Two			Patient Three		
	no pain or anx	anx	mod pain	sev pain	no pain or anx	anx	mod pain	no pain or anx	anx	mod pain
T1	137	17	9	5	156	9	3	163	4	1
T2	135	17	13	3	156	10	2	161	5	2
T3	132	18	14	4	155	10	3	159	7	2
T4	132	19	10	7	154	10	4	160	7	1
T5	134	19	14	1	156	9	3	161	5	2
T6	132	21	13	2	153	13	2	160	7	1
T7	133	18	17	0	154	11	3	161	5	2
T8	136	13	19	0	155	10	3	161	5	2
T9	140	16	12	0	155	11	2	163	4	1
T10	134	18	14	2	156	9	3	161	5	2
T11	131	19	18	0	156	10	2	163	4	1
T12	135	17	15	1	154	11	3	159	7	2
T13	140	17	11	0	154	11	3	161	5	2
T14	130	20	18	0	155	11	2	161	5	2
T15	132	19	16	1	155	10	3	163	3	2
T16	135	19	9	5	154	11	3	161	5	2
T17	132	18	17	1	154	11	3	161	5	2
T18	135	17	16	0	154	9	5	162	6	0
T19	133	18	17	0	153	11	4	161	6	1
T20	136	16	16	0	155	10	3	161	6	1
T21	137	15	16	0	153	10	5	162	4	2
T22	132	18	16	2	155	9	4	160	5	3
T23	135	16	17	0	157	10	1	163	3	2
T24	134	18	11	5	156	9	3	159	8	1
T25	133	20	15	0	156	10	2	161	5	2
T26	134	16	18	0	149	15	3	157	6	5
T27	135	18	15	0	157	9	2	160	5	3
T28	134	19	14	1	153	11	3	162	4	2
T29	134	18	16	0	151	14	3	161	5	2
T30	133	17	18	0	154	13	1	162	4	2
T31	134	19	15	0	154	11	3	162	4	2
T32	136	19	13	0	156	10	2	161	6	1
T33	134	20	14	0	158	8	2	161	5	2
T34	132	20	16	0	155	9	4	162	5	1

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APPENDICES

Appendix 1

Analgesia and Sedation in the Burned Child

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Clinical studies of burn pain characteristics show very clear-cut differences between continuous pain and pain due to therapeutic procedures such as dressing changes and physiotherapy. These separate components have to be considered.

In the acute phase, along with resuscitation, analgesia needs to be attended to, but because of the often unstable haemodynamic state of the child, as well as poor bio-availability of drugs other than via the intravenous route, the drug of choice is morphine, given at the low dose of 25–50mcg/kg/dose intravenously to be repeated as necessary to achieve analgesia. This may be as much as the full dose of 100–200 mcg/kg/dose 4 hrly in the stable child. Follow with a constant infusion at 10–20mcg/kg/min.

Some of the main features of burn pain are its long lasting course, the repetition of highly painful procedures which may cause psychological disturbances if the pain is not managed properly, the potential need for non-pharmacological techniques such as the use of ice, the consideration of anxiety factors and depression – separation from and home, disfigurement etc.

One may consider pain in two main categories: physical and emotional. Physical because of the acute burn injury and the subsequent management which may involve surgery, COD and physiotherapy and emotional fear of disfigurement and separation from family. The emotional fears are greater in victims of child abuse.

In this unit, we aim therapy at three major components: analgesia, anxiolysis and anterograde amnesia for COD.

Other factors which require management include: itching, depression, side–effects of opioids eg. Nausea, vomiting, urinary retention, and gastric irritation as a result of NSAID's.

Children who require general anaesthesia for change of dressing (COD):

1. Burns of greater than 20% TBSA
2. Hand burns
3. Severe facial burns, inhalation injuries
4. Removal of staples, especially on hands and feet, perineum, neck and face.
5. Children where conventional ward drugs are inadequate, causing stress to the patient or the staff.
6. Big children who are difficult to handle in the ward.
7. Where joint and scar manipulation may be painful.

Useful facts about drugs commonly used in the burns unit:
All drugs should be given on a mg/kg basis. Those occasionally given on ml/kg basis have been worked out on a mg/kg basis before the suspension has been mixed. Do not scale an adult dose down to give to a child.

1. **Morphine:** is a naturally occurring opioid which undergoes metabolism in the liver and its active metabolite is excreted by the kidneys. The elimination half life in the newborn is longer than the infant or older child (thus needs a smaller and less frequent dose if given at all). Morphine is also an opioid analgesic which has been successfully used for many years and stood the test of time. It is cost effective and are indicated for moderate to severe pain (e.g. post operative or acute burn pain).

   How to use it:
   IVI – bolus 25–100mcg/kg/dose 3–4 hourly (slow injection over a minute).
   Infusion: 10–4- mcg/kg/hr. To mix this infusion take 0.5 mg/kg of morphine and make this up to 50mls in normal saline and run this at 1 – 4 ml/hr (this is equal to 10 – 40

ml/kg/hr). If you want to use another size of syringe, it works out to 0.1 mg/kg of morphine per 10 ml syringe of normal saline.
PCA (Patient control analgesia) is useful in the older child (> 5 years of age) and not critically ill.
IMI: To be avoided if at all possible. The treatment should not be more painful than the burn.
Orally (po): The route is not often used in the burns unit but may have a place in the more chronic cases. Dose is 0.3 mg/kg/dose 4hrly.

Side effects:
Respiratory depression
Nausea and vomiting: delayed gastric emptying and stimulation of the CETZ
Itching
Urinary retention
Constipation
Sedation

Contra indications: Allergy to morphine or sensitivity to opioids.
Porphyria

Caution in:
- the hypovolaemic, hypotensive child
- renal failure: morphine metabolises to renally excreted products which in renal failure may accumulate and cause respiratory depression
- liver failure: decreased metabolism of morphine thus higher serum levels and greater side effects.
- severe head injury and or raised intra-cranial pressure
- respiratory depression.

2. **Pethedine: (Meperidine)** is a synthetic opioid which is one tenth the strength of morphine but has a similar duration of action. It is metabolised in the liver to normeperidine which can cause CNS excitation and seizures. Normeperidine is excreted by the kidneys so may and may accumulate with renal failure and cause respiratory depression.
Dose: **IVI**: 0.5 mg/kg/dose 4hrly slow bolus
IMI 1mg/kg/dose usually given under GA to avoid IMI in the awake child.

3. **Codiene:** is an opioid commonly used either alone or in combination with for example paracetamol to treat mild to moderate pain. It is only available in oral form at the Red Cross Children's Hospital because it is a very painful injection and the incidence of adverse reactions is much higher.
Effects: Analgesia: after an oral dose analgesia occurs at 20 minutes and peaks at 60–120 minutes.
Antitussive: Potent
Sedation: as with all opioids.
Dose: 0.5-1mg/kg/dose 4–6 hourly. At Red Cross Children's Hospital codeine and paracetamol are available in a syrup combination where a dose of 1ml/kg will give the patient a dose of codeine of 1mg/kg/dose and a paracetamol dose of 20mg/kg/dose.

4. **Valoron drops:** (Tilidine) Traditionally given as a 1 drop/year. This dose however under-doses most patients as the correct dose is 1mg/kg/dose 6–8 hourly and each drop contains 2.5mg. Valoron is an orally absorbed synthetic narcotic analgesic and as such has the same side effects and contra – indications as those mentioned above. It is indicated for acute, moderate to severe pain. Valoron given concurrently with paracetamol each 6hrly, but alternating is a very good analgesic combination – i.e. valoron given at 6, 12, 6, 12 and paracetamol given at 9, 3, 9, 3.

NON-OPIOID ANALGESICS. (Paracetamol (panado), Ibuprofen (Brufen), Mefanic acid (Ponstan))

Paracetamol: is the most popular analgesic for the paediatric population for mild to moderate pain. Also acts as an anti-pyretic.. It is a non-steroidal anti-inflammatory.
In American literature it is called Acetaminophen and locally has numerous trade names, the most common being Panado. It may occur alone of in combination with a variety of other drugs for example:

Stopayne: paracetamol + codeine + phenergan.
Myprodol: paracetamol + codeine + brufen
Panadene: paracetamol + codeine

As mentioned above, this is a very good drug alone or in combination with others e.g. codiene or valoron.
Dose: Oral: 20mg/kg/dose 6 – 8 hrly
PR: 30-40 mg/kg/dose 8 hrly
Available in syrup, suppository or tablet form. The suppositories are 125 mg and 250 mg only. The tablets are usually 500mg each. The syrup dose per ml varies with the different formulation so check before you use it. At RXH, 5ml contains 125mg and with codeine each ml contains 1mg of codeine and 20mg of paracetamol so the dose of this combination is **1ml/kg/dose.**

IBUPROFEN (BRUFEN)
Non – steroidal anti inflammatory.
Dose: 5-6 mg/kg/dose 8hrly (maximum 20mg/kf/day)
Only available in syrup form at RXH at present.
Diclofenac (Panamor or Voltaren) is available in suppository form as 12.5 mg and 25 mg supps)
Dose is 1-2 mg/kg/dose bd.

MEFANIC ACID (PONSTAN)
Non steroidal anti-inflammatory
Available in syrup and suppositories. Suspension: 50mg/5ml.
Dose: 5-6mg/kg/dose 4hrly.
All these anti-inflammatories (NSAIDS) are from different classes of the family. The exhibit their anti-inflammatory effects by inhibiting prostaglandin synthesis at the level of cyclooxygenase, so block the production of prostaglandins that stimulate free nerve endings in the peripheral nervous system. They may also inhibit central prostaglansin synthesis to provide analgesia. NSAIDS are rapidly and completely absorbed when taken orally, metabolised by the liver and excreted by the kidneys. 5-10% of the drug is excreted in the unmetabolised form.

Caution: -Renal dysfunction: inhibition or renal prostaglandins further decreases renal blood flow and glomerular filtration rate may induce renal failure.

- Hypovolaemia: for the same reason
- Gastric irritation: contra-indicated in patient with GIT ulcers, gastritis, diarrhoea, vomiting.
- Bleeding problems: DIC, on anti-coagulants etc. NSAIDS inhibit platelet function for the duration of drug administration ie. Reversable effect, cf aspirin where the effect lasts the duration of the life span of the platelet. Paracetamol has no effect on platelet function.
- Bronchoconstriction: not for use in severe asthmatics.
- Closed head injuries, eye injuries.

Paracetamol is in a class of its own in that it can be used in most cases when one would avoid other anti-inflammatories.

BENZODIAZEPINES:

Midazolam:
- is a short acting benzodiazepine which has two very good properties – anxiolysis and anterograde amnesia.
- is used as a premed for theatre as well as for COD
- is available in tablet form: blue 15mg or white 7.5 mg tablets.
- Vials: 15mg/3ml or 5mg/5ml for IVI use. This liquid is not stable in a syrup medium for longer than a few hours so it should not be kept if mixed to facilitate administration down a NGT.

Dose: PO 0.25 – 0.5mg/kg/dose. In burns, use the bigger dose.
IVI 0.1 mg./kg/dose
Infusion; 0.05 – 0.2mg/kg/hr
Intranasal: 0.3 – 0.4 mg/kg/dose. This route leaves a very bitter taste at the back of the mouth or throat for a couple of days.

Beware of concomitant use with opioids, especially IVI, causing respiratory depression and haemodynamic instability.

OTHER DRUGS:

1. **ATERAX**: (Hydroxyzine) is an anxiolytic, antipruritic which lasts 4 – 6 hrs. Not good for sedation. Dose: 2 – 4 mg/kg/day in 3-4 divided doses. Is good for itching in burned patients.
2. **VALLERGAN:** (Trimeprazine) 2-4 mg/kg/dose. Usually used as a premed for theatre. Very good sedative, mild-emetic. Beware of concomitant use with opioids. Contains Tartrazine therefore avoid in sensitive patients.
3. **TRICHLORAL:** (Chloral hydrate): Good sedative but poor anxiolytic or amnesic qualities. Dose: 50 – 70 mg/kg/dose. Poor for long term sedation.
4. **PROMETHAZINE:** (Phenergan): very good for itching but much more sedating than Aterax. This can be an advantage in the burned patient.
   Dose: 0.1 mg/kg/dose 8hrly. This drug has a long half life so may only required twice a day.
5. **KETAMINE:** is an anaesthetic induction agent with analgesic properties. It should not be used in anaesthetic doses in the ward.
   Dose: analgesia IVI: 0.25 – 0.5 mg/kg/dose
   IMI: 2 – 4 mg/kg/dose
   PO: 5 – 6 mg/kg/dose

Analgesia Medicine Chart:

Pt. Weight:.....

The following medication to be given 30 minututes before dressing change procedure.

Midazalam(0.25 – 0.5 mg/kg) PO				Panado –CO (1 ml/kg)PO				Ponstan (6.5 mg/kg) PO				Brufen (5 – 6mg/kg) PO			
Dose:		Dr.:		Dose:		Dr:		Dose:		Dr:		Dose:		Dr.:	
Date	Dose	Sign	Time	Date	Dose	Sign	Time	Date	Dose	Sign	Time	Date	Dose	Sign	Dose

Valaron drops (1drop / year)				Aterax (0.5 – 1.0 mg/kg)				Morphine							
Dose:		Dr.:		Dose:		Dr:		Dose:		Dr:		Dose:		Dr:	
Date:	Dose:	Sign:	Time:	Date:	Dose:	Sign:	Time:	Date:	Dose:	Sign:	Time:	Date:	Dose:	Sign:	Time

Appendix 2

The Burn Observational Pain and Anxiety Scale (BOPAS).

Pain is a subjective and individual experience, as no two people experience pain in the same manner. The individuality of each patient, previous pain experiences, cognitive developmental level, age, possibility of regression, the circumstances surrounding the burn injury as well as the nature, location and size of then burn injury should be brought into context during the assessment process. It is also important to involve the parents / caregiver in the assessment process. Information regarding the words used by the patient to express pain and individual pain behaviour could be valuable in the assessment process.

Procedural pain and anxiety should be assessed for the first three days post admission in order to facilitate baseline readings. Thereafter procedural burn pain can be assessed as needed. Patients should be assessed individually according to the BOPAS specifications. Behaviour as identified by the BOPAS should be displayed for a minimum of 15 seconds.

Observed pain and anxiety behaviour are identified and scored separately during the three stages of wound care: the first stage is the removal of the bandages, the second the debridement and cleaning of the wound (the most painful stage) and the third stage, the reapplying of anti-microbial cream and clean bandages. Behaviour indicative of either pain or anxiety as described by the various categories / indicators is only scored once per stage, and only when present for a minimum of 15 seconds. For example if the patient is positively scored for crying in pain during the debridement phase, it cannot be scored a second time for the same behaviour (crying in pain) during that phase (debridement).

Scoring:
The following numerical values: 0 = no pain / anxiety, 1 = behaviour indicative of anxiety, 2 = behaviour indicative of pain, 3 = behaviour indicative of severe pain. These numerical values only identified the presence of either anxiety or pain and not the intensity of pain or anxiety.

Differentiating between pain and anxiety.
It is assumed that since each patient had received the standard pre procedural combination of analgesics and anxiolytic agents, a certain level of sedation and anxiolysis had been achieved prior to commencing with wound care procedures. Assessments are focused on the adequacy of these drugs and the level of sedation and anxiolysis for each individual patient.

It is important to note the patient's behaviour before the procedure, before being taken to the procedure room.

Pain scored with either the numerical value 2 or 3 is only positive identified and scored accordingly when "response-to-pain-behaviour" occurred as a result of an introduced and identifiable pain stimulus. For example wound care procedures, touching the open wound, washing the open wound, removing bandages could be painful and could be scored as such.

Anxiety scored only with the numerical value 1 is positively identified when there is a discrepancy between the child's behaviour and the severity of the wound, the type of injury and status of healing. Patient behaviour that is in contrast to the severity of

the wound and applied procedure or occurring in the absence of induced pain stimuli. Anticipated pain could also lead to anxiety responses.

Calculation of pain and anxiety scores:
Pain and anxiety scores are separately calculated by means of a mathematical formulae that allows for the calculated results to be presented in percentages. By treating the calculated scores in an equal manner and by producing subsequent percentages, the conclusion as to the dominance of either pain or anxiety during wound care procedures could be established. Pain and anxiety scores presented in this manner not only allows for the plotting of a pain/anxiety profile on a graph, but would allow for the daily efficacy of the prescribed drugs to be adjusted if needed.

The number of observed indicators for both pain and anxiety are separately added (summed) and divided between the total number of indicators present (n=84) and them multiplied by a 100 to provide for a percentage score. The formulae used for this is:

$$\frac{\Sigma(n)\ \text{observations}}{(n)\ \text{categories}} \times 100$$

Interpretation of pain and anxiety scores:
The following discussion on the interpretation of pain and anxiety scores is based on experience and need to be further investigated.

Due to the pre-procedural administration of analgesic and anxiolytic agents, the presentation of a 100% or even a 50% anxiety profile is highly unlikely. A 0% score is equally unlikely in the assessment of recent fresh burn injuries as such a score (0%) could only be achieved with a patient under general anaesthesia.

A score of < 10% would suggest minor pain or anxiety and would not require any changes to the prescribed drug regime. Percentages of between 10% - 25% are indicative of mild to moderate pain and anxiety. However, when above 15%, changes to drug doses or the inclusion of supplementary therapies are suggested. Moderate to severe pain and anxiety could be translated in percentages ranging from20% - 35%. Severe pain and anxiety is indicated in percentages ranging from 35% or more. Changes in the pharmacological approach and doses are indicated in these cases.

The BOPAS Scale for burned children.

Crying:

Dressings off.

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
No Crying				
Moaning/ Protesting				
Crying				
Screaming				

Debridement / Wound cleaning.

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
No Crying				
Moaning / Protesting				
Crying				
Screaming				

Dressings on

	No Pain = 0 Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Pain = 3 (P)
No Crying				
Moaning / Protesting				
Crying				
Screaming				

Total: **Anxiety:** _____

Pain: _____

Definitions: Crying

No Crying: 0 **(No pain / anxiety)**	Child not crying, Smiling No behaviour indicative of stress observed.
Moaning / Protesting: 1 (A)	Child moaning silently, groaning, whimpering: indicating fear, with no obvious pain stimulus present.
Moaning / Protesting: 2 (P)	Child moaning silently, groaning, whimpering, sighing: Indicating pain with a definite observable pain stimulus present in response to direct contact with wound area.
Crying: 1 (A)	Onset of tears, soft "non – worded sounds" of short duration. Child can be calmed or distracted by mother / nurse. Crying without any direct interference with burn wound, or any other observable pain stimuli. No other obvious reason for behaviour than fear or anxiety.
Crying :2 (P)	Crying gently / whimpering or full lunged sobbing. Not easily consolable or distracted. Tears – soft "non-worded" sound for a longer period. Observable pain stimulus present – patient responding to direct contact with open wound area.
Scream: 1 (A)	Shrill non - worded vocal expression. Scream without any other reason than fear or anxiety – absence of direct contact with wound or any other form of pain stimuli. Child can scream / shout verbal indicators of pain in the absence of pain stimuli or direct contact with wound area.
Scream: 3 (P)	Child is in full lunged cry – sobbing with or without complaining of pain. Shrill vocal expression of pain of high intensity. Child can scream / shout verbal indicators of pain in response to direct contact with wound area or pain stimuli.

Facial expression

Dressings off

	No Pain = 0 No Anxiety =0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Smiling				
Composed				
Facial contortion				
Frozen watchfulness				
Grimace				

Debridement

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Smiling				
Composed				
Facial contortion				
Frozen watchfulness				
Grimace				

Dressings On

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Smiling				
Composed				
Facial contortion				
Frozen watchfulness				
Grimace				

Total: **Anxiety:** _____

Pain: _____

Definitions: Facial expression.

Smiling: 0 (No pain / anxiety)	Positive facial expression – of happiness or pleasure. Patient could be grinning or even laughing.
Composed controlled: 1 (A)	Neutral facial expression. Appears calm, tolerant and impersonal – facial tenseness observable, clenching of teeth.
Composed controlled: 2 (P)	This in older children could indicated pain – e.g. in boys who due to cultural reasons refuse / are not allowed to express / indicate pain. Score only positive if an observable / identifiable pain stimulus is present, or in response to direct contact with open wound. It is not uncommon for patients in this category to avoid eye contact with those around them.
Facial distortion: 1 (A)	Facial distortion / contortion - because the child is crying for no other reason than fear or anxiety. Absence of pain stimuli. Score positively if "Crying" in anxiety was scored in previous section. Facial distortion - where facial features are distorted, facial muscle movement in the absence of pain and in reaction to anxiety and fear.
Facial distortion: 2 (P)	Facial distortion because child is crying / screaming in reaction to pain stimuli or direct touch to the open wound area. Facial features are distorted, especially the mouth and eyes.
Frozen watchfulness: 1 (A)	Patient is suspicious and apprehensive, appearing cautious and observant. Reaction in the absence of an obvious pain stimuli.
Frozen watchfulness: 2 (P)	Child is suspicious and nervous, follows every move with the eyes in reaction to a painful stimuli and / or direct contact with the (open) wound area.
Grimace: 1 (A)	Grimace, pulling of a face, frowning without any pain indicators present, in the absence of direct contact with the wound. Often in anticipation of pain.
Grimace: 3 (P)	Definite observable strong facial (mouth) contortion indicating pain and displeasure. Score only if a definite pain stimulus is present or in reaction to direct open wound contact.

Verbal indicators.

Dressings off.

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain (P)
Not crying				
Not verbal				
Other complaints				
Pain complaints				

Debridement

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain (P)
Not crying				
Not verbal				
Other complaints				
Pain complaints				

Dressings on

	No Pain = 0 No Anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain (P)
Not crying				
Not verbal				
Other complaints				
Pain complaints				

Total: **Anxiety:** _____

Pain: _____

Definitions: Verbal indicators

Not crying: 0 (No pain /anxiety)	Child makes positive statements. Chatter / talking about issues not related to the procedure - facial expression calm, smiling.
Not verbal: 1 (A)	Not talking – appears to be anxious. Child is unnaturally silent – refuse to communicate, or drawn into a conversation. Child could also display crying behaviour in the absence of a definite observable pain stimulus or direct contact with the wound. Behaviour could in addition be the result of the cognitive development level of the child or regression.
Not verbal: 2 (P)	Not communicating or refusing to do so in the presence of pain: direct contact with the open wound, painful treatment or direct observable pain stimulus. Behaviour could also be an inability to express pain due to the level of cognitive development or regression.
Other complaints: 1 (A)	Patient complains about everything else but pain. Complaints are expressions of negative feelings, fear and anxieties. Could be verbal expression of delay, termination or resistance to procedure (e.g. please don't do this, I want my mommy / daddy / granny). Also information seeking behaviour: ask questions about medical treatment / procedure / nursing staff.
Other complaints: 2 (P)	Child complains of pain that is not related to the burn injury, wound care procedure. e.g. my head is sore, my stomach hurts.
Pain complaints: 1 (A)	Child complains about pain, makes statement about pain in the absence of a direct pain stimuli, direct contact with the wound. Normally occurs before commencing with the procedure, either in the treatment room or en route. Anticipated pain reaction as a result of anxiety of fear.
Pain complaints: 3 (P)	Child complains about pain in reaction to direct touch to the open wound, definite observable pain stimulus in reaction to for example: painful burn injury, procedure or treatment. Uses words, statements and phrases that refer to pain and discomfort. In very young children, children in regression or with cognitive developmental delays, only one word referring to, or indicating pain will be used. (it is advised that a list of possible words / pain indicators should be compiled with the mother's help for children from different language, cultural groups.)

Hand / Touch behaviour:

Dressings off

	No pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Not touching				
Touching				
Guarding				
Restrained				
Grabbing				
Trembling				
Balled				
Reaching				

Debridement

	No pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Not touching				
Touching				
Guarding				
Restrained				
Grabbing				
Trembling				
Balled				
Reaching				

Dressings on

	No pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Not touching				
Touching				
Guarding				
Restrained				
Grabbing				
Trembling				
Balled				
Reaching				

Total: **Anxiety:** _____

Pain: _____

Definitions: Hand / Touch behaviour.

Not touching: 0 (No pain)	Hands are relaxed, lying still in one position.
Touch: 1 (A)	Child is gently touching, feeling the wound area – most often over bandages, or during exposure to the open wound. Being confronted with the extent of the physical damage to the body could cause anxiety.
Touch: 2 (P)	Child is stroking the wound area, either over the bandage or in direct contact with the open wound. Normally in reaction to painful stimuli towards the end of the procedure (dressing on stage).
Guarding: 1 (A)	Pushes the hand of anybody wanting to touch the wound away. Reaction of fear or anxiety, occurring in the absence of direct touch to, or stimulation of the wound area.
Guarding: 2 (P)	Pushes people / hands of anybody wanting to touch either the patient or the wound area away. Tries to protect the wound area from being touched. Response in reaction to a painful stimulus, or painful procedure.
Restrained: 1 (A)	Patient's hands are restrained to allow for procedures to be carried out. Patient appears to be nervous and anxious. No pain stimulus present. Normally occurring before the debridement / washing of the wound.
Restrained: 2 (P)	Child is in definite pain, is being hurt and is reacting to pain by trying to prevent procedure from being carried out. Restrained to allow for procedure.
Grab: 1 (A)	Child is grabbing / clutching / holding the wound area or afflicted body part in the absence of pain – normally before commencing with the procedure.
Grab: 2 (P)	Child is grabbing / holding / clutching the wound area or afflicted body part in the presence of a painful stimuli or in reaction to direct touch to the open wound area.
Hands trembling: 1 (A)	Nervous shaking / trembling in the absence of pain, normally before the procedure.
Hands trembling: 3 (P)	Shaking / trembling of hands in reaction to severe pain. Normally during wound care procedure and in response to direct touch to the open wound area. Hands could be moist / "sweaty".
Hands balled: 1 (A)	Hands balled tightly in a fist, one or both hands holding on to either somebody else's hand or the sheet in the absence of a pain stimulus – normally before commencing the procedure or during the first few minutes of removing the bandages.
Hands balled: 2 (P)	Same as above, only in response to a pain stimulus or direct touch of the open wound area or " the washing" of the wound area.
Reach: 1 (A)	Child is reaching out but not touching the wound – just holding the hand in the air - normally the action observed before "guarding" - in the absence of pain or direct contact with the open wound
Reach: 2 (P)	Same as above, but in response to pain or direct touch to the wound area. Movement of the hand is sudden although the wound area / body part is never touched.

Torso / Body:

Dressings off.

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Shifting				
Tense / rigid				
Shivering				
Restrained				
Antalgic behaviour				

Debridement

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Shifting				
Tense / rigid				
Shivering				
Restrained				
Antalgic behaviour				

Dressings on

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Shifting				
Tense / rigid				
Shivering				
Restrained				
Antalgic behaviour				

Total: **Anxiety:** _____

Pain: _____

Definitions: Torso / Body

Neutral: 0 (No Pain)	Body is at rest / relaxed. Patient is inactive.
Shifting: 1 (A)	Body is in motion – transferring or altering the body position – often in a serpentine way. Normally observed before commencing with the procedure, the dressing off stage.
Shifting: 2 (P)	Repositioning of the body in response to pain: direct touch of open wound, pain stimuli. (Often seen during debridement stage.)
Tense / Rigid: 1 (A)	Body is rigid and tensed. Sometimes noticeable contraction of torso muscles in response to a sharp intake and holding of breath or shallow fast breathing. No specific pain indicators / stimuli present on direct contact with open wound area.
Tense / Rigid: 2 (P)	Body is arched or rigid and tense. Noticeable contraction of torso muscles in response to a sharp intake and holding of breath or shallow fast breathing. Notice prominent display of ribcage.
Shivering: 1 (A)	Nervous shaking / shivering of body – nervous tension in reaction to fear and anxiety. Exclude shivering in response to procedural washing / showering as the patient might be cold.
Shivering: 3 (P)	Shivering as a result of and in response to severe pain – very rare as most patients are pre-medicated for procedures.
Restrained: 1 (A)	Physical resistance - patient is exerting bodily force to prevent procedure from happening resulting in the patient being restrained. No obvious pain – reacting in fear or anxiety.
Restrained: 2 (P)	Physical resistance because of pain – patient is trying to prevent further pain by resisting procedure – restrained to complete procedure.
Antalgic behaviour: 1 (A)	Child is trying to protect him/herself, prevent him/herself from being moved, placed lying down or placed in position to start with wound care procedures. No direct exposure to pain, direct contact with open wound area – patient's reaction is in response to fear and anxiety.
Antalgic behaviour: 2 (P)	Same as above – child is reacting during the procedure in response to pain.

Legs and Feet

Dressings off

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Squirming				
Kicking				
Drawn up				
Restrained				
Feet crossed				
Toes pulled up				

Debridement

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Squirming				
Kicking				
Drawn up				
Restrained				
Feet crossed				
Toes pulled up				

Dressings On

	No Pain = 0 No anxiety = 0	Anxiety = 1 (A)	Pain = 2 (P)	Severe Pain = 3 (P)
Neutral				
Squirming				
Kicking				
Drawn up				
Restrained				
Feet crossed				
Toes pulled up				

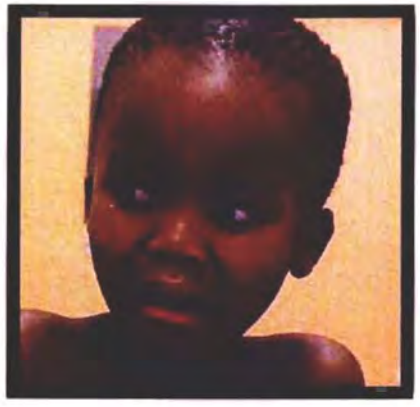
Total: **Anxiety:** _____

Pain: _____

Legs and Feet: Definitions

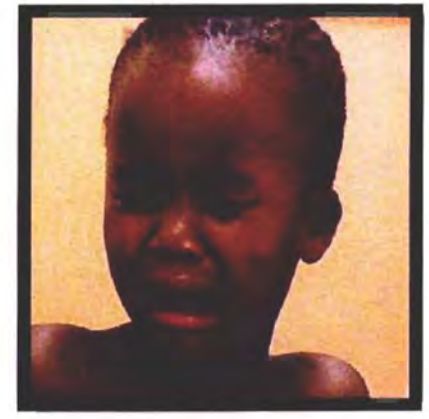
Neutral and calm: 0 (No Pain)	Legs may be in any position, but are relaxed.
Squirming: 1 (A)	Restless, jittery, wriggling leg movements in response to anticipated pain – no direct observable pain stimulus present – no direct touch to the open wound.
Squirming: 2 (P)	Restless, jittery, wriggling leg movement in response to pain stimuli, e.g. direct touch to open wound area, washing of wound, removing of bandages.
Kicking: 1 (A)	Kicking not in response to pain related to the injury or treatment, rather as a response to anticipated pain in the form of a temper tantrum.
Kicking: 2 (P)	Kicking and struggling in response to a painful stimuli – respond to "hurt" – i.e. direct touch to the open wound area, removal of bandages, washing of wound.
Drawn up / Tense: 1 (A)	Drawn up / tense with obvious observable fear – no pain stimuli present. Anticipated pain, response often observed in the procedure room before the procedure.
Drawn up / Tense: 2 (P)	Legs and knees drawn up and held tightly to body in response to painful procedure.
Restrained: 1 (A)	Restrained to allow procedure to be carried out – patient respond to anticipated pain and anxiety – total absence of pain stimuli.
Restrained: 2 (P)	Restrained because of patient response to painful procedure – to allow for procedure to be carried out.
Feet crossed: 1 (A)	Feet crossed but relaxed at the ankles, placed on top of each other - anxiety response in reaction to anticipated pain.
Feet crossed: 2 (P)	Feet crossed at the ankles, tense in reaction to pain – legs are tense or drawn up.
Toes pulled up: 1 (A)	Toes, normally the big toes are either pulled up or pushed forward in response to anxiety – a response often observed in younger patients. This response indicated anxiety in the absence of pain stimuli.
Toes pulled up: 2 (P)	Same as above, this time in reaction to pain stimuli during wound care procedure. More pronounced than response for anxiety.

Facial expression changing from Anxiety to Pain

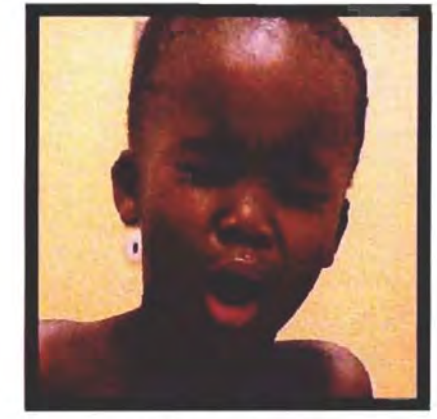


Frozen watchfulness in anxiety

Facial contortion in pain

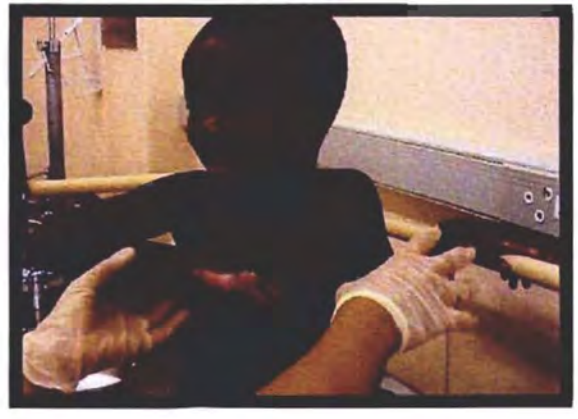


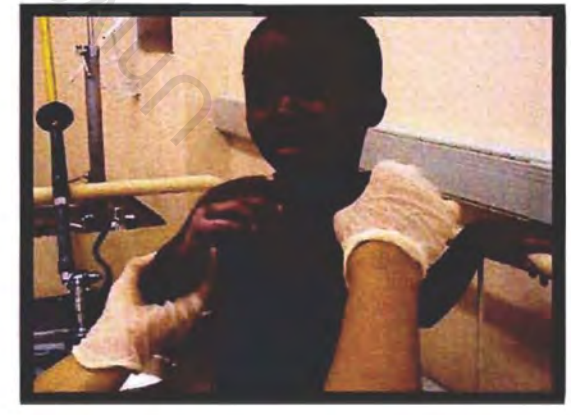
Crying in pain



Scream in pain

Restrained in Anxiety





Feet : Anxiety and Pain

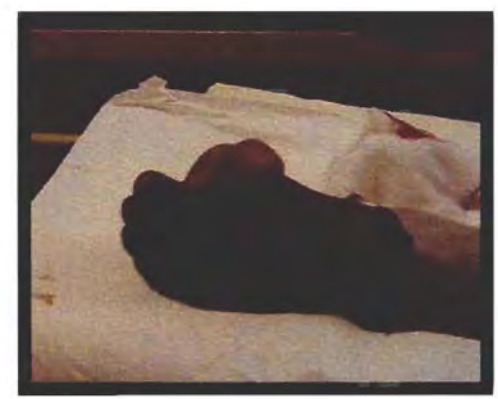
Relaxed: No anxiety; No pain

Feet crossed: - Anxiety

Feet crossed at ankles: Pain

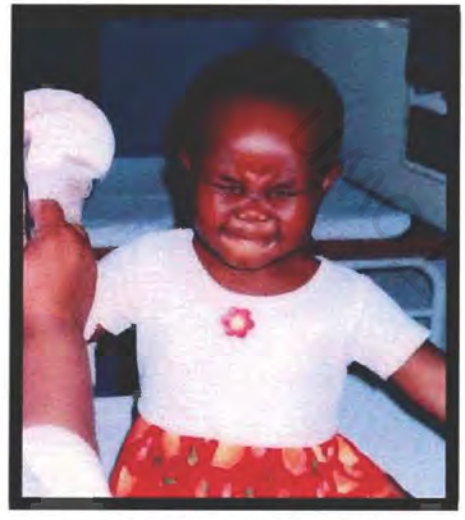
Toes splayed: Anxiety

Toes pulled up: Anxiety



Toes pulled up: Pain

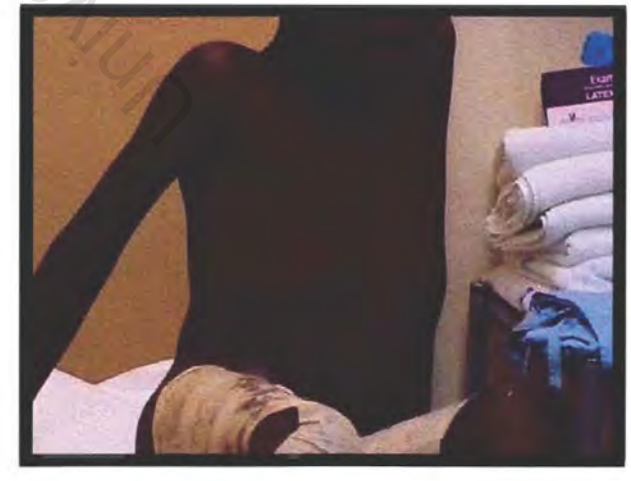
Anticipated pain in an out-patient aged 4; 6 weeks post-burn. No painful stimuli. Healed burn, hand splint not yet removed



Facial contortion: Anxiety
Grimace: Anxiety

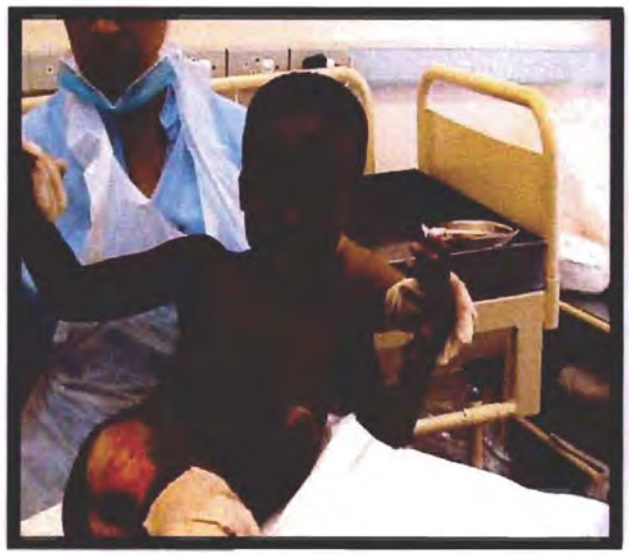
An example of a hand balled in either Anxiety or Pain

Torso / Body: Tense or rigid in either Anxiety or Pain. Notice prominent display of ribs

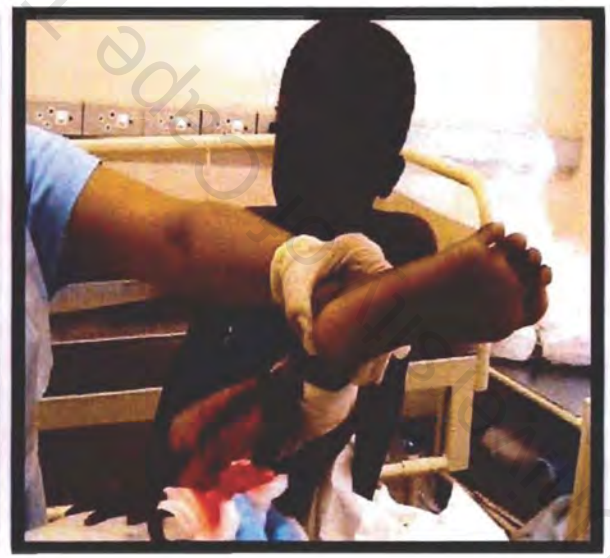


Pain in reaction to introducing a painful stimuli

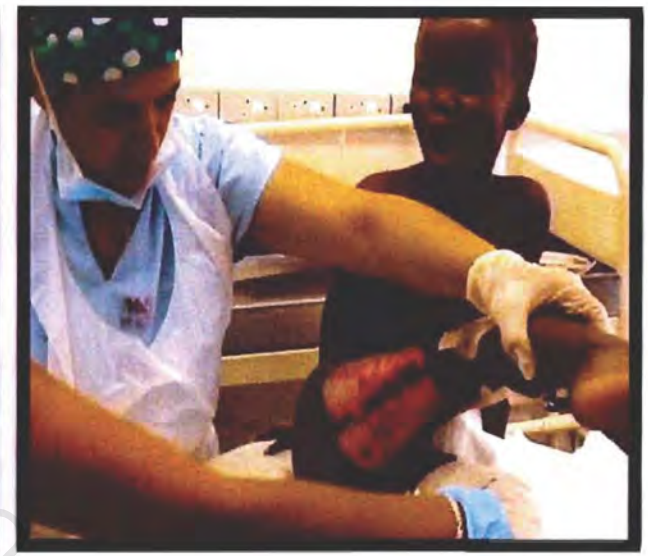
Note facial expressions



Frozen watchfulness: Anxiety
Restrained: Anxiety
Facial contortion: Anxiety



Touch donor site: introduce pain stimuli



Scream: Pain
Facial contortion: Pain

APPENDIX 3

PARENTAL CONSENT FORM FOR INCLUSION IN PAIN ASSESSMENT STUDY:

I, THE UNDERSIGNED:

.....

MOTHER / FATHER / CAREGIVER of

.....

hereby give my consent for the above child to be included in the Pain Assessment Study as discussed with me and that he/she could be photographed / video graphed during dressing change procedures in the Burns Unit and Outpatients.

Participation in this study is voluntary and you may withdraw your consent to participation at any time. Such refusal or discontinuance will not affect your child's right to treatment or medical care in any way.

I fully realize:

1. **That this photograph / video material becomes the property of the Red Cross Hospital to be used at their discretion.**
2. **I can not in any way make any claim whatsoever on the Red Cross Children's Hospital or the Cape Provincial Administration as a result of publicity in this connection.**
3. **That the investigator will make reasonable effort to protect my child from any unnecessary harassment.**

The ethical and personal rights of the child will always be respected and upheld.

SIGNATURE: ..... DATE: .....