Colour change in traumatised anterior permanent teeth

A Prospective cohort observational study

Alia Husian M Al Awami

Supervisors

Dr P.F.Day

Prof. S. Westland

Prof. M. S. Duggal

Submitted in accordance with the requirements for the degree of Doctor of Clinical Dentistry (DClinDent) in Paediatric Dentistry

University of Leeds

School of Dentistry

Department of child dental health

August 2015

The candidate confirms that the work submitted is her own and that the appropriate credit has been given where reference has been made to the work of others.

This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

Dedicated to my Family

My Husband, Maher

My three daughters, Farah, Ward, and Zain

My Mother, sisters, and brothers

My Mother in-low, sisters and brothers in-low

Acknowledgment

It would not be possible to accomplish this work without the help and support of the kind people around me

First and foremost I would like to express my sincere gratitude to my supervisor, Dr. P. F. Day who was abundantly helpful and offered invaluable assistance, support and guidance.

I also owe a great debt and thanks to my second supervisor, Prof. S. Westland who gave generously of his time and provided the most generous and careful attention and ideas about colour science.

My husband, Maher, deserve special mention. I am eternally grateful for the support and encouragement of my loving, caring and generously giving husband; he was the first and best inspiration behind this achievement that started four years ago.

I would also like to thank the staff of the Medical and Dental Illustration department, Angus Robertson, Maria Clarke, Zoe Kakiziba, and Colin Sullivan for their help and patience throughout the study

Special thanks to my colleagues for their support during patients' recruitment and all the encouragement and friendship

Abstract

Background: There is limited information about colour change following traumatic dental injuries (TDI), and any variable associated with discolouration. It is now increasingly recognised that children's perception and satisfaction are important and may provide an insight into the psychosocial impact of their oral health and their wider quality of life. Therefore, research to quantify colour change with time following TDI and the patient's perception is important. This study was designed to identify any association between clinical variables and discolouration following TDI.

Aim: To investigate the change in colour of permanent teeth following TDI in children. To explore what variables are associated with discolouration. To examine methods of measuring colour change including IKAM system (objective measure), the use of a shade guide (clinical pseudo objective measure), patient's perception (patient reported measure) and to evaluate the agreement between these three methodologies.

Method: Children following TDI were invited to participate in an observational prospective cohort. Colour change was measured using patients' perception, investigator's perception (using a shade guide) and an objective digital system (IKAM). Measurements were taken at baseline, 3 months and 6 months following the TDI with IKAM providing objective CIELAB colour scores.

Results: Thirty-nine children, with 73 traumatised teeth, completed the study. Twenty-six children attended two follow-up reviews comprising 52 teeth, and

thirteen children attended for one follow-up visit only with 21 teeth. A heterogenous sample of TDI was recruited including various types of hard tissue injuries and periodontal injuries with variable pulpal survival and periodontal healing outcomes.

At the last review (n=73 teeth) the objective overall colour change was ΔE 5.45 (SD +/- 2.80) with a mean change in ΔL* 0.74 (lighter), Δa* 0.69 (redder) and Δb* 1.73 (yellower). There was little consistency between patients reported colour change and that recorded by the investigator using a shade guide.

There was no significant difference in ΔE values as measured by IKAM in comparison with the patients' or investigator's perception.

Conclusions: Following TDI, there was an observable colour change identified by an objective measure, IKAM. On average, teeth got predominantly yellow and to a lesser extent lighter and redder. Patients and investigator measures were inconsistent when compared to the objective measure (IKAM). No variables were identified to be associated with colour change. However several variables came to significance ($p<0.05$). These variables were; time interval between the baseline assessment and the final review, presence of hard tissue injury, splinting, and restoration placed at or before baseline.

Table of content

List of figures

List of tables

Abbreviations

AA	Alia Alawami (the main investigator)
$Ca(OH)_2$	Calcium Hydroxide
CDH	Children's Dental Health
CIE	Commission Internationale de l'E´clairage
CIELAB	Three-dimensional colour space. L is the lightness coordinate that ranges between white to black, A is the red-green axis, B is the yellow-blue axis.
COSMIN	Consensus-based standards for selection of Health Measurement
CHX	Chlorhexidine
ΔE	Delta E
ECOHIS	Early Childhood Oral Health Impact Scale
GMTA	Grey Mineral Trioxide Aggregate
LDI	Leeds Dental Institute
MTA	Mineral Trioxide Aggregate
NaOCl	Sodium hypochlorite
NRES	National Research Ethics Service
OHRQoL	Oral Health-related Quality of Life

OIDP	Oral Impact on Daily Performance
PA	Point Accuracy
PCO	Pulp Canal Obliteration
PDL	Periodontal Ligament
RCT	Root Canal Treatment
RGB	Red, Green, Blue
ROI	Region Of Intrest
SD	Standard Deviation
SM	Saleh Muhammad (the investigator of the pilot study)
TAB	Transient Apical Breakdown
TDI	Traumatic Dental Injury

Chapter 1 Introduction & literature review

1.1 Prevalence of Trauma Dental Injuries (TDI)

1.1.1 In United Kingdom

Dental injuries are a common occurrence in childhood and constituting a dental public health concern. The UK children's dental health (CDH) survey of 2013, http://www.hscic.gov.uk/catalogue/PUB17137/CDHS2013-Report2-Dental-Disease.pdf, found that around one in ten children had sustained TDI to their incisors (12% at age 12 and 10% at age 15). In comparison to 2003 national Child Dental Survey (Chadwick et al., 2006) the proportion of children with a TDI to their permanent incisors has remained similar. The analysis of the CDH survey 2013 was restricted to 12 and 15 year olds to avoid the problems associated with analysing the mixed dentition of 8 year olds. The total number of 12 and 15 years old children with any TDI to permanent incisors was 2,532 and 2,418 respectively. The sample size was powered to look at caries and therefore the size of these groups to examine trauma was probably not large enough to give an accurate picture. There was, however, a decline in trauma observed in 15 year old boys; from 17% falling to 11% between 2003 and 2013. For all age groups, it was observed that the prevalence of trauma was higher in boys than girls, though the only difference was at age 12 where boys were twice as likely to have sustained damage.

In the CDH survey 2013, the prevalence of TDI was also analysed in relation to the observed overjet. The traumatic damage to incisors, for 12 and 15 year olds, was observed to be greater in children with 6mm or more overjet, although the differences were not statistically significant. In 15 year old boys, with an overjet of 6mm or greater, around two in ten had suffered traumatic damage, compared to one in ten where the overjet less than 6mm. Amongst 12 year olds whose overjet was less than 6mm, boys were more likely to have traumatic damage than girls; the difference at age 15 was not statistically significant.

The teeth most likely to be affected by TDI are the upper central incisors (Glendor, 2008). In the CDH survey 2013 the most common injury was enamel fracture. When compared to 2003, there was an increase in the number of enamel fractures at 12 years of age from 28.2 to 36 per thousand upper central incisors, and a decrease from 28.2 to 20.9 at age 15 years.

In 2013, there were increases in missing upper central incisors in both age groups. From 0.5 and 0.1 per thousand permanent incisors in 2003, for 12 and 15 years old respectively to 2.1 and 1.1 per thousand upper central incisors respectively [Table 1.1].

	12 years old		15 years old	
	2003	2013	2003	2013
Discolouration	1.9	1.0	2.6	2.4
Fracture (enamel)	28.2	36.0	28.2	20.9
Fracture (enamel & dentine)	6.8	7.4	5.9	9.4
Fracture (involving pulp)	0.2	0.1	0.4	*
Missing due to trauma	0.5	2.1	0.1	1.1
Acid etch composite	10.9	10.3	13.1	8.4
Permanent replacement	0.4	0.6	5.1	1.2
Temporary restoration	*	-	-	-

Table 1.1 Rate of different types of traumatic damage per thousand upper central incisors, by age 12 and 15 years old children in England, Wales, and Northern Ireland 2003 and 2013 Child Dental Health survey.

1.1.2 International prevalence of TDI

The prevalence of TDI in permanent teeth varies between and within countries. Although the oral region comprises as small as an area of 1% of the total body area, the prevalence of TDI is high throughout the world. Statistics from most countries show that one fourth of all school children and almost one third of adults have suffered a trauma to the permanent dentition (Glendor, 2008).

Table 1.2 shows the prevalence of TDI to permanent teeth in population-based surveys in different regions of the world.

Region	Survey	Age group	Sample size	Prevalence	Place of registration
USA	(Shulman and Peterson, 2004)	6-20	6558	16.0	Dental clinic
Israel	(Sgan-Cohen et al., 2005)	9-13	1195	29.6	At school
Kuwait	(Årtun et al., 2005)	13-14	1583	14.5	At school
Thailand	(Malikaew et al., 2006)	11-13	2725	35.0	At school
South Africa	(Naidoo et al., 2009)	11-13	1665	6.4	At school
Iran	(Navabazam and Farahani, 2010)	9-14	1440	27.56	At school
Palestine	(Livny et al., 2010)	6th grade	804	17.7	At school
India	(Kumar et al., 2010)	12-15	963	14.4	At school
Nigeria	(Taiwo and Jalo, 2011)	12	719	15.2	At school
India	(Patel and Sujan, 2012)	8-12	3708	8.79	At school
Swiss	(Schatz et al., 2013)	6-13	1900	16.1 in boys 12.1 in girls	8 Dental schools
Brazil	(De Frujeri et al., 2014)	12	1118	14.63 23.40	Public school Private school

Table 1.2 International prevalence of TDI to permanent teeth in population based survey in different regions of the world.

1.2 Aetiology and risk factors related to TDI

The number of aetiologies of TDI has increased dramatically in last 30 years. It includes oral factors, environmental factors, and human behaviour.

- Increased overjet with protrusion and incompetent lip coverage had been previously described as having a significant association with increased TDI among many different populations. However, the inconsistency in the definition of protrusion (greater than 3-3.5 mm in some studies, whereas

in others greater than 5 mm) makes it difficult to compare studies and to draw a firm conclusion (Glendor, 2008).

- The major environmental factor of TDI is material deprivation. It was reported that 34-44% prevalence of dental injuries in the UK were in deprived areas, and that TDI were positively correlated with deprivation (Marcenes and Murray, 2002). In contrast Rhouma et al. (2013) reported no significant association between dental injury in 5 years old children and increasing socioeconomic deprivation in Scotland.
- Human behaviour such as children hyperactivity, risk-taking, or children who were being picked on or bullied by other children experienced more dental trauma than other children. Children's hyperactivity had been linked to the surrounding environment, as the child can express his or her hyperactivity with less risk if the environment is safe (Odoi et al., 2002).
- Presence of illness, such as epilepsy and cerebral palsy, which include uncontrolled head movements seemed to be more important factor causing TDI than increased overjet (Girdler and Smith, 1999, Holan et al., 2005). A very high frequency of TDI has been found among patients with learning difficulties and hearing and visual impairment (Johnson, 1975).
- It had been reported that home and its neighbourhood are the most common place of injury in preschool and school-aged children, whereas physical leisure activities, violent incident and traffic accidents account for most TDI among adults (Glendor, 2008).

There are differences in the proportion of causes of TDI between countries and also in a region with both urban and rural areas. This difference is probably depends on a number of factors, including population type, age group, culture, region in the world and the environment. For example, it was found that violence was the main cause of TDI in 6-12 years old children in Iraq and Sudan with 36% and 71% respectively, which can be compared with only 3% in both population that were caused by sports (Baghdady et al., 1981). In contrast, in Japan and in the UK reports showed that sport to be among the main cause of TDI in teenagers (Uji and Teramoto, 1988, Blinkhorn, 2000). Whereas in Brazil, it has been found an almost equal occurrence of TDI resulting from sports (19%) and violence (16%) (Marcenes et al., 2000). Nicolau et al. (2001) reported that the proportion of unknown causes of TDI was 40%. If the number of unknown causes had been less, there would probably have been a greater distribution of other causes. Unknown causes might be a strategy used by an individual to conceal the real cause (e.g. violence) of the TDI. This means that violence, as a cause of TDI, has probably been underestimated in many countries. Thus, it is difficult to compare countries, but it is probably possible within a given country.

1.3 Tooth discolouration definition, and classification

Discolouration of a tooth is defined as a change in the normal colour of a tooth (Watts and Addy, 2001). Tooth discolouration has been classified according to

the location of the discolouring agents, as intrinsic, extrinsic, or internalised stain (Watts and Addy, 2001, Sulieman, 2005).

- Intrinsic discolouration occurs following a change to the structural composition or thickness of the dentinal hard tissues during tooth development and results in an alteration of the light transmitting properties of the tooth structure, and it could be pre- or post-eruptive staining. Local factors such as injuries are known to affect the developing dentition and cause discolouration as a consequence. In addition, a number of metabolic diseases and systemic factors are also recognised such as, congenital hyperbilirubinaemia, congenital erythropoietic porphyria, alkaptonuria, amelogenesis imperfecta, dentinogenesis imperfecta, tetracycline staining, fluorosis, enamel hypoplasia, pulpal haemorrhagic products, root resorption, ageing (Watts and Addy, 2001).
- Extrinsic discolouration where the staining is not within the tooth substance. The causes of extrinsic staining can be divided into two categories; direct staining by compounds incorporated into the pellicle layer and producing a stain as a result of the basic colour of the chromogens derived from dietary components, beverages and mouthrinses. Indirect staining is associated with cationic antiseptics and metal salts that are either colourless or of a different colour of the stain produced, as a result of a chemical interaction with another compound. Extrinsic tooth discolouration

has usually been classified according to the origin of the stain whether metallic, or non-metallic (Watts and Addy, 2001, Sulieman, 2005).

- Internalised tooth discolouration is another category that describes the changes in normal tooth colour. It is the incorporation of extrinsic stain within the tooth substance during dental development via a defect (developmental or acquired) or as a result of trauma (Watts and Addy, 2001, Sulieman, 2005). For example; extrinsic stains can penetrate into enamel defects, or TDI may results in loss of enamel or enamel cracks, both of which facilitate internalisation of extrinsic stains.

1.4 Types, and causes of discolouration following trauma

Discolouration of the teeth is common following trauma. The 2013 Child Dental Health survey reported a prevalence of discolouration between 1 - 2.4% per thousand upper central incisor in 12 and 15 years old children respectively. Different colours represent different clinical entities, some of which represent pulpal necrosis, whereas others indicate pulpal damage with subsequent healing. Furthermore, discolouration can occur as a result of materials used for subsequent endodontic treatment.

1.4.1 Pulpal haemorrhage

Multiple authors have studied the effect of pulp haemorrhage on the discolouration of teeth, particularly following severe trauma. Pulp haemorrhage has been proposed as a cause of tooth discolouration, it is thought to be the haemolysis of the red blood cells followed by the accumulation of the haemoglobin molecule or other haematin molecules and their penetration into the dentinal tubules. The severity of discolouration is determined by the extent of this process (Watts and Addy, 2001, Sulieman, 2005).

Erythrocytes require a normal inflammatory response to allow the breakdown of the haemoglobin; the erythrocytes in the pulp chamber are surrounded by dentine and cementum, which isolates them from any inflammatory or healing responses from adjacent tissues. If a pulp does not survive or if revascularisation does not occur, the haematin material from the erythrocytes remains within the pulp chamber and the tooth appears with a pinkish hue (Marin et al., 1997). While in some cases, pinkish discolouration may occur initially after trauma, that can disappears in two to three months as a result of revascularisation (Watts and Addy, 2001).

Andreasen (1989) defined grey discolouration in the crown after traumatic injury, together with periapical radiolucency and loss of pulp sensibility, as the classical criteria for the diagnosis of pulp necrosis. In view of loss of pulp sensibility is the major criteria and at least one other clinical and/ or radiographic sign were considered necessary before the diagnosis is made.

1.4.2 Transient apical breakdown (TAB)

Transient apical breakdown (TAB) is a resorption of the apical periodontium in the form of a radiolucency or expansion of the periodontal (PDL) space, that appeared spontaneously sometime after injury, and which at later follow-up returns to normal without further radiographic change or is accompanied by surface resorption and/or pulp canal obliteration (Andreasen and Andreasen, 2006).

Transient colour and sensibility change could also appear simultaneously with TAB, and return to normal with the normalisation of the periapical condition. Andreasen (1986) found that 27 out of 637 luxated teeth exhibited TAB. Thus, of these 27 cases, 10 demonstrated temporary colour change where return to normal colour occurred before or simultaneously with the disappearance of the TAB. There were 8 cases of the 10 that demonstrated both colour and electrometric sensibility changes. In all cases grey discoloration was recorded.

TAB appeared to be related to moderate injuries, such as extrusion and lateral luxation. Moreover, the stage of root development was found to be of importance. TAB is characterised by either moderate injury to the pulp or a moderate combined injury to the PDL and the pulp in mature teeth. Also it appears to be a phenomenon linked to the repair processes in the traumatised pulp and periodontium of luxated mature teeth (Andreasen, 1986).

1.4.3 Endodontic materials

Pulp death may follow severe trauma and endodontic treatment often becomes necessary (Marin et al., 1997). Chemicals and Materials used in root canal treatment can induce coronal tooth discolouration if they are left in the crown of the tooth during or after root canal treatment. The most common materials cause this internalised staining of dentine include irrigants, medicaments, core filing materials and root filling cements.

Sodium hypochlorite (NaOCl), at varying concentrations, is the most common irrigant. Sodium hypochlorite is a bleaching agent and is not usually considered to cause tooth discolouration. However, it has been reported that NaOCl cause dentine discolouration. Gutiérrez and Guzmán (1968) reported that the discolouration was a result of the contact of NaOCl with erythrocytes and its high tendency to crystallise on the root dentine. Vivacqua-Gomes et al. (2002) observed a dark brown precipitate that can stain the dentine, adhere to the floor of the pulp chamber, access cavity and root canal walls. One can argue that in the former study the NaOCl solutions used were undiluted and 10%, which consider a high concentration, and in the later study NaOCl was combined with chlorhexidine (CHX) gel. Other authors have reported the same type of discolouration when NaOCl has been used with CHX solutions (Basrani et al., 2007, Marchesan et al., 2007, Bui et al., 2008, Akisue et al., 2010, Krishnamurthy and Sudhakaran, 2010, Nassar et al., 2011, Souza et al., 2013).

Calcium hydroxide and Ledermix® are the most commonly used intra-canal medicaments in many parts of the world. The main therapeutic components of

Ledermix® are triamcinolone acetonide and demethylchlortetracycline. Tetracycline is known to produce colour change in hard tissue including teeth (Kim and Abbott, 2000, Kim et al., 2000a, Kim et al., 2000b).

Kim and Abbott (2000) examined the discolouration properties of $Ca(OH)_2$ along with Ledermix. They did not find significant difference of the $Ca(OH)_2$ group of mature teeth when it was compared with the control (saline filled teeth), but conversely the $Ca(OH)_2$ group of immature teeth showed significant increase in lightness and yellowness. It was found that after 12 weeks, Ledermix paste had caused grey-brown discolouration in the crowns of both mature and immature extracted teeth. The teeth with Ledermix paste became dark brown only upon exposure to sunlight (Kim and Abbott, 2000, Kim et al., 2000a, Kim et al., 2000b). Similar results were also reported (Lenherr et al., 2012), as severe and increasing discolouration occurred in the Ledermix bovine teeth specimens especially after the specimens had been exposed to indirect sunlight; this is an important clinical finding. These results suggest but cannot prove that anterior teeth would probably show more discolouration than posterior teeth, particularly if paste was left in the crown.

In a randomised control trial aimed to assess the discolouration of teeth after avulsion and replantation (Day et al., 2011), in which teeth were randomly assigned to either UltracalXS® (non-setting calcium hydroxide paste) or Ledermix® as the initial root canal medicament. Eight of the 22 patients recruited were concerned with the colour of their avulsed teeth. Seven of these patients had been randomised to the Ledermix® group, and one patient in the UltracalXS® group expressed dissatisfaction with the colour. There was a

noticeable darkening and greying effect of the teeth in the Ledermix® group and a yellowing effect in the UltracalXS® group. This finding, however, was based on colour change measured following the obturation of both tooth groups with gutta-percha and therefore the discolouration could not be attributed to the intra-canal medicaments only. Furthermore, multiple operators were involved in this study and the details of the application method were not mentioned as to whether the operators had completely removed the materials from the access cavity.

Other medicaments, such as formocresol and iodoform-based medicaments, have also been reported to cause coronal discolouration (Gutiérrez and Guzmán, 1968, Kupietzky et al., 2003). Dankert and Wemes (1976) demonstrated the ability of formocresol, especially with repeated applications, to penetrate dentine and cementum, particularly in young patients. This diffusion is attributed mainly to the small molecular composition of formocresol and the wider dentinal tubules in young patients. In addition to its discolouration potential, gingival necrosis and bone sequestration have also been reported (Cambruzzi and Greenfeld, 1983).

Sealers themselves have also been evaluated as to their discolouration potential. Vanderburgt et al. (1986) evaluated the staining characteristics of eight sealers in an in vitro study. The results showed that sealers produced marked discolouration within several weeks, with some sealers producing more marked changes than the others; AH26 caused a moderate grey discolouration within one week, apparently the silver corrodes to a grey-black, which likely contributes to the staining. Although the other sealers tested did not contain

silver, or any other heavy metal, they obviously contained ingredients that could stain dentine. The same results were reported by (Parsons et al., 2001) in their longitudinal study, as AH26 and Kerr pulp canal sealer caused slightly more discolouration. However, the use of silver-free AH26, caused significant tooth discolouration as reported by (Partovi et al., 2006); therefore, it can be argued that silver ions are not the sole reason for tooth discolouration by AH26. Interestingly, in these two studies no effort was made to remove the smear layer or the sealer from the chamber which could affect the staining potential (Kouvas et al., 1998).

Davis et al. (2002) noticed that the greatest tooth discolouration was in the cervical third, which is consistent with other reports (Vanderburgt et al., 1986, Parsons et al., 2001, Partovi et al., 2006). It has been shown that tooth discolouration may not necessarily be related to the materials penetration into dentine, and may be related to the discoloured materials that had been retained for long periods in the pulp chamber.

Mineral trioxide aggregate (MTA) is a useful material for situations like direct pulp capping and root perforations. Several studies have reported the ability of MTA to cause tooth discolouration. This is probably a result of the oxidation of some elements in the material (Ahmed and Abbott, 2012). In a laboratory study (Lenherr et al., 2012), there was a significant progressive discolouration between baseline and 12 months in bovine teeth specimens of the white MTA + blood. Grey MTA showed severe discolouration immediately after the placement of the GMTA. However, white MTA gave good results in a case report of vital pulpotomy following a complicated crown fracture, although it

induced a slight grey discolouration at one month review which became of patient's and parents' concern. The discolouration was successfully managed by complete removal of the discoloured WMTA and internal bleaching after formation of a hard tissue bridge (Belobrov and Parashos, 2011).

1.5 Tooth discolouration impact on patients and their perception

The traumatic injuries of the teeth constitute unfortunate, painful, and distressing events with multilevel consequences for children and their families, which involve not only physical health but also economic, social, and psychological wellbeing of individuals (Sheiham and Croog, 1981, Lee and Divaris, 2009).

In a population-based matched case-control study for Brazilian schoolchildren (Cortes et al., 2002). The prevalence of oral impacts, measured by the Oral Impact on Daily Performances (OIDP) index, was higher for children with untreated fractured teeth (study group) than for the children with non-fractured teeth (control group). Sixty-six percent of children from the study group experienced at least one impact on their daily living in the last six months. For both groups of children the most prevalent OIDP impact was 'smiling, laughing and showing teeth without embarrassment' with the proportion being higher for cases than for the control. All other oral impacts were more prevalent for cases than for controls. The least impact for both groups was speaking and

pronouncing clearly. The same level of impact for treatment of dental trauma on the daily activities of adolescents was reported in Southern Brazil (Ramos-Jorge et al., 2007) measured by OIDP, 40% presented at least one negatively affected daily activity in the previous six months even after treatment, when compared with adolescents with no history of dental trauma. This suggests that even with restoration efforts, the consequences of the trauma leaves impacts that cannot be fully eliminated, but merely minimised.

A number of 108 children who attended a UK dental hospital, for management of traumatised permanent incisors, completed a self-report questionnaire at baseline, and the outcome variables were assessed again at a 6-month follow-up (Porritt et al., 2011). Psychosocial outcomes assessed included children's oral health-related quality of life (OHRQoL) and health-related quality of life (HRQoL), their mean scores indicating that children had a relatively low number of impacts on their quality of life following dental injuries. Within the child's HRQoL, the most impact was upon missing school to go to the dentist, followed by worry over what will happen to them and feelings of anger, and the most impacts within the OHRQoL was upon food stuck in between their teeth, and difficulty chewing or biting firm foods. The least impacted upon areas included difficulty in speaking words, followed by other children teasing or calling them names. No significant associations were identified for time since injury, number of appointments attended, number of teeth injured, severity and visibility of the injury. The only demographic variable that was significant was gender, where girls were found to report impacts more than boys. At the 6-month follow-up, school-related activities and functional limitations persisted to be the most areas

of impacts, but with significant improvements for all items except of social impacts related to children's OHRQoL.

In a study comparing the impact of traumatic dental injuries and malocclusion on quality of life of young children in primary dentition stage. Parents' responses of the Early Childhood Oral Health Impact Scale (ECOHIS) were used to assess the frequency in which oral disease and treatment affect their child's OHRQoL. They observed that the presence of malocclusion did not show a negative impact on the overall OHRQoL, while complicated dental injuries showed a negative impact on the symptoms, psychological, self-image/social interaction and family function domains of OHRQoL and in the overall mean ECOHIS score (Aldrigui et al., 2011). This is probably due to the sequelae from the untreated TDI, such as pulp necrosis. In addition, the time and urgency of treatment following this type of injury may lead to parents' missing work and the financial expense of dental care both of which may affect the parents' responses.

The functional and psychosocial impacts of post-traumatic appearance may continue to be reported long after initial or definitive treatment (Lee and Divaris, 2009). Thirty-nine percent of Swedish adults who had suffered from dental trauma as children were unsatisfied with either the colour and/or the anatomic form of the traumatised teeth or restoration 15 years later (Robertson and Noren, 1997), and most patients with a yellowish obliterated tooth were also dissatisfied (Robertson, 1998). In Brazilian adolescents, the psychosocial impacts were not eliminated even after definite treatment including orthodontic alignment (Ramos-Jorge et al., 2007).

It has been recognised that psychosocial impacts of dental trauma in childhood may be severe (Fakhruddin et al., 2008), so aesthetic consideration should not be neglected. Vlok et al. (2011a) investigated young people's, aged between 6 and 24, perceptions of photographs of common traumatic injuries. Children were also asked to estimate the likely pain different injuries would cause. It was found that there were age differences, not only in the perception of the discomfort, but also in the aesthetic impact. Sixty-nine percent of the participants thought tooth extrusion would hurt the most, and it was also ranked as having the greatest aesthetic impact. It is possible that the presence of blood may have influenced the younger participants scoring of the extrusion, with the associated bleeding as the injury likely to hurt most. The image of avulsion was more acceptable to the younger children as it is more likely to fit with peers in the mixed dentition phase. In contrast, the image of a discoloured tooth was least acceptable, which suggest that children may be aware of the impact of this appearance. Older participants were more likely to focus on the injury to the tooth itself, with complicated crown fracture being scored as the most painful, and it was deemed to be the most difficult type of trauma for a dentist to treat among all age groups.

1.6 Science of colour

1.6.1 Nature of colour

Colour is all about light. For colour to be seen, light is reflected from an object and stimulates the neural sensors in the eye's retina to send a signal that is interpreted in the visual cortex of the brain (Brewer et al., 2004).

The reflected components of incident white light determine the colour of an object (Russell et al., 2000). Transparent materials allow for the passage of light with little change. Translucent materials scatter, transmit and absorb light. Opaque materials reflect and absorb; however they do not transmit. Most of the colour found in a natural tooth is established within the tooth (Seluk and Lalonde, 1985). The semi-translucent structure of teeth makes colour matching procedure more complex when compared with an opaque object (Barrett et al., 2002). Surface characteristics, such as gloss, curvature and texture affect the degree of light diffusion when striking the particular object (Preston, 1985).

1.6.2 Effect of the surroundings

Eye perception of a colour is affected by the reflection, and the surrounding colours interference. Therefore, it is critical to have a neutral background colour, also the effects of clothing, and make-up, especially lipstick, must be neutralised. It has often been stated that since our eyes can be fooled into seeing colours differently by surroundings, one should stare at a tooth for less than five seconds because our eyes become accommodated to the colours of

red and yellow. Looking continuously at an object of one colour will produce an after-image. To reduce its effect, it is recommended to look at a blue object (such as the patient's bib) between assessing different shade tabs (Boksman, 2007).

1.6.3 Light quality

The quality of the light source is the most influential factor when determining tooth shade. A frequent recommendation in the dental literature is to take shades in daylight at mid-day, but this light can vary tremendously depending on weather conditions, time of year and global positioning. Dental unit lights are usually incandescent lights that emit light high in the red-yellow spectrum and are low at the blue end. Exact shade selection and reproduction is impossible without a full colour spectrum light source. Full spectrum light emitting diodes (LEDs) are now replacing incandescent bulbs (Boksman, 2007) and improve the ability of clinicians to shade match.

1.6.4 Three dimensions of colour

Albert Munsell described colour as a three dimensional phenomenon, which are critical elements to consider when discussing colour (Fondriest, 2003), Figure 1.1 illustrating Munsell colour system.

- Hue is the quality that distinguishes one colour from another (i.e. red, blue, green etc). Hue is a physiologic and psychological

interpretation of a sum of wavelengths. In dental terms, hue is represented by the letter A, B, C, or D on the commonly used Vita Shade Guide (Boksman, 2007).

- Value or brightness is the amount of light that is reflected from an object. Value is the most important dimension of colour. Munsell described value as a white to black grey scale. Bright objects have lower amounts of grey and low value objects have larger amounts of grey and will appear darker (Boksman, 2007).
- Chroma is the saturation, intensity, or strength of a specific colour. Any change in chroma has a corresponding change in value. Chroma and value are inversely related, as chroma is increased, the value is decreased. Chroma is represented by numbers on the Vita Shade Guide.

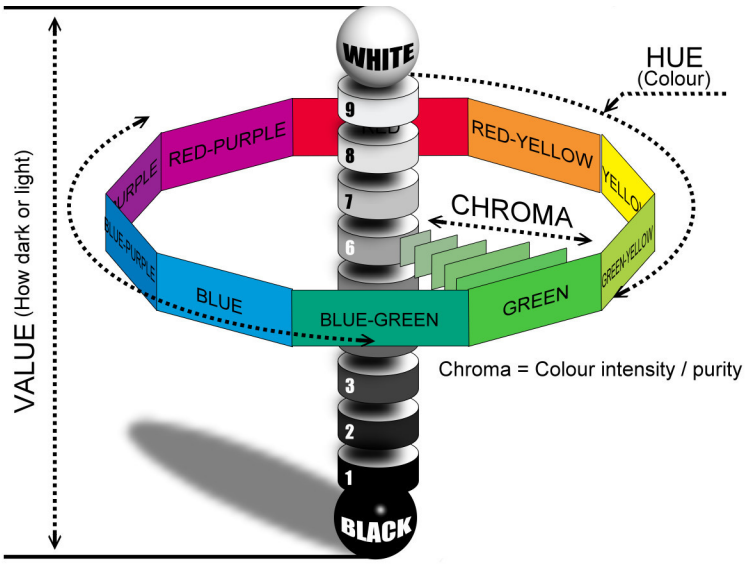

Figure 1.1 An illustration of Munsell colour system. Image was taken from http://www.paintbasket.com/munsell/munsell_print.jpg

1.6.5 Translucency

Translucency is another dimension beyond hue, chroma, and value that is significant when mimicking nature. Translucency can be defined as the gradient between transparent and opaque. Human teeth are characterised by varying degrees of translucency. The translucency of enamel is a function of wavelength. The longer the wavelength, the higher the translucency. Therefore, enamel is more translucent in light rich in yellow and red, and will show more dentine making the tooth appear redder with higher chroma and low value than it actually is. Generally, increasing the translucency of a crown lowers its value because less light returns to the eye. With increased translucency, light that enters is scattered within the restoration. Normally, increasing opacity or reflectivity increases value (Fondriest, 2003).

1.6.6 Fluorescence

Fluorescence is considered a subset of reflectivity. In a natural tooth it primarily occurs in the dentine due to the higher amount of organic material present. The more the dentine fluoresces, the lower the chroma. By definition, fluorescence is the absorption of light by a material and the spontaneous emission of light in a longer wavelength. With the characteristic of fluorescence, the restorations look brighter and more alive. Fluorescent powders are added to crowns to increase the quantity of light returned back to the viewer, to block out discolourations, and to decrease chroma (Fondriest, 2003).

1.6.7 Opalescence

It is a phenomenon where a material appears to be one colour when light is reflected from it and looks another colour when light is transmitted through it. The hydroxyappatite crystals of enamel act as prisms and refract (bend) different wavelengths to varying degrees. Wavelengths of light have different degrees of translucency through teeth and dental materials. When illuminated, enamel will transilluminate the reds and scatter the blues within its body. This is why enamel appears bluish at the incisal edge even though it is colourless. The opalescent effects of enamel brighten the tooth and give it optical depth and vitality (Fondriest, 2003).

1.6.8 Metamerism

The colour of an object depends on the object itself, the observer, and the illumination. The spectral distribution of the light under which an object is viewed differs among illuminants. The light being reflected by, or transmitted through, the illuminated object depends on this distribution. Furthermore, an observer could have the perception of the same colour when comparing two objects with a specific illuminant, yet different colours when another illuminating light source is used. This phenomenon is known as metamerism; that is when objects appear to be colour matched under one illumination but different under another illumination (Corcodel et al., 2010).

In the daily lives of patients, many different light sources are present, for example daylight, incandescent light, or illuminants comparable with store or

office light sources. Good colour matching of a dental restoration by a dentist under daylight conditions may not result in a match under other light conditions. This metameric effect between teeth and dental restorations could have a negative effect on dental aesthetics. Therefore, careful shade matching should be performed and confirmed under different lighting conditions, such as natural daylight and fluorescent light to avoid the problem of metamerism (Corcodel et al., 2010).

1.6.9 Optical properties of teeth

The colour of a tooth is determined by a combination of its optical properties. When light encounters a tooth, four phenomena associated with the interactions of the tooth with the light flux can be described (Joiner, 2004).

1. Specular transmission of the light through the tooth.
2. Specular reflection at the surface.
3. Diffuse light reflection at the surface.
4. Absorption and scattering of light within the dental tissues.

An in vitro study showed that the colours of 28 teeth from different patients where the enamel was removed correlated strongly with the colours of the complete tooth (ten Bosch and Coops, 1995). Thus, this study confirmed that tooth colour is determined mainly by dentine, with enamel playing only a minor role through scattering at wavelength in the blue range.

The degree of scattering and absorption of light in the tooth enamel also play a role in determining the colour of the tooth. If light falls on a tooth, part of the light is scattered and then absorbed. The other part is scattered and pass the enamel layer, resulting in its translucent appearance. Other incident photons undergo a sideward displacement in the enamel and emerge at a certain distance from the place of incidence and cause volume reflection (Vanderburgt et al., 1990).

Vaarkamp et al. (1995) measured the propagation of light through 0.85 mm thickness human enamel and dentine bars. It was concluded that the dentinal tubules are the predominant cause of scattering in dentine, and the hydroxyapatite crystals contribute significantly to the scattering in enamel and that the influence of the prism structure on the light propagation is small.

1.6.10 Tooth colour distribution

Colour of the tooth is differs in different regions of an individual tooth. In a study on extracted teeth (O'Brien et al., 1997), the distribution of colour was identified for middle, gingival, and incisal regions by using a spectrophotometer and the Munsell colour system. The statistical analysis showed that there was a significant colour differences between regions, gingival area was slightly darker than the middle and incisal edge, and these differences were also clinically significant. In general, the maxillary anterior teeth were slightly more yellow than mandibular anterior teeth, and the maxillary central incisors were higher in value than the lateral incisors and canines.

According to the results of an observational study (Jahangiri et al., 2002), it was suggested that there was a significant relationship between tooth shade and skin colour. Individuals with medium to dark skin tones were more likely to have teeth with higher values (lighter), whereas individuals with lighter skin tones tended to have teeth with lower values (darker), regardless of gender or age.

In general, natural tooth colour has a significant tendency to increase with the age of the subject, generally becoming darker and more yellow (Jahangiri et al., 2002).

1.7 Colour measurement in dentistry

The perception of tooth colour is a complex phenomenon, with many factors influencing its overall appearance; such as lighting conditions, translucency, opacity, light scattering, gloss and the human eye and brain. The measurement of tooth colour is possible via a number of methods including visual subjective comparisons with shade guides, and instrumental objective measurements using spectrophotometers, colourimeters, and computer analysis of digital images. Each method has its own limitations and set of advantages and disadvantages (Joiner, 2004).

1.7.1 Visual technique

Visual colour determination is the most frequently applied method in dentistry. It is a subjective process whereby the tooth and the shade guide are observed simultaneously under the same lighting conditions. General variables such as external light conditions, experience, age, and fatigue of the human eye and physiological variables such as colour blindness may lead to inconsistencies and bias (Joiner, 2004).

The process includes colour, shape, structure, gloss, and dissimilarities between the centre and the sides of a tooth. The effects of these factors may be interpreted differently by different observers (Vanderburgt et al., 1990).

A number of methods for taking tooth shades visually have been described. In general, the basic shade of a tooth is represented only in the middle third. Owing to the range of colour changes from the incisal to gingival areas, the experienced observer must focus on the middle third of the tooth. It has been recommended to re-arrange the shade guide from the lightest to darkest and the value should be selected first. The basic hue and chroma variations are then be determined (Joiner, 2004).

The range of shades available is inadequate and does not cover the complete colour space of natural tooth colour; the shades are not systematically distributed; the results cannot be transformed into the CIELAB colour scale (Vanderburgt et al., 1985); and none of the commercially available shade guides are identical (Joiner, 2004).

Despite these limitations, the human eye is very efficient in detecting even small differences of colour between two objects. The tooth colour discrimination of individuals can be improved with training and experience. Moreover, the use of shade guides is a quick and cost-effective method for measuring tooth colour (Joiner, 2004).

1.7.1.1 Shade guides

A shade guide is composed of a set of tooth-shaped porcelain tabs intended to cover the range of colours present in human teeth.

The shade guides that are the most widely used today have not changed much in the last 50 years. In the mid-1970s, the limitation of the available shade guides and porcelain formulation had been identified, and there was many calls upon dental manufacturers to invest in reformulation, quality control in porcelain production, and development of logically ordered shade guides that would allow for proper orientation within the colour space of natural teeth.

Modern shade guides are arranged using the Munsell colour system and tend to be grouped in terms of hue, value and chroma (Brook et al., 2007).

The shade guide most commonly used for indirect restorations is based on the Vita Classical shades [Figure 1.2]. The Vita Classic shade guide is organised into groups of similar hues (A to D), with these groups being divided further via numerical values (1 to 4). Generally, the Chroma (intensity of colour) increases and Value (lightness) decreases as the numbers rise (Brewer et al., 2004). The shade tabs arrangement in the Vita Classical is by hue, however Value-based

shade guides are a more accurate means of shade selection. The Vita classical shade guide can be rearranged according to a value-based ordering system (B1, A1, A2, D2, B2, C1, C2, D4, D3, A3, B3, A3.5, B4, C3, A4, and C4). The human eye is more sensitive to changes in value rather than subtle changes in hue (Brewer et al., 2004).

Figure 1.2 Vita Classic shade guide arranged by hue-based ordering system. Image was taken from http://www.dentamedical.com/cart/index.php?main_page=product_info&products_id=84

Significant advances in shade guide organisation and coverage of natural tooth colour space has been developed. An example is the Vitapan 3D-Master Shade System (Vita Zahnfabrik, Bad Sackingen, Germany). The manufacturer claims that this shade system provides a systematic arrangement of ‘‘virtually all existing natural tooth shades’’ and it has been determined that the order of colour dimensions in this guide is adequate. Based on spectrophotometric measurements of natural teeth, the shade guide is organised so that it covers the three-dimensional natural tooth colour space in logical, visually equidistant order. The tabs are arranged in five clearly discernible value levels [Figure 1.3], within each level are tabs that represent different chromas and hues. The five

levels cover that area of the CIELAB colour solid occupied by natural teeth, with approximately 50% of natural tooth shades occupying the middle value levels (Groups 2, 3, and 4), and about 2% of natural teeth occupy the outer levels (Groups 1 and 5). The sequence of shade selection is value, then chroma, followed by hue. The selection process is simplified because the number of choices decreases throughout the procedure.

Figure 1.3 Vitapan 3D-Master Shade System. Image was taken from https://www.vita-zahnfabrik.com/en/VITA-Toothguide-3D-MASTER-26230,27568,86077.html

Paravina et al. (2001) analysed and compared the shade tab arrangement of Vitapan Classic and Vitapan 3D-Master shade guides. According to them, the value-based arrangement of the Vitapan 3D-Master shade guide was more consistent and they recommended that the tabs of Vitapan Classic guide should also be arranged according to the value of the shades.

Hammad (2003) reported that by using Vita Lumin Vacuum shade guide, intra-rater repeatability among prosthodontists was significantly higher than among general practitioners. However, when using Vitapan 3D-Master shade guide, intra-rater repeatability among general practitioners improved significantly.

1.7.1.2 Shade selection

Shade selection is an important procedure to provide patients with an aesthetic restoration that match the patient's existing dentition.

The light source for colour matching is critically important because of its influence on the quality and intensity of light reaching the teeth to be matched. Traditionally, it has been thought that natural daylight is the best colour matching light source. However, it is not dependable because of its variable colour temperature, which influences its spectral composition, and its inconsistent intensity due to varying cloud cover and atmospheric pollutants.

The benefits of performing colour matching under controlled standard full-spectrum illumination have been reported (Bergen and McCasland, 1977). Controlled lighting sources in the dental operatory and laboratory should be spectrally balanced in the visible range (380–780 nm) and should have a colour temperature of approximately 5500‒K and a Colour Rendering Index of >90.

It may be helpful to use an auxiliary light source that provides the appropriate spectral balance and diffuse illumination and is bright enough to overcome the effects of ambient illumination. The intensity should be comfortable to the eyes; too much compromises the ability to discriminate small colour differences. A number of lighting manufacturers supply bulbs that meet these requirements (Brewer et al., 2004).

The operatory ceiling, walls, counter tops, and cabinets are reflectors that contribute to the intensity and colour of the ambient lighting and therefore should have a high Munsell Value and low Chroma. Pastels and neutral grey

have been suggested for walls, staff clothing, and patient napkin (Brewer et al., 2004).

Dagg et al. (2004) investigated the relative importance of four factors related to the shade taking procedure; light quality, the difference between two brands of porcelain, the thickness of porcelain, and the experience of the observer. Light quality was the most critical influencing factor in the selection of correct shades, with the ideal light giving more accurate results, and under these conditions thicker samples gave better results. The experience of the observer was found to be an important factor. Hammad (2003) found that prosthodontists demonstrated superior reproducibility in shade selection than general practitioners who both had an average experience of 14 years.

Certain practical guidelines should be followed when selecting shades visually (Ho et al., 2007),

- It should be completed before tooth preparation, as teeth can become dehydrated and result in higher value.
- Better to be done at the beginning of the day, so the dental team is not fatigued.
- The surroundings should be of neutral colour.
- Remove lipstick; bright patient's clothes could be masked.
- Teeth to be matched should be clean.
- Patient should be in an upright position at the operator's eye level and the shade guide should be at arms length so the most colour sensitive part of the retina will be used.

- Shade selection should be made quickly in about 5 seconds, to avoid fatiguing the cones of the eyes, if so, dentists can look at a blue object (bib) while resting the eyes.
- Use colour corrected light illumination, which should be of a diffuse nature.
- Shade should be matched at the middle of the tooth, starting by selecting the value, followed by chroma then hue.
- Examine tooth for translucency and any characterisations, e.g. craze line, hypocalcification, etc.

If having trouble determining Hue, one should reference the natural canine, which is of higher chroma so the dominant hue is more apparent (Brewer et al., 2004).

1.7.2 Instrumental technique

The Commission Internationale de l'E´clairage (CIE), an organisation devoted to standardisation in areas such as colour and appearance, defined in 1931 a standard light source, developed a standard observer and enabled the calculation of tristimulus values, which represent how the human visual system responds to a given colour. In 1976, the CIE further defined a colour space; CIE LAB that supports the accepted theory of colour perception based on three separate colour receptors (red, green and blue) in the eye and is currently one of the most popular colour spaces. The CIE Lab colour space represents a uniform colour space, with equal distances corresponding to equal perceived

colour differences. In this three-dimensional colour space the three axes are L*; a* and b* (McLaren, 1987).

In this system, the colour space consists of three coordinates: L*, a* and b* [Figure1.4]. The L* refers to the lightness coordinate, and its value ranges from 0 for absolute black to 100 for absolute white. The a* and b* are the chromaticity coordinates in the red–green axis and yellow–blue axis, respectively. Positive a* values reflect the red colour range and negative values indicate the green colour range. Similarly, positive b* values indicate the yellow colour range while negative values indicate the blue colour range. The differences in the lightness and chromaticity coordinates (L*, a*, b*) as a result of UV light exposure are determined first, and the total colour change (ΔE) can be calculated using the relationship

$$\Delta \mathrm{E} = \sqrt{\Delta L^{*2} + \Delta a^{*2} + \Delta b^{*2}}$$

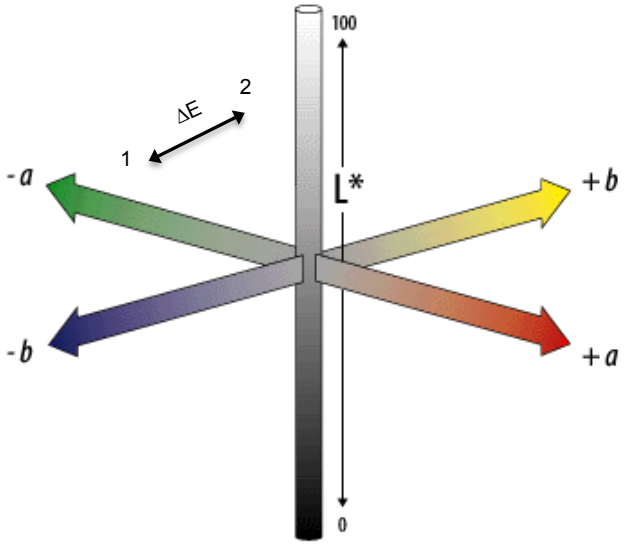

Figure1.4 CIELAB colour space. L is the lightness coordinate that ranges between white to black, a is the red-green axis, b is the yellow-blue axis. A point in this three dimensional space can be identified for every object. A change in colour (from point 1 to point 2) is represented by ΔE and can be calculated by the distance between the two points. This value expresses the size of the colour change but not the direction. Image was taken from http://dba.med.sc.edu/price/irf/Adobe_tg/models/cielab.html

This system gives a numerical value for each colour in each of the three coordinates. In addition the change in colour with time, or for objects of two different colours can be calculated for the three coordinates (ΔL*, Δa*, Δb*) and the distance between the two points on the colour space can be calculated to give a ΔE.

Instrumental colour analysis offers a potential advantage over visual colour determination, because instrumental readings are objective, can be quantified and are more rapidly obtained. Instrumental shade taking systems make measurements at one or a number of points on a tooth‘s surface. The recorded values can be available to the dentist, patient and technician almost immediately. Numerous systems are available, they are more reproducible than

humans, with more recent studies showing day-to-day repeatability of 83% to 100% (Horn et al., 1998).

However, there are downsides with some of these devices, including edge-losses, instrumental drift, approximation and cost. Furthermore, colour measurements of the same sample over time have previously been shown to produce colour difference values that would be visible (Horn et al., 1998). Their use in the oral environment used to be challenging owing to cross infection issues, but this has now largely been overcome.

1.7.2.1 Shade-taking devices

These devices are a means to improve the assessment of tooth colour by clinicians and technicians. Such devices give control over external light conditions by measuring the surface colour of a sample by the total amount of reflected light from the sample, and the photo-optical measurement allows quantification of colour using CIE (Commission Internationale de l'E´clairage) L* a* b* coordinates. Based on CIE L* a* b* parameters, data on tooth colour obtained from computerised devices such as colourimeters and spectrophotometers allow for an objective mathematic comparison.

Spectrophotometers measure one wavelength at a time from the reflectance or transmittance of an object. However, Tung et al. (2002) stated that the facts of the complexity of spectrophotometers, its cost, and the difficulty in its clinical use to measure tooth colour, has limited its use in dental research and in clinical settings.

The mathematical background of the spectrophotometric shade assessment, and the improved standardisation of the measuring procedure compared to observation by human eye, may account for its reproducibility and furthermore explain why the spectrophotometer offers a closer match in 90% of cases (Paul et al., 2002, Paul et al., 2004).

During the last two decades the use of colorimeters has rapidly escalated in dentistry. The first colorimeters were developed already in 1870s, but until 1990s their main uses were in chemistry where concentrations of substances were determined by measuring colour intensities (Stock, 1994). Colourimeters have colour filters that approximate the spectral function of the standard observer's eye. Colourimeter measurements have been compared with spectrophotometer readings and deemed reliable and accurate for colour difference measurements (Brook et al., 2007).

In a study attempted to compare the shade matching abilities of dental students and dental technician students to the shade determined using a colourimeter, Klemetti et al. (2006) showed that only 8% to 34% of the shade tabs selected, using three different commercial shade guides, matched those recorded by the colourimeter. Thus, digital colorimeter may be a useful educational tool in teaching and standardising the shade selection procedure.

With adequate knowledge and training, colourimetry and spectrophotometry methods are fairly easy to use. However, these methods incorporate variability of results when measuring curved and translucent tooth surfaces. Therefore, measuring small sample areas may be required that may result in inadequate measure of the colour of the whole tooth surface.

1.7.2.2 RGB devices (Digital cameras)

Digital image analysis is an alternative objective approach that been used recently for colour measurement for teeth and skin. A typical digital image analysis system comprises a high-resolution digital camera attached to image acquisition software. Results are usually given as CIELAB coordinates or (RGB) Red, Green, Blue values (Brook et al., 2007).

Studies have shown the suitability and precision of digital image analysis systems for quantifying tooth colour clinically using CIELAB colour coordinates. These studies investigated bleaching for quantifying changes in tooth colour (Donly et al., 2005), assessed plaque coverage on teeth (Li et al., 2006), or for quantifying demineralised white lesions on anterior teeth (Benson et al., 2005). They all concluded that digital image analysis is a valuable method for these assessments.

Digital image analysis offers advantages that includes; it requires quick and simple training, non-contact approach can objectively measure large surface areas of a tooth. Using this method images can be stored to allow subsequent analysis and repeat measurement (Brook et al., 2007).

1.7.3 Perceptibility and acceptability (detectable colour change by human eye and when this discolouration necessitates further treatment?)

In the majority of dental colour studies, colour is quantified using the CIELAB colour space, and the associated ΔE of the perceived colour difference between a pair of coloured samples under a given set of experimental conditions. However these values are of little clinical meaning without establishing the parameters that have some practical implication. Therefore, it is important to determine the perceptible colour difference, which is the smallest value of colour difference that can be detectable by a human observer (perceptibility threshold), and the value of colour difference that most individuals would consider unacceptable (acceptability threshold).

Several studies have attempted to investigate the threshold for perceptibility and/or acceptability of colour difference in dentistry. Table summarises the results of these studies, showing that the absolute perceptibility ranges from 1.8 to 3.7 ΔE, and the acceptability in an aesthetic sense ranges from 1.25 to 6.8 ΔE of dental colour difference in humans.

Study	Perceptibility threshold (ΔE)	Acceptability threshold (ΔE)	Samples
(Ruyter et al., 1987)	NM*	3.3	Composite resin
(Seghi et al., 1989)	2	NM*	Monochromatic porcelain discs
(Johnston and Kao, 1989)	3.7	6.8	Composite veneer and compared teeth
(Douglas and Brewer, 1998)	NM*	1.7-2.7	Metal-ceramic crowns
(Ragain and Johnston, 2000)	NM*	2.72	Translucent porcelain desk
(Lindsey and Wee, 2007a)	NM*	1.25 - 2.8	Computer simulated teeth
(Douglas et al., 2007)	2.6	5.5	Test denture with interchangeable tooth
(Ghinea et al., 2010)	1.8	3.46	Dental ceramics
(Lindsey and Wee, 2010)	NM*	1.45-2.9	Digital facial portrait
(Alghazali et al., 2012)	1.9	4.2	Interchangeable teeth on phantom head

Table 1.3 A summary of the studies investigated the perceptibility and/or acceptability threshold of colour difference in dentistry. The mean colour perceptibility threshold ranging between 1.8 to 3.7 ΔE, and the mean colour acceptability threshold ranging between 1.25 to 6.8 ΔE, those were determined for 50% of dental professional observers. NM* indicating not measured.

Visual colour assessment by human observers depends on several factors, related to the illumination, the object and the observer. Some variables, which can result in variation, include characteristics and position of the illuminant, environment, perception angle, fatigue, emotions, colour perception deficiencies in the observers, and the colour detection difference amongst individuals.

Colour detection varies considerably between individuals and within individuals over time. Also, given that individuals detect a colour difference between two objects, there is likely to be variation in opinions regarding the acceptability of this difference. It has been reported that significant differences were found between the experiment groups in regard to acceptability of colour differences. Ragain and Johnston (2001) reported that patients were less able to identify

small colour differences between tooth and resin composite materials than were dental professionals. However, dental auxiliaries proved to be more discriminating in accepting colour differences between tooth and resin composite materials than were patients.

1.8 Rationale of the study

Colour change following traumatic dental injury (TDI) is an area that has received little attention in the dental trauma literature. Where it is mentioned in the scientific literature, it is only a simple description of how many teeth have turned a certain colour. There is no quantification of how much colour change has occurred and over what time frame. Furthermore there is minimal research aimed at identifying the potential causes of this discolouration.

This study examined this area using a prospective cohort observational study of children who have suffered TDI to their permanent dentition. To assess any colour change the IKAM camera system was used as the gold standard. Measurements from the IKAM were compared to standard clinical methods using a shade guide and patient perception. For patients, especially children and adolescents any colour change in their teeth can be a source of concern. Therefore, this study assessed whether the children had noticed any colour change and whether they wanted further treatment to improve it.

Chapter 2 Laboratory study

2.1 Introduction

Before the clinical study could be commenced a number of laboratory studies were required to establish the reproducibility of the IKAM equipment. The most important variable was temperature. The temperature of the camera or room temperature could affect colour measurements of an image.

The IKAM Digital Colour Measurement System [Figure 2.1] was used to record photographic images during this study. The IKAM is manufactured by DCM®, West Yorkshire, UK with D-65 illuminant. This is a standard digital camera with controlled lighting, which is set up to take a picture of patient‘s teeth.

This system uses an Olympus 3040 digital camera with a cross-polarised light source mounted in the IKAM housing. This is supported by a stand to hold the unit at a patient friendly height with a patient positioning device located at the opposite end to the camera. Lighting was provided from an Olympus TrueLux C12 incorporating a uniform daylight light source calibrated at 65 degrees Kelvin. Photography was carried out using both cross-polarised and non-polarised light.

Specific software [MATLAB] was then be used to measure the colour values (RGB) of teeth.

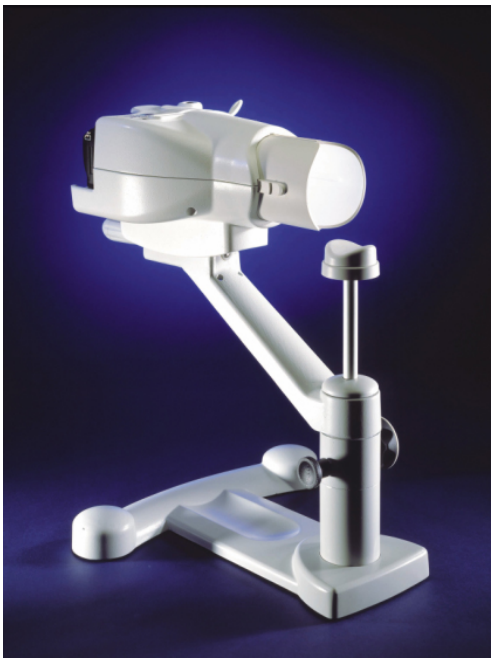

Figure 2.1 IKAM camera system

The in vitro work was undertaken to validate the reproducibility of the IKAM system. The IKAM was to be used in the clinical study as the objective measurement against which all comparisons would be made. It was therefore necessary to ensure that all the images produced by the IKAM were standardised.

The temperature of the camera is related to the light bulb; this can become warmer with time, and hence may affect the colour measurements of an image. It was therefore necessary to consider the variation of temperature with time when the system is turned on, and to ascertain the time taken to reach a constant temperature (after which a consistent image can be taken).

The temperature of the room might also affect the image, which might be influenced by the time of the day the image was taken, and the type of light

source in the room where the image was taken. Two laboratory studies were carried out to evaluate the time-temperature profile of the IKAM system

2.2 Aims

To validate the reproducibility of the IKAM camera system (objective measure of colour change).

2.3 Hypothesis

The null hypothesis for this study was that:

- There will be no effect of the camera warm-up time on image values.
- There will be no effect of the room temperature on image values.

2.4 Materials & Methods

2.4.1 Study A

To evaluate the warm-up time of the light bulb of the IKAM camera system, 13 images were taken of a grey card [Figure 2.2]; the grey card was used as an object in the scene as it has a constant colour and reflectance. Therefore, if the system is stable over time then the RGB values captured by the IKAM system of the grey card should also be consistent.

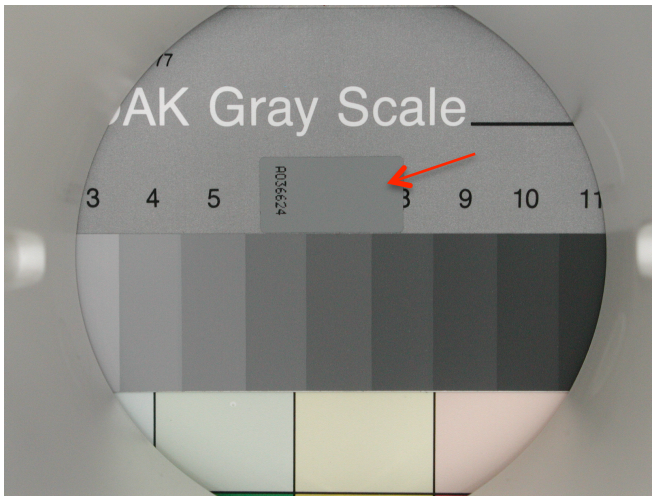

Figure 2.2 Photographs were taken for the grey card by IKAM. The grey card (red arrow) is placed on a neutral grey colour background.

Images were taken from 30 seconds after the camera was turned on, up to 67 minutes later all on the same day as shown in Table 2.1, the images were captured more frequently at the beginning of the time period. The images were saved onto a CD and the RGB values for each image were extracted using computer software (MATLAB).

Image	1	2	3	4	5	6	7	8	9	10	11	12	13
Minutes	0.5	1	1.5	2	4	8	10	12	14	16	32	48	67

Table 2.1 The time at which each image was taken after the camera had been turned on.

2.4.2 Study B

Study B was carried out after analysing the data from Study A. To check the effect of room temperature on image values, 22 images of the grey card were taken at different times of the day over a two weeks period using the IKAM camera system [Table 2.2]. These images were each taken after the 5 minutes warm up of the camera (according to the results of Study A) had elapsed. Images were saved onto a CD and analysed by MATLAB software as Study A.

Day	1	4	7	9	10	11	14
Time of the day	11:06	10:21	11:36	16:14	10:23	16:04	11:20
	11:14	10:27	11:37	16:20	10:28	16:10	11:25
		16:57	11:41		15:20		
		17:02			15:25		
		17:03			16:20		
					16:28		

Table 2.2 The time at which each image was taken over a seven day's period (the days were not consecutive).

2.5 Results

2.5.1 Study A

The RGB values with different periods of time following the switching on of the camera are shown in Figure 2.3. There was a sharp drop in the RGB values from 30 seconds to approximately 5 minutes; this drop was dramatic specifically for the green and blue values. There is some fluctuation after the fourth minute

for all the three values, which is followed by a constant reading starting from about 15 minutes. Only after 4-5 minutes were sufficiently small tolerances in RGB readings achieved. After this time there was still variability in RGB but it was more likely to relate to random noise.

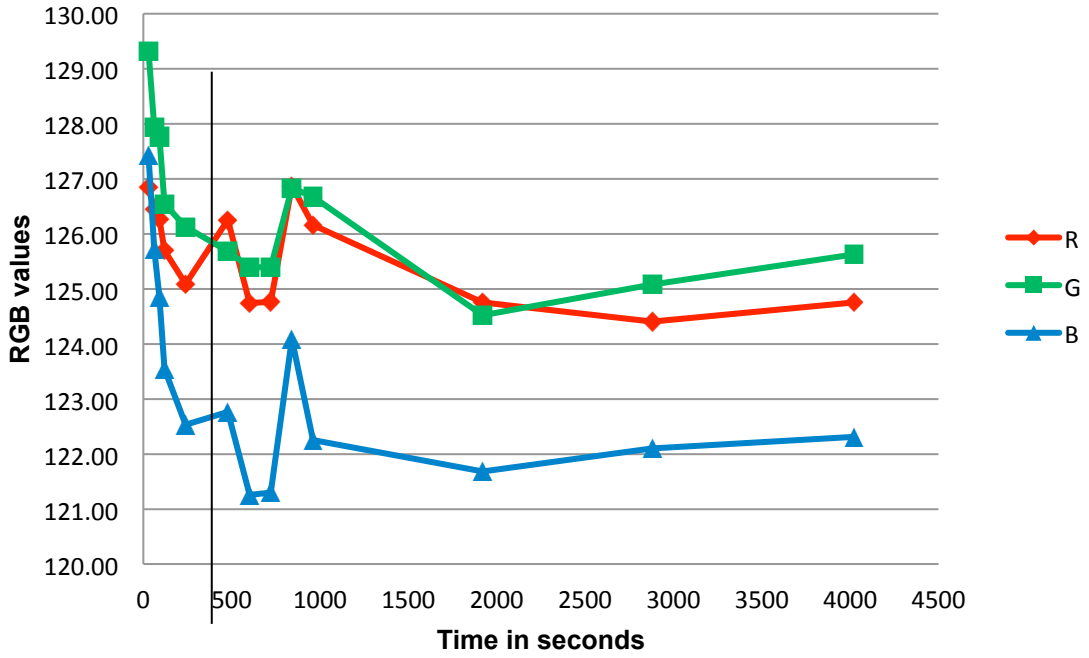

Figure 2.3 RGB values for the images taken in Study A. The black perpendicular line represents the time when the RGB values dropped and started to be consistent after 5 minutes.

2.5.2 Study B

In this part of the in vitro work, the effect of the room temperature over time was tested again using a grey test card. RGB values against time in hours were plotted as shown in Figure 2.4. Over the seven-day period there was no

evidence of a trend for the RGB values. There was some random noise, which was particularly evident in the variability in the RGB values taken in the same hour on any particular day and also some random noise evident in RGB values between different days.

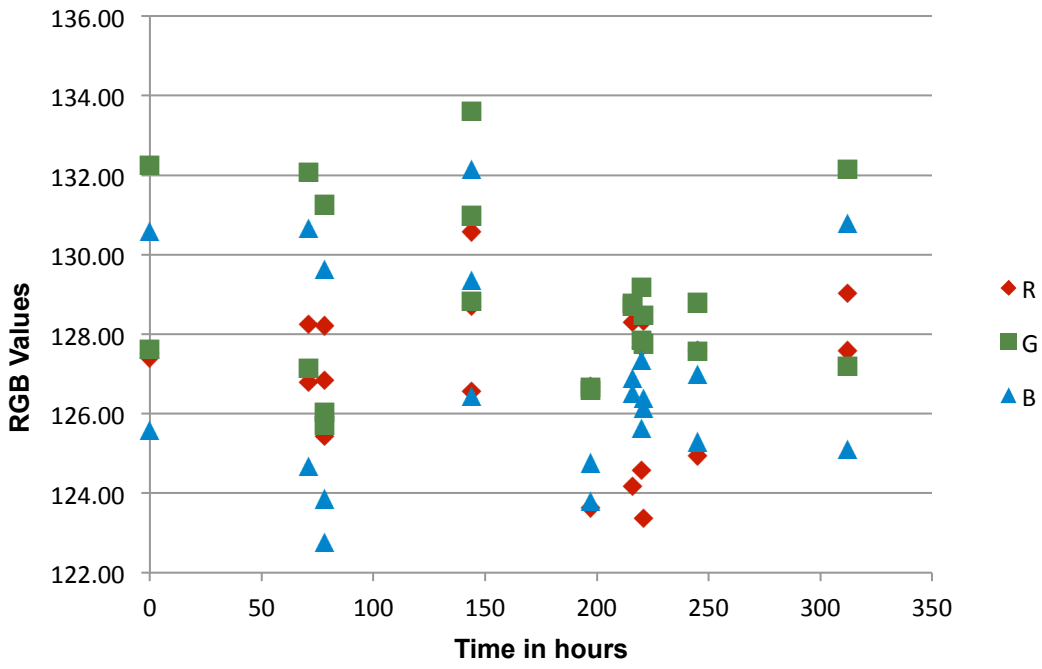

Figure 2.4 RGB values for the images taken in Study B.

From this pilot work, the standard deviations of the RGB values were calculated to quantify the random noise of the IKAM system and these approximated 2 RGB units. RGB values were converted first to XYZ and then to CIELAB colour space as shown in Table 2.3. The average CIELAB values (averaged over all the measurements) was L* = 53.7, a* = -1.1, and b* = 0.8.

The colour differences (ΔE) of each measurement from the mean were then calculated. The average colour difference was about 1 CIELAB unit for each of the L*, a*, and b* axes. Again this variability can be calculated as a ΔE change in colour of approximately 1 CIELAB unit.

	Hours	R	G	B	X	Y	Z	L*	a*	b*	ΔE*
1	0	127.40	132.25	130.59	21.17	22.74	24.60	54.81	-2.13	0.26	1.59
2	0	127.52	127.62	125.58	20.24	21.39	22.66	53.37	-0.44	1.09	0.81
3	71	128.25	132.08	130.68	21.28	22.76	24.63	54.83	-1.69	0.25	1.38
4	71	126.80	127.15	124.68	20.01	21.19	22.33	53.15	-0.62	1.28	0.88
5	78	128.22	131.26	129.64	21.09	22.51	24.22	54.56	-1.45	0.47	0.98
6	78	126.84	126.03	123.86	19.82	20.88	22.01	52.82	-0.12	1.28	1.41
7	78	125.44	125.72	122.76	19.51	20.67	21.62	52.58	-0.68	1.56	1.42
8	144	126.56	130.98	129.36	20.79	22.30	24.10	54.34	-1.96	0.30	1.18
9	144	130.57	133.60	132.15	21.94	23.40	25.24	55.48	-1.40	0.38	1.85
10	144	128.70	128.82	126.43	20.63	21.81	23.01	53.83	-0.51	1.27	0.77
11	197	123.64	126.58	124.76	19.48	20.80	22.31	52.73	-1.46	0.60	1.06
12	197	126.68	126.66	123.80	19.88	21.03	22.01	52.98	-0.56	1.55	1.17
13	216	124.17	128.77	126.89	19.98	21.47	23.13	53.46	-2.08	0.41	1.08
14	216	128.31	128.70	126.52	20.56	21.75	23.03	53.76	-0.57	1.12	0.63
15	220	124.58	129.17	127.35	20.12	21.61	23.31	53.62	-2.07	0.38	1.05
16	220	127.68	127.85	125.63	20.30	21.46	22.69	53.45	-0.50	1.17	0.76
17	221	123.38	127.76	126.15	19.69	21.13	22.83	53.09	-1.95	0.30	1.16
18	221	128.32	128.46	126.39	20.52	21.69	22.98	53.70	-0.46	1.10	0.71
19	245	124.93	128.79	126.98	20.10	21.53	23.17	53.53	-1.80	0.47	0.78
20	245	127.60	127.56	125.30	20.23	21.37	22.56	53.35	-0.43	1.23	0.88
21	312	129.04	132.15	130.78	21.41	22.85	24.68	54.91	-1.43	0.33	1.34
22	312	127.58	127.20	125.11	20.16	21.27	22.48	53.24	-0.27	1.18	1.04
SD		1.86	2.23	2.58				0.78	0.70	0.47	
Mean								53.71	-1.12	0.82	1.09

Table 2.3 RGB, XYZ, CLELAB values for the images taken in Study B.

2.6 Discussion

Study A suggested a minimum of 4-5 minutes warm-up time for the camera and associated lighting before consistent readings for the images can be expected.

In Study B the temperature *per se* was not measured since the exact effect of temperature on camera responsivity would still need to be determined. Rather, the camera RGB responses were measured over time. The variation of RGB values led to some images appearing more reddish or bluish. These differences are likely to result from changes in the temperature between each day, either from the lighting effect, the camera itself, or both. The consistency over the time of the IKAM system was acceptable.

From the literature a change of less than 1 ΔE is generally not detectable by the human eye (Lindsey and Wee, 2007b). Therefore the reproducibility of the IKAM system is, on occasions, noticeable; therefore, it is not negligible. This kind of variability is inherent with the camera system and needs to be either tolerated or accounted for. The latter option was preferred and a uniform grey patch was to be used in each clinical picture as an anchor, of a fixed value, to correct the images accordingly.

The above in vitro study results suggested that colour changes of, on average, 1 CIELAB unit (which is visually noticeable) could occur even for a control tooth where no traumatic dental injury or treatment has occurred simply because of the noise in the IKAM system. Therefore, to minimise this variation a standard grey block was used in each image [Figure 2.5]. This provided a constant reference in each image taken by the IKAM system. Each image could then be

corrected by the use of the grey block to remove the variability in the system. If the block was lighter than normal then we need to make the image darker to compensate, and if the block was darker than normal we need to make the image lighter to compensate. Then any difference in tooth colour between photographs from baseline to the follow-up visits could be assumed to be related to the patient, their injury and/or treatment rather than the IKAM system. Specifically the corrected R_C value of each pixel was calculated from the raw R value thus

$$R_C = R \times R_S/R_T$$

Where R_T and R_S refer to the average R values of the grey block in the test image and standard (baseline image) respectively. Similar equations are used to correct the G and B values too. In this way variation due to the system (e.g. temperature) between baseline and test images was accounted for.

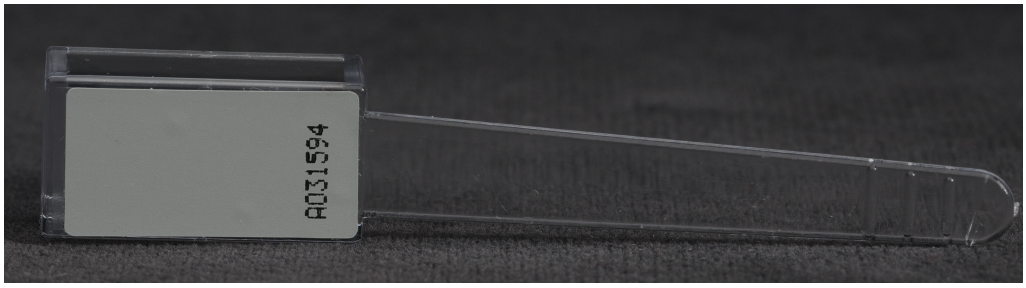

Figure 2.5 Grey block. The grey card is placed on a block that had been incorporated into each image.

2.7 Conclusion

Following the laboratory work the following steps were considered to standardise the images taken by the IKAM system:

1. The IKAM equipment was allowed to warm up for a minimum of five minutes prior to the photograph of the injured tooth or teeth being taken.
2. Due to the variation in the system, a grey block was used in each photograph taken to correct the review image to that of the baseline image.

Chapter 3 Clinical Study

3.1 Material & Methods

3.1.1 Study design

A prospective cohort observational design was used to assess colour change following traumatic dental injuries (TDI) in children. The study continued the work of an earlier pilot study undertaken by Saleh Muhammad (SM) in 2011. An ethics application was originally submitted by Dr. Muhammad and approved by the Research Ethics Committee (NRES) (11/H1306/3) [Appendix A]. A substantial amendment to change the principal researcher was submitted and approved by NRES on 29 June 2012 [Appendix B]. The thesis will report the results from the work of the primary investigator (AA) only.

3.1.2 Aims

- To investigate the change in colour of permanent teeth following TDI in children.
- To explore what variables are associated with the colour change.
- To examine methods of measuring colour change including IKAM system (objective measure), the use of a shade guide (clinical pseudo objective measure), patient's perception (patient reported measure).
- To evaluate the agreement between these three methodologies.

3.1.3 Hypothesis

The null hypothesis for the study was that:

- There will be no colour change in permanent teeth in children following TDI.
- There will be no agreement between the three different methods of colour measurement.

3.1.4 Study sample

Children were identified for this research project by their attendance at the Leeds Dental Institute (LDI). All children attending either for acute care or a review appointment at the trauma clinic at LDI were invited to participate in the study if they met the inclusion criteria (described below). Where children and parents were extremely stressed or anxious at their acute presentation, then this approach was delayed until the following clinical review appointment.

3.1.5 Inclusion and Exclusion Criteria

3.1.5.1 Inclusion criteria

The following children were eligible to participate in the study:

1. Aged 6 to 16 years.
2. Receiving dental care following a TDI to their permanent anterior dentition.

3. Will cooperate with the three colour change assessments.
4. Whose parent/guardian is happy to participate and have completed the consent form.

3.1.5.2 Exclusion criteria

The following children were excluded from the study:

1. Below 6 and above 16 years of age.
2. Unable to cooperate for any of the three colour assessments.
3. Where no TDI had been sustained to their permanent dentition.
4. Accompanied by an adult who is not their parent or legal guardian.
5. Parents/guardian or child who refuse to participate in the research study.
6. TDI greater than six months since the time of injury.
7. Where root canal treatment had already commenced for the traumatised tooth or teeth.

3.1.6 Clinical study protocol

A. Patient recruitment
   - Potential subjects attending the trauma clinic at LDI or in the acute care clinic were met by the investigator (AA). Both of which are held in the LDI paediatric dentistry clinic.

- If the parents and the child were interested in participating in the study, they were given an information sheet [Appendices C, D].
- Time was allowed for discussion and any further questions about the study were answered by the investigator (AA).
- When they were happy to participate, consent and assent form, where applicable, were completed [Appendices E, F].

B. Baseline visit

- Baseline data was collected at the same time as consent was taken.
- A data collection sheet was used to record each patient's information, including patient's demographics, the traumatised tooth or teeth, the type of traumatic injury, the pulpal and periodontal healing outcomes of the injury, and the type of treatment performed. This information was collected from the patient's records or from the clinician who looked after the patient. (Appendix G).
- Assessment of the colour of the traumatised tooth by three methods: IKAM, investigator's perception, and patient's perception.
- The principal investigator (AA) carried out the "Investigator's Perception" in the clinic setting. A Vita classic shade guide was used. Details of how this assessment were undertaken is described in section 3.1.7.1 page 58.

- Patient's perception regarding the colour of their traumatised tooth was obtained by asking the patient the following questions:
    - ✓ Do you think the colour of your injured tooth/teeth has change? (yes/no).
    - ✓ Has the colour become better or worse since the last visit? (better/worse).
    - ✓ Are you happy with the colour of your tooth? (yes/no).
    - ✓ Do you want treatment to improve the colour of the injured tooth? (yes/no).
- A close-up photograph was taken of the patient's injured tooth or teeth using the IKAM equipment in the Medical and Dental Illustration Department of the LDI. A trained medical photographer from the department took the photographs. The methodology used is described in section 3.1.7.2 page 60. A clinical photography consent form was completed prior to the photographs being taken [Appendix H].

C. Review visits (at 3 months and 6 months)

- At review visits to the trauma clinic, similar records to those taken at baseline were also collected. These included IKAM data, investigator's perception, and patients' perception.
- The outcomes with respect to the pulpal and periodontal healing, and the treatment provided were updated and recorded.

3.1.7 Methodology used for assessment of colour (equipment used in the study)

3.1.7.1 Shade guide (investigator perception using a shade guide for assessment of colour change)

The Vita Lumin Classic™ shade guide (Vita Zahnfabriek, Bad Sackingen, Germany) [Figure 3.1] was used in the study. It consists of 16 tabs of different shades of porcelain white colour (from light white up to dark white). In the Vita Lumin Classic, the hue was categorised by letters:

- A= reddish-brownish
- B= reddish-yellowish
- C= greyish
- D= reddish-grey

Figure 3.1 Vita Classic shade guide.

The chroma and value are communicated by a system of numbers; 1= least chromic to 4 the most chromic.

The shade guide was rearranged according to a value-based ordering system (B1, A1, A2, D2, B2, C1, C2, D4, D3, A3, B3, A3.5, B4, C3, A4, and C4). The investigator (AA) used this shade guide to find the closest match for the patient‘s tooth. Shade selection was carried out in the paediatric dentistry clinic. The clinic has windows at one end of it and is lit with fluorescent light which are switched on throughout the year. To enhance consistency of shade taking, AA undertook a period of training prior to commencing the study with one of the Consultants in the Restorative Department. For standardisation of shade matching technique, the following principles were followed:

1. Visual shade selection was performed by the same investigator (AA).
2. The same shade guide was used throughout the study and disinfected following standard clinic protocols between patients.
3. Shade selection was performed at the start of the patient’s visit and before the dental treatment commenced.
4. Elimination of any brightly coloured clothing by the use of a clinic bib and the removal of any lipstick.
5. The tooth should be clean to remove all adherences, plaque, pigmentation or tartar prior to the shade being taken.
6. The investigator’s eyes were allowed to rest by focusing on a grey-blue surface immediately before a comparison.
7. The investigator observed the tooth for short periods, of less than 15 seconds.

8. The tooth was kept moist throughout the process. If there was any concern about the teeth drying out the patient was asked to lick their teeth.

The investigator performed the shade selection three times per tooth at the beginning of each visit. The final shade assessment was determined following the principle of majority. If all the three shade evaluations were differed, the investigator's eyes were allowed to rest by focusing on a grey-blue surface, and then the shade selection process was performed again, until consistency was achieved.

3.1.7.2 IKAM to assess colour change

The patients had photographic records taken prior to any clinical treatment being undertaken. These photographs were taken at the the Medical and Dental Illustration Department at LDI), in which the medical photographers had received standard training in the use of the (IKAM) system. Each photograph included a standardised grey block.

The IKAM Digital Colour Measurement System is described in an earlier section 2.1 page 42.

Photography was carried out, in a darkened studio, with the subject area central and perpendicular to a predetermined distance of 25cm from the focal plane of the camera [Figure 3.2]. The camera was set at 100 ISO and an exposure of 1/25 of a second at f2.8 was made for each digital photograph. When the IKAM long cone steamed up by patient's breath, a fan was used for ventilation and

prevention of fogging of the photograph. The traumatised teeth were first photographed by cross-polarised light, together with a known pantone grey reference (with RGB values of an equal amount of red, green and blue colour). A second photograph to show the normal appearance of the dentition was photographed with non-polarised light.

Figure 3.2 Photograph is taken by the IKAM with the patient's chin positioned on the chin rest while the patient is holding the cheek retractors. A is the light box, B is the camera housing, C is the IKAM cone and D is the chin rest.

3.1.7.3 Colour measuring programme

The images of the patient's tooth, which were taken at the review visits, were compared with the baseline image in order to assess any colour change of the tooth during the period of the study. In order to quantify any colour change,

dedicated software was used. This was created by the centre for the Colour Design and Technology, Universty of Leeds. The colour_correct2 programme used MATLAB software, student version R2014a, The MathWorks.

The programme was used to adjust the RGB values of the tooth in the follow-up visits by comparing the RGB values of the grey block in both the baseline and the review images. The grey block allowed the correction between the images to ensure each photograph was standarised and any colour change was related to changes in the tooth rather than the photograph. This correction was undertaken by comparing the RGB values of the grey block in each image and correcting the colour of the grey block in the second image to that of the RGB values in the first baseline image. The difference in the RGB values was then used to correct the rest of the photograph. This corrected review photograph was then used to assess any colour change. The region of interest (ROI) in both photographs was identified and the programme calculated their RGB and L*, a*, b* values. The change in colour between these two areas was calculated as summative CIELAB ΔE value as well as changes in the individual components L*, a*, b* values [Figure 3.3].

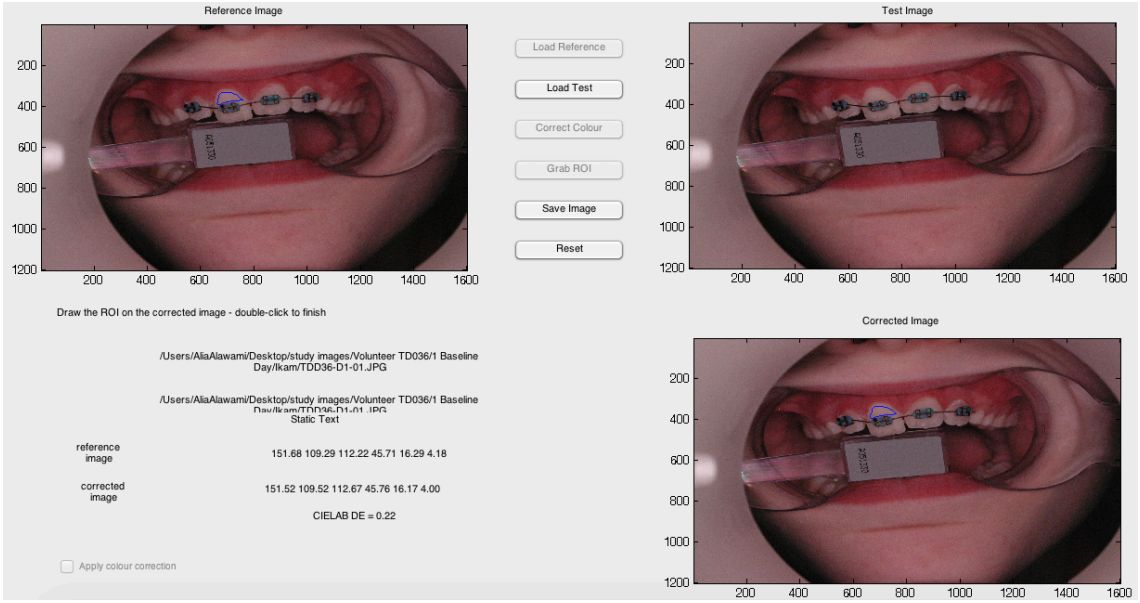

Figure 3.3 The colour_correct2 programme working in MATLAB software. This programme was used to estimate the colour change of two photographs taken at two time points. The picture in the top left hand side was the baseline photograph (reference image). The picture in the top right hand side was the picture taken at a review visit (test image). Before any change in colour could be assessed between the two, the colour of the review photograph was corrected to that of the baseline photograph. This was carried out by selecting a reference point in the grey block in both the baseline and the review photograph. The programme then calculated the RGB values for this reference point between the two photographs, and then used this ratio to correct the colour of the review photograph. The colour corrected review photograph was then showed in the lower right hand side. The ROI was then mapped out (see blue outline) in both the baseline and the corrected review photograph, and the programme was then displayed the RGB and L*, a*, b* values of the ROI, as well as the difference in colour in CIELAB DE.

3.1.8 Data processing and analysis

3.1.8.1 Colour analysis

The steps of colour quantification were carried out using the MATLAB software. This programme was utilised to correct the colour of photographs taken at different visits in order to calculate if there was any change in tooth colour between the baseline and the review assessment (visit one or visit two). The same ROI was then mapped out for the baseline and corrected photograph for

the traumatised tooth. The programme then calculated the RGB and L*, a*, b* values for the two ROI together with the change in colour between these two areas to give a CIELAB ΔE value. For each tooth, a minimum of three measurements were made until a consistent result was attained. The results of each measurement were then averaged to give the final values for each photograph and the CIELAB ΔE. The programme is shown in more detail in Figure 3.3.

3.1.8.2 Precision and reproducibility

3.1.8.2.1 System precision (reference point precision)

One part of the colour measurement process was identified as an area which could introduce error into the colour assessment. This was the use of the grey block in the baseline and follow-up photograph (point accuracy= PA). Although the grey block was manufactured of a uniform neutral middle grey colour, when the grey card was magnified, it was noticed that some pixels were reddish and others were greenish, which indicated variability in the consistency of the grey card.

Before the programme could be used, the investigator identified the most appropriate size of pixel area for colour correction. When correcting the colour of the second photograph to the first, the programme used a square-block pixel area centred on the point selected on both images. This area can vary from one pixel upwards working in square numbers (1X1, 2X2, 3X3 etc). Therefore, the smaller pixel area selected the wider the potential for variability in the RGB

values to be seen. To reduce this variability, a large square area was required without going over the edges of the grey card. To quantify this, the numbers of the pixels in the grey card itself were calculated and found to equal 200 X 400 pixels. It was calculated that the width of +/- 25, which would give a square number of 51X51 (2600 pixels) was appropriate. This minimised any errors from one or more pixels not being uniformly grey while reducing the risk of selecting a point that would include an area outside the grey card [Figure 3.4].

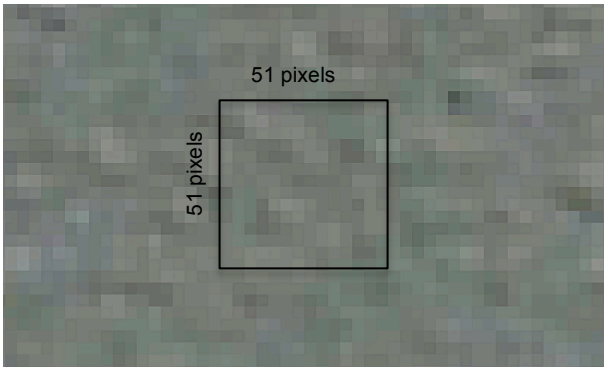

Figure 3.4 Magnified image of the grey card showing the variability in colour of the pixels. The black square is the square-block pixel area centred on the selection point. The larger square area would reduce the variability in RGB values of the selection.

To calculate the consistency of this process, the colour_correct2 programme was used to correct the colour of an image, by selecting a point in the centre of the grey card using the same image in both reference image (image1) and test image (image2). The process was repeated ten times for the same images. The L*a*b* values of the selected square area within the grey card in both images together with the mean and the standard deviation are reported in the results section 3.2.9.1 page 93.

3.1.8.2.2 Region of interest precision (ROI)

A second potential error in the colour analysis calculation was selecting the same ROI in the baseline and review images. If the two images were exactly the same alignment, it would be possible to just copy the ROI cross. But the two images were taken months apart, so for each photograph the ROI had to be mapped by the investigator in each image. This introduced the potential for a further error.

To calculate the size of this potential error, the colour_correct 2 programme was used. The software in the colour correction programme was modified to ensure no colour correction was undertaken between the reference and test image. Ten teeth were randomly selected using an online random number generator http://www.randomizer.org/form.htm. The potential error by selecting a different area of measurement between the two images was assessed. Using the same picture in both the reference image (image1) and test image (image2), the ROI was mapped in both images and the LAB values and CIElab ΔE were calculated. This process was repeated 5 times for each tooth. The LAB values were averaged and SD was calculated.

The calculations for these two sources of error were carried out to investigate the overall precision of the system on colour change ΔE. The estimate error values for each ROI, PA and overall error CIElab ΔE value are reported in section 3.2.9.2 page 94.

3.1.8.3 Data processing software

All data was entered into SPSS spreadsheet (Statistical Package for the Social Sciences- version 22, SPSS Inc, Chicago, USA) for data analysis. For each variable the data was assessed. For continuous data the Shapiro-Wilk test was used to assess if the data was normally distributed. If normally distributed, data were summarised using means and standard deviations. If not normally distributed medians and inter quartile ranges were used.

To evaluate the association between colour change and various clinical variables the following data manipulation was required.

3.1.8.4 Data variables

The dependent objective variable was ΔE, which represent the change in tooth colour between two appointments. It was calculated from the equation:

$$\Delta E = \sqrt{\Delta L^{*2} + \Delta a^{*2} + \Delta b^{*2}}$$

The L*, a*, b* values were obtained for the baseline and the review image, the colour changes ΔL*, Δa*, Δb* were calculated by subtracting the baseline values from review values.

The investigator's perception for colour change measured by the shade guide, and the patient's perception for colour change measured by the patient's response to the four questions, were the other subjective dependent variables.

For the patient's response to the four questions about the colour change, only the first question (Do you think the colour of you injuried tooth/teeth has

changed? Yes/No) was considered in the data analysis, as it was the question that represented the patient's perception of the colour change.

The Vita Classic shade guide had been rearranged according to a value-based ordering system; hence each shade guide tab was given a number according to its lightness from 1 to 16, in order to transform the data from categorical data to numerical data. Therefore, the shade difference between the baseline and the follow-up review was calculated.

The independent variables were: the time interval between the original injury and the baseline assessment (in weeks), time interval between the baseline and the last follow-up (in months), participant gender, participant age, hard tissue injury, PDL injury, baseline and follow-up pulpal status, baseline and follow-up PDL status, and the treatment at baseline and follow-up.

Pulpal status were categorised into:

- Vital.
- Non-vital.
- Pulp canal obliteration (PCO).
- Uncertain where inconsistent findings were recorded.

The PDL status was categorised into:

- Favourable included PDL healing with surface resorption.
- Unfavourable included ankylosis, infection related resorption.

3.1.8.5 Data management

3.1.8.5.1 Calculation of the collinearity for the patients who had been reviewed twice

In order to assess whether the patients who attended only one review were likely to have similar colour change as the patients who attended two reviews, the linear correlation between first review ΔE and second review ΔE for patients who had been reviewed twice was calculated by Pearson correlation tests. These tests used the data set of all teeth for the patients who had two reviews. This was 26 patients and 52 teeth.

The linear correlation between first review ΔL*, Δa*, Δb*, and second review ΔL*, Δa*, Δb*, and between the first review shade match and second review shade match, as well as the patient's answer to question one in both reviews were all calculated.

3.1.8.5.2 Merging data

Twenty-six patients suffered multiple teeth injury; it would require a more complex data analysis to control this type of correlation. Therefore the data was merged and only included the most discoloured tooth from each patient. This was 39 teeth in 39 patients from which the results were obtained.

3.1.8.5.3 Simplifying data structure for logistic regression modelling

To facilitate for the analysis and due to very small data set, some variables were simplified further for meaningful statistical analysis. The following recoding implemented:

- The age of the patients had been grouped into bands; (6 to 7), (8 to 9), (10 to 11), (12 to 13), and 14 years or over.
- The types of hard tissue injury and the types of PDL injury had been reconstructed and recorded as presence of hard tissue injury and presence of PDL injury.
- Baseline pulpal status and last review pulpal status reconstructed and recoded as two category variables. Pulpal status is either “vital” or “Other”.
- Baseline PDL status and Last review PDL status reconstructed and recoded as two category variables. PDL status is either “Favourable healing” or “Other”.
- The treatment for each review was the treatment given at the previous review except if the treatment was only monitoring, as the colour change resulting from one treatment is likely to be seen at the next time point.
- Types of treatment were combined to a few homogenous treatments and were re-categorised as follows:

    1- Root canal treatment (RCT) group, includes:

        a) RCT.

        b) Pulp extirpation.

c) Pulp extirpation & composite build-up.

d) C'vek pulpotomy & composite build-up.

2- Restoration group, includes:

a) Composite build-up.

b) Pulp capping & composite build-up.

3- Fixation (Splint)

a) Splint.

b) Repositioned & splint.

c) Repositioned, splint & pulp extirpation.

d) Replant & splint.

e) Replant, splint & pulp extirpation.

In order to be able to compare the IKAM measurement with patient's perception and investigator perception, the following data recoding were implemented:

- ΔE measured by IKAM was categorised as follows:

  1 = ΔE ≤ 3.

  2 = ΔE > 3 and ≤ 5.

  3 = ΔE > 5 and ≤ 8.

  4 = ΔE > 8.

- The investigator's perception measured by the shade difference was categorised as follows:

  0 = no difference.

  1 = one difference in either direction (-1 is lighter, +1 is darker).

2 = two differences

3 = three or more differences (3 to 13)

- For the patients' perception, only the first question was considered (Do you think the colour of your injured tooth/teeth had changed? YES/NO) during the analysis of the level of agreement between the three methodologies.

3.1.8.6 Statistical analysis

Using linear regression analysis with ΔE as the dependent variable against the time between the original injury and the baseline assessment of colour, time between the baseline and the final clinical visit, gender, age group, hard tissue injury, PDL injury, final review pulpal and PDL status, and the type of dental treatments undertaken were all treated as independent variables. The following modelling assumptions were made, that the ΔE was a continuous variable and approximately normally distributed; and the association between dependent and independent was not non-linear (does not need to be perfect linear). The independent variables were continuous or categorical and did not require any assumptions.

To compare the validity of the two subjective measures of colour change (shade guide and patient perception) against the objective measure (IKAM), a Chi-Square test was used to assess the agreement between the three methodologies.

Statistical modelling was only possible following the data management described in section 3.1.8.5 page 69.

3.1.8.7 Sample size calculation

Calculations from the early study by Muhammad (2011) based on his findings provided a power calculation estimate of 80 teeth. Very limited information was provided on how this calculation was undertaken or what the outcome measure was. Therefore the plan for this study was to recruit between 50-100 patients. From this larger sample, a more accurate sample size could be estimated.

3.2 Results

3.2.1 Patient recruitment

Children were recruited between April 2013 and May 2014. The follow-up period continued until December 2014 to allow sufficient time for their first and second review appointments. Fifty-one patients with traumatised teeth met the inclusion criteria and consented to take part in this study. The participants were 11 females and 40 males with a mean age of 9.7 (SD +/- 2.2) years. The average follow-up duration for the first review was 5.67 months (SD +/- 3.5), and for the second review was 10.5 months (SD +/- 3.23) from the baseline visit. The flowchart for patients' recruitment is presented in Figure 3.5.

Twenty-eight children attended for two follow-up visits. Photographs of participant number 15 could not be analysed because the baseline image was taken in non-polarised setting, the second follow-up photograph for participant number 16 could not be used for the same reason and only the first follow-up was considered. Thirteen children attended only one follow-up visit, among which seven were lost to follow-up, five were discharged, and one had withdrawn after their first follow-up. The baseline image for participant number 26 was lost; therefore it was not included in the analysis. Ten children failed to attend any of their follow-up appointments among which six were lost to follow-up, three were discharged after the baseline, and one was consented and the child's colour perception was assessed, but no shade matching and baseline photograph was taken on the day of the recruitment because the patient had to leave the clinic. The total number of the children that formed the dataset from

which the results were reported was 39. Twenty-six were followed up to two visits constituting 52 teeth. Thirteen children were followed-up only once constituting 21 teeth.

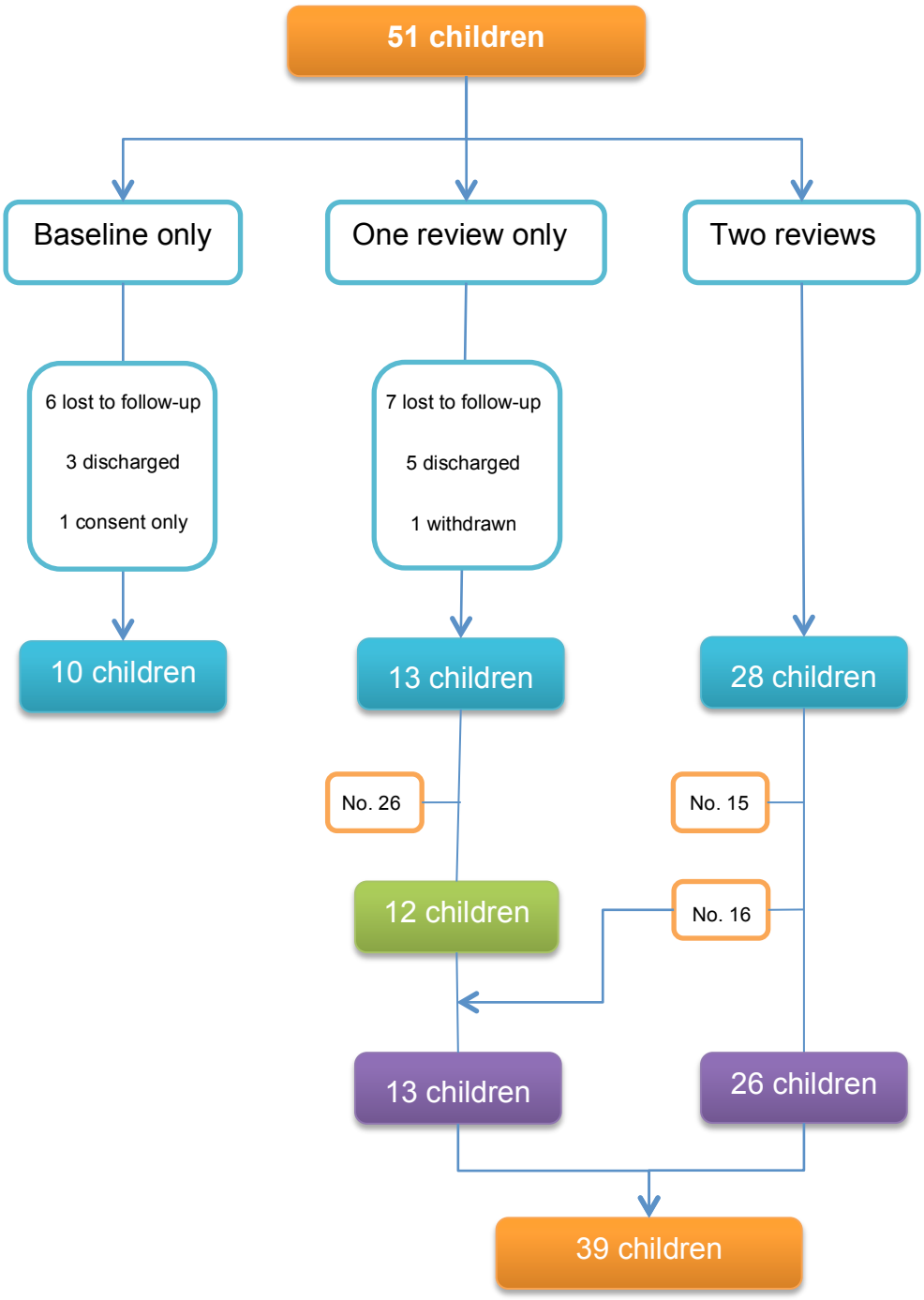

Figure 3.5 Flowchart of patients' recruitment. Patient no.15, the baseline image was taken in non-polarised setting. Patient no.16, the second review image was taken in non-polarised setting, therefore only the first review image was used. Patient no.26, the baseline image was lost.

3.2.2 The type of traumatic injury and the associated pulpal and periodontal ligament healing observed

There were 73 teeth injured in total, 13 children suffered injury to one tooth, 21 children had injuries to two teeth, two children had three teeth injured, and three children had four teeth injured. Only one child sustained injuries to mandibular teeth (one central incisor), and all other children's injuries were to maxillary teeth (61 central incisors, 11 lateral incisors).

The diagnosis of the injury was categorised into hard tissue injury and periodontal ligament (PDL) injury. Thirty-five teeth sustained hard tissue injury, 44 teeth sustained PDL injuries, with only six teeth suffered concomitant hard tissue and PDL injuries. As shown in Table 3.1, enamel dentine fracture was the most frequent type of hard tissue injury with 48.6% followed by complicated enamel dentine fracture with 28.6%. With regard to PDL injuries the most frequent was lateral luxation (22.7%), followed by extrusion (20.5%) [Table 3.2]. The concomitant injuries included: three teeth had intrusion with enamel dentine fracture, of which one of them was complicated. One tooth had lateral luxation with complicated enamel dentine fracture, one tooth was avulsed and the enamel was fractured, and one tooth had root fracture and extrusion.

Hard tissue injury	Frequency	Percentage
E#	2	5.7
E/D#	17	48.6
E/D/P#	10	28.6
E/D/P/C	1	2.9
Root#	5	14.3
Total	35	100.0

Table 3.1 The frequency of hard tissue injury for the 73 teeth that been reviewed during the study. E# is enamel fracture, E/D# is enamel dentine fracture, E/D/P# complicated crown fracture, E/D/P/C is crown root fracture, Root# is root fracture.

PDL injury	Frequency	Percentage
Concussion	3	6.8
Subluxation	7	15.9
Extrusion	9	20.5
Intrusion	5	11.4
Lateral Luxation	10	22.7
Avulsion	7	15.9
Alveolar#	3	6.8
Total	44	100.0

Table 3.2 The frequency of PDL injury for the 73 teeth that been reviewed during the study. Six teeth had concomitant hard tissue and PDL injuries.

The diagnosis of healing was categorised into pulpal survival and periodontal ligament healing. These were recorded by the clinician who saw the patient. Table 3.3 and Table 3.4 show the types of pulpal and PDL healing for the injured teeth of all patients based on their final review.

Pulpal survival	Frequency	Percentage
Vital	48	65.8
Non-vital	21	28.8
PCO	1	1.4
Uncertain	3	4.1
Total	73	100.0

Table 3.3 The pulpal survival of the 73 teeth that been reviewed during the study, based on the final review for each tooth.

PDL survival	Frequency	Percentage
Favourable	66	90.4
Unfavourable	7	9.6
Total	73	100.0

Table 3.4 The PDL healing for the 73 teeth that been reviewed during the study, based on the final review for each tooth. Definition of favourable and unfavourable is recorded in section 3.1.8.4 page 68.

3.2.3 Patient, Shade Guide and IKAM assessment of colour change following traumatic dental injuries

3.2.3.1 IKAM (L*a*b* values) detection of colour change

3.2.3.1.1 Children attended two follow-up visits

For 52 teeth, the mean and standard deviations (SD) of the L*a*b* and ΔE are shown in Table 3.5. The overall mean colour change was a ΔE 4.59 (SD +/-3.134) at the first review, and ΔE 5.57 (SD +/-3.04) at the second review. The overall mean change in L* (ΔL*) was 0.32 (SD +/- 5.42) which represented a general small tendency of slight lightening of the traumatised teeth in the L* scale. With

regard to the change in a* (Δa*) was 0.26 (SD +/- 1.93), tooth colour shifted slightly toward red on its scale based on the value of its mean. Similarly the change in b* (Δb*) 1.71 (SD +/- 2.21), tooth colour moved slightly to the yellow end of the spectrum. The greatest colour change was seen on the b* axis, namely a yellowing of the teeth.

	Mean	Std. Deviation
Baseline L*	48.28	6.54
Baseline a*	12.31	3.33
Baseline b*	6.48	1.52
Time interval between baseline and first review was 4.92 months		
1st review L*	48.41	7.90
1st review a*	12.03	3.98
1st review b*	7.63	2.08
1st review ΔE	4.59	3.13
Time interval between baseline and second review was 10.50 months		
2nd review L*	48.60	7.15
2nd review a*	12.57	3.92
2nd review b*	8.19	2.52
2nd review ΔE	5.57	3.04

Table 3.5 The mean and SD of the L*a*b* values and ΔE for the 52 teeth that been reviewed twice. The mean time interval between the baseline and the first review was 4.92 months, and the mean time interval between the baseline and the second review was 10.50 months.

3.2.3.1.2 Children attended one follow-up visit only

For 21 teeth, the mean and standard deviations (SD) of the L*a*b* and ΔE are shown in Table 3.6. The overall mean colour change was a ΔE 5.14 (SD +/-2.1).

The overall mean change in L* (ΔL*) was 1.65 (SD +/- 4.32) represents a small tendency to shift toward the lighter end in the L* scale. The change in a* (Δa*) was -0.42 (SD +/- 1.5), tooth colour shifted slightly toward green on its scale based on the value of its mean. With regard to the change in b* (Δb*) was 1.86 (SD +/- 1.97), tooth colour moved slightly to the yellow end of the spectrum.

	Mean	Std. Deviation
Baseline L*	53.08	6.11
Baseline a*	11.24	3.51
Baseline b*	6.61	2.38
Time interval between baseline and first review was 7.15 months		
1st review L*	54.73	8.19
1st review a*	10.82	4.13
1st review b*	8.47	2.78
1st review ΔE	5.14	2.10

Table 3.6 The mean and SD of the L*a*b* values and ΔE for the 21 teeth that been reviewed once. The mean time interval between the baseline and the review was 7.15 months.

3.2.3.2 Patients perception of colour change

3.2.3.2.1 Children attended two follow-up visits

At their follow-up visits, children were asked four questions about their perception of any colour change to their traumatised tooth or teeth. The summary of patients' answers to the four questions, for the 26 children who attended the two follow-up visits, is presented in Table 3.7. During the first

follow-up, among the four children who reported that the colour had got worse, only one child was happy with the colour and did not wish to have treatment to improve it. During the second follow-up, from the seven children who reported that the colour had got worse, three children were happy with the colour and did not wish to have treatment to improve it.

All children who were unhappy about the colour of their injured teeth, during the first and second reviews, wanted treatment to improve the colour. However, some children wished to have treatment to improve the colour of their traumatised teeth although they reported that they were happy with the colour.

Question		First review (n= 26)	Second review (n=26)
Do you think the colour of your injured tooth/teeth has changed?	Yes	10	12
	No	16	14
Has the colour become better or worse?	Better	6	5
	Worse	4	7
Are you happy with the colour of your injured tooth/teeth?	Yes	20	21
	No	6	5
Do you want to have treatment to improve the colour of your tooth/teeth?	Yes	10	7
	No	16	19

Table 3.7 A summary of patients' responses to the four questions that measured the patients' perceptions to the colour change of their traumatised teeth. For the 26 children who been reviewed twice.

3.2.3.2.2 Children attended one follow-up visit only

The summary of patients' answers to the four questions, for the 13 children who attended one follow-up visit only, is presented in Table 3.8. The two children,

who reported that the colour had got worse, were unhappy with the colour of their teeth and wanted to have treatment to improve it. All the other children were happy with the colour of their traumatised teeth, however, three of them wanted to have treatment to improve the colour.

Question		First review (n=13)
Do you think the colour of your injured tooth/teeth has changed?	Yes	4
	No	9
Has the colour become better or worse?	Better	2
	Worse	2
Are you happy with the colour of your injured tooth/teeth?	Yes	11
	No	2
Do you want to have treatment to improve the colour of your tooth/teeth?	Yes	5
	No	8

Table 3.8 A summary of patients' responses to the four questions that measured the patients' perceptions' to the colour change of their traumatised teeth for the 13 children who been reviewed only once.

3.2.3.3 Shade guide (Investigator's) perception of colour change

3.2.3.3.1 Children attended two follow-up visits

The investigator's perception of colour change using the shade guide has recorded a change in colour in 33 teeth out of 52 between the baseline and the second follow-up visit. The colour got darker in 28 teeth with changes in hue and/or chroma. Nine teeth were one shade darker than the baseline (+1). The maximum shade difference was 13 shades darker that was associated with a

root fracture. However, the colour change was lighter in five teeth, with four teeth assessed as one shade lighter (-1) and one tooth assessed as two shades lighter (-2). Table 3.9 below shows the shade difference between the baseline and the second follow-up (negative values indicates lighter shade difference)

Shade difference	Frequency	Percentage
-2	1	1.9
-1	4	7.7
0	19	36.5
+1	9	17.3
+2	7	13.5
+3	6	11.5
+5	4	7.7
+6	1	1.9
+13	1	1.9
Total	52	100.0

Table 3.9 The shade difference between the baseline and the second review for the 25 teeth that been reviewed twice. Negative values indicating how many tabs the shade had got lighter, positive value indicating how many tabs the shade had got darker, and zero indicating no shade difference.

3.2.3.3.2 Children attended one follow-up visit only

In 10 out of 21 teeth, the investigator using the shade guide, recorded different shades for the two appointments. The investigator recorded darker shades during the last follow-up, ranging between one to five shades darker. The shade difference between the baseline and the last follow-up is presented in Table 3.10

Shade difference	Frequency	Percentage
0	11	52.4
+1	1	4.8
+2	4	19.0
+3	4	19.0
+5	1	4.8
Total	21	100.0

Table 3.10 The shade difference between the baseline and the last review for the 21 teeth that been reviewed only once, half of the teeth changed shades ranging between one to five shades darker.

3.2.4 Calculation of the collinearity for the patients who been reviewed twice

3.2.4.1 Collinearity for the IKAM measurements

The linear correlation (collinearity) between changes in tooth colour (ΔE) at first review and second reviews were calculated and presented in Table 3.11

		1st review ΔE	2nd review ΔE
1st review ΔE	Pearson Correlation	1	.615**
	Sig. (2-tailed)		.000
	N	52	52
2nd review ΔE	Pearson Correlation	.615**	1
	Sig. (2-tailed)	.000	
	N	52	52

Table 3.11 The collinearity between ΔE at first review and second review for the 52 teeth that been reviewed twice.

There was a significantly strong linear correlation (collinearity) between first review ΔE and second review ΔE. The linear correlation was 0.615.

Similar significant results were produced for the linear correlation between first review and second review ΔL*, Δa*, and Δb* that is presented in Table 3.12. The linear correlation was 0.66, 0.55, 0.54 for ΔL*, Δa*, Δb* respectively.

Variables	Pearson Correlation	P-value Sig. (2-tailed)
Between ΔL* for 1st & 2nd review	.666**	.000
Between Δa* for 1st & 2nd review	.550**	.000
Between Δb* for 1st & 2nd review	.535**	.000

Table 3.12 The collinearity between ΔL*, Δa*, Δb* at the first and the second review for the 52 teeth that been reviewed twice.

This analysis showed that for the 52 teeth that been reviewed twice, the colour change seen in the first review was likely to progress and get worse at the second review. This correlation was statistically significant.

3.2.4.2 Collinearity for the investigator perception

Pearson correlation was also produced for the investigator perception between the first and second review. The linear correlation was 0.560, and significant collinearity with a p-value < 0.05.

3.2.4.3 Collinearity for the patients' perception

The patients' perception of colour change is a binary outcome for the patients' responses to question one ("Do you think the colour of your injured tooth/teeth has changed?") with either yes or no. There was significant collinearity, $p<0.05$ using a Chi-Square Test.

In summary: There was significant collinearity between the first and second review for the three measurements of colour change; IKAM, the investigator perception, and the patients' perception.

3.2.5 The linear regression modelling to establish clinical variable with colour change

To determine possible associations between colour changes and different clinical variables a linear regression analysis was undertaken and is displayed in Table 3.13. The dependent variable was ΔE (at second review where patients has attended two visits and at one review where patients has attended only one visit.). The independent variables were: time between the original injury and the baseline assessment of colour, time between the baseline and the final clinical visit, gender, age group, hard tissue injury, PDL injury, last review pulpal status, last review PDL status, and the types of dental treatment undertaken.

None of the explanatory variables was significantly associated with objective measure of colour change at 5% level (with 95% confidence). A number of variables showed association at a 10% level, these were: time between the

baseline and last review, hard tissue injury, splinting and restoration placed at or prior to baseline visit. This meant that the colour of the tooth was more likely to change where there was a longer time interval between baseline and review assessment, the presence of a hard tissue injury, where splinting has been undertaken and the presence of restoration at or before baseline visit.

Model	Unstandardised Coefficients		Standardised Coefficients	t	Sig.
	B	Std. Error	Beta		
Time interval (injury to baseline)	.013	.072	.030	.183	.856
Time interval (baseline to review)	**.262**	**.135**	**.293**	**1.938**	**.060**
Participant gender	1.685	1.127	.230	1.495	.143
Age groups	-.022	1.158	-.003	-.019	.985
Presence of hard tissue injury	**1.864**	**.943**	**.298**	**1.977**	**.055**
Presence of PDL injury	-1.157	.974	-.185	-1.188	.242
Final pulpal status	-1.593	1.016	-.241	-1.568	.125
Final PDL status	-.412	2.315	-.028	-.178	.860
RCT category	.914	1.908	.086	.479	.635
Splint category	**3.312**	**1.926**	**.273**	**1.719**	**.094**
Restoration category	**2.659**	**1.364**	**.408**	**1.950**	**.059**

Table 3.13 Linear regression analysis with ΔE as dependent variables and each of the independent variables separately (not controlling for other variables).

3.2.6 Agreement between the three measures of colour change

3.2.6.1 Patient perception versus IKAM (L*a*b* values)

The IKAM was a continuous measure and it was normally distributed [Figure 3.6].

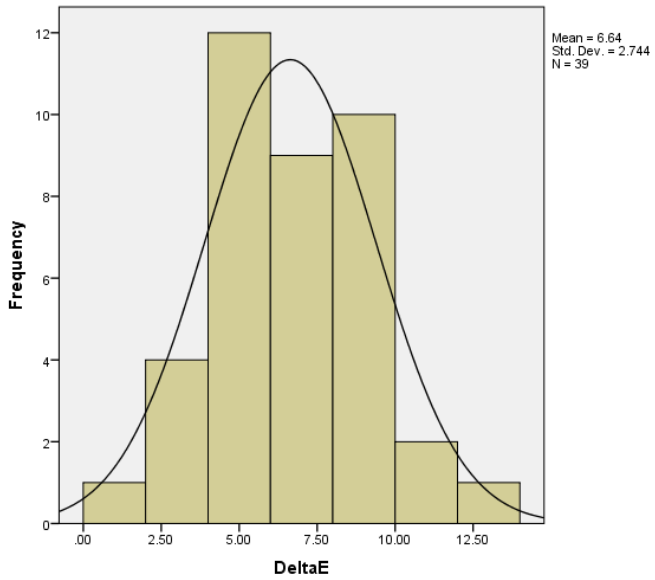

Figure 3.6 Plot of IKAM measurement of colour change (ΔE) for the dataset of 39 teeth. The data were normally distributed.

As explained in the methods section 3.1.8.5.3 page 71, In order to be able to compare the IKAM measurement with patient's perception, ΔE measured by IKAM was grouped into four categories:

ΔE ≤ 3.

ΔE > 3 and ≤ 5.

ΔE > 5 and ≤ 8.

ΔE > 8.

Table 3.14 shows the agreement between patient's perception measured by the response of patients to the first question and the IKAM measurement.

		Patient Perception of change in colour at final review (do you think the colour of your injured tooth/teeth has changed?)		
		Yes	No	Total
IKAM groups	ΔE <=3	1	2	3
	3< ΔE <=5	5	6	11
	5< ΔE <=8	4	8	12
	ΔE >8	6	7	13
Total		16	23	39

Table 3.14 Comparison between patients' perception of colour changed measured by the patients response to question 1 in their final review and IKAM detection measured by ΔE categories between baseline and final review.

Only sixteen children reported a change in colour of their injured teeth. However, the IKAM recorded ΔE greater than 3 for almost all the teeth.

There was no agreement between IKAM and patients' perception, giving Chi-Square value of 0.597 and a p-value = 0.927.

3.2.6.2 Shade guide (investigator) versus IKAM (L*a*b* values)

In methods 3.1.8.5.3 page 71, the investigator's perception was measured by the shade difference and was grouped as follows:

0 = no difference.

1 = one difference in either direction (-1 is lighter, +1 is darker).

2 = two differences.

3 = three or more differences (3 to 13).

Table 3.15 shows the agreement between investigator's perception measured by the shade difference and the IKAM measurement.

		The difference in shade (investigator perception) between baseline and final review				
		No Shade difference	One Shade difference	Two Shade differences	3 or more Shade differences	Total
IKAM_cat	ΔE <=3	1	1	1	0	3
	3< ΔE <=5	5	2	2	2	11
	5< ΔE <=8	7	2	1	2	12
	ΔE >8	4	5	1	3	13
Total		17	10	5	7	39

Table 3.15 Comparison between the IKAM categories of colour change and the difference in shade between the baseline and the last review measured by the investigator's perception.

In 17 teeth the investigator reported no difference in shade matching between the baseline and the final review. However, the IKAM detected a change in their colour with 16 teeth out of 17 having a ΔE greater than 3.

The Chi-Square test showed no agreement between IKAM and shade difference reported by the investigator with a value of 5.12 and a p-value = 0.824.

3.2.6.3 Patient perception versus shade guide (Investigator's) perception of colour change

A comparison was made between the shade guide (investigator) measure and patient's perception to assess the agreement in colour change of the traumatised teeth. This is shown in Table 3.16. In 21 cases there was agreement between the two measures of colour change. In 12 cases there was a change in investigator perception of colour change that was not identified by the patient. There was no significant agreement between investigator's perception and patients' perception of colour change (Fisher's Exact test p=0.8).

		Shade difference between Baseline and last review								Total
		-1	0	1	2	3	5	6	13	
Patient Perception of change in colour at the final review	Yes	2	6	4	3	1	0	0	0	16
	No	1	11	3	2	3	1	1	1	23
Total		3	17	7	5	4	1	1	1	39

Table 3.16 Patients' perception of colour changed measured by the children response at their last review and comparison to the shade difference recorded by the investigator between baseline and last review. The red numbers indicates the number of cases that showed agreement between the two measures.

3.2.7 Precision and reproducibility

3.2.7.1 Reference point precision (point accuracy PA)

As explained in section 3.1.8.2.1 page 64, an area that could introduce error into the colour assessment process, was the identification of the same reference point on the grey block (point accuracy= PA) between two different photographs.

Table 3.17 shows the mean and standard deviation of any error introduced by choosing a slightly different reference point on the grey block on the same photograph inserted into reference (image1) and test image (image2) areas on colour_correct2 programme. The ΔE was very small with a ΔE of 0.06 (+/- 0.02).

	Image1			Image2			ΔE
	L*	a*	b*	L*	a*	b*	
1	48.99	1.68	-.18	48.99	1.59	-.23	.10
2	48.96	1.69	-.18	48.99	1.71	-.15	.05
3	48.99	1.68	-.18	48.98	1.65	-.22	.06
4	48.99	1.68	-.20	49.02	1.65	-.18	.04
5	48.99	1.68	-.18	48.98	1.65	-.22	.06
6	49.03	1.64	-.19	48.99	1.68	-.19	.05
7	49.03	1.67	-.11	49.02	1.65	-.18	.08
8	49.03	1.67	-.11	49.03	1.66	-.12	.02
9	49.03	1.66	-.16	49.03	1.66	-.12	.04
10	49.03	1.64	-.13	48.99	1.71	-.15	.09
Mean	49.0070	1.6690	-.1620	49.0020	1.6610	-.1760	.0568
Std. Dev	.02584	.01729	.03327	.02044	.03446	.04033	.02440

Table 3.17 The L*a*b* values of the selected square area within the grey card in both image1 and image2. The process was repeated 10 times for the same images. Then the mean and standard deviation was calculated to quantify the possible error introduced by the point accuracy (PA).

3.2.7.2 Region of interest precision (ROI)

The second potential area of inaccuracy was selecting the same ROI in two different images taken at two different time points. Following the methodology described in section 3.1.8.2.2 page 66, this was estimated for ten randomly selected patient's photographs. The selected teeth varied in the nature of their injury and included teeth with and without hard tissue injuries. With TDI, some injuries can involve fracture to the crown of the tooth. In these injuries there is a smaller amount of the residual tooth available to calculate the ROI. Four of the selected teeth had less than half the crown available for the ROI assessment and produced an error of 0.35 (SD +/- .08) compared to an error of 0.32 (SD +/- .09) when more than half the tooth was available. The overall error for the ROI was 0.33 (SD +/- 0.08) [Table 3.18].

	Image1			Image2			ΔE (Std.dev)
	L*	a*	b*	L*	a*	b*	
1	56.10	7.20	8.93	56.17	7.30	8.75	0.26 (+/- 0.03)
2	60.97	8.81	6.28	60.58	9.07	6.16	0.41 (+/- 0.17)
3	58.00	6.24	7.59	58.12	6.35	7.37	0.28 (+/- 0.10)
4	58.26	11.35	3.86	58.29	11.51	3.82	0.19 (+/- 0.03)
5	55.50	12.87	6.02	55.73	12.88	5.81	0.34 (+/- 0.08)
6	45.26	16.24	4.25	45.43	16.18	4.04	0.37 (+/- 0.11)
7	48.98	15.53	6.85	49.36	15.50	6.64	0.45 (+/- 0.16)
8	42.83	16.07	5.72	43.02	16.12	5.54	0.28 (+/- 0.07)
9	47.70	16.04	8.58	48.04	15.95	8.39	0.43 (+/- 0.14)
10	45.22	14.67	4.71	45.40	14.69	4.55	0.28 (+/- 0.12)
						Mean (overall ROI error)	0.3290 (+/- 0.08)

Table 3.18 The mean L*a*b* values of 10 randomly selected teeth with different types of injury; the same image was used in image1 and image2 without colour correction. Then the mean and standard deviation were calculated to quantify the possible potential error of selecting different ROI. Number 1, 7, 8, and 9 were all had crown fracture with less than half of the crown was available.

Therefore, the total potential residual error within the methodology used to calculate the change in colour using the objective IKAM measure was 0.06 (PA) + 0.33 (ROI). This gave a total error of 0.39.

3.2.8 Null Hypothesis

The following were recognised in response to the null hypothesis of this study;

- There was consistent and marked colour change for teeth suffering TDI, which disproves the first hypothesis (There will be no colour change in permanent teeth in children following TDI).

- There was no significant agreement between the one objective (IKAM) and two subjective measures (patients' perception and investigator perception) of colour change for teeth suffering TDI; therefore the second hypothesis was upheld (There will be no agreement between the three methods of colour measurement).

3.3 Discussion

3.3.1 Patient recruitment and retention

Following traumatic dental injuries (TDI) children are referred to Leeds Dental Institute (LDI) for specialist dental care at the trauma clinic. Once the initial care is provided, most children are seen for further treatment and follow-up in the time frame advocated by national and international TDI guidelines (Albadri et al., 2010, Andersson et al., 2012, Day and Gregg, 2012, DiAngelis et al., 2012). Other children access care at LDI following referral from their own dentist where they feel the child requires specialist trauma management.

The inclusion criteria were relatively flexible, thereby allowing many patients to be eligible for the study. No patient who was eligible to participate refused to participate.

Potential eligible subjects were identified from the trauma clinic list or from their attendance at acute care clinic. Children with acute injuries frequently attended with little or no warning. These children were approached by the investigator upon their arrival at the department. On two or three occasions, it was not appropriate to recruit the patients during their first acute care, as a result of the severe injury and/or the level of stress the child and/or the parents displayed. On these occasions, the information sheet about the study was given out, and they were approached on their subsequent visit in respect to participating in the study.

The total study duration was 21 months. Patients' recruitment was performed in 14 months, and the follow-up period was continued for a further seven months

to permit time for two review appointments. Majority of patients seen in trauma clinics were for follow-up care and reviews with their original TDI occurring several weeks or months earlier. Fifty-one patients were recruited to this study with the average time between the original injury and recruitment being 11 weeks.

The trauma clinic receives between 1-3 new referrals a week. Potentially up to 180 patients might have been seen in the recruitment period. The main barriers for recruiting more patients were twofold: in some cases the TDI had occurred greater than 6 months before attendance or root canal treatment had already commenced for the traumatised teeth. In both these circumstances the patient was ineligible for recruitment. Therefore this prospective clinical study recruited a reasonable size sample for the potential patients available.

In the study protocol, the review visits were set ideally at three months and six months. This was not possible for all participants. The study design was pragmatic with data collection only occurring where the patient was already attending for their treatment or review visit. Therefore where clinical care necessitated a different follow-up regime the patient was not asked to attend specifically for the study. The review visit assessments were varied and this was reflected in the timing of the mean and standard deviation of the review appointment. For children who attended two review appointments, the mean time interval was 4.92 months and 10.50 months for the first and second review respectively. Children who attended only one review visit had a mean time interval of 7.15 months.

Unfortunately, not all of the 51 patients were used in data analysis; only 39 patients formed the dataset from which the results were reported. Details of patients' retention is presented in the results section 3.2.1 pages 74-76.

3.3.2 IKAM

The IKAM is a reproducible non-contact colour measurement of the entire tooth surface. Đozic et al. (2004) & (2007) reported that the IKAM performed equally well with respect to precision and reliability in both standardised in-vitro setting and in clinical conditions. Taking photographs using IKAM requires special training on photographic methods to maximise its capabilities. In addition, the practitioner needs a basic understanding of computer technology and image manipulation, to optimise the benefits and cost-effectiveness of the process. All the photographs taken during this study using the IKAM were performed in the Medical and Dental Illustration department (M&DI), in which all the staff members had received standard training in the use of the IKAM.

At the end of their appointment, patients were sent from trauma clinic to the M&DI to have their photographic records. The time taken for the IKAM photographs added 10 to 15 minutes to the patient's appointment. The time could extend further if there was fogging of the photograph as a result of their breath. Whenever this happened, the cone was cooled using a fan prior to taking a further photograph.

Based on the results obtained from the in-vitro work, section 2.5.1 page 46, and in order to minimise the time for IKAM photographs, the investigator would

notify the M&DI at the beginning of the trauma clinic if the IKAM would be needed.

During the study a few problems were identified with IKAM photographs which led to the loss of data. Two images were taken in a non-polarised setting; these images could not be used because the light reflection would influence CIELAB values. Furthermore one baseline image was lost and this meant none of their data could be analysed. Finally the image analysis using MATLAB software was time consuming, around 7-10 minutes needed for each image analysis.

The colour_correct2 programme working in MATLAB software was used for quantitative assessment of any colour changes of the traumatised teeth between the baseline and any time points. The comparison was made between the baseline and the first review, and then between the baseline and the second review. The colour_correct2 programme works by selecting a reference point on the grey block of the baseline image, and then to select a point on the grey block on the review image. The programme then compared the RGB values of these two points, making them identical, and then uses the difference to adjust the colour of the entire review image. Lastly the programme displays the corrected review image, which the colour change will be assessed against it.

When selecting the reference point, the programme used a square block pixel area centered on the selected point on both images. The programme was predetermined to select 51X51 square block pixel area (The process of identifying the appropriate pixel area to reduce the variability and to increase the reproducibility was described in the method chapter section 3.1.8.2.1 page 64). Therefore, selecting the same reference points in both images was a

critical stage that could introduce error in the colour correction process. This potential error was calculated to be ΔE = 0.06. It provided evidence that the system was consistent and gave almost the same value every time it was used for a single image. This was considered very impressive compared with the error produced in the previous pilot study by (SM). In this earlier work a square block pixel area, 11X11, that introduced an estimated error of ΔE = 0.65.

The other area that could introduce error when the colour_correct2 programme was used, was the precision in identifying the same region of interest (ROI) on the injured tooth in both photographs. The size of this area varied depending on the type of the injury. It could be the whole original crown, half or less than half of the crown. Furthermore, the alignment of both photographs was not identical, as they were taken several months apart and no aligning device was used. There was a very small difference for the ROI with different amounts of crown available. As identified in section 3.2.9.2 page 94, this difference was a ΔE of 0.03 (half crown = 0.35, full crown = 0.32). The total ROI error was calculated to be ΔE = 0.33.

These calculations showed a total error of up to ΔE = 0.39 was possible. The total error was very small; therefore it indicated that the calculation of colour change between two images was related to change in tooth colour and not to the error within its measurement. This was much less than the total error calculated by (SM) in his earlier study, where the error was estimated to be ΔE = 1.24. Wee et al. (2006) explored the average system errors using digital imaging systems to be at higher levels compared to the present study, they

found that the error of three commercial cameras used in dentistry, at various calibration methods, ranging from ΔE 1.79 to 5.25 units.

The IKAM used in this study compares favourably to the many other objective techniques to monitor colour change in teeth. These frequently use expensive equipment and require a sterilisable adaptor for each patient to ensure calculation is taken from identical points; furthermore they give a limited area measurement. It has been reported that colour communication is best performed using reference photography obtained using a digital camera (Chu et al., 2010).

3.3.2.1 Objective colour change measured by IKAM

For all the 73 teeth that were evaluated during this study, the overall mean colour change at the final review was a ΔE 5.45 (SD +/- 2.80). This change was comprised of a mean change in L* (ΔL*) of 0.74 (SD +/- 5.14) with teeth becoming lighter, Δa* of 0.69 (SD +/- 1.83) minor tendency toward red end of the red-green spectrum, and Δb* of 1.73 (SD +/- 2.13) teeth got yellower. For all these changes the standard deviation was larger than the mean change showing a wide range in colour changes seen. Also, this large value of standard deviation is indicative of the presence of outliers within the dataset. It had been reported that a ΔE as small as 1.8 is perceptible (Ghinea et al., 2010), and a ΔE as small as 1.25 is unacceptable (Lindsey and Wee, 2007b), for 50% of dental professional observers.

The overall mean of L*, a* and b* at the baseline was 49.65, 12.00 and 6.52 respectively; and at the final review 50.36, 12.07 and 8.27 respectively.

Đozic et al. (2004) assessed the possibility of using a digital camera to obtain reproducible L*a*b* values of the cervical, middle, and incisal segments of 50 vital upper right central incisors. They reported that the L*a*b* values of the three tooth segments differed significantly. Table 3.19 shows the mean CIELAB values of the three segments in 50 vital teeth measured in the study of Đozic et al. (2004).

	L* (SD)	a* (SD)	b* (SD)
Cervical	71.7 (+/- 6.0)	2.4 (+/- 1.7)	18.5 (+/- 3.8)
Middle	73.8 (+/- 5.7)	-1.3 (+/- 1.4)	15.9 (+/- 3.8)
Incisal	62.2 (+/- 6.5)	-2.2 (+/- 1.6)	14.0 (+/- 3.6)

Table 3.19 The mean CIELAB values of three segments of 50 vital upper central incisors measured in the study of Đozic et al. (2004).

The L*, a*, b* values obtained in the present study, at the baseline or at the final review, were not in agreement with Đozic et al. (2004). In (Đozic et al.) study they assessed the L*,a*,b* values of adults teeth with an average age of 32.8 years (SD +/- 12.4), all teeth were vital, and the illumination was standardised using ring flash that could have added to the lightness of the recorded images. In the present study, the teeth were all for children with an average age of 9.7 years (SD +/- 2.2); all teeth sustained different types of TDI that could have an influence on tooth vitality and consequently the colour.

For the individual L*a*b* scores for baseline and final follow-up for each tooth, the colour change was predominantly related to the increase in the b* value and the teeth got yellower in colour compared to the baseline visit, followed by a minor shift toward the lighter end at the L* scale, and toward red in the a* scale as well. When the components of the total colour change were calculated as a fraction, the change in delta b made up 55% of the colour change with the two other components ΔL and Δa making up 23% and 22% respectively. The yellowing of teeth is a physiological process of aging. For example over time the enamel of teeth becomes thinner allowing the yellower dentine to increasingly be seen. Therefore it could be argued that in this sample the global effect of the trauma led to a premature ageing of the traumatised tooth or teeth.

3.3.3 Patients' perception of colour change

The value patients placed on the colours of their teeth is important. Frequently discolouration may not be that noticeable to other people but it affects their own perception of themselves (Joiner, 2004). It is common that clinicians are concentrating on treating dental injuries, and they may not always appreciate how patients, particularly younger ones, perceive the significance of their injuries. This may have an impact on how patients follow instructions and attend for follow-up care. Greater awareness of patient's perspective may therefore help to improve communication, patient compliance and hence treatment outcomes (Vlok et al., 2011b).

Porritt et al. (2011) reported that children with TDI had more impacts on their OHRQoL than was previously reported by children with caries and malocclusion (Jokovic et al., 2006). On each of the follow-up visits in this study, the patients were asked four questions about their perception of colour change of their traumatised teeth. These questions were locally formulated specifically for this study and had not been used previously in the literature and neither had they undergone a validation process.

Children were encouraged to give their own perception without the help of their parents/guardian. At each visit, the investigator reminded the patients that the questions were all about the colour of their injured tooth/teeth only. The four questions were perceivable at any patient's age, with only binary answer option available (Yes/No and Better/Worse). After reviewing the results, the raw answers appeared to conflict with each other. Based on the patients' responses at the final review, patients could be broadly fitted in the following categories:

- Six patients thought that the colour of their injured teeth had got worse, were unhappy about the colour, and wanted treatment to improve it.
- Three patients thought that the colour had got worse, but were happy about it and did not want any treatment to improve the colour.
- Only one patient reported that the colour had got better, but still was unhappy about the colour and wanted treatment to improve it.
- Four patients had not noticed any colour change or colour had got better, were happy about it, but still wanted treatment to improve the colour.
- Twenty-five patients reported no colour change or colour had got better, were happy about it, and did not wanted treatment to improve the colour.

These categories demonstrated that there were conflicts in patients' responses. Some patients were unsatisfied with the colour of their injured teeth, whether discolouration had occurred or not, they wanted treatment to improve the colour of their teeth. In contrast, other patients were satisfied with the colour of their injured teeth, despite the discolouration, and they did not want any treatment to improve the colour. A possible explanation in this situation may be that these children may be anxious or had developed anxiety following the TDI and were unwilling to have any other treatment that they thought was unnecessary and optional. Porritt et al. (2011) reported that school-related activities was the most affected area of children's HRQoL, followed by children feeling anxious about what will happen to them at their next dental visit.

Looking at Table 3.7 page 82 for the perception of the patients who had been reviewed twice. The number of the patients who reported that the colour of their injured teeth had got worse was increased at the second review. However the level of satisfaction had increased, as well as fewer patients wanting treatment to improve the colour of their injured teeth at their second review. This may indicate, that the discolouration may have increased gradually between appointments, but satisfaction may have also increased as patients adapted to the new colour of their tooth. Therefore the desire to have treatment to improve the colour may become less. Another possible explanation is that some children, particularly younger age, did not understand the questions, which resulted in inconsistency in their responses at different time points. Designing and validating questions for use in research is a long and complex process with

many different steps that need to be undertaken to ensure the questions are appropriately worded for children's understanding (Gilchrist et al., 2014).

For the statistical modelling and comparison of the three different measures of colour change, only the first question was used. The first question specifically related to the patient's perception of any colour change (Do you think the colour of your injured tooth/teeth has changed?), while the other questions were more related to the acceptability of the colour change. Patient perception was found to be inconsistent with the objective measure of colour change, namely the IKAM (L*a*b* values). From the 39 teeth, IKAM detected change in colour greater than 3 ΔE for 36 teeth. However, more than half of the children failed to perceive the colour change. A value of 3 ΔE had been previously identified as noticeable by normal human perception (Ragain and Johnston, 2001) and it is also clinically visible and unacceptable (Ghinea et al., 2010, Alghazali et al., 2012). The main component of colour change in the CIELAB colour scale in this study was predominantly related to the increase in the b* value, which indicated that most teeth had got yellower. Therefore, children may be less perceptible to the yellowish discolouration than to darkening as identified in a study by Day et al. (2011). It had been reported that patients were less likely to report small colour differences between tooth and resin composite materials than were dental professionals (Ragain and Johnston, 2001).

For both patients who reported the colour of their injured teeth had changed, and patients who did not report any colour change, the mean ΔE was 7.22 (SD +/- 3.2) and 6.14 (SD +/- 2.42) respectively, both values were previously reported as perceivable as well as unacceptable according to the perceptibility

and acceptability studies (Alghazali et al., 2012). However, the mean ΔL* for patients who reported a colour change was -0.23 (SD +/- 7.1), the mean Δa* was 0.22 (SD +/-2.02), and the mean Δb* was 2.17(SD +/-2.32) that indicated slight darkening of the traumatised teeth in the L scale, and a predominant shift toward the yellow end of the spectrum. Compared to the mean ΔL*,Δa*, and Δb* values for patients who failed to perceive any colour change 2.55 (SD +/- 5.13), -0.5 (SD +/- 1.85), 1.7 (SD +/- 2.3) respectively, indicated the predominant change was a shift toward the lighter end of the spectrum. Therefore children with TDI were less likely to notice any change in colour where the direction of colour change was to make the tooth lighter in colour.

3.3.4 Shade guide

Visual colour determination by comparison of patient's teeth with the commercially available shade guides is the most frequently applied method in clinical dentistry. However, it is considered highly subjective (Vanderburgt et al., 1990, Joiner, 2004).

The colour standard of the commercially available shade guides varies greatly. Due to difficult-to-control parameters during their fabrication, none of the commercially available dental shade guides are identical. Therefore the same "Vita Lumin Classic™" shade guide was used throughout this study, in order to ensure standardisation and reproducibility.

It has been shown that the Vita Classic shade tabs are not systematically distributed in the colour space relevant to the human teeth, and that there is

even overlapping (Miller, 1987). However, to date, the Vita Classic shade guide remains the most commonly used shade guide, legitimising its use in this study.

Brewer et al. (2004) recommended to have a second observer stand about 3 feet behind the primary observer to verify the selected shade. This was not feasible in this study, as the same two standardised observers would be required to undertake at least 221 shade assessments for all the patients recruited throughout the study.

In this study, the shade guide selection was carried out in the paediatric dentistry clinic, which is lit with regular cool white fluorescent lights and which is high in green-yellow spectrum. The overall perception of tooth colour is influenced by various factors such as lighting conditions, translucency, opacity, gloss, and the limitation of the human eye and brain. All these factors, except for the lighting conditions, are inherent properties of the teeth or the observers, which cannot be controlled. The quantity of light is important for optimum comfort and work efficiency. However, the intensity of the dental operatory lighting may not be selected for colour matching. Nonetheless, traditional recommendations for ambient lighting are a reasonable guide for establishing a comfortable environment (Brewer et al., 2004).

The colours of the majority of patients' teeth, assessed by the investigator, were darker at the follow-up visits. Thirty-one teeth were assessed to have a darker shade between the baseline and the final review with a range of 1 to 3 shades. Only 5 teeth were lighter, and 30 teeth had no change in shade assessment between the baseline and the last follow-up.

Yılmaz et al. (2011) evaluated the effect of two different arrangements of shade tabs on the repeatability and accuracy of shade selection. It had been found that the use of manufacturer's value-order arrangement did not enhance the accuracy and repeatability of shade selection results. These results might be attributed to the in vitro character of their study, where all the measurement conditions were standardised in terms of the illumination source and the grey background of the test tabs. Furthermore, the observers in this study were all restorative clinicians who routinely performed shade selections and were familiar with the shade guide used in this study. In contrast, Paravina (2001) concluded that better shade matching results were provided when the shade guide was ordered according to the ΔE in relation to the lightest tab when compared to the manufacturer hue/chroma order. Every efforts were made to standardise as many possible variables that could influence the shade assessment process during this study, including: the use of the same shade guide, performing the shade assessment by the same investigator, at the same lighting conditions for all patients, and taking the shade at the beginning of each patient's appointment before providing any treatment. However, shade assessment using visual techniques could be influenced by other factors. The study duration was 21 months, which indicated that the study period was during different seasons of the year, bright warm days and dark cold days, which could significantly add an affect on the lighting condition on the clinic that has windows at one end of it. Furthermore, the presence of composite restorations in some teeth may affect the shade assessment particularly as composite can pick up stains and discolouration over time. In addition there were several cases

that were wearing fixed orthodontic appliances that added to the difficulty of accurately undertaking the shade selection process.

Several studies investigated the effect of different lighting conditions on the visual assessment of teeth shades. Della Bona et al. (2009) explored two lighting environments, they reported that the cool white fluorescent lighting provided a more consistent illumination than natural sunlight. This observation was in agreement with Saleski (1972) and Paravina (2001) indicating that consistency of artificial lighting may contribute to a more accurate shade-match than natural daylight. However, not all of these studies used an objective measure to compare the accuracy of their findings.

The investigator's perception of colour change was also not in agreement with the IKAM detection of colour change. In 16 teeth, the IKAM detected colour change greater than 3 ΔE where the investigator recorded no shade difference for these teeth. In 20 teeth, the investigator recorded a shade difference and the IKAM detected a colour change greater than 3 ΔE.

The mean ΔE value for the teeth which the investigator reported no shade difference was 6.14 (SD +/- 2.6), while for the teeth that the investigator reported a different shade between the baseline and the final review the mean ΔE was 6.98 (SD +/- 2.91), both values were previously identified as perceivable by 50% of dental professional observers (Alghazali et al., 2012). Interestingly, for the teeth the investigator did not report any shade difference, the predominant change in the L*a* and b* values was on the L scale with a ΔL* of 2.22 (SD +/- 5.26) that indicated the teeth had got lighter in shade, and for the teeth the investigator recorded a different shade the predominant change

was in the b* value with the mean Δb* of 2.00 units, which indicated the teeth had got yellower. This suggested that the investigator was more sensitive to the yellowish discolouration than the lightening change in colour, which may explain the inconsistency between the investigator's perception and the IKAM despite all good practices used with shade assessment.

3.3.5 Patients' perception versus shade guide (investigator's) perception of colour change

In 12 cases the investigator recorded a different shade between the baseline and the final review that was not identified by the patients, compared to 6 cases where the investigator recorded no shade difference however the patients perceived a colour change. The disagreement was not found to be significant, however, it could be due to that some children did not understand the question, or were not bothered about any colour change. As both measures have been found to be inconsistent in measuring colour change in respect to the objective IKAM measurements it is unsurprising that these two measurements did not agree.

3.3.6 Statistical analysis

3.3.6.1 Calculation of the collinearity for the patients who had been reviewed twice

In the dataset of the present study, there were 13 patients who attended only one review visit, compared to 26 patients attended for two reviews. It was therefore necessary to assess the presence of straight-line relationship between each pair of our dependent variables (IKAM, investigator's perception, patients' perception) between first and second review, which was assessed by the collinearity. Collinearity or linear correlation describes the relation between two continuous variables, in terms of both the strength of the relationship and the direction.

The linear correlation produced a value for r, the correlation coefficient, and a p-value < 0.05, which indicated 95% confidence in the result. This confirmed that teeth continued to discolour in the same direction with time. Therefore, we do not have to consider the interim results. In other words, if the data was not available for the second review, the data at the first review can be used as a good proxy to avoid excluding patients who did not attend the second review. Hence, the final review for each patient was considered in data analysis, and the colour difference was measured between the baseline and the final review for each patient.

3.3.6.2 Patient rather than tooth related data

Some patients had more than one tooth injured; the injured teeth from the same patient will potentially be correlated and required a more complex data analysis (multi-level modelling or random effect modelling) to control this type of correlation. However, it was deemed to be too complex to undertake such modelling with such a small dataset. Therefore the data was merged to include only the most discoloured tooth for each patient. Hence, the total number of teeth that formed the dataset from which the results were reported was 39 teeth in 39 patients.

3.3.7 Variables associated with objective colour change

The variables that showed association with the objective measure of colour change (IKAM) were; the time between the baseline and the last review, hard tissue injury, splinting and restoration placed at or prior to baseline visit.

This indicated that the longer the time interval between the baseline and the assessment, the more colour change of the tooth was likely to progress.

The presence of hard tissue injury and restoration were also associated with colour change. These two variables were actually related, as all hard tissue injuries, apart from root fracture, would normally require restoration. When the types of treatment were grouped, the restoration group included; composite build-up on its own and composite build-up following pulp capping. These types of treatments were required where there was a hard tissue injury without pulp involvement, or with minor pulp involvement where vitality is maintained and

pulp capping was deemed necessary. Therefore, the colour change may actually relate to the presence of composite restorations rather than the presence of hard tissue injury on its own merit. Although, great caution was undertaken not to include the composite restorations during mapping out the region of interest (ROI) small involvement of composite restoration within the ROI could affect the L*a*b* values of the selected area.

Splinting was also found to cause discolouration. This may be related to the severity of the PDL injury, as splinting would normally be required following a severe PDL injury. Otherwise, it could be related to the presence of residue of the composite materials after splint removal, or conversely, excessive removal of the composite which may lead to loss of enamel and increased dentine visibility.

3.3.8 Limitations of the present study and future research

Although the study was conducted using the available subjects and expensive resources, in hindsight several improvements could have been made which include:

- By incorporating a larger sample in the study would provide a greater representation of the populations and more conclusive results.
- By training on the use of Vitapan 3D master shade guide, and a better control over the lighting condition during shade guide assessment may reduce the inconsistency in shade guide taking which was identified in this study.

- Recruiting patients as close to their original injury date as possible. There is a potential risk that colour change is most apparent soon after the injury and therefore recording the colour at an early point would be appropriate.
- Excluding patients with TDI with less than half of the crown available for colour assessment, due to severe crown fracture or presence of fixed orthodontic appliance.
- Longer follow-up reviews can also be considered to assess the change in colour with time, as colour change may continue over a longer period. This would permit analysis of whether colour change is associated with normal physiology or pathology as a result of the TDI outcomes.
- Validation of the questions for the measurement of patients' perception requires further research following internationally recognised criteria, which was produced by Consensus-based Standards for the Selection of Health Measurement Instruments initiative (COSMIN).

Further work is needed in this area, which should include measurement of colour change in a similar age group of children where there has been no traumatic dental injury. This would provide a control group permitting a comparison to establish how much colour change there is naturally where there is no trauma in an adolescent population.

3.4 Conclusions

1. Following TDI, there was an observable colour change identified by an objective measure, IKAM. On average, teeth got predominantly yellower and to a lesser extent lighter and redder.
2. Subjective patients and investigator measures of colour change were inconsistent when compared to the objective measure (IKAM).
3. No variables were significantly associated with colour change, although several came to significance ($p<0.05$). These variable were; time interval between the baseline assessment and the final review, presence of hard tissue injury, splinting, and restoration placed at or before baseline.

References

<CDHS2013-Report2-Dental-Disease.pdf>.

AHMED, H. M. A. & ABBOTT, P. V. 2012. Discolouration potential of endodontic procedures and materials: a review. *International Endodontic Journal,* 45**,** 883-897.

AKISUE, E., TOMITA, V. S., GAVINI, G. & DE FIGUEIREDO, J. A. P. 2010. Effect of the combination of sodium hypochlorite and chlorhexidine on dentinal permeability and scanning electron microscopy precipitate observation. *Journal of endodontics,* 36**,** 847-850.

ALBADRI, S., ZAITOUN, H. & KINIRONS, M. 2010. UK National Clinical Guidelines in Paediatric Dentistry. Treatment of traumatically intruded permanent incisor teeth in children. *International Journal of Paediatric Dentistry*.

ALDRIGUI, J. M., ABANTO, J., CARVALHO, T. S., MENDES, F. M., WANDERLEY, M. T., BONECKER, M. & RAGGIO, D. P. 2011. Impact of traumatic dental injuries and malocclusions on quality of life of young children. *Health Qual Life Outcomes,* 9**,** 78.

ALGHAZALI, N., BURNSIDE, G., MOALLEM, M., SMITH, P., PRESTON, A. & JARAD, F. D. 2012. Assessment of perceptibility and acceptability of color difference of denture teeth. *J Dent,* 40 Suppl 1**,** e10-7.

ANDERSSON, L., ANDREASEN, J. O., DAY, P., HEITHERSAY, G., TROPE, M., DIANGELIS, A. J., KENNY, D. J., SIGURDSSON, A., BOURGUIGNON, C. & FLORES, M. T. 2012. International Association of Dental Traumatology guidelines for the management of traumatic dental injuries: 2. Avulsion of permanent teeth. *Dental Traumatology,* 28**,** 88-96.

ANDREASEN, F. M. 1986. Transient apical breakdown and its relation to color and sensibility changes after luxation injuries to teeth. *Endodontics and Dental Traumatology,* 2**,** 9-19.

ANDREASEN, F. M. 1989. Pulpal healing after luxation injuries and root fracture in the permanent dentition. *Endodontics & Dental Traumatology,* 5**,** 111-131.

ANDREASEN, F. M. & ANDREASEN, J. O. 2006. Resorption and mineralization processes following root fracture of permanent incisors. *Dental Traumatology,* 4**,** 202-214.

ÅRTUN, J., BEHBEHANI, F., AL-JAME, B. & KEROSUO, H. 2005. Incisor trauma in an adolescent Arab population: prevalence, severity, and occlusal risk factors. *American journal of orthodontics and dentofacial orthopedics,* 128**,** 347-352.

BAGHDADY, V. S., GHOSE, L. J. & ENKE, H. 1981. Traumatized anterior teeth in Iraqi and Sudanese children-a comparative study. *Journal of dental research,* 60**,** 677-680.

BARRETT, A. A., GRIMAUDO, N. J., ANUSAVICE, K. J. & YANG, M. C. K. 2002. Influence of tab and disk design on shade matching of dental porcelain. *Journal of Prosthetic Dentistry,* 88**,** 591-597.

BASRANI, B. R., MANEK, S., SODHI, R. N., FILLERY, E. & MANZUR, A. 2007. Interaction between sodium hypochlorite and chlorhexidine gluconate. *Journal of endodontics,* 33**,** 966-969.
BELOBROV, I. & PARASHOS, P. 2011. Treatment of Tooth Discoloration after the Use of White Mineral Trioxide Aggregate. *Journal of Endodontics,* 37**,** 1017-1020.
BENSON, P., ALI SHAH, A. & ROBERT WILLMOT, D. 2005. Measurement of white lesions surrounding orthodontic brackets: captured slides vs digital camera images. *The Angle Orthodontist,* 75**,** 226-230.
BERGEN, S. F. & MCCASLAND, J. 1977. Dental operatory lighting and tooth color discrimination. *The Journal of the American Dental Association,* 94**,** 130-134.
BLINKHORN, F. 2000. The aetiology of dento-alveolar injuries and factors influencing attendance for emergency care of adolescents in the North West of England. *Dental Traumatology,* 16**,** 162-165.
BOKSMAN, L. 2007. Shade Selection. *Ontario Dentist*.
BREWER, J. D., WEE, A. & SEGHI, R. 2004. Advances in color matching. *Dental clinics of North America,* 48**,** 341-58.
BROOK, A. H., SMITH, R. N. & LATH, D. J. 2007. The clinical measurement of tooth colour and stain. *International Dental Journal,* 57**,** 324-330.
BUI, T. B., BAUMGARTNER, J. C. & MITCHELL, J. C. 2008. Evaluation of the interaction between sodium hypochlorite and chlorhexidine gluconate and its effect on root dentin. *Journal of Endodontics,* 34**,** 181-185.
CAMBRUZZI, J. V. & GREENFELD, R. S. 1983. Necrosis of crestal bone related to the use of excessive formocresol medication during endodontic treatment. *Journal of endodontics,* 9**,** 565-567.
CHADWICK, B. L., WHITE, D. A., MORRIS, A. J., EVANS, D. & PITTS, N. B. 2006. Non-carious tooth conditions in children in the UK, 2003. *British Dental Journal,* 200**,** 379-384.
CHU, S. J., TRUSHKOWSKY, R. D. & PARAVINA, R. D. 2010. Dental color matching instruments and systems. Review of clinical and research aspects. *Journal of Dentistry,* 38**,** e2-e16.
CORCODEL, N., HELLING, S., RAMMELSBERG, P. & HASSEL, A. J. 2010. Metameric effect between natural teeth and the shade tabs of a shade guide. *European journal of oral sciences,* 118**,** 311-316.
CORTES, M. I. D., MARCENES, W. & SHEIHAM, A. 2002. Impact of traumatic injuries to the permanent teeth on the oral health-related quality of life in 12-14-year-old children. *Community Dentistry and Oral Epidemiology,* 30**,** 193-198.
DAGG, H., O'CONNELL, B., CLAFFEY, N., BYRNE, D. & GORMAN, C. 2004. The influence of some different factors on the accuracy of shade selection. *Journal of Oral Rehabilitation,* 31**,** 900-904.
DANKERT, J. & WEMES, J. 1976. Diffusion of f ormocresol and glutaraldehyde through dentin and cementum. *Journal of endodontics,* 2**,** 42-46.
DAVIS, M. C., WALTON, R. E. & RIVERA, E. M. 2002. Sealer distribution in coronal dentin. *Journal of Endodontics,* 28**,** 464-466.
DAY, P. & GREGG, T. 2012. Treatment of avulsed permanent teeth in children. *Faculty Dental Journal,* 3**,** 166-169.

DAY, P. F., DUGGAL, M. S., HIGH, A. S., ROBERTSON, A., GREGG, T. A., ASHLEY, P. F., WELBURY, R. R., COLE, B. O. & WESTLAND, S. 2011. Discoloration of Teeth after Avulsion and Replantation: Results from a Multicenter Randomized Controlled Trial. *Journal of Endodontics,* 37**,** 1052-1057.

DE FRUJERI, M., FRUJERI, J. A., BEZERRA, A. C., CORTES, M. I. & JUNIOR, E. D. 2014. Socio-economic indicators and predisposing factors associated with traumatic dental injuries in schoolchildren at Brasilia, Brazil: a cross-sectional, population-based. *BMC oral health,* 14**,** 91.

DELLA BONA, A., BARRETT, A. A., ROSA, V. & PINZETTA, C. 2009. Visual and instrumental agreement in dental shade selection: Three distinct observer populations and shade matching protocols. *Dental Materials,* 25**,** 276-281.

DIANGELIS, A. J., ANDREASEN, J. O., EBELESEDER, K. A., KENNY, D. J., TROPE, M., SIGURDSSON, A., ANDERSSON, L., BOURGUIGNON, C., FLORES, M. T. & HICKS, M. L. 2012. International Association of Dental Traumatology guidelines for the management of traumatic dental injuries: 1. Fractures and luxations of permanent teeth. *Dental Traumatology,* 28**,** 2-12.

DONLY, K. J., KENNEDY, P., SEGURA, A. & GERLACH, R. W. 2005. Effectiveness and safety of tooth bleaching in teenagers. *Pediatric dentistry,* 27**,** 298-302.

DOUGLAS, R. D. & BREWER, J. D. 1998. Acceptability of shade differences in metal ceramic crowns. *The Journal of prosthetic dentistry,* 79**,** 254-260.

DOUGLAS, R. D., STEINHAUER, T. J. & WEE, A. G. 2007. Intraoral determination of the tolerance of dentists for perceptibility and acceptability of shade mismatch. *Journal of Prosthetic Dentistry,* 97**,** 200-208.

ĐOZIC, A., KLEVERLAAN, C. J., AARTMAN, I. H. & FEILZER, A. J. 2004. Relation in color of three regions of vital human incisors. *Dental Materials,* 20**,** 832-838.

DOZIĆ, A., KLEVERLAAN, C. J., EL-ZOHAIRY, A., FEILZER, A. J. & KHASHAYAR, G. 2007. Performance of Five Commercially Available Tooth Color-Measuring Devices. *Journal of Prosthodontics,* 16**,** 93-100.

FAKHRUDDIN, K. S., LAWRENCE, H. P., KENNY, D. J. & LOCKER, D. 2008. Impact of treated and untreated dental injuries on the quality of life of Ontario school children. *Dent Traumatol,* 24**,** 309-13.

FONDRIEST, J. 2003. Shade matching in restorative dentistry: The science and strategies. *International Journal of Periodontics & Restorative Dentistry,* 23**,** 467-479.

GHINEA, R., PÉREZ, M. M., HERRERA, L. J., RIVAS, M. J., YEBRA, A. & PARAVINA, R. D. 2010. Color difference thresholds in dental ceramics. *Journal of Dentistry,* 38**,** e57-e64.

GILCHRIST, F., RODD, H., DEERY, C. & MARSHMAN, Z. 2014. Assessment of the quality of measures of child oral health-related quality of life. *BMC oral health,* 14**,** 40.

GIRDLER, N. & SMITH, D. 1999. Prevalence of emergency events in British dental practice and emergency management skills of British dentists. *Resuscitation,* 41**,** 159-167.
GLENDOR, U. 2008. Epidemiology of traumatic dental injuries--a 12 year review of the literature. *Dent Traumatol,* 24**,** 603-11.
GUTIÉRREZ, J. H. & GUZMÁN, M. 1968. Tooth discoloration in endodontic procedures. *Oral Surgery, Oral Medicine, Oral Pathology,* 26**,** 706-711.
HAMMAD, I. A. 2003. Intrarater repeatability of shade selections with two shade guides. *Journal of Prosthetic Dentistry,* 89**,** 50-53.
HO, C., SYD, B. & DENT, G. 2007. Shade selection. *Australian Dental Practice***,** 116-8.
HOLAN, G., PERETZ, B., EFRAT, J. & SHAPIRA, Y. 2005. Traumatic injuries to the teeth in young individuals with cerebral palsy. *Dental Traumatology,* 21**,** 65-69.
HORN, D. J., BULAN-BRADY, J. & HICKS, M. L. 1998. Sphere spectrophotometer versus human evaluation of tooth shade. *Journal of Endodontics,* 24**,** 786-790.
JAHANGIRI, L., REINHARDT, S. B., MEHRA, R. V. & MATHESON, P. B. 2002. Relationship between tooth shade value and skin color: An observational study. *Journal of Prosthetic Dentistry,* 87**,** 149-152.
JOHNSON, J. E. 1975. Causes of accidental injuries to the teeth and jaws*. *Journal of public health dentistry,* 35**,** 123-131.
JOHNSTON, W. & KAO, E. 1989. Assessment of appearance match by visual observation and clinical colorimetry. *Journal of Dental Research,* 68**,** 819-822.
JOINER, A. 2004. Tooth colour: a review of the literature. *Journal of Dentistry,* 32**,** 3-12.
JOKOVIC, A., LOCKER, D. & GUYATT, G. 2006. Short forms of the Child Perceptions Questionnaire for 11–14-year-old children (CPQ11–14): development and initial evaluation. *Health and quality of life outcomes,* 4**,** 4.
KIM, S. T. & ABBOTT, P. 2000. The effects of Ledermix paste as an intracanal medicament on the discolouration of teeth. *Australian endodontic journal : the journal of the Australian Society of Endodontology Inc,* 26**,** 86-7.
KIM, S. T., ABBOTT, P. V. & MCGINLEY, P. 2000a. The effects of Ledermix paste on discolouration of immature teeth. *International Endodontic Journal,* 33**,** 233-237.
KIM, S. T., ABBOTT, P. V. & MCGINLEY, P. 2000b. The effects of Ledermix paste on discolouration of mature teeth. *International Endodontic Journal,* 33**,** 227-232.
KLEMETTI, E., MATELA, A. M., HAAG, P. & KONONEN, M. 2006. Shade selection performed by novice dental professionals and colorimeter. *Journal of Oral Rehabilitation,* 33**,** 31-35.
KOUVAS, V., LIOLIOS, E., VASSILIADIS, L., PARISSIS-MESSIMERIS, S. & BOUTSIOUKIS, A. 1998. Influence of smear layer on depth of penetration of three endodontic sealers: an SEM study. *Endodontics & Dental Traumatology,* 14**,** 191-195.

KRISHNAMURTHY, S. & SUDHAKARAN, S. 2010. Evaluation and prevention of the precipitate formed on interaction between sodium hypochlorite and chlorhexidine. *Journal of endodontics,* 36**,** 1154-1157.
KUMAR, A., BANSAL, V., VEERESHA, K. L. & SOGI, G. M. 2010. Prevalence of traumatic dental injuries among 12-to 15-year-old schoolchildren in Ambala district, Haryana, India. *Oral health & preventive dentistry,* 9**,** 301-305.
KUPIETZKY, A., WAGGONER, W. F. & GALEA, J. 2003. The clinical and radiographic success of bonded resin composite strip crowns for primary incisors. *Pediatr Dent,* 25**,** 577-581.
LEE, J. Y. & DIVARIS, K. 2009. Hidden Consequences of Dental Trauma: The Social and Psychological Effects. *Pediatric Dentistry,* 31**,** 96-101.
LENHERR, P., ALLGAYER, N., WEIGER, R., FILIPPI, A., ATTIN, T. & KRASTL, G. 2012. Tooth discoloration induced by endodontic materials: a laboratory study. *International Endodontic Journal,* 45**,** 942-949.
LI, S., KLUKOWSKA, M. & WHITE, D. 2006. Digital Plaque Imaging in a China Clinical Population. *The 84th General Session of the International Association for Dental Research, Abst,* 2272.
LINDSEY, D. T. & WEE, A. G. 2007a. Perceptibility and acceptability of CIELAB color differences in computer-simulated teeth. *J Dent,* 35**,** 593-9.
LINDSEY, D. T. & WEE, A. G. 2007b. Perceptibility and acceptability of CIELAB color differences in computer-simulated teeth. *Journal of Dentistry,* 35**,** 593-599.
LINDSEY, D. & WEE, A. 2010. Assessing tooth color differences in digital facial portraits. *Journal of dental research,* 89**,** 1254-1258.
LIVNY, A., SGAN-COHEN, H. D., JUNADI, S. & MARCENES, W. 2010. Traumatic dental injuries and related factors among sixth grade schoolchildren in four Palestinian towns. *Dental traumatology,* 26**,** 422-426.
MALIKAEW, P., WATT, R. G. & SHEIHAM, A. 2006. Prevalence and factors associated with traumatic dental injuries (TDI) to anterior teeth of 11-13 year old Thai children. *Community dental health,* 23**,** 222.
MARCENES, W., ALESSI, O. & TRAEBERT, J. 2000. Causes and prevalence of traumatic injuries to the permanent incisors of school children aged 12 years in Jaragua do Sul, Brazil. *International dental journal,* 50**,** 87-92.
MARCENES, W. & MURRAY, S. 2002. Changes in prevalence and treatment need for traumatic dental injuries among 14-year-old children in Newham, London: a deprived area. *Community dental health,* 19**,** 104-108.
MARCHESAN, M. A., JÚNIOR, B. P., DE FREITAS AFONSO, M. M., SOUSA-NETO, M. D. & PASCHOALATO, C. 2007. Chemical analysis of the flocculate formed by the association of sodium hypochlorite and chlorhexidine. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology,* 103**,** e103-e105.
MARIN, P. D., BARTOLD, P. M. & HEITHERSAY, G. S. 1997. Tooth discoloration by blood: An in vitro histochemical study. *Endodontics & Dental Traumatology,* 13**,** 132-138.

MCLAREN, K. 1987. Colour space, colour scales and colour difference. *Colour physics for industry. Huddersfield: H. Charlesworth & Co Ltd,* 1987**,** 97-115.
MILLER, L. 1987. Organizing color in dentistry. *The Journal of the American Dental Association,* 115**,** 26E-40E.
MUHAMMAD S 2011. Comparative Pilot study to assess Colour Change in Traumatised Teeth. *University of Leeds M.Dent.Sci thesis.*
NAIDOO, S., SHEIHAM, A. & TSAKOS, G. 2009. Traumatic dental injuries of permanent incisors in 11-to 13-year-old South African schoolchildren. *Dental traumatology,* 25**,** 224-228.
NASSAR, M., AWAWDEH, L., JAMLEH, A., SADR, A. & TAGAMI, J. 2011. Adhesion of Epiphany self-etch sealer to dentin treated with intracanal irrigating solutions. *Journal of endodontics,* 37**,** 228-230.
NAVABAZAM, A. & FARAHANI, S. S. 2010. Prevalence of traumatic injuries to maxillary permanent teeth in 9-to 14-year-old school children in Yazd, Iran. *Dental traumatology,* 26**,** 154-157.
NICOLAU, B., MARCENES, W. & SHEIHAM, A. 2001. Prevalence, causes and correlates of traumatic dental injuries among 13-year-olds in Brazil. *Dental traumatology,* 17**,** 209-213.
O'BRIEN, W. J., HEMMENDINGER, H., BOENKE, K. M., LINGER, J. B. & GROH, C. L. 1997. Color distribution of three regions of extracted human teeth. *Dental Materials,* 13**,** 179-185.
ODOI, R., CROUCHER, R., WONG, F. & MARCENES, W. 2002. The relationship between problem behaviour and traumatic dental injury amongst children aged 7–15 years old. *Community dentistry and oral epidemiology,* 30**,** 392-396.
PARAVINA, R. D. 2001. Evaluation of a newly developed visual shade-matching apparatus. *The International journal of prosthodontics,* 15**,** 528-534.
PARAVINA, R. D., POWERS, J. M. & FAY, R. 2001. Dental color standards: shade tab arrangement. *Journal of Esthetic and Restorative Dentistry,* 13**,** 254-263.
PARSONS, J. R., WALTON, R. E. & RICKS-WILLIAMSON, L. 2001. In vitro longitudinal assessment of coronal discoloration from endodontic sealers. *Journal of Endodontics,* 27**,** 699-702.
PARTOVI, M., AL-HAVVAZ, A. H. & SOLEIMANI, B. 2006. In vitro computer analysis of crown discolouration from commonly used endodontic sealers. *Australian endodontic journal : the journal of the Australian Society of Endodontology Inc,* 32**,** 116-9.
PATEL, M. & SUJAN, S. 2012. The prevalence of traumatic dental injuries to permanent anterior teeth and its relation with predisposing risk factors among 8-13 years school children of Vadodara city: An epidemiological study. *Journal of Indian Society of Pedodontics and Preventive Dentistry,* 30**,** 151.
PAUL, S., PETER, A., PIETROBON, N. & HAMMERLE, C. H. F. 2002. Visual and spectrophotometric shade analysis of human teeth. *Journal of Dental Research,* 81**,** 578-582.

PAUL, S. J., PETER, A., RODONI, L. & PIETROBON, N. 2004. Conventional visual vs spectrophotometric shade taking for porcelain-fused-to-metal crowns: a clinical comparison. *The International journal of periodontics & restorative dentistry,* 24**,** 222-31.
PORRITT, J. M., RODD, H. D. & BAKER, S. R. 2011. Quality of life impacts following childhood dento-alveolar trauma. *Dental Traumatology,* 27**,** 2-9.
PRESTON, J. 1985. Current status of shade selection and color matching. *Quintessence international (Berlin, Germany: 1985),* 16**,** 47.
RAGAIN, J. C. & JOHNSTON, W. M. 2000. Color acceptance of direct dental restorative materials by human observers. *Color Research & Application,* 25**,** 278-285.
RAGAIN, J. C. & JOHNSTON, W. M. 2001. Minimum color differences for discriminating mismatch between composite and tooth color. *Journal of Esthetic and Restorative Dentistry,* 13**,** 41-48.
RAMOS-JORGE, M. L., BOSCO, V. L., PERES, M. A. & GERENT PETRY NUNES, A. C. 2007. The impact of treatment of dental trauma on the quality of life of adolescents - a case-control study in southern Brazil. *Dental Traumatology,* 23**,** 114-119.
RHOUMA, O., MCMAHON, A. D. & WELBURY, R. 2013. Traumatic dental injury and social deprivation in five-year-old children in Scotland 1993-2007. *British dental journal,* 214**,** E26-E26.
ROBERTSON, A. 1998. A retrospective evaluation of patients with uncomplicated crown fractures and luxation injuries. *Endodontics & Dental Traumatology,* 14**,** 245-256.
ROBERTSON, A. & NOREN, J. G. 1997. Subjective aspects of patients with traumatized teeth - A 15-year follow-up study. *Acta Odontologica Scandinavica,* 55**,** 142-147.
RUSSELL, M. D., GULFRAZ, M. & MOSS, B. W. 2000. In vivo measurement of colour changes in natural teeth. *Journal of Oral Rehabilitation,* 27**,** 786-792.
RUYTER, I., NILNER, K. & MÖLLER, B. 1987. Color stability of dental composite resin materials for crown and bridge veneers. *Dental Materials,* 3**,** 246-251.
SALESKI, C. G. 1972. Color, light, and shade matching. *The Journal of prosthetic dentistry,* 27**,** 263-268.
SCHATZ, J. P., HAKEBERG, M., OSTINI, E. & KILIARIDIS, S. 2013. Prevalence of traumatic injuries to permanent dentition and its association with overjet in a Swiss child population. *Dental traumatology,* 29**,** 110-114.
SEGHI, R., HEWLETT, E. & KIM, J. 1989. Visual and instrumental colorimetric assessments of small color differences on translucent dental porcelain. *Journal of Dental Research,* 68**,** 1760-1764.
SELUK, L. W. & LALONDE, T. D. 1985. Aesthetics and communication with a custom shade guide. *Dental clinics of North America,* 29**,** 741-&.
SGAN-COHEN, H. D., MEGNAGI, G. & JACOBI, Y. 2005. Dental trauma and its association with anatomic, behavioral, and social variables among fifth and sixth grade schoolchildren in Jerusalem. *Community dentistry and oral epidemiology,* 33**,** 174-180.

SHEIHAM, A. & CROOG, S. H. 1981. The psychosocial impact of dental diseases on individuals and communities. *Journal of behavioral medicine,* 4**,** 257-72.
SHULMAN, J. D. & PETERSON, J. 2004. The association between incisor trauma and occlusal characteristics in individuals 8–50 years of age. *Dental traumatology,* 20**,** 67-74.
SOUZA, M., CECCHIN, D., BARBIZAM, J. V., ALMEIDA, J. F., ZAIA, A. A., GOMES, B. P. & FERRAZ, C. C. 2013. Evaluation of the colour change in enamel and dentine promoted by the interaction between 2% chlorhexidine and auxiliary chemical solutions. *Australian Endodontic Journal,* 39**,** 107-111.
STOCK, J. T. 1994. The Duboscq colorimeter and its inventor. *Journal of Chemical Education,* 71**,** 967.
SULIEMAN, M. 2005. An overview of tooth discoloration: extrinsic, intrinsic and internalized stains. *Dental update,* 32**,** 463-471.
TAIWO, O. O. & JALO, H. P. 2011. Dental Injuries in 12-year Old Nigerian students. *Dental traumatology,* 27**,** 230-234.
TEN BOSCH, J. & COOPS, J. 1995. Tooth color and reflectance as related to light scattering and enamel hardness. *Journal of dental research,* 74**,** 374-380.
TUNG, F. F., GOLDSTEIN, G. R., JANG, S. & HITTELMAN, E. 2002. The repeatability of an intraoral dental colorimeter. *Journal of Prosthetic Dentistry,* 88**,** 585-590.
UJI, T. & TERAMOTO, T. 1988. Occurrence of traumatic injuries in the oromaxillary region of children in a Japanese prefecture. *Dental Traumatology,* 4**,** 63-69.
VAARKAMP, J., TENBOSCH, J. J. & VERDONSCHOT, E. H. 1995. Propagation of light through human dental enamel and dentin. *Caries Research,* 29**,** 8-13.
VANDERBURGT, T. P., TENBOSCH, J. J., BORSBOOM, P. C. F. & PLASSCHAERT, A. J. M. 1985. A new method for matching tooth colors with color standards. *Journal of Dental Research,* 64**,** 837-841.
VANDERBURGT, T. P., MULLANEY, T. P. & PLASSCHAERT, A. J. M. 1986. Tooth discoloration induced by endodontic sealers. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics,* 61**,** 84-89.
VANDERBURGT, T. P., TENBOSCH, J. J., BORSBOOM, P. C. F. & KORTSMIT, W. 1990. A comparison of new and conventional methods for quantification of tooth color. *Journal of Prosthetic Dentistry,* 63**,** 155-162.
VIVACQUA-GOMES, N., FERRAZ, C., GOMES, B., ZAIA, A., TEIXEIRA, F. & SOUZA-FILHO, F. 2002. Influence of irrigants on the coronal microleakage of laterally condensed gutta-percha root fillings. *International Endodontic Journal,* 35**,** 791-795.
VLOK, J. L., WORTHINGTON, E. M., HINDSON, J. A., DAVIDSON, L. E., THOMSON, W. M. & DRUMMOND, B. K. 2011a. Young people's perceptions of photographs of dental trauma. *Dental Traumatology,* 27**,** 109-112.

VLOK, J. L., WORTHINGTON, E. M., HINDSON, J. A., DAVIDSON, L. E., THOMSON, W. M. & DRUMMOND, B. K. 2011b. Young people's perceptions of photographs of dental trauma. *Dent Traumatol,* 27**,** 109-12.

WATTS, A. & ADDY, M. 2001. Tooth discolouration and staining: a review of the literature. *British Dental Journal,* 190**,** 309-316.

WEE, A. G., LINDSEY, D. T., KUO, S. & JOHNSTON, W. M. 2006. Color accuracy of commercial digital cameras for use in dentistry. *Dental Materials,* 22**,** 553-559.

YıLMAZ, B., YUZUGULLU, B., ÇıNAR, D. & BERKSUN, S. 2011. Effects of shade tab arrangement on the repeatability and accuracy of shade selection. *The Journal of prosthetic dentistry,* 105**,** 383-386.

List of appendices

Appendix A Ethical approval granted from NRES

NHS

National Research Ethics Service

Leeds (East) Research Ethics Committee

Yorkshire and Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 3050108

CHILDRENS

DEPARTMENT

Dr Saleh Muhammad
Paediatric Dentistry Department
Leeds Dental Institute
Worsley Building, Clarendon Way
LS2 9LU

21 February 2011

Dear Dr Muhammad

Study Title:	**Colour change in traumatised teeth as assessed by different methodologies**
REC reference number:	**11/H1306/3**
Protocol number:	**n/a**

2/3/11

Thank you for your letter of 16th February 2011 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to

the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

1. The Leeds East Research Ethics Committee needs to be indentified in the PIS

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Protocol	15.0	17 November 2010
Response to Request for Further Information		
Participant Information Sheet: Children aged 11-16 yrs	6	09 November 2010
Participant Information Sheet: aged 11-16	7	09 January 2011
REC application		11 January 2011
Student CV		
GCP certifcate for CI		
Participant Information Sheet: parent/guardian	4	09 November 2010
Participant Information Sheet: Parent/Guardian	5	09 January 2011
Evidence of insurance or indemnity		
(None)		09 February 2011
Investigator CV		
Participant Consent Form: Parent/guardian	5	09 November 2010
Participant Consent Form: Assent form for children 11-16yrs	5	09 November 2010
Covering Letter		11 January 2011
Covering Letter		14 February 2011
Medical & Dental Illustration Clinical Photography Request Form		
GCP certificate for student investigator		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating

Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/H1306/3	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Prof Alan Ebbutt
Vice Chair

Email: jade.thorpe@leedspft.nhs.uk

Copy to: *Mrs Rachel De Souza*
Dr Peter Day, Leeds Dental Institute

Appendix B Substantial amendment approval by NRES

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds East

Yorkshire and Humber REC Office
First Floor, Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Tel: 0113 3050108
Fax:

29 June 2012

Dr Saleh Muhammad
Paediatric Dentistry Department
Leeds Dental Institute
Worsley Building, Clarendon Way
LS2 9LU

Dear Dr Muhammad

Study title: **Colour change in traumatised teeth as assessed by different methodologies**
REC reference: **11/H1306/3**
Protocol number: **n/a**

The above amendment was reviewed at the meeting of the Sub-Committee held on 28 June 2012 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Certificate - GCP training 16/02/2012		
Investigator CV	Dr. Alawami	
Notice of Substantial Amendment (non-CTIMPs)		
Certificate - Patient Informed Consent for Clinical Trials workshop 18/04/2012		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

NHS
Health Research Authority

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/H1306/3:	**Please quote this number on all correspondence**

Yours sincerely

pp
Alan Ebbutt
Vice Chair

E-mail: jade.thorpe@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Ann Gowing*
Mrs Rachel De Souza, University of Leeds

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds East

Attendance at Sub-Committee of the REC meeting on 28 June 2012

Name	*Profession*	*Capacity*
Prof Alan Ebbutt	Statistician	Expert
Mr Tom Wilson	Consultant ENT Surgeon	Expert

Appendix C Parent/guardian information sheet about the study that was given when the investigator met the potential subject

Leeds Dental Institute UNIVERSITY OF LEEDS

Parent/Guardian Participant Information Sheet, Version 5, 09-1-11

Study Title: Colour Change in Traumatised Teeth

We would like to invite your child to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it will involve for your child. One of our research team will go through the information sheet with you and answer any questions you have. This will take about 5 minutes.

What is the purpose of this study?

The purpose of this study is to measure any change in colour over time of your child's tooth following its dental injury and subsequent treatment. The chances of your child's tooth discolouring vary and for many children there is no obvious change in colour following their injury or treatment. If any discolouration occurs that your child is unhappy with, treatment is available to improve its appearance.The study aims to start to identify possible causes for these colour changes.

Why have I/my child been asked to participate?

Your child has been invited to join this research study because he/she attends the paediatric dental trauma clinic at Leeds Dental Institute.

What will be involved if I/my child take part in this study?

We will measure any colour change by:

- The use of two photographic systems to analyse the colour change.
- The use of a shade guide to match the closest colour to that of your child's tooth. This is similar to matching paint from a paint chart. This step will be carried out by one member of the research team.
- The same member of the research team will ask your child whether he/she feels the colour of their traumatised tooth has changed. If he/she answers yes, then your child will be asked a second question to ascertain if he/she is concerned enough to have further treatment to improve the colour of this tooth?

Photographic records are standard practice for all patients seen on the trauma clinic whether they are part of the study or not. The traumatised tooth of your child will be photographed over several visits which will coincide with your attendance at the trauma clinic. These photographs will be taken in the Photography Department of Leeds Dental Institute. For this research study, only close up view photographs of the tooth (not showing the child's face) will be used.

It is up to you as parent or legal guardian to decide whether your child participates in the research study. If you agree to take part, we will then ask you to sign a consent form.

You are free to withdraw at any time, without giving a reason. This will not affect the care your child receives from the trauma clinic.

You and your child will be seen by a member of the research team over several visits when attending for treatment at the trauma clinic. Treatment will be provided as usual. Either before or after the treatment, the colour of the traumatised tooth will be assessed. This will take 10-15 minutes.

This study research might give us some information about which teeth are most likely to discolour and the frequency of this discolouration. Another reason for this study is that we do not always know the best way of treating traumatised teeth with respect to any colour change. To find out, we need to compare change in colour with different treatments. As part of the study, the research team will look at your child's dental records to collect information about the injury and treatment. This study will help us to choose treatments which minimise any colour change. We cannot promise the research study will help your child but the information we collect from this research study will help improve the treatment of children with traumatised teeth in the future. If your child's tooth does discolour and they request treatment to improve the situation, this treatment will be provided whether you are part of the study or not.

What are the advantages and disadvantages of taking part?

There is no payment to participate in this study. You and your child will be seen only when you are attending for treatment. There are no disadvantages (e.g. discomfort, inconvenience) or additional risks and side effects from participating. If the research study ends before your child completes their treatment, it will still continue.

Can I/my child withdraw from the study at any time?

If you decide to withdraw from the study we will discuss with you what you would like us to do with the information that we have already collected about your teeth. If you or your child has any further concerns about this study or how it is conducted you should ask to speak to the researchers who will answer your questions[1] (see the contact details at the end of information sheet). The research is carried out under the supervision of Dr. Peter Day, Consultant in Paediatric Dentistry, Leeds Dental Institute.

Will the information obtained in the study be confidential?

All information which is collected about your child during the course of the research study will be kept strictly confidential and in a way which your child cannot be identified individually.

What will happen to the results of the study?

The results of the research study can be made available to the participants at the end of the study on request. The results will be published in the form of a report or journal article but neither your child's name nor any information which could identify them will appear.

Who has reviewed this study?

The Leeds dental Institute is the organisation sponsoring and funding this research study. All research in the Leeds Dental Institute (NHS Trust) is looked by independent group of people, called Research Ethics Committee, to protect your (child) interests. This research study has been reviewed and given favourable opinion by IRAS Research Ethics Committee.

In case of any questions or concerns, please feel free to contact the principal investigator of the research study, the telephone number and email address are given below:

(1)Dr P Day
Consultant in Paediatric Dentistry
Paediatric Dentistry Department
Leeds Dental Institute
Worsley Building, Clarendon Way
LS2 9LU
0113 3436139
0113 3436140
p.f.day@leeds.ac.uk

If you are unhappy and wish to complain formally, you can do so and contact details are given below:

Mrs Clare Skinner
Faculty Research Office, Faculty of Medicine & Health
University of Leeds
Clarendon Way, Leeds LS2 9

Thank you for taking time to read this information sheet

Appendix D Participant information sheet about the study that was given when the investigator met a potential subject aged 11-16 years

Leeds Dental Institute

UNIVERSITY OF LEEDS

Participant Information Sheet (aged 11-16)

Version 7, 09/1/11

Study Title: Colour Change in Traumatised Teeth

We are asking if you would join in our research study. Before you decide if you want to join in, it is important to understand why the research is being done and what it will involve for you. Please consider this information sheet carefully. Talk to your family, friends or dentist if you want to. One of our dentists will go through the information sheet with you and answer any questions you have. This will take about 5 minutes.

What is the purpose of this study?

In this study we are trying to measure any change in colour in your injured tooth. For many children there is no obvious change in colour following your injury or treatment we provide. If any discolouration occurs, that you are unhappy with, we can provide further treatment to improve its appearance.

Why have I been asked to participate?

You have been invited to join our research study because you are attending the paediatric dental trauma clinic and receiving dental care for your injured tooth.

What will happen to me if I take part in the research?

Over a number of visits, we will use three methods to test if there is any change in the colour of your injured tooth. These methods are:

- Using two different cameras to take photographs of the injured tooth. The computer system will then give us a measurement of the colour of your injured tooth.
- Matching your current tooth colour to the closest colour on a colour chart for teeth (called 'shade guide'). This is the same as matching paint from a paint chart.
- We will also ask you if you are worried about the colour of your injured tooth.

You will be seen by one of our dentists at Leeds Dental Institute for treatment at the trauma clinic. Treatment will be provided as usual. Either before or after your dental treatment session depending on which is less time consuming the colour of your traumatised teeth will be measured over several visits. This will take a maximum of an additional 10-15 minutes.

Do I have to take part?

It is up to you to take part in the research study. If you agree to join we will ask you to sign a form. We will give you a copy of this information sheet and your signed form to keep.

What are the advantages and disadvantages of taking part?

There are no disadvantages (e.g. discomfort, inconvenience) additional risks or side effects from participating.

What if I do not want to do the research anymore?

You are free to stop at any time during the research study without giving a reason. If you decide to stop, this will not affect any subsequent care you receive.

Will my dental details be kept private if I take part?

We will keep your information in confidence. This means only those in the research team will see any patient information.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the IRAS Research Ethics Committee.

Thank you for reading this – please ask any questions if you need to.

In case of any questions or concerns, please feel free to contact the principal investigator of the study, the telephone number and email address are given below:

Dr P Day
Consultant in Paediatric Dentistry
Paediatric Dentistry Department
Leeds Dental Institute
Worsley Building, Clarendon Way
LS2 9LU
0113 3436139
0113 3436140
p.f.day@leeds.ac.uk

Appendix E Consent form used to consent parent/guardian of the participant

Leeds Dental Institute UNIVERSITY OF LEEDS

Ethics number: Patient identification number for this study:

Parent/Guardian participant Consent Form (version 5, 09-11-10)

Title of the Project: Assessment of Colour Change in Traumatised Teeth Initials

1. I confirm that I have read and understood the information sheet dated 09/11/2010 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my child's participation is voluntary and that my child and/or myself are free to withdraw at any time without giving any reason, without my dental care or legal rights being affected. ☐
3. I agree for my child to take part in the above study. ☐
4. I understand that relevant sections of my child's dental records may be looked at by research team members from Leeds Dental Institute, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's dental records. ☐

Parent/Guardian Name:.....Sign:.....Date:.....

Researcher taking consent

Name: .....Sign:.....Date.....

Appendix F Assent from used to consent participants aged 11-16 years

Leeds Dental Institute UNIVERSITY OF LEEDS

Ethics number: Patient identification number for this study:

Assent Form for Children (aged 11-16), version 5, 09/11/10

Title of the Project: Assessment of Colour Change in Traumatised Teeth

1. Have you read (or had read to you) the information sheet for this project?	Yes ☐	No ☐
2. Has somebody else explained this project to you?	Yes ☐	No ☐
3. Do you understand what this project is about?	Yes ☐	No ☐
4. Have you asked all the questions you want?	Yes ☐	No ☐
5. Have you had your questions answered in a way you understand?	Yes ☐	No ☐
6. Do you understand, that you can withdraw from this project at any time ? This will not affect the dental care you receive at Leeds Dental Institute.	Yes ☐	No ☐
7. Are you happy to take part?	Yes ☐	No ☐

If any answers are "no" or you do not want to take part, do not sign your name!

If you do want to take part, you can write your name below

Your Name.....Date.....

Researcher taking consent

Name:.....Sign:..... Date:.....

Appendix G Data collection sheet that was used to record the relevant information about the participant

Subject code:

Volunteer Personal sheet

First name:	Surname:
Date of birth:	Gender: Male O Female O

Inclusion criteria Check List*

	Yes	No
age 6 to 16 years		
Child is receiving dental care following trauma to their permanent anterior dentition		
Child's parent/guardian are happy to participate and have signed the consent form		
Child can cooperate for a dental shade colour measurement and photographic records		

**Note:* if any of the above questions are answered "No", the subject should be discontinued from the study as a "Screen Failure" on the study conclusion page.

Researcher's signature: .... Date: .....

Subject code:

Exclusion criteria Check List*

	Yes	No
age < 6 or >16 years		
Uncooperative child who will not cooperate for obtaining a dental shade colour measurement and photographic records		
Child who are accompanied by an adult who is not their parent or legal guardian.		
Childr who refuses to participate.		
Child appears to be stressed or is anxious e.g. patients presenting with acute trauma		
Child who has not sustained trauma to his/her permanent dentition or are r receiving dental treatment for other conditions.		
Parent/guardian who refuses to participate.		

**Note:* if any of the above questions are answered "Yes", the subject should be discontinued from the study as a "Screen Failure" on the study conclusion page.

Researcher's signature: .... Date: .....

Subject code:

Fitness and Eligibility in Participant in the Study

In the researcher's opinion, on the basis of the screening assessments and Inclusion and Exclusion criteria, is the subject eligible to participate in the study?

Yes O No O

Researcher's signature: ..... Date: .....

Subject code:

Screening Visit check List

	Yes	No
Personal data sheet completed		
Dental history completed		
Inclusion criteria sheet completed		
Exclusion criteria sheet completed		
Eligibility sheet completed		
Participant's Information Sheet		
Participant's Consent Form		

Researcher's signature: .... Date: .....

Subject code:

First Visit (Date_ _/_ _/_ _ _ _)

Traumatised tooth	Type of injury	Outcome (pulpal & periodontal healing)	Treatment

	Yes	No
Patient perception 1. Do you think the colour of your injured tooth/teeth has changed? 2. Has the colour become better or worst since the last visit? 3. Are you happy with the colour of your tooth? If the answer for this question is "No" ask question 4. 4. Do you want treatment to improve the colour of your traumatised tooth?		
Dentist perception using Standard Dental Shade Guide Vita Lumin Classic ™ shade guide		

	Yes	No
Ikam		
Digital Image System		

Subject code:

Second Visit (Date_ _/_ _/_ _ _ _)

Re-consent obtained and documented in participant's dental notes	Yes o No o

Traumatised tooth	Type of injury	Outcome (pulpal & periodontal healing)	Treatment

	Yes	No
Patient perception 1. Do you think the colour of your injured tooth/teeth has changed? 2. Has the colour become better or worst since the last visit? 3. Are you happy with the colour of your tooth? If the answer for this question is "No" ask question 4. 4. Do you want treatment to improve the colour of your traumatised tooth?		
Dentist perception using Standard Dental Shade Guide Vita Lumin Classic [Tm] shade guide		

	Yes	No
Ikam		
Digital Image System		

Subject code:

Third Visit (Date_ _/_ _/_ _ _ _)

Traumatised tooth	Type of injury	Outcome (pulpal & periodontal healing)	Treatment

	Yes	No
Patient perception 1. Do you think the colour of your injured tooth/teeth has changed? 2. Has the colour become better or worst since the last visit? 3. Are you happy with the colour of your tooth? If the answer for this question is "No" ask question 4. 4. Do you want treatment to improve the colour of your traumatised tooth?		
Dentist perception using Standard Dental Shade Guide Vita Lumin Classic ™ shade guide		

	Yes	No
Ikam		
Digital Image System		