

**The outcome and prognostic factors affecting the success of
traumatic injuries of permanent teeth:**

A retrospective study

ELIANA HADJANTONIS

Submitted in accordance with the requirements for the degree of
Doctorate of Paediatric Dentistry

The University of Leeds
Leeds Dental Institute
Division of Child Dental Health

November 2016

The candidate confirms that the work submitted is her own and that 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.

Dedication

Dedicated to my family

My fiancé, mum, dad, sister, brother

Acknowledgements

It would not have been possible to write this doctoral thesis without the help and support of people around me, to only some of whom it is possible to give particular mention here.

I am truly thankful to my supervisors Professor Monty Duggal, Professor Jack Toumba and Theresa Munyombwe for their help and guidance.

A special gratitude I give to my friends Thelma Stavrou and Valanto Soteriou for their great support throughout my studies.

Lastly, but definitely the biggest acknowledgement goes my beloved family. I owe a very important debt to my wonderful fiancé Marios Aristotelous for his unflinching love, outstanding support and continued encouragement throughout my studies. I greatly appreciate his patience, understanding and for helping me get through this thesis with optimism. My deepest gratitude also goes to my lovely parents, brother and sister. Words are not sufficiently enough to express my appreciation for the sacrifices they have made, for always believing in me and for their unconditional love and support throughout my life. Without the moral and emotional support of my whole family, this thesis would certainly not have existed.

Abstract

Background: Severe dento-alveolar trauma to anterior teeth in children can have a devastating long-term consequence for function and aesthetics. Successful treatment of traumatic injuries in a growing child is dependent on many factors; some related to the injury itself and some to the treatment provided.

Aims: To identify the prognostic factors which affect the outcome for two groups of traumatic injuries to permanent teeth in children and adolescents; luxation injuries (intrusion, extrusion, lateral luxation) and complicated crown fractures and to determine their final success.

Method: This study was a retrospective study evaluating the factors, which affect the clinical and radiographic outcomes of luxation injuries and complicated crown fractures. Clinical dental records and radiographs of 620 patients who attended the Paediatric Dentistry Department at Leeds Dental Institute during the period 2003-2013 were screened. The initial treatment outcome for the complicated crown fractures and the final outcome for both groups of injuries were classified as success or failure according to the criteria developed for this study. Various prognostic factors that could influence the clinical and radiographic outcomes of traumatised teeth were recorded using a special data extraction proforma. Statistical analysis involved simple descriptive analysis followed by a univariate regression analysis to determine the association between the prognostic factors and the outcomes. Additionally, a multivariable logistic regression analysis was conducted to identify which predictors remained significant when in combination with each other.

Results: The study recruited 108 cases with 146 traumatised permanent teeth. In the group of complicated crown fractures, the initial treatment success following pulp capping or partial pulpotomy was 40%. Partial pulpotomy had a higher success rate (54.4%) than pulp capping (15.4%). The final clinical success rate was 93% and the radiographic success rate was 85.3%. The univariate regression analysis revealed that the type of initial treatment significantly affected the initial treatment outcome whereas the stage of root development affected the final outcome. For luxation injuries, 81.5% were clinically successful and 72.6% were radiographically successful. Univariate regression analysis revealed the predictors that significantly affected the clinical and radiographic success were; severity of injury, combination injury, method of repositioning and duration of splinting. The multivariable regression model revealed that the method of repositioning and time since trauma to repositioning significantly affected the clinical success whereas only the method of repositioning significantly affected the radiographic success.

Conclusion: Complicated crown fractures were considered to have a higher clinical and radiographic success than luxation injuries. The stage of root development appeared to significantly affect the final outcomes in complicated crown fractures. The severity of luxation injury, presence of crown fracture, method of repositioning and duration of splinting had significant associations with the final outcomes in the group of luxation injuries.

Contents

Dedication	i
Acknowledgements	ii
Abstract	iii
Contents	v
List of tables	x
List of Figures	xii
List of Abbreviations	xiii
Chapter One	1
Literature Review	1
1.1 Introduction to Literature Review	1
1.2 Traumatic Dental Injuries in Children	1
1.3 The Prevalence of Traumatic Dental Injuries in Children	3
1.4 Background Factors Associated with TDI in Children	4
1.4.1 Age.....	4
1.4.2 Gender	4
1.4.3 Race and Ethnicity	5
1.4.4 Socio-economic Status	5
1.5 Aetiology and Predisposing Factors Associated with TDI	6
1.5.1 Aetiology	6
1.5.2 Predisposing Factors	7
1.6 Type of Traumatic Dental Injury	8
1.6.1 Fracture Injuries	8
1.6.2 Luxation Injuries.....	8
1.7 Complicated crown fractures.....	9
1.7.1 Pulp capping	10
1.7.2 Pulpotomy	11
1.7.3 Cervical pulpotomy.....	18
1.8 Luxation Injuries	19
1.8.1 Healing and complications	19
1.9 Intrusion	30
1.9.1 Age.....	31
1.9.2 Stage of root development	31
1.9.3 Associated crown fracture.....	32

1.9.4 Multiple intruded teeth.....	32
1.9.5 Severity of intrusion.....	33
1.9.6 Method of repositioning.....	34
1.9.7 Treatment delay	35
1.9.8 Published Guidelines	35
1.9.9 Type and duration of splinting	36
1.9.10 Time of pulp extirpation.....	36
1.9.11 Tooth survival.....	37
1.10 Extrusion	39
1.10.1 Stage of root development.....	40
1.10.2 Severity of extrusion.....	41
1.10.3 Treatment delay	41
1.10.4 Associated crown fracture.....	42
1.11 Lateral Luxation.....	44
1.11.1 Stage of root development	45
1.11.2 Degree of lateral luxation	46
1.11.3 Associated crown fracture.....	47
1.11.4 Treatment delay	49
1.11.5 Type and duration of splinting	49
1.12 Non-vital Immature teeth.....	50
1.12.1 Apexification in non-vital immature teeth.....	50
1.13 Factors Affecting the Endodontic Treatment Success.....	54
1.14 Rationale of the study	57
Chapter Two	58
Aims and Hypothesis.....	58
2.1 Aims.....	58
2.2 Research Questions.....	58
2.3 Null Hypothesis	59
Chapter Three.....	60
Materials and Methods	60
3.1 Ethical Approval	60
3.2 Methodology for Sample Selection.....	60
3.2.1 Identification of the Sample	60
3.2.2 Selection Criteria.....	61

3.3 Methodology for Data Collection	62
3.3.1 Data recording methods.....	62
3.3.2 Information extracted from the clinical records.....	63
3.4 Data variables	64
3.4.1 Prognostic Factors	65
3.5 Methodology for the Assessment of Variables	67
3.5.1 Types of Trauma.....	67
3.5.2 Severity of Trauma.....	67
3.5.3 Stage of root development	67
3.5.4 Quality of apical barrier	69
3.5.5 Quality of Root Canal Obturation	69
3.5.6 Quality of coronal seal.....	70
3.5.7 Clinical and radiographic Outcomes.....	71
3.6 Summary of Definition of Outcome Measures.....	76
3.6.1 Criteria for survival	76
3.6.2 Complicated crown fractures.....	76
3.6.3 Luxation injuries	78
3.7 Intra-examiner Reliability.....	80
3.8 Sample Size Calculation	81
3.9 Statistical Tests	82
Chapter Four	83
Results	83
4.1 Study sample	83
4.2 Descriptive Statistics	85
4.2.1 Demographic Factors.....	85
4.2.2 Trauma details	85
4.3 Complicated Crown Fractures.....	88
4.3.1 Time to initiation of treatment.....	88
4.3.2 Type of initial treatment received	88
4.3.3 Stage of root development	89
4.3.4 Outcome of initial treatment provided.....	90
4.3.5 Root canal treatment received	91
4.3.6 Total treatment period since trauma.....	92
4.3.7 Final outcome	92

4.3.8 Survival	96
4.4 Luxation injuries	97
4.4.1 Severity of injury.....	97
4.4.2 Stage of root development	98
4.4.3 Combination Injuries	99
4.4.4 Method of repositioning.....	101
4.4.5 Time of repositioning.....	102
4.4.7 Splinting period	103
4.4.8 Time of pulp extirpation.....	104
4.4.9 Pulpal healing complications.....	105
4.4.10 Periodontal healing complications.....	106
4.4.11 Root canal treatment.....	107
4.4.12 Total treatment/review time	108
4.4.13 Final clinical outcome.....	109
4.4.14 Final radiographic outcome	112
4.4.15 Survival	116
4.5 Association between the outcome and prognostic factors	118
4.5.1 Results from Univariate Analysis for Complicated Crown Fractures.....	118
4.5.2 Results from univariate and multivariable analyses for luxation injuries	122
Chapter Five	128
Discussion.....	128
5.1 Introduction	128
5.2 Study Aims Appraisal	128
5.3 Appraisal of Methodology.....	129
5.3.1 Obtaining Ethical Approval.....	129
5.3.2 Study design	130
5.3.3 Sample Identification.....	130
5.3.4 Classifications and Evaluation Criteria	131
5.3.5 Statistical Analyses of the data	134
5.4 Appraisal of Results	136
5.4.1 Demographic Factors.....	136
5.4.2 Gender	136
5.4.3 Age at Trauma	136

5.4.4 Teeth involved in Trauma.....	137
5.4.5 Complicated crown fractures.....	137
5.4.6 Luxation injuries	140
5.5 Study Limitations and Challenges Encountered.....	145
5.6 Future Research	146
Chapter Six	147
Conclusion	147
References.....	148
APPENDIX 1: E-mail confirming DREC approval of the study	I
APPENDIX 2: Letter confirming University of Leeds sponsorship.....	II
APPENDIX 3: Letter from NRES confirming favourable opinion	IV
APPENDIX 4: Letter of approval by Research & Innovation	VIII
APPENDIX 5: Data Extraction Proforma	XIII

List of tables

Table 1: Summary of studies on partial pulpotomy for complicated crown fractures	14
Table 2: The treatment approaches for intrusion injury as per the guidelines	35
Table 3: Summary of studies on intrusion injury	38
Table 4: Summary of studies on extrusion injury	43
Table 5: Summary of studies on lateral luxation injury	48
Table 6: Reason for exclusion of clinical records.....	84
Table 7: The frequency distribution of teeth involved in complicated crown fractures and luxation injuries	86
Table 8: The frequency of the four different types of trauma	87
Table 9: Types of initial treatment provided for complicated crown fractures	88
Table 10: The final clinical outcome for teeth with complicated crown fracture in respect to the stage of root development.....	94
Table 11: The final radiographic outcome for teeth with complicated crown fracture in relation to the stage of root development.....	95
Table 12: The final radiographic outcome for teeth with complicated crown fracture in relation to the quality of obturation.....	96
Table 13: The distribution of the severity for luxation injuries	97
Table 14: The main reasons for inadequate obturation.....	108
Table 15: The final clinical outcome for the luxation injuries	109
Table 16: The final clinical outcome for teeth with luxation injury related to the severity of injury.....	110
Table 17: The final clinical outcome for teeth with luxation injury in relation to the method of repositioning	111
Table 18: The final radiographic outcome of luxation injuries.....	112
Table 19: The reasons for final radiographic failure	113
Table 20: The final radiographic outcome for teeth with luxation injury in relation to the severity of injury.....	114
Table 21: The final radiographic outcome for teeth with luxation injury in respect to the method of repositioning.....	115
Table 22: The survival of the 4 luxation injuries.....	116
Table 23: The reasons for tooth loss.....	117

Table 24: The regression coefficients (B) and corresponding 95% confidence intervals from the univariate analyses of factors associated with initial outcome in the complicated crown fractures	119
Table 25: The regression coefficients and corresponding 95% confidence intervals from the univariate analyses of factors associated with final clinical outcome in the complicated crown fractures	120
Table 26: The regression coefficients and corresponding 95% confidence intervals from the univariate analysis of factors associated with final radiographic outcome in the complicated crown fractures	121
Table 27: The regression coefficients and corresponding 95% confidence intervals from the univariate and multivariable analyses of factors associated with the final clinical outcome in the luxation injuries	124
Table 28: The regression coefficients and corresponding 95% confidence intervals from the univariate and multivariable analyses of factors associated with the final radiographic outcome in the luxation injuries	127

List of Figures

Figure 1: Classification of stage of root development.....	68
Figure 2: A flow chart showing the distribution of the sample.....	84
Figure 3: The distribution of the stage of root development for complicated crown fractures	89
Figure 4: The outcome of initial treatment provided for complicated crown fractures	90
Figure 5: The quality root canal obturation of complicated crown fractures	91
Figure 6: The distribution of final clinical and radiographic outcomes	93
Figure 7: The distribution of the stage of root development at the time of luxation injury.....	98
Figure 8: The distribution of associated crown fracture within each luxation injury	100
Figure 9: The method of repositioning for the three luxation injuries	101
Figure 10: The distribution of pulpal healing complications of luxation injuries	105
Figure 11: The distribution of periodontal healing complications of luxation injuries	106
Figure 12: The quality of obturation of luxation injuries	107

List of Abbreviations

CI	Confidence Interval
DREC	Dental Research Ethics Committee
IRR	Infection Related Root Resorption
IADT	International Association Dental Traumatology
MBL	Marginal Bone Loss
MTA	Mineral Trioxide Aggregate
NRES	NHS Research Ethics Service
PDL	Periodontal Ligament
PCO	Pulp Canal Obliteration
RRR	Replacement Root Resorption
R&D	Research and Development
SRR	Surface Root Resorption
TDI	Traumatic Dental Injury

Chapter One

Literature Review

1.1 Introduction to Literature Review

With the aid of various available search engines, the relevant published literature has been explored in order to establish current knowledge on the prognostic factors affecting the success of traumatic injuries of permanent teeth in children and adolescents.

1.2 Traumatic Dental Injuries in Children

Trauma has been defined as a reasonably severe, non-physiological lesion to any part of the body (Andreasen, 1985). Any thermal, chemical or mechanical injury affecting the dentition should be categorised as a dental trauma and its effect as a traumatic dental injury (TDI) causes an irreversible damage to a number of highly specialised cells in the pulp and the supporting periodontal structures (Andreasen, 1985).

Traumatic dental injury has been considered a serious dental public health problem in children and adolescents because of its high prevalence, occurrence at a young age, the clinical implications and costs involved in its treatment as well as the social impact on children and their families (Glendor, 2008). It has been well documented in the literature that traumatic dental injuries occur frequently in preschool, school-aged children and young adults, comprising 5% of all injuries for which people seek treatment in dental clinics and hospitals (DiAngelis et al., 2012).

Furthermore, the treatment of dental trauma can be complicated and expensive, frequently involving participation of other health care professionals. As a result of the severity of damage to traumatised teeth, the treatment can also continue for the rest of the patient's life with lengthy treatment plans (Glendor, 2008). In the UK, it is estimated that the average total cost for treating a young patient with a traumatic dental injury is £856. This estimate was calculated by considering the direct costs of patient outpatient visits but also the indirect costs of a lost working day for parents (Wong and Kolokotsa, 2004).

In addition, there is emerging evidence to suggest that dento-alveolar trauma has the potential to influence children's quality of life. Children who have sustained a traumatic dental injury can experience emotional stress, pain and discomfort (Porritt et al., 2011). A case control study conducted in Brazil has revealed that children with untreated fractured teeth were 20 times more likely to report a negative impact on their quality of life than children with no history of traumatic dental injury. The appearance of untreated fractured teeth was a major concern to the children where they would avoid smiling, talking, showing their teeth without embarrassment and socialising with others. Children also reported difficulties in eating, enjoying food or brushing their teeth (Ilma de Souza Cortes et al., 2002). Even though the restoration of teeth appears to improve the social aspects of the quality of life, it has been documented that the functional limitations of the injury may continue (Fakhruddin et al., 2008). Moreover, few studies have also investigated the psychosocial impact of dental trauma on the emotional wellbeing of the family. The children's parents expressed their concerns, worries and uncertainty over their child's future which also remained at the follow-up appointments (Berger et al., 2009, Porritt et al., 2013).

1.3 The Prevalence of Traumatic Dental Injuries in Children

Traumatic Dental Injuries are common amongst children. A 12 year international review of the literature reported that a total of 25% of all school children have suffered some type of dental trauma to the permanent dentition (Glendor, 2008). Furthermore, one third of adults have sustained traumatic dental injuries to the permanent dentition, with most of the incidences occurring before the age of 19 years (Glendor, 2008). A number of epidemiological studies have investigated the prevalence of traumatic dental injuries in different child populations of various age groups. In general, the prevalence of these injuries appears to vary considerably between studies. A Malaysian study analysing the distribution of dental traumatic injuries amongst 16 year old children reported a prevalence of 4.1% (Nik-Hussein, 2001). On the other hand, a study conducted in Sweden on children of similar age, stated that 35% of these children had suffered dental trauma (Borssén and Holm, 2000). One reason for this reported variation is due to the implementation of different methodologies in the collection of the data. Additionally, the data may reflect different socio-economic, behavioural and cultural diversities (Glendor, 2008). Nevertheless, two large national surveys in the United States demonstrated the high prevalence of dental trauma by stating that one in six adolescents had evidence of traumatic dental injuries (Kaste et al., 1996, Shulman and Peterson, 2004). Similarly, the Children's Dental Health Survey of 2013 in the United Kingdom stated that 12% of 12 year olds and 10% of 15 years olds had sustained dental trauma to their permanent incisors. These results were overall very similar to the survey conducted ten years before (Pitts et al., 2015).

1.4 Background Factors Associated with TDI in Children

1.4.1 Age

Age is a well-known risk variable. Several studies have reported that most of the traumatic dental injuries occur during childhood and adolescence. The peak incidence of traumatic dental injuries in the permanent dentition is found at 9-10 years of age, during which children start to get involved in vigorous playing and sports activities (Andreasen et al., 2011). It has been suggested that the incidence gradually decreases with age, particularly after the age of 24-30 years (Shulman and Peterson, 2004).

1.4.2 Gender

It is well documented in the literature that gender is also a well-known risk factor to dental trauma. For many years, there has been a general finding that males experience traumatic dental injuries at least twice as often as females (Glendor, 2008). This was explained by the higher participation of males in leisure activities and contact sports. However, recent studies have documented a reduction in this difference as a result of girls getting more involved in sports that were traditionally regarded as boys' games (Andreasen et al., 2013). On the other hand, a recent national health survey in the United Kingdom has shown that the prevalence of dental trauma remains higher in males rather than in females. This finding was more noticeable in the 12 year age group, where trauma was observed twice as high in boys (16%) compared to girls (8%). Similarly, an increased trend in the prevalence of trauma in boys was observed in the 15 year age group (Pitts et al., 2015).

1.4.3 Race and Ethnicity

There is no clear relationship between dental trauma, race and ethnicity. Ethnic minorities live in deprived areas with limited resources and poor financial status, making it difficult to clearly analyse the effects of such factors on the prevalence of dental traumatic injuries.

1.4.4 Socio-economic Status

The available evidence concerning the association between socio-economic status and the prevalence of traumatic dental injury is scarce. Bendo et al. (2009) conducted a review on the relationship between socio-economic status and TDI with inconclusive results. Some of the available studies reported a higher prevalence of TDI among adolescents from higher compared to those from lower socio-economic groups (Marcenes et al., 2001). This was explained as children from higher socio-economic status have more access to horse riding, swimming pools and contact sports as well as having the ownership of bicycles and skateboards (Glendor, 2008). On the contrary, a study conducted in the United Kingdom has shown a higher prevalence of TDI in deprived areas such as 23.7% in Newham of London compared to the overall 17% in the whole of England (Marcenes and Murray, 2001). It is thought that deprived areas have more unsafe play grounds, sport facilities, streets and houses where children are more prone to falls and collisions thus dental trauma. Finally, further data from the Children's Dental Health Survey 2013 in the United Kingdom, concluded that there was no significant association between the experience of TDI and socio-economic position of the family (Pitts et al., 2015).

1.5 Aetiology and Predisposing Factors Associated with TDI

1.5.1 Aetiology

1.5.1.1 Unintentional Causes of TDI

It has been suggested that the most common reason of traumatic dental injury in preschool children of ages 0-6, is as a result from falls and collisions. Due to the lack of experience and coordination, children are at high risk of trauma and these events usually occur in the home environment (Andreasen et al., 2013). Additionally, school children between ages 7-15 years may sustain dental trauma as a result from falling but also from being pushed and hit in sports or school areas. On the other hand, in adolescents the injuries mainly result from push/hit injuries which predominantly occur during leisure hours (Petersson et al., 1996). Furthermore, dental trauma can present secondary to traffic accidents such as pedestrian, bicycle or car-related injuries. A study conducted by Acton et al. (1996) has shown that 31% of children under the age of 15 years experienced facial and traumatic dental injuries as a result of bicycle accidents. Finally, traumatic dental injuries can occur in children with underlying medical illness or disability such as patients with epilepsy, cerebral palsy or learning difficulties (Andreasen et al., 2013, Glendor, 2009).

1.5.1.2 Intentional Causes of TDI

Child physical abuse or non-accidental injury (NAI) is a tragic cause of oral injuries in children. In the UK, it has been reported that at least one child per 1000 suffers from severe physical abuse (Welbury et al., 2012). A number of studies in the literature have shown that up to 49-75% of all cases of child abuse involve trauma to the head, neck, mouth and teeth (da Fonseca et al., 1992, Becker et al., 1978, Cairns et al., 2005). In addition, the act of violence often results in maxillofacial injuries. A study performed by Dimitroulis and Eyre (1991)

at a maxillofacial unit in central London in the United Kingdom reported that over a 7 year period, 62% of all injuries were as a result of assaults.

1.5.2 Predisposing Factors

It has been conclusively shown in previous research that children and adolescents with increased overjet with protrusion and inadequate lip coverage are at increased risk of TDI to permanent maxillary teeth (Burden, 1995, Glendor, 2009). A study conducted by Shulman and Peterson (2004) stated that the overjet was the only occlusal covariant that significantly associated with traumatic dental injury after adjusting for confounders such as age, gender and ethnicity. Moreover, a systematic review looking at the relationship of overjet and dental trauma concluded that children with an overjet larger than 3mm were approximately twice as much at risk to anterior incisors than children with a smaller overjet (Nguyen et al., 1999). In addition, it appears that the risk of injury increases with increasing overjet (Nguyen et al., 1999). Furthermore, current data from the United Kingdom has revealed that traumatic dental injury was more prevalent in children with overjet of more than 6mm for both the 12 and 15 year age groups studied (Pitts et al., 2015). However, this association was not statistically significant due to the small sample size (Pitts et al., 2015).

1.6 Type of Traumatic Dental Injury

Dental Trauma in children can result in a number of different injury types involving the tooth and the supporting structures. This can present as a fracture or luxation of teeth and sometimes in combination with each other.

1.6.1 Fracture Injuries

Fracture injuries are the most common type of traumatic dental injury to occur in the permanent dentition. It has been reported that a crown fracture confined to enamel is the most common type of fracture followed by uncomplicated crown fracture (Andreasen et al., 2013).

1.6.2 Luxation Injuries

Luxation injuries are also common in the young permanent dentition. The factors that determine the type of luxation injury appear to be the force and direction of impact (Andreasen and Andreasen, 1985). In summary, luxation injuries can be categorised as concussion, subluxation, extrusive luxation, lateral luxation and intrusion. A large clinical study carried out over a 12 year period, studied 10,116 teeth and showed that apart from the uncomplicated crown fractures compromising 35% of the sample, the next most common injuries were the concussions and subluxations compromising 24% and 22.2% of the sample respectively (Lauridsen et al., 2012b). On the other hand, it has been well documented in studies that intrusion is the least likely injury to occur in the permanent dentition (Andreasen et al., 2013).

The aim of the current study is to concentrate on four specific traumatic dental injuries namely complicated crown fractures, intrusion, extrusion and lateral luxation. Therefore, the following section of the literature will discuss these four traumatic injuries in detail.

1.7 Complicated crown fractures

A complicated crown fracture is defined as a fracture involving the enamel and dentine with loss of tooth structure and exposure of the pulp (Andreasen et al., 2011). Among all crown fractures, the complicated crown fractures have a prevalence of 5-8% in the permanent dentition (Glendor, 2008).

The pathophysiology of a complicated crown fracture is described as a fracture that causes laceration of the pulp and therefore exposure to the oral environment. During the early changes in the pulp, haemorrhage and local inflammation occurs, caused by the breakdown products from the lacerated tissue and bacterial toxins. Initially, a fibrin clot is formed over the wound surface, which resolves after a couple of days. The subsequent changes can either be proliferative (polyp-polyp) or destructive such as an abscess or pulp necrosis (Andreasen et al., 2013).

The aim of treatment of complicated crown fractures is to preserve a vital, non-inflamed pulp biologically covered by a continuous hard tissue barrier (Andreasen et al., 2013). This is especially important for young immature teeth (Güngör, 2014). This is because loss of pulp vitality before a tooth fully matures may leave the tooth vulnerable to fracture with the presence of unfavourable crown-root ratio. Therefore, preservation of pulp vitality is extremely important to allow continued root development of the tooth (Welbury et al., 2012).

In general, there are three therapeutic approaches for the treatment of traumatically exposed pulps namely pulp capping, pulpotomy (partial pulpotomy - Cvek's pulpotomy, cervical pulpotomy) and pulpectomy (Glendor, 2008). Both, pulp capping and pulpotomy are considered therapeutic techniques to allow pulpal healing and thus preserve pulp vitality in young traumatised permanent incisors. Andreasen et al. (2013) reported that only histological techniques could confirm pulpal healing status. However, a fairly accurate evaluation can be made according to some criteria such as no history of clinical symptoms, normal response to pulp sensibility tests, evidence of a hard tissue barrier, continued root development in immature teeth and no radiographic sign of any pathological changes (Andreasen et al., 2013, Loest, 2006). Finally, the choice of treatment

will depend on several factors such as degree of exposure, time elapsed between accident and treatment and the stage of root development (Fuks et al., 1987).

1.7.1 Pulp capping

Pulp capping is characterised as the procedure in which the exposed dental pulp is covered with a protective dressing or cement that protects the pulp from additional injury and allows healing and repair (Lim and Kirk, 1987). The procedure involves washing the fracture surface and pulpal wound with saline and once the bleeding has stopped, the pulp is covered with a pulp capping agent such as calcium hydroxide. Finally, glass ionomer cement is applied over the pulp capping agent, and the tooth is restored with a good coronal resin composite restoration (Andreasen et al., 2013).

It is currently accepted that that pulp capping is indicated in both mature and immature teeth, with pinpoint uncontaminated (within 24 hours) pulp exposures with no associated injury to the supporting tooth (Fuks et al., 1982, Andreasen et al., 2013). Lim and Kirk (1987) explained that it is the state of the pulp and the degree of contamination that enters the pulp, rather than the size of the exposure, that determines the prognosis of pulp capping. It is believed that for pulp capping to be effective, the mechanical damage and inflammation in the pulp cannot be deeper than the necrotising effect of calcium hydroxide (Andreasen et al., 2013).

Several studies in the literature evaluated the success and the factors, which affect the outcome of pulp capping. Fuks et al. (1982) studied 38 mature teeth that presented with a pinpoint crown fracture exposure and reported an 81.5% success rate following pulp capping. In addition, Ravn (1982) examined 111 crown fractured teeth that were treated with pulp capping with a follow-up period of more than 23 months. In this study, the stage of root development of teeth was assessed as open or closed apices. A success rate of 90% was reported, which was clearly associated with the stage of root development. More specifically, all teeth with open apices were successful whereas the 87.8% of

teeth with closed apices showed success. Furthermore, it is believed that the treatment was successful because the teeth were treated immediately after trauma and the pulp remained healthy. Similarly, Lim and Kirk (1987) explained that bacterial pulpal contamination appears to be the main factor that determines the prognosis of pulp capping. This theory is based on findings found in animal studies which stated that if the pulp was to be exposed to the oral environment for more than 24 hours, the prognosis of pulp capping was reduced (Cox et al., 1982). It was further concluded that even when the tooth was restored, bacteria could still enter through open dentinal tubules or through microleakage at the tooth-restoration interface (Lim and Kirk, 1987).

1.7.2 Pulpotomy

Pulpotomy is defined as the procedure in which part of the dental pulp is surgically removed to a level of clinically healthy pulp, allowing the rest of the pulp to remain alive and continue with normal function (Bimstein and Rotstein, 2016).

1.7.2.1 Partial pulpotomy

Dr Miomir Cvek introduced 'Cvek's partial pulpotomy' in 1978 and described it as a procedure where the damaged and inflamed tissue was removed to a level of amputation 2mm below the exposure site until fresh bleeding was encountered (Cvek, 1978). The amputation level was based on a histological study in monkey teeth which has shown that the inflammation and associated bacterial invasion was usually contained within the superficial 2mm of an exposed pulp (Cvek et al., 1982). It was also thought to be deep enough for an adequate cavity for both dressing and sealing material. The pulpal wound was subsequently rinsed with saline until the bleeding stopped. Following which, the wound was covered with calcium hydroxide and an appropriate sealing cement was placed in the coronal cavity (Andreasen et al., 2013). Therefore the

rationale of partial pulpotomy was based on the assumption that inflammation and impaired vascularity caused by the traumatic injury would be confined to the superficial area of the coronal pulp while the radicular pulp would be healthy (Welbury et al., 2012). This treatment approach is indicated in both mature and immature teeth showing vital pulp tissue at the exposure site. Research has shown that neither exposure size nor time interval between injury and treatment are critical for healing when only superficial layers of the pulp are removed (Andreasen et al., 2013). Compared to pulp capping, it has been shown in the literature that partial pulpotomy ensures a better wound control (Fuks et al., 1987). This is reflected through its high success rate of 94-100% and it is therefore preferred as a treatment option (Table 1).

A number of published studies have investigated the factors that may affect the outcome of teeth treated with Cvek's partial pulpotomy.

1.7.2.1.1 Time interval

Some authors suggest that the time elapsing from the fracture to pulpotomy is important in order to avoid bacterial contamination and therefore allow healing. On the other hand, others have advised that the time between the injury and treatment has only a limited influence on the long term outcome of partial pulpotomy. From a clinical point of view, complicated crown fractures should be treated as an emergency to alleviate symptoms and to reduce the possibility of wound healing complications. Cvek (1978) examined 60 crown fractured permanent incisors treated with partial pulpotomy with a mean follow-up period of 31 months. The treatment delay ranged between 1 hour to 90 days and it was concluded that the time was not critical for healing, based on treatment success of 96%. A few years later, Cvek (1993) carried out another clinical study of 178 crown-fractured incisors treated with partial pulpotomy with a follow-up period of 3 to 15 years. No statistical significant difference in the frequency of healing was found in teeth treated within 72 hours after the injury and those treated after a longer interval, with a success of 96% and 87.5% respectively. Furthermore, it was reported that all failures could be diagnosed within the first 26 months

following treatment, suggesting that a reasonable follow-up to confirm pulpal healing was three years. Similarly, de Blanco (1996) studied 30 permanent incisors in 28 patients undergoing Cvek pulpotomy with a time interval between pulp exposure and treatment ranging from 2 hours to 9 days, and found that this variable did not affect the success of treatment. More specifically, all teeth healed following Cvek pulpotomy. On the other hand, Fuks et al. (1987) treated 63 teeth with Cvek pulpotomy in either less than 1 hour, between 1-4 hours or more than 4 hours following the injury and found a decreasing success rate of 96%, 91% and 89% respectively.

1.7.2.1.2 Stage of root development

The effect of stage of root development upon pulpal healing has also been reported in the literature. In the clinical study of Cvek (1993), out of the 178 teeth that were studied, 90 had immature apices where as 88 had mature apices. No statistical association could be found between the stage of root development and pulpal healing. This result was also supported by the study of Fuks et al. (1987) who concluded that irrespective of the degree of root development, partial pulpotomy could be successful as long as healthy pulps were diagnosed at assessment. Similarly, de Blanco (1996) reported a 100% success rate for both 10 teeth with open apices and 20 teeth with closed apices, suggesting that the success rate of Cvek pulpotomies was not affected by the stage of root development at the time of treatment. On the other hand, Cvek (1978) found that all the teeth with open apices healed where as 92% of the teeth with closed apices showed signs of pulpal healing. It was concluded that a Cvek pulpotomy had a better prognosis in a tooth with an open apex rather than a tooth with a closed apex (Cvek, 1978). Table 1 below summarises the studies on partial pulpotomy.

Table 1: Summary of studies on partial pulpotomy for complicated crown fractures

Study	Follow up	Apex	Time interval	Number of teeth	Success rate Number (%)
Cvek (1978)	14-60 months	All	1 hour till 90 days	60	58 (96%)
		Open		28	28 (100%)
		Closed		32	30 (94%)
Fuks et al. (1987)	6-12, 23-24 or 25-50 months	All		63	59 (94%)
		Open		10	8
		Closed		53	51
		<1 day		46	44 (96%)
		1-4 days		11	10 (91%)
>4h days	9	8 (89%)			
Cvek (1993)	36-180 months	All	1 till 984 hours	178	169 (95%)
		Open		90	
		Closed		88	
de Blanco (1996)	1 to 8 years	All	1 hour to 9 days	30	30 (100%)
		Open		10	
		Closed		20	

1.7.2.1.3 Combination injuries

The effect of an associated luxation injury on the pulpal healing of crown fractured teeth has also been studied. Robertson et al. (2000) investigated 103 teeth with pulp exposures, where 69 teeth had an associated luxation injury. It was concluded that an associated luxation injury significantly increased the likelihood of pulp necrosis from 0% to 14%. This was explained by the fact that an associated luxation injury can compromise the pulp circulation and thus healing. This study further concluded that in the case of concomitant luxated teeth, the stage of root development also had an important role on the risk of pulp necrosis (Robertson et al., 2000).

1.7.2.1.4 Capping material

Prevention of infection is considered a major concern when performing vital pulp therapy. Pulp exposures are vulnerable to infection, as there is no self-healing capacity unless the wound is properly protected. Therefore, the material selection is a critical step towards this goal. For vital pulp therapies in permanent teeth, several capping agents such as zinc oxide eugenol, corticosteroids, antibiotics and calcium hydroxide have been proposed. Calcium hydroxide has been widely recognised as the most common wound dressing and has been the gold standard in dentistry. In the last two decades, mineral trioxide aggregate (MTA) has been introduced for its possible use in pulp capping and pulpotomy procedures (Güngör, 2014).

1.7.2.1.4.1 Calcium hydroxide in vital pulp therapy

The effect of calcium hydroxide on the pulp has been extensively studied in the literature (Andreasen et al., 2013). An important characteristic of calcium hydroxide is its high pH of 12.5. Therefore, when placed over vital pulp tissue, it induces the release of a number of wound healing signals. A zone of liquefaction

necrosis subjacent to calcium hydroxide and a deeper zone of coagulation necrosis next to the vital pulp tissue are formed. The latter zone appears to stimulate the formation of a bone-like hard tissue bridge, containing cells and vascular inclusions, between it and the vital pulpal tissue. After 2-3 weeks, new odontoblast-like cells appear adjacent to the initial hard tissue bridge and normal dentine begins to form (Bakland and Andreasen, 2012). It is believed that calcium hydroxide has no beneficial effect on healing of chronically inflamed pulps and therefore it should be placed on healthy pulp tissue. Additionally, it possesses excellent antibacterial properties which allows a bacteria-free environment at the amputation site during hard tissue bridge formation (Andreasen et al., 2013). On the other hand, evidence has also demonstrated the problems associated with the use of calcium hydroxide. It is believed that the initial zones of sterile pulp necrosis created by pulp therapy may become infected at a later time through microleakage under restorations, leading to pulpitis and subsequently pulp necrosis. This is because as a result of unavoidable dissolution, calcium hydroxide loses its antibacterial property allowing bacteria to enter the pulp (Güngör, 2014). Additionally, as a result of vascular inclusions an incomplete coronal hard tissue barrier is formed and bacteria can easily invade through the tunnels. Finally, as a result of its high pH, calcium hydroxide can change the physical structure of dentine increasing the risk for a cervical root fracture (Bakland and Andreasen, 2012).

1.7.2.1.4.2 MTA in vital pulp therapy

Mineral trioxide aggregate (MTA) was firstly recommended in 1930s. In the early 1990s, Torabinejad and colleagues at Loma Linda University in California USA developed MTA as a root filling material, and since then it has numerous clinical applications in the endodontic field (Lee et al., 1993, Andreasen et al., 2013).

MTA consists of a mineral powder containing tricalcium silicate, tricalcium aluminate, tricalcium oxide and other mineral oxides (Torabinejad et al., 1995). Hydration of the powder results in a colloidal gel, which solidifies in a few hours (White et al., 2002). When first developed, MTA was a grey material and

owing to its discolouration potential, white MTA has now been introduced. It has a similar pH to calcium hydroxide, ranging between 10.2 and 12.5 during the first three hours of setting after which it remains constant. While MTA sets in 3 hours, its compressive strength continues to increase over a period of 3 weeks (Andreasen et al., 2013).

Numerous studies have shown that MTA has impressive physical and chemical properties and is a highly biocompatible material that is well tolerated by tissue cells both in the pulp and peri-radicular areas. It is thought to have similar antibacterial properties as calcium hydroxide. However, compared to calcium hydroxide, MTA has a prominent characteristic to resist bacterial penetration by establishing a tight physical adaptation to adjacent dentine (Andreasen et al., 2013).

The exact mechanism whereby MTA induces a hard tissue bridge is partly understood. It has been suggested that by its high pH effect, MTA stimulates the release of wound healing signals and a chemical bond between MTA and dentine is formed, called hydroxyapatite. It is believed that this layer provides the tight seal that prevents and reduces bacterial penetration to the pulp amputation site. MTA also induces a very narrow zone of coagulation necrosis at the vital pulp site. A reparative dentinogenesis zone is found next to the coagulation necrosis zone. Subsequently, the dentinal bridge is formed and this appears to be faster than with calcium hydroxide. In addition, fewer vascular inclusions have been found in the hard tissue bridge compared to calcium hydroxide, and therefore preventing bacterial penetration at the pulp amputation site (Bakland and Andreasen, 2012).

Another advantage of MTA is its hydrophilic property which can be placed in clinical situations where moisture cannot be controlled. On the other hand, the use of MTA at the coronal part of the tooth can cause discolouration and can be an aesthetic problem (Güngör, 2014).

As MTA is relatively new, there have been only a few studies in humans demonstrating the hard tissue inducing effect of MTA in crown fractured teeth. A recent systematic review performed by Fransson et al. (2015) concluded that there was insufficient evidence that mineral aggregate promotes hard tissue

formation more frequently than calcium hydroxide. In conclusion, more long term research is required to study the effectiveness of MTA (Güngör, 2014).

1.7.3 Cervical pulpotomy

Cervical pulpotomy is indicated when necrotic tissue or impaired vascularity is encountered at the exposure site, and therefore further amputation is required at the coronal part of the tooth. For immature teeth, cervical pulpotomy is considered the treatment choice where-as pulpectomy is usually carried out in mature teeth (Andreasen et al., 2013). Two published studies have demonstrated the success of cervical pulpotomy to range between 72-79%. Hallett and Porteous (1963) studied 93 teeth and reported a success of 72% where-as the study of Gelbier and Winter (1988) on 175 teeth has shown pulpal healing of 79% following treatment. On the other hand, some authors claim that except in special clinical scenarios, a cervical pulpotomy is no longer indicated as Cvek's pulpotomy can have a more favourable prognosis (Bimstein and Rotstein, 2016). Unlike cervical pulpotomy, partial pulpotomy is a more conservative procedure. This is because partial pulpotomy involves minimal injury to the pulp and preserves the cell rich coronal pulp tissue. This tissue possesses a better healing potential and maintains the physiological deposition of dentine in the cervical area. In addition, the natural colour and translucency of the tooth is preserved (Fong and Davis, 2002, Güngör, 2014)

In addition, the influence of treatment delay has been studied in teeth treated with cervical pulpotomy. Fuks et al. (1982) found a significant relationship between pulp necrosis and a treatment delay of more than 24 hours. This finding was consistent with the study of Gelbier and Winter (1988) where a significant relation to pulp necrosis as well as an inferior rate of hard tissue barrier formation was reported in cases where treatment was carried out later than 24 hours after the injury (Andreasen et al., 2002).

1.8 Luxation Injuries

Luxation injuries comprise 15-61% of dental traumas to permanent teeth.

Extrusive luxation is defined as partial displacement of the tooth following the axis of the tooth out of its socket but without leaving the socket. On the other hand, lateral luxation is defined as eccentric displacement, other than axial, of the tooth. Finally, intrusive luxation is defined as displacement of the tooth deeper into the alveolar bone where the direction of dislocation follows the axis of the tooth. Both lateral luxation and intrusive luxation may be accompanied by comminution or fracture of the alveolar socket (Andreasen et al., 2013).

1.8.1 Healing and complications

Luxation injuries represent a combined injury to the pulp and periodontium. Experimental studies in monkeys have examined the histological response of luxation injuries on the periodontium and pulp. In extrusive luxation, the immediate changes are characterised by complete rupture of the PDL fibres and neurovascular supply to the pulp. On the other hand, lateral luxation involves a complex injury rupture or compression of the PDL fibres, severance of the neurovascular supply of the pulp and fracture of the alveolar socket wall. In addition, intrusive luxation is described as an extensive crushing injury to the PDL and alveolar socket with rupture of the neurovascular supply of the pulp (Andreasen et al., 2013).

1.8.1.1 Pulpal revascularisation (healing)

Luxation injuries usually imply partial or total disruption of the neurovascular supply to the pulp. In cases of partial disruption, reduced circulation can still be maintained throughout the pulp, with complete reconstitution of the neurovascular supply after a few weeks. On the other hand, in cases of total rupture of the neurovascular supply, gradual revascularisation will take place in an apico-coronal direction at a rate of approximately 0.5mm vessel ingrowth per day. Successful revascularisation presents as narrowing of the pulp canal together with positive sensibility testing at 2-3 months after the injury (Andreasen et al., 2011).

1.8.1.2 Pulp necrosis

It is described in the literature that the revascularisation process is dependent on two factors such as the size of the apical foramen as well as on the presence or absence of bacteria in the healing site. Therefore, unsuccessful pulpal revascularisation presents an infected pulp which is diagnosed as pulp necrosis. The classical signs of pulp necrosis are discolouration of the crown, negative sensibility testing and persistent tenderness to percussion. Moreover, radiographically it may present with an apical radiolucency or widened periodontal ligament as early as 2 to 3 weeks after the injury. However, this apical radiographic change can also be temporary, representing transient apical breakdown as described in section 1.8.1.4. In addition, it is thought that the presentation of peri-apical pathology is due to an infection induced release of osteoclast activating factors and it is currently considered the only reliable sign of pulp necrosis. On average, pulp necrosis can be diagnosed about 2 years after the luxation injury (Andreasen et al., 2013).

The incidence of pulp necrosis in luxation injuries has been demonstrated in studies to range between 15-59% (Andreasen et al., 2013). Andreasen and Pedersen (1985) conducted one of the largest studies where he examined 637 luxated teeth and reported an incidence of 24%. On the other hand, Oikarinen et al. (1987) studied 147 teeth and found pulp necrosis at a frequency of 50%. In addition, a number of studies investigated the factors which may influence the development of pulp necrosis. Andreasen and Pedersen (1985) stated that after adjusting for a number of other factors, only the extent of the initial injury to the pulp and periodontium (type of luxation) as well as the repair potential of the injured tooth (stage of root development) were significantly related to the development of pulp necrosis. These findings were in agreement with an earlier study of Andreasen (1970).

1.8.1.2.1 Type of luxation Injury

Andreasen and Pedersen (1985) documented that the greatest frequency of pulp necrosis was encountered among intrusions (85%) followed by lateral luxation (58%) and extrusion (26%).

1.8.1.2.2 Stage of root development

Moreover, teeth with completed root formation demonstrated a greater risk of pulp necrosis (38%) than teeth with incomplete root formation (8%) (Andreasen and Pedersen, 1985). The theory behind this is based on the fact that any slight movement of the apex can presumably occur in immature teeth, without disruption of the blood vessels passing through the apical foramen. In addition the process of revascularisation is more easily achieved in teeth with a wide apical foramen, thus favouring pulp survival.

In addition, Andreasen et al. (1986) studied a sample 226 extruded, laterally luxated, intruded maxillary permanent incisors for up to 10 years, and documented that pulp survival after luxation injuries with displacement was

dependent upon the size of the apical contact between the pulp and periodontium i.e. diameter of apical foramen. More specifically, for extruded and laterally luxated teeth, the smaller the diameter the greater the probability of pulp necrosis. On the other hand, intruded teeth with incomplete root development with a radiographic diameter of $\geq 1.2\text{mm}$ were associated with a much higher probability of pulp survival than teeth with completed root development and a radiographic diameter $\leq 0.7\text{mm}$ (Andreasen et al., 1986).

1.8.1.3 Pulp canal obliteration

Pulp canal obliteration (PCO) is a type of healing complication, regarded as a response to a severe injury to the neurovascular supply to the pulp. Healing involves revascularisation and innervation of the ischemic pulp which leads to an accelerated dentine deposition (Andreasen et al., 2011).

A number of studies have shown that pulp canal obliteration was frequently encountered after luxation injuries of permanent teeth, with an incidence ranging between 3-35% (Andreasen et al., 1987, Crona-Larsson et al., 1991, Andreasen et al., 2013). It is thought that pulp canal obliteration is strongly related to the severity of the luxation injury, more commonly seen in severely mobile or displaced teeth where there has been loss and re-establishment of the neurovascular blood supply. A large study performed by Andreasen et al. (1987), examined 637 luxated teeth and reported a frequency of 16% of either partial or complete pulp canal obliteration. Moreover, pulp canal obliteration was more prevalent in the extrusion (49%), followed by lateral luxation (31%) and intrusion (13%) group compared to other luxation injuries (Andreasen et al., 1987). Furthermore, it has been established from the literature that pulp canal obliteration occurs more frequently in teeth with incomplete root formation (Andreasen et al., 1987, Andreasen et al., 2013).

In general, pulp canal obliteration appears between 3-12 months after injury with a clinical presentation of yellow crown discolouration. Radiographically, the first sign of obliteration is reduction in the size of the coronal chamber followed by

gradual narrowing of the root canal (Andreasen et al., 2013). The possible effect of treatment variables on the development of pulp canal obliteration has also been investigated. It has been reported that only one variable, the type of fixation was found to be significantly related to pulp canal obliteration. More specifically, the use of orthodontic band/resin splints were followed by a significant increase in pulp canal obliteration and it is thought that this was a result of additional trauma of the already damaged periodontium due to forceful placement of the bands (Andreasen et al., 1987).

Additionally, studies have demonstrated that pulp necrosis may be a late complication following pulp canal obliteration. The pathogenesis of this event has not yet been determined but it has been shown to occur in 1-16% of cases. One of the early studies which investigated the incidence of pulp necrosis in 76 teeth with pulp canal obliteration, found an incidence of 16% over a period of 3-21 years (Eklund et al., 1975). A later study conducted by Robertson et al. (1996) included 82 luxated teeth with a mean follow up period of 16 years. Radiographic peri-apical lesions suggestive of pulp necrosis developed in seven teeth (9%) where this incidence increased over time. On the other hand, Andreasen et al. (1987) found only 1% of the 96 luxated teeth with pulp canal obliteration had developed pulp necrosis over a mean follow up period of 3.6 years. The low incidence of pulp necrosis in this study could have been due to the short follow-up period.

1.8.1.4 Transient apical breakdown

Transient apical breakdown (TAB) is described as the presentation of temporary apical radiographic change in the region of apical foramen following acute dental trauma and in connection with healing. It is thought that as a result of displacement of the root after luxation, the vascular supply at the apical foramen could be partially or totally severed, leading to ischaemic changes in the pulp (Andreasen et al., 2013). As part of the revascularisation healing process, osteoclastic activity will start in the base of the socket and at the apical foramen

in order to create space for ingrowth of new tissue. As this process is transient the radiolucent area will disappear when revascularisation is complete.

Evidence has shown that more than 4% of luxation injuries showed evidence of TAB. It is also thought that TAB is commonly associated with moderate luxation injuries such as in extruded and laterally luxated teeth, which involve moderate damage to both the pulpo-periodontal injury complex (Andreasen, 1986, Andreasen et al., 2011). It appears that the radiographic presentation of TAB is evident 2-12 months following traumatic dental injury. Another characteristic of TAB is that teeth may initially show evidence of pulpal damage such as loss of sensibility and/or colour change which return to normal at the same time as resolution of TAB (Andreasen, 1986).

1.8.1.5 Internal bone formation (pulp bone)

Hertwig's epithelial root sheath (HERS) is described as a continuous sleeve of epithelial cells which separates the pulp from the dental follicle. HERS completely encloses the dental papilla except for an opening in its base called the primary apical foramen, through which the pulp receives its neurovascular supply.

Root formation is determined by the activity of HERS and root growth is dependent upon a continuous proliferation of epithelium. During incomplete repositioning in a luxation injury HERS suffers injury due to ischaemia. Similarly, a forceful repositioning can cause all or part of HERS to be crushed. Further root growth may therefore be partially or totally arrested, and bone and PDL derived tissue from the base of the socket invade the root canal to form intra-radicular bone which is separated from the canal wall by internal periodontal ligament (Heling et al., 2000, Andreasen et al., 2013).

1.8.1.6 Root development

Acute trauma such as forceful displacement of an immature permanent tooth can cause damage to the HERS and lead to partial or complete arrest of root development (Andreasen et al., 2013). Andreasen and Pedersen (1985) documented that 3% of the luxation injuries had signs of arrested root development where intrusion had the highest percentage at 16% followed by lateral luxation at 5% and extrusion at 6%. In addition disturbed root development could be found at 2% in all luxation injuries, where both lateral luxation and intrusion had 6% compared to extrusion at 4%.

1.8.1.7 External root resorption

The damaged inflicted to the periodontal structures and the pulp by luxation injury can result in three types of external root resorption. It is thought that following a severe dental injury such as lateral luxation or intrusion, the PDL responds to a variety of insults. These can include temporary compressive, tensile or shearing stresses which result in haemorrhage and oedema, rupture or contusion of the PDL, all of which can induce varying wound healing events. As a result of the injury, there is loss of the protecting cementoblast layer and the epithelial rests of Malassez along the root surface. When these layers disappear, osteoclasts and macrophages gain access to remove the damaged PDL and therefore wound healing is initiated (Andreasen et al., 2011). It is believed that during this process, not only are necrotic PDL tissue remnants removed but sometimes also bone and cementum. The latter can lead to either surface or inflammatory resorption depending upon the age of the patient, the stage of root development and pulp status. When large areas of the PDL are traumatised, competitive wound healing processes begin between bone marrow derived cells destined to form bone and PDL derived cells which are programmed to form PDL fibres and cementum resulting in replacement resorption (Trope, 2002, Andreasen et al., 2013).

Several studies have demonstrated the prevalence of root resorption irrespective to the luxation injury, to range between 1-18% (Andreasen and Pedersen, 1985, Oikarinen et al., 1987, Crona-Larsson et al., 1991). Andreasen and Pedersen (1985) also investigated the prevalence of resorption for each luxation injury in 637 teeth. It was reported that surface resorption was a very common finding in both lateral luxation and intrusion groups, at a frequency of 26% and 24% respectively but less commonly found in the extrusion group (6%). On the other hand, infection related resorption was more frequently presented in the intrusion group (38%) compared to lateral luxation (3%) and extrusion (6%) groups. Similarly, replacement resorption had its highest frequency in the intrusion injuries at a frequency of 24% compared to lateral luxation (1%) and extrusion (0%).

1.8.1.7.1 Surface resorption (repair-related resorption)

Surface resorption represents a healing response that occurs as a result to localised injury of the periodontal ligament or cementum. The damage is confined to the layer of PDL closest to the cementum. Histologically, this site will be resorbed by macrophages and osteoclasts resulting in a saucer-shaped cavity on the root surface. Radiographically, the small excavations may be visible four weeks following injury. In comparison to other types of resorption, surface resorption is not progressive but rather is self-limiting, repaired by cementum and insertion of new Sharpey's fibres (Tronstad, 1988, Andreasen et al., 2013).

1.8.1.7.2 Infection related resorption

This resorption entity occurs when there is an untreated infection of the root canal space combined with damage to the periodontal membrane and cementum. Injury to the root surface will initially induce small resorption cavities. As these resorption cavities expose the dentinal tubules, infected tissue from

the root canal diffuses through the tubules to the lateral periodontal tissues. This results in continuation of the osteoclastic process and an associated inflammation in the PDL leading to resorption of the lamina dura adjacent to bone as well as tooth structure (Trope, 2002). Radiographically, infection related resorption presents as radiolucent bowl-shaped resorption cavities along the root surface with corresponding excavations in the adjacent bone. Evidence has shown that the first radiographic sign can be as early as 2 weeks (Tronstad, 1988). Clinically, the tooth may be mobile and tender to percussion with a dull tone.

It is well established that the treatment of infection related resorption should include elimination of bacteria from the root canal and dentinal tubules by endodontic treatment. Subsequently, the resorption is arrested and the cavity is filled with cementum or bone according to the type of vital tissue found next to the resorption site. It is interesting to state that if not treated, the resorption can progress very rapidly and may result in total resorption of the root of young immature teeth, as early as one month following the injury (Tronstad, 1988, Andreasen et al., 2013).

1.8.1.7.3 Replacement root resorption (Ankylosis)

Replacement root resorption occurs when there has been significant damage to the periodontal membrane such as following an intrusion injury. It is described as the root surface having no vital PDL and absence of infection within the root canal space. In such situations, competitive healing events will take place whereby healing from the socket wall (creating bone via bone marrow derived cells) and healing from adjacent PDL next to the root surface (creating cementum and Sharpey's fibres) will take place simultaneously. Due to the predominant healing response from the socket wall, the root surface is repopulated by the adjacent bone marrow cells with osteogenic potential. The root becomes part of the normal bone remodeling system and is gradually replaced by bone (Andreasen et al., 2013).

Histologically, ankylosis represents a fusion of the alveolar bone and the root surface. Radiographically, it can be diagnosed 2 months after the injury and it is characterised by disappearance of the PDL space and continuous replacement of root with bone. Clinically, the tooth is immobile and percussion test may reveal an ankylotic tone (Tronstad, 1988).

It is well established in the literature that ankylosis can anchor the tooth in its position and thus disturb the normal growth of the alveolar process. This results in gradual infra-occlusion of the tooth (Tronstad, 1988). In children, replacement resorption can be rapid especially if ankylosis occurs before puberty, with loss of the tooth within 1-5 years. On the other hand, in older patients, an ankylotic tooth can be retained; the life span varies from 10-20 years due to the slow remodelling rate of bone in older age groups. There is no effective treatment for ankylosis. However, where infra-occlusion shows a discrepancy in the gingival margins of the ankylotic tooth, then intervention is necessary (Andreasen et al., 2011).

1.8.1.8 Internal Root Resorption

It has been reported in the literature that root canal resorption is a rare finding in luxated teeth with a frequency of 2%.

1.8.1.8.1 Root canal replacement resorption

This resorption type is described as an irregular enlargement of the pulp chamber as a result of deposition of bone at the expense of dentine. It is believed after some time, the resorption process becomes arrested and complete pulp canal obliteration takes place (Andreasen et al., 2013).

1.8.1.8.2 Root canal inflammatory resorption

This resorption entity is characterised as an oval shaped enlargement within the pulp chamber, usually located in the cervical aspect of the pulp. It is thought that a necrotic zone of bacteria is responsible for the inflammatory resorption and therefore root canal treatment is the choice of treatment (Trope, 2002).

1.8.1.9 Loss of marginal bone

Evidence has shown that when the PDL is compressed in intrusive or lateral luxation, the macrophage/osteoclast removal around traumatised teeth occurs prior to periodontal healing. This healing complication manifests clinically as gingival granulation tissue at the site of compression and radiographically as breakdown of the lamina dura and can be either temporary or permanent (Andreasen et al., 2011). It has been reported in the literature that the incidence of loss of marginal bone ranges from 5 to 24% among luxated teeth (Andreasen and Pedersen, 1985, Oikarinen et al., 1987). More specifically, Andreasen and Pedersen (1985) showed that a greater proportion of the intruded teeth presented with this complication compared to the other types of luxation injuries. It is believed that the loss of marginal bone support increases with increasing age, duration of splinting and extent of displacement. In addition, it has been shown that the repositioning procedure following intrusion plays a role in periodontal healing where surgical repositioning can result in greater loss of marginal bone (Andreasen et al., 2013).

1.9 Intrusion

Intrusion is considered a rare type of injury, accounting for 0.3% to 1.9% of all traumas affecting the permanent dentition. It appears to more commonly occur in the age group of 6-12 years and more frequently in boys rather than girls (Andreasen et al., 2006c). It is described as being the most severe form of luxation injuries resulting in catastrophic damage of the periodontium, pulp and alveolar bone (Andreasen et al., 2013). It represents a very complex wound, involving disruption of the marginal gingival seal, contusion of the alveolar bone, disruption of the periodontal ligament fibres, damage to cementum and disruption of the neurovascular supply to the pulp (Andreasen et al., 2011).

Clinically, the crown of the tooth appears shortended. Due to their locked position in the bone, most intruded teeth are not sensitive to percussion and are firm in their socket. The percussion test will reveal a high-pitched metallic sound, similar to an ankylosed tooth. Radiographically, the tooth appears dislocated in an apical direction with partial or complete disappearance of the periodontal ligament space (Andreasen et al., 2013).

Due to the severity of the intrusion injury, healing complications dominate the healing pattern. The injury caused to the periodontium has been found to often result in root resorption, marginal bone breakdown whereas the injury to the pulp can lead to pulp necrosis and arrested root formation in immature teeth (Andreasen et al., 2006b).

The aim of treatment is to restore the tooth to its original position by decompressing the injured tissues and re-establishing the normal relationship between the tooth and bone (Al-Badri et al., 2002). Treatment can be performed either actively by repositioning (surgical or orthodontic extrusion) or passively by spontaneous re-eruption (Andreasen et al., 2006a).

A number of studies have been carried out to examine the predictors; both injury and treatment related that may affect the healing outcome of intruded permanent teeth.

1.9.1 Age

Andreasen et al. (2006a) completed one of the largest clinical studies where 140 intruded permanent teeth in 114 patients were examined prospectively, with a follow-up of at least one year. It was reported that age was related to pulp necrosis, root resorption and defects in marginal periodontal healing where patients younger than 12 years old had the lowest complication rate. This was explained by taking into account the denser and more mineralised alveolar bone surrounding the tooth found with increasing age, thus allowing more injury to the root surface (Andreasen et al., 2006a).

1.9.2 Stage of root development

Several studies have also studied the effect of stage of root development on the incidence of pulp necrosis, root resorption and marginal bone loss in intruded teeth.

As described above, pulp survival is more likely to occur in immature teeth than in mature teeth following a luxation injury. Andreasen et al. (2006a) found that root development was strongly correlated with pulp survival where there was an increased chance of revascularisation in teeth with open apices.

Furthermore, Andreasen et al. (2006a) reported a weak correlation between root resorption and stage of root development. However, there was a trend where teeth with early stage of root development had a slightly lower frequency of root resorption compared to more mature teeth. On the other hand, Al-Badri et al. (2002) studied 61 intruded permanent incisors over a minimum follow-up period of 1.5 years and reported a significant relationship between degree of apical development and resorption with an increased prevalence in the fully developed roots. In addition, Tsilingaridis et al. (2012) conducted a study on 61 intruded teeth and found that replacement root resorption presented less frequently in teeth with very immature and immature teeth compared to mature teeth, concluding that stage of root development had a significant influence on the

development of replacement root resorption. This association is possibly as a result of the more resilient bone and a thicker periodontal ligament found in immature teeth allowing intrusion with less damage on the periodontal ligament (Andreasen et al., 2006a).

With regards to the incidence of marginal bone loss, Andreasen et al. (2006a) concluded this healing complication was more prominent in teeth with completed root formation. This is because more intensive damage is expected in mature teeth who have a denser and more mineralised bone resulting in compressive damage to the periodontal ligament (Andreasen et al., 2006a).

Finally, based on the available research, 88-98% of mature teeth are expected to experience pulp necrosis, 51-73% to be diagnosed with root resorption and 44% are assumed to have marginal bone loss. In contrast, immature teeth are expected to have a lower frequency of pulp necrosis and marginal bone loss of 61-67% and 5% respectively (Albadri et al., 2010).

1.9.3 Associated crown fracture

The effect of an associated crown fracture with exposed dentine on the healing outcome of intruded teeth was also explored in the study of Andreasen et al. (2006a). It was concluded that an associated crown fracture could result in more frequent pulp necrosis, possibly as a result of bacterial invasion through dentinal tubules into an ischaemic pulp. An associated crown fracture with intrusion is a common injury pattern therefore this factor can be considered important when assessing the prognosis of intruded teeth (Andreasen et al., 2006a).

1.9.4 Multiple intruded teeth

Andreasen et al. (2006a) found that multiple adjacent intruded teeth were more frequently associated with interproximal marginal bone loss than a single intrusion.

1.9.5 Severity of intrusion

Furthermore, the severity of intrusion has been investigated in the literature, as a possible predictor influencing the healing outcome of intruded teeth. A recent Scandinavian multicentre study conducted by Tsilingaridis et al. (2016) examined 230 teeth retrospectively, based on patient materials from three previously published studies conducted in Denmark, Sweden and Norway (Andreasen et al., 2006a, Wigen et al., 2008, Tsilingaridis et al., 2012). The degree of intrusion was classified as mild (1-<3mm), moderate (3-7mm) and severe (>7mm). This study concluded that the degree of intrusion was significantly related to both the development of pulp necrosis as well as replacement resorption. In particular, pulp necrosis was found less frequently in teeth with mild intrusion than in teeth with moderate and severe intrusion. In teeth with mild intrusion, less damage to the pulp tissue in the apical area of the tooth can be expected and this may facilitate pulp revascularisation. In addition, no replacement root resorption was found in teeth with mild intrusion indicating the low risk of resorption in these teeth. On the other hand, severely intruded teeth had a higher risk of developing replacement resorption than moderately intruded teeth. This is because a severe intrusion involves the root being forced high up in the alveolar bone leading to extensive damage to the periodontal ligament and adjacent bone therefore increasing the risk of replacement resorption. This was in agreement to an earlier study of Al-Badri et al. (2002) who reported that apart from the stage of root development, the severity of intrusion was also related to the incidence of root resorption. In this study, severity of intrusion was recorded as moderate (0-2mm), severe (3-4mm) or very severe (5mm or more). It was concluded that the prevalence of resorption was higher in the more severely intruded teeth but also it was detected earlier (Al-Badri et al., 2002). In addition, Humphrey et al. (2003) studied 31 permanent incisors over a mean follow-up period of 3.7 years also stated that the severity of intrusion was significantly related to the development of replacement root resorption where incisors intruded greater than 6mm were more prone to replacement root resorption.

1.9.6 Method of repositioning

The effect of the method of repositioning on the healing outcome of intruded teeth has been studied extensively in the literature.

A recent systematic review conducted by AlKhalifa and AlAzemi (2014) found three published studies that met the inclusion criteria. According to these three published studies, spontaneous re-eruption appears to result in the fewest complications such as pulp necrosis, infection related resorption and replacement root resorption compared to active repositioning, given that the infection can be controlled by endodontic therapy if needed (Andreasen et al., 2006b, Wigen et al., 2008, Tsilingaridis et al., 2012). This result was in accordance to a similar age group (6-17 years) found in the three included studies. On the other hand, Al-Badri et al. (2002) found that root resorption was not related to the repositioning procedure but rather the severity of injury and the stage of root development influenced the healing outcome as already described. However, this study included both orthodontic and surgical repositioning as one treatment group and therefore was unable to conclude between the two treatments. Furthermore, Andreasen et al. (2006b) reported passive repositioning also favours marginal bone healing as a result of no additional damage inflicted to the already injured periodontium. However, spontaneous eruption might be an unreliable treatment method due to mucosal closure when the tooth is intruded at or below bone level (Andreasen et al., 2006b). The difference in the healing complications between the two active treatment options, surgical and orthodontic repositioning has also been investigated. Several studies have concluded no significant differences on adverse outcomes between orthodontic and surgical repositioning (Andreasen et al., 2006b, Wigen et al., 2008). In addition, Tsilingaridis et al. (2012) could not find a firm conclusion between the two active treatments.

1.9.7 Treatment delay

Andreasen et al. (2006b) reported that treatment delay, whether repositioning was carried out before or after 24 hours had no effect upon healing.

1.9.8 Published Guidelines

Based on the available evidence, the UK National Clinical Guidelines 2010 recommend that the chosen treatment approach should be influenced by the stage of root development and severity of intrusion (Albadri et al., 2010). These guidelines support that passive repositioning is favourable for immature teeth due to their eruptive potential whereas surgical repositioning should be considered for teeth with severe intrusion or in the cases of multiple intrusions. Table 2 below summarises the treatment approaches as per the guidelines.

Table 2: The treatment approaches for intrusion injury as per the guidelines

Degree of Intrusion	Incomplete root development	Complete root development
Mild (<3mm)	PR	PR preferred, if PR not working after 2-3 weeks start OR
Moderate (3-6mm)	PR (if PR not working after 2-3 weeks start OR)	SR or OR (both appropriate)
Severe >6mm	PR (if PR not working after 2-3 weeks start OR)	SR

Key of Table 2: PR=Passive Repositioning, OR=Orthodontic Repositioning, SR= Surgical Repositioning

1.9.9 Type and duration of splinting

In addition, both the type and duration of splinting have been researched in the literature as possible factors affecting healing of intruded teeth. Andreasen et al. (2006b) stated that most of the teeth were splinted for 6-8 weeks with different types of rigid, semi-rigid and flexible splints. It was concluded that neither the type of splint nor duration of splinting appeared to have a significant effect on the type of healing. On the other hand, Al-Badri et al. (2002) recommended that a shorter period of 10 days could permit a sufficient reduction in mobility to allow function. Furthermore based on the available evidence, the International Traumatology Guidelines 2012 suggest that once an intruded tooth has been repositioned surgically or orthodontically, it should be stabilised with a flexible splint for 4-8 weeks (DiAngelis et al., 2012). It is believed that a flexible splint will stabilise the tooth, allow physiological tooth movement and promote pulp and periodontal healing (Albadri et al., 2010).

1.9.10 Time of pulp extirpation

As already described, pulp necrosis is significantly related to apical development where mature teeth are at increased risk of loss of vitality compared to immature teeth (Andreasen et al., 2006a). This association was also supported by a later study performed by Stewart et al. (2009) in 55 intruded teeth with a mean follow up of 2.3 years. In this study, it was concluded that given the higher prevalence of pulp necrosis in mature teeth, early pulp extirpation was justified to prevent the development of infection related root resorption.

In addition, the UK National Clinical Guidelines 2010 suggest that immature teeth should be closely monitored and root canal treatment initiated only following diagnosis of pulp necrosis. On the other hand, mature teeth with moderate to severe intrusion should be extirpated approximately 2 weeks after the injury (Albadri et al., 2010).

1.9.11 Tooth survival

The factors that may have an impact on the tooth survival of intruded teeth and the incidence of tooth loss has also been documented. Humphrey et al. (2003) examined 31 intruded teeth over a mean follow-up period of 9.3 years and reported that the severity of intrusion was significantly related to the tooth survival. In particular, incisors intruded more than 6mm had a significantly decreased survival compared with incisors intruded less than 3mm. This finding was consistent with the study of Kinirons and Sutcliffe (1991) who studied 29 teeth and similarly reported a trend towards reduced survival for severely intruded teeth of more than 5mm at 2 year follow-up, with high prevalence of infection and replacement root resorption in these teeth. Additionally, Wigen et al. (2008) studied 51 teeth aged 6-17years and found that 78% of teeth survived over a period of 4 years, reporting that the most common reason of tooth loss was progressive replacement root resorption. Furthermore, Andreasen et al. (2013) constructed survival curves based on published data and reported that was expected that approximately 30% of teeth were lost after 15 years, irrespective of the root stage of development of teeth.

It can be concluded that due to the rare occurrence of intrusion, there are only a few studies available in the literature. In addition, most studies conducted on intrusion have their own limitations such as small sample size, unclear outcome assessment and presence of selection bias. Overall, there is a lack of scientific evidence to support the best treatment approach for this type of injury. Therefore it is important that high quality observational studies with a sufficiently high number of patients are to be conducted in the future (AlKhalifa and AlAzemi, 2014).

Table 3 on the next page summarises the results of the published studies on healing complications and survival of teeth.

Table 3: Summary of studies on intrusion injury

Study	Teeth	Age years mean (range)	Pulp necrosis	Root resorption	Loss of marginal bone	Tooth Survival Follow-up (mean)
Andreasen and Pedersen (1985)	61	(6-67)	52 (85%)	40 (66%)	19 (31%)	n/a
Kinirons and Sutcliffe (1991)	29	9.5 (7-12)	n/a	11 (38%)	7 (24%)	20 (69%) 2 years
Al-Badri et al. (2002)	61	9.3 (7-14)	n/a	36 (59%)	n/a	48 (79%) (1.5 years)
Humphrey et al. (2003)	31	9.3 (6-18)	14 (45%)	25 (80%)	12 (39%)	26 (83%) (3.7 years)
Andreasen et al. (2006c)	140	15.6 (6-67)	124 (88%)	67 (48%)	45 (32%)	112 (80%)
Wigen et al. (2008)	51	(6-17)	29 (57%)	Total (38%) IRR:26% RRR:12%	n/a	40 (78%) (4 years)
Stewart et al. (2009)	55	(6-14)	25 (45%)	17 (31%)	n/a	50 (91%) (2.3 years)
Tsilingaridis et al. (2012)	60	(6-16)	23 (38%)	11 IRR 20 RRR	n/a	49 (82%) (47.8 months)

Key of Table 3: IRR=Infection related resorption, RRR=Replacement root resorption, n/a= No information given in study.

1.10 Extrusion

Extrusion accounts for approximately 3% of all traumatic injuries in the permanent dentition (Andreasen, 1970). It is described as an injury that causes complete rupture of the neurovascular blood supply of the pulp and severance of the periodontal ligament resulting in pulpal infraction and loosening of the tooth together with displacement in an axial direction (Andreasen et al., 2013).

Clinically, the tooth appears elongated and most often with lingual deviation of the crown associated with bleeding from the periodontal ligament/gingival sulcus. Radiographic evidence will confirm the displacement from the socket with an expanded periodontal ligament space and intact alveolar bone (Lee et al., 2003).

It has been suggested that the treatment for an extruded tooth should involve repositioning by gently re-inserting the tooth into the socket (DiAngelis et al., 2012). Following which, the tooth should be splinted using a flexible splint for two weeks to maintain the tooth in an anatomically correct position during the healing process. The aim of treatment is to facilitate periodontal ligament healing and possibly pulpal revascularisation as well as to ensure that the vitality of Hertwig's epithelial root sheath and continued root development (Andreasen et al., 2013). In addition, regular follow-ups are indicated following treatment for continued assessment of pulp and periodontal healing (DiAngelis et al., 2012).

The research to date includes very few studies that investigated the factors that may affect the outcome of extruded teeth.

1.10.1 Stage of root development

As previously described, the stage of root development has been shown to be the significant predictor of pulp healing in luxation injuries (Andreasen et al., 2013). As part of the study of Andreasen and Pedersen (1985), a total of 53 extruded teeth were examined. It was found that teeth with open apices had an established pulp survival of 91% over a 10 year period. On the other hand, 55% of teeth with closed apices experienced pulp necrosis over a 10 year period. In addition, pulp canal obliteration was a more frequent finding for teeth with incomplete root formation as part of pulpal revascularisation healing, compared to teeth with closed apices.

It is also well documented in the literature that the stage of root development acts as a risk factor to periodontal healing (Andreasen et al., 2013). A longitudinal cohort study conducted by Hermann et al. (2012) examined the risk of periodontal healing in 82 extruded teeth for three years following the injury. It was reported that both surface resorption and marginal bone loss occurred significantly more often in teeth with mature rather than immature root development. This finding was justified as immature teeth have more resilient bone with a shock absorbing effect which reduces the amount of damage caused to the affected tissues. Similarly, Andreasen and Andreasen (1985) stated that surface resorption was more common in mature teeth, whereas the majority of the immature teeth showed evidence of periodontal healing. Furthermore, it was concluded that inflammatory root resorption was expected in all stages of root development in association with pulp necrosis (Andreasen et al., 2011). Additionally, evidence has shown that the incidence of replacement resorption was very rare in extrusive injuries. Hermann et al. (2012) found no teeth with replacement root resorption. Similarly, Andreasen and Andreasen (1985) found none of the extruded teeth with ankylosis and concluded that this type of healing usually results from a crushing rather than a tearing injury such as extrusion.

1.10.2 Severity of extrusion

The severity of intrusion has also been studied in a number of studies. Lee et al. (2003) carried out a longitudinal study on the outcome of 55 extruded incisors with a mean follow-up of 1,320 days, and found pulp necrosis the most common healing complication. Overall 43% of the sample had evidence of pulp necrosis which was more frequently found in more severely intruded teeth, although this association was not found to be significant. On the other hand, pulp canal obliteration was present in 35% of the teeth where this healing complication was significantly related to the severity of the injury. In particular, teeth with mild extrusion ($\leq 2\text{mm}$) were nearly threefold more likely to be diagnosed with pulp canal obliteration than teeth with severe extrusion ($> 2\text{mm}$). This was explained by the fact that teeth with severe extrusion are more likely to sustain complete severance of pulpal vasculature and become necrotic compared to those with mild extrusion. In addition, Humphreys et al. (2003) studied 72 teeth and reported that 43% of the sample showed evidence of pulp necrosis. This healing complication was significantly more common in teeth with closed apices and in severely intruded teeth ($> 3\text{mm}$).

1.10.3 Treatment delay

Humphreys et al. (2003) also investigated the effect of treatment delay of repositioning since trauma on healing. Minimal delay was categorised as a delay of less than 3 hours where as significant delay was defined as delay of more than 3 hours. It was concluded that the delay in repositioning did not affect the development of pulp necrosis.

1.10.4 Associated crown fracture

It has been well established in the literature that successful pulp healing following injury is critically dependant on the absence of bacteria within the root canal. Therefore, a concomitant crown fracture with exposed dentinal tubules may represent a way for bacteria to gain access to the injured pulp, leading to pulp revascularisation failure. This theory was investigated by Lauridsen et al. (2012a) who examined 25 extruded teeth with concomitant crown fracture without pulp exposure. In this study, it was concluded that the overall risk of pulp necrosis increased from 56.5% to 76.5% in teeth with mature root development, although this was not statistically significant.

Table 4 on the next page summarises the studies of extrusion on healing complications and survival.

Table 4: Summary of studies on extrusion injury

Study	Teeth	Predictor	Pulp necrosis	Pulp canal obliteration	Root resorption	Survival
Andreasen and Pedersen (1985)	5		14 (26%)	24 (45%)		53/53
	33	Open ap.	3 (9%)	20 (61%)	4 (12%)	
	20	Closed ap.	11 (55%)	4 (20%)	4 (20%)	
Humphreys et al. (2003)	72		31(42%)	n/a	IRR	72/72
	36	Open ap.	9		11(15%)	
	36	Closed ap.	22			
		Moderate	15			
		Severe	16			
Lee et al. (2003)	55		23(42%)	19 (35%)	IRR 3 (6%)	54/55
		Immature	11	16		
		Mature	12	3		
		Mild	6			
		Severe	7			
Hermann et al. (2012)	82	Immature	n/a	n/a	IRR 1	82/82
		Mature			IRR 2 SR 6 MBL 7	

Key of Table 4: IRR= Infection related resorption, SR=Surface resorption, MBL=Marginal bone loss, open ap.= open apex, closed ap.=closed apex, n/a=not applicable.

1.11 Lateral Luxation

Lateral Luxation is described as an injury that results in disruption of the neurovascular blood supply at the apex of the tooth and severance of the periodontal ligament combined with a fracture of either the labial or palatal/lingual alveolar bone. Tissue compression will typically occur in the cervical part of the root and in the apical area where the apex of the tooth is displaced into the bone (Andreasen et al., 2013). Its frequency has been found to be 11% among traumatised teeth examined at a major trauma centre (Borum and Andreasen, 2001).

Clinically the tooth is immobile due to its bony lock and percussion produces a high metallic sound. On radiographic assessment, a laterally luxated tooth shows an increased periodontal space apically when the apex is displaced labially (Andreasen et al., 2011).

The aim of treatment of laterally luxated teeth is to establish reorganisation and reestablishment of the periodontal fibres and pulpal revascularisation. In teeth with immature root development, this can either occur by ingrowth of new blood vessels into the pulp chamber or by end-to end anastomoses of the blood vessels in the apical area. On the other hand, for teeth with mature root development, this healing process is affected by the small contact area between the ischaemic pulp and the periodontal tissue (Lauridsen et al., 2012a). The International Dental Traumatology guidelines (IADT) 2012 suggest that a lateral luxated tooth should be repositioned either digitally or using a forceps into its correct position. The tooth should then be stabilised for 4 weeks using a flexible splint (DiAngelis et al., 2012). It is thought that repositioning is usually forceful and therefore a traumatogenic procedure. This is because this type of luxation is characterised by the forceful displacement of the root tip through the facial alveolar wall, where the tooth needs to be dislodged and then manoeuvred apically into the correct position (Lauridsen et al., 2012a). As part of their management, the pulpal and the periodontal condition of these injured teeth should be monitored closely (DiAngelis et al., 2012).

The literature search revealed only a few studies that have assessed the prognosis of laterally luxated teeth and the factors that may affect the outcome of these injuries.

1.11.1 Stage of root development

Similar to the other two luxation injuries, the stage of root development appears to influence both pulpal and periodontal healing in laterally luxated teeth. It is well established in research that immature teeth have superior healing potential compared to mature teeth. As part of a large multivariate analysis performed by Andreasen and Pedersen (1985), a total of 122 laterally luxated teeth were examined. In this study, it was reported that laterally luxated teeth with closed apices were significantly more likely to develop pulp necrosis than those with immature apices. More specifically, it was found that almost 75% of laterally luxated teeth with closed apices became necrotic within the first year following the injury (Andreasen and Pedersen, 1985). In addition, the pulp survival of these injured teeth was determined over a 10 year period, where it was estimated that immature teeth had a survival of 91%, compared to the 23% survival of mature teeth. While pulp necrosis was rare in teeth with open apices, pulp canal obliteration was a frequent sequela in which revascularisation occurred, compared to teeth with closed apices (Andreasen et al., 1987, Andreasen et al., 2011). Ferrazzini Pozzi and Von Arx (2008) also examined 47 laterally luxated teeth over a period of four years and reported that none of the teeth with open apices showed any healing complications. Instead, the most frequent complication was pulp necrosis and it was only found in teeth with closed apices.

In addition, as a result of the compression of periodontal ligament, both inflammatory and replacement resorption can occur but it has been stated in several studies that these are rare healing complications (Andreasen et al., 2011). However, if seen, replacement root resorption tends to be located at the cervical region where the compression zones are located.

On the other hand, surface resorption has been found to be a common healing presentation, where it is said to occur more often in mature teeth rather than immature teeth. Hermann et al. (2012) carried out a longitudinal cohort study on 179 laterally luxated teeth and reported a significantly higher risk of repair related resorption in teeth with mature root development (29.5%) rather than immature development (2.1%). In addition, all cases of repair related resorption were located in the apical part of the root and manifested as a slight rounding of the apex. This typical location of repair related resorption is explained by the theory that during lateral luxation the apex of the tooth is forced through the labial bone plate causing the apical PDL and blood vessels to be traumatised. On the other hand, replacement root resorption and marginal bone loss presented only in mature teeth.

Overall, based on research conducted by Andreasen and Pedersen (1985) periodontal healing was estimated to be achieved for 91% of teeth with open apices over a 10 year period, compared to the 61% of teeth with closed apices (Andreasen et al., 2013).

1.11.2 Degree of lateral luxation

The degree of lateral luxation has not been studied thoroughly as only a few studies reported the coronal displacement of the injured teeth. A retrospective study performed by Nikoui et al. (2003), evaluated the outcome of 58 permanent laterally luxated incisors with a mean follow up of four years. The degree of lateral luxation was categorised as mild if $\leq 2\text{mm}$ and severe if more than 2mm. In this study, both pulp canal obliteration and pulp necrosis were two common healing complications. However, neither the stage of root development nor degree of lateral luxation were significantly associated with the two healing outcomes (Nikoui et al., 2003).

1.11.3 Associated crown fracture

Additionally, the impact of concomitant injuries on the outcome of lateral luxated teeth has also been recorded in the literature. Lauridsen et al. (2012a) examined the influence of a crown fracture without pulp exposure on the risk of pulp necrosis in 33 teeth with lateral luxation. In this study, it was found that a concomitant crown fracture injury can significantly increase the risk of pulp necrosis. This hypothesis was explained by the assumption that bacteria can get access to the injured pulp through the exposed dentinal tubules of a crown fracture. More specifically, for teeth with immature root development the risk increased from 4.7 to 40%, where-as for teeth with mature development, the risk increased from 65.1% to 93% at 12 months following the injury (Lauridsen et al., 2012a). However, the limitations of this study were stated due its small sample size, three different crown fracture injuries were combined into one group and treatment delay was not examined as a possible confounder.

Table 5 on the next page summarises the studies conducted on lateral luxation including the incidence of healing outcomes in relation to some predictors.

Table 5: Summary of studies on lateral luxation injury

Study	Teeth	Predictor	Pulp necrosis	Pulp canal obliteration	Root resorption	Survival
(Andreasen and Pedersen, 1985)	122		71 (58%)	34 (28%)		n/a
	34	Open ap.	3 (9%)	24 (71%)	3 (9%)	
	88	Closed ap.	68 (77%)	10 (11%)	34 (39%)	
Nikoui et al. (2003)	58		23 (40%)	23 (40%)	n/a	58/58
		Immature	3	6		
		Mature	20	17		
Lauridsen et al. (2012a)	179			n/a	n/a	n/a
	48	Immature				
	5	Fracture	2 (40%)			
	43	No fracture	2 (4.7%)			
	131	Mature				
	28	Fracture	26 (93%)			
	103	No fracture	67 (65%)			
Hermann et al. (2012)	179		n/a	n/a		179/179
	48	Immature			SR 1,IRR 1	
	131	Mature			SR 37 IRR 2 RRR 1	

Key of Table 5: open ap.=open apex, closed ap.=closed apex, SR= Surface Resorption, IRR=Infection Related Resorption, RRR=Replacement Root Resorption, n/a= no information given in study.

1.11.4 Treatment delay

It is thought that a definite relationship between treatment delay of both laterally luxated and extruded teeth and occurrence of healing complications is as yet uncertain (Andreasen et al., 2002). In a study of 189 injured teeth, Andreasen (1970) found that periodontal healing was negatively influenced by a treatment delay of 5 hours or more. However, this study included all luxation injuries grouped as one category of luxation injury.

1.11.5 Type and duration of splinting

The type and duration of splinting had been studied as possible treatment variables to affect the healing outcome of traumatised teeth. As part of an evidence-based appraisal review paper, Kahler and Heithersay (2008) evaluated 12 clinical studies and concluded that the overall healing outcome and prognosis of traumatised teeth was determined by the type of injury rather than the type of splint or fixation period. However, this study included not only luxated teeth but also avulsed and root fractured teeth. Similarly, the International Traumatology Guidelines 2012 also supported that neither a specific type of splint nor the duration of splinting were significantly related to healing outcomes such as external root resorption and dento-alveolar ankylosis. Based on the available evidence, it has been recommended to utilise a non-rigid splint for a short period of time, where laterally luxated teeth should be splinted for a period of four weeks. It is therefore best practice to reposition the tooth to its correct position, provide patient comfort and improve function (DiAngelis et al., 2012).

1.12 Non-vital Immature teeth

The incidence of loss of vitality of immature permanent incisors due to trauma has been reported to be around 6% (Mackie, 1998). It is thought that the necrotic pulp acts as an irritant to the peri-apical tissues. It is known that bacteria in the root canal system are the main cause of apical periodontitis. In order to achieve healing of the periodontal tissues and thus maintain the traumatised immature teeth for as long as possible, a complete root canal treatment is required (Bakland and Andreasen, 2012).

It is well established that the endodontic treatment of immature permanent incisors is a challenging task for clinicians. Teeth present with wide open apices, large canals and lack of an apical stop complicate the obturation procedure. In addition, immature teeth have thin dentinal walls of the root canals making them more prone and liable to fracture, even under normal physiological forces (Al Ansary et al., 2009). Following establishment of an accurate diagnosis of pulp necrosis, the aim of treatment is to eliminate bacterial infection from the root canal and prevent re-infection of the root canal space by providing conditions conducive to healing of the periapical tissues (Mackie, 1998).

1.12.1 Apexification in non-vital immature teeth

Apexification has been defined as a method used to induce a calcified barrier to act as an apical stop in immature permanent teeth with open apices where a root canal material can be condensed preventing its extrusion beyond the apex into the surrounding tissues (Rafter, 2005). Numerous materials have been proposed in the literature to allow root-end induction in immature teeth. For many years, calcium hydroxide has been known to be the most widely used material to successfully achieve an apical barrier in immature teeth. However, in recent years a lot of interest has been centred on the use of MTA in apexification and many clinicians have now drifted in using this material instead (Bakland and Andreasen, 2012).

1.12.1.1 Calcium Hydroxide

Apexification using calcium hydroxide was firstly introduced by Frank (1966) and has been widely used ever since.

Clinical and experimental studies have demonstrated the effect of calcium hydroxide on peri-radicular healing of necrotic immature teeth. Peri-radicular healing has been shown to be dependent on the antibacterial properties of calcium hydroxide to eliminate the root canal microflora and arrest inflammatory root resorption (Barnett, 2002). In addition, similar to the hard tissue barrier formed during pulpotomy, calcium hydroxide induces the formation of a hard tissue barrier when placed apically during apexification. This mineralised barrier has been described as osteodentine or cementum-like hard tissue (Barnett, 2002, Bakland and Andreasen, 2012). It is believed that the success rate of calcium hydroxide to achieve peri-apical healing and formation of a peri-apical barrier has been reported to range between 77%-98%, with an average of 95% (Vojinović, 1981, Mackie et al., 1988, Cvek, 1992).

Apexification with calcium hydroxide has enjoyed good success; however the disadvantages of using calcium hydroxide have been highlighted in various studies. Firstly, the apexification procedure may take many months and require multiple visits over a long period of time, making patient compliance a problem (Sarris et al., 2008). It has been suggested that the time required to form a calcific apical barrier ranges from between 6 and 18 months, with an average of 9 months (Kinirons et al., 2001, Yassen et al., 2012). In addition, it is well documented in the literature that the long term application of calcium hydroxide can weaken the dentine and increase the risk of root fracture. A number of *in vitro* experiments have showed a reduction in the mechanical properties of radicular dentine after exposure to calcium hydroxide for 5 weeks or longer (Yassen and Platt, 2013). For example, Twati et al. (2009) examined 30 extracted premolar teeth and found a significant reduction in the hardness of dentine with increasing periods of calcium hydroxide application. The main reason for this could be attributed to the proteolytic capacity of calcium hydroxide in the denaturation and dissolution of dentinal protein (Twati et al.,

2009, Andreasen et al., 2013). In a 4-year retrospective clinical study evaluating the prognosis of luxated non-vital immature teeth treated with calcium hydroxide, Cvek (1992) reported a 40% cervical root fracture amongst 397 immature teeth. Furthermore, the prognosis may be further compromised by the presence of numerous vascular channels in the hard tissue bridge and temporary coronal seal resulting in microleakage (Sarris et al., 2008). In addition, a recent systematic review of randomised controlled trials assessing the success of calcium hydroxide, only found two studies that met the inclusion criteria. However, both studies had short term follow-up of patients. It can therefore be concluded that there is a weak unreliable evidence to support the use of calcium hydroxide in multi visit apexification of traumatised necrotic immature anterior teeth and more research should be carried out on this topic (Al Ansary et al., 2009).

1.12.1.2 Mineral Trioxide Aggregate (MTA)

The properties of MTA and its use in vital pulp therapy have been described earlier in section 1.7.2. Apart from this clinical application, it is believed that the qualities of MTA make it a suitable material for creating an apical barrier in immature teeth prior to obturation.

The success of this material is possibly related to the combination of a bacteria seal in the apical foramen of the root canal as well as the extraordinary cementum and PDL inducing potential of MTA (Bakland and Andreasen, 2012). A recent review article described the mechanism of action of MTA on pulpal and periodontal tissues when placed apically. It is thought that following placement, MTA immediately releases calcium ions activating cell attachment and proliferation in an antibacterial environment due to its high pH (Parirokh and Torabinejad, 2010a). Furthermore, MTA activates cytokine production and encourages differentiation and migration of hard tissue producing cells whereby hydroxyapatite is formed on the MTA surface and a biological seal is created (Parirokh and Torabinejad, 2010a). Another advantage of MTA is its ability to

reduce the treatment time to induce the apical barrier. Compared to calcium hydroxide, an apical barrier using MTA can be induced in a single visit.

Several clinical studies have demonstrated the success of periapical healing following treatment with MTA in immature teeth with pulp necrosis. Sarris et al. (2008) evaluated the success rate of a single visit apexification in 17 non-vital immature teeth with a mean follow-up of 12.5 months. In this study, a clinical success of 94% and a radiographic success of 76% were found. Similarly, Simon et al. (2007) examined the outcome of MTA apical barrier in 57 immature teeth with a follow-up between 6 and 36 months. It was found that 81% of the cases had a reduction in the size of pre-operative peri-apical lesions. Overall based on published data, the success rate of MTA in the treatment of non-vital immature teeth is on average 89% with a range between 77-100% (Bakland and Andreasen, 2012).

In addition, the use of MTA in the apexification procedure has been compared to the gold standard, calcium hydroxide. A systematic review found only two studies which met their inclusion criteria and it was concluded that either calcium hydroxide or MTA may be used for the apexification of immature non-vital teeth, as both can be equally successful. However this review stated that there was a limited body of clinical studies in the literature in order to make clear conclusions (Chala et al., 2011). On the other hand, a recent randomised control trial compared the use of calcium hydroxide and MTA in two groups of 15 patients. Results showed that at 12 months follow-up the MTA group displayed better results in terms of apical closure and four out of the 15 calcium hydroxide teeth exhibited coronal or radicular fractures. It was therefore concluded that apexification using MTA seems to be preferable to calcium hydroxide to achieve the apical barrier but also to limit the risk of root fracture (Bonte et al., 2015). However this study was based on a small sample size with a follow-up of only up to one year. Therefore, it can be concluded that there is a need for long term clinical studies with large sample sizes to demonstrate the effectiveness and safety of MTA over calcium hydroxide.

Despite the high success rate of using MTA in inducing an apical barrier, some drawbacks of this material nevertheless have been highlighted in the literature.

One concern has to do with whether or not MTA exerts the same weakening effect upon dentine as calcium hydroxide. This is because 66% of MTA is made up of calcium hydroxide and has a similar pH to calcium hydroxide. An *in vitro* study reported that following application of MTA, a high pH level was maintained in the root canal for many months compromising the structural strength of dentine (White et al., 2002). Other drawbacks of MTA include its discolouration potential, presence of possible toxic elements in the material composition, difficult handling characteristics, its high material cost and the difficulty of removal after curing (Parirokh and Torabinejad, 2010b).

1.13 Factors Affecting the Endodontic Treatment Success

Several studies have been carried out with the objective to determine the success and/or failure of endodontic treatment. In addition, some of these studies have investigated the factors that may affect the outcome of root canal treatment. It is important to mention that different studies have used different criteria and methodologies to determine the success of endodontic treatment, therefore making comparison between studies not always possible.

In histological terms, endodontic success has been defined as complete repair of periapical tissues without the presence of inflammatory cells (Abbott, 1991). On the other hand, the treated tooth should be evaluated clinically through the absence or presence of any symptoms and by analysing the radiographic findings at the recall visit (Loest, 2006, Chandra, 2009).

In general, periapical healing after treatment and obturation with various filling materials has been reported in clinical studies to range between 76-91% (Cvek, 1992, Çahşkan and Şen, 1996). One material that has been extensively studied as an intra-canal medicament is calcium hydroxide, the properties of which have already been described. Its use as an initial dressing prior to obturation with a filling material, has shown a high frequency of periapical healing (Morfis and Siskos, 1990, Cvek, 1992). Cvek (1992) treated 885 luxated non vital incisors with calcium hydroxide and reported that 95% of these teeth showed signs of

periapical healing. In addition, 193 teeth had radiographic evidence of infection related resorption where during treatment with calcium hydroxide the resorption was arrested in 182 teeth (97%) (Cvek, 1992).

Furthermore, the use of gutta-percha as a filling material has been well established in the literature. In the study of Cvek (1992), teeth filled with gutta-percha were reviewed four years later and the periapical status of these obturated teeth remained unchanged in 92% of cases irrespective of root development. It can be concluded that a high frequency of long-lasting periodontal healing can be achieved by utilising gutta-percha following chemo-mechanical debridement of the root canal system (Barnett, 2002).

The presence or absence of pre-operative periapical pathology prior to root canal treatment has been studied as a factor that could affect the success of endodontic treatment. The presence of periapical lesions invariably implies that there is chronic infection in the root canal system (Chandra, 2009). A systematic review conducted by Ng et al. (2008) reported that the success rate of endodontic treatment were decreased between 9-13% when a radiograph shows signs of a periapical lesion. This is because anaerobic bacteria are found in infected canals which are more difficult to destroy during debridement. On the other hand, researchers did not find a significant difference between the size of the periapical lesions and the success rates of endodontic treatment (Ng et al., 2008).

In addition, it is well established that the quality of the root filling is an important factor affecting the endodontic success. The radiographic presence of voids in the root canal filling material has been shown to significantly lower success rates than those with a homogeneous root canal filling. In particular, Ng et al. (2008) stated a 25.9% reduced chance of success in root treated teeth presenting with inadequate endodontic fillings radiographically.

Furthermore, the effect of the length of the root canal filling material upon the endodontic success has been researched extensively in the literature (Chandra, 2009). Most studies categorise the length of the root canal filling as flush (0-2mm within the radiographic apex), short (more than 2mm above the radiographic apex) and long (beyond the radiographic apex). It is currently

indicated that flushed root canal fillings are associated with the highest success rates compared with long or short fillings, as there is a reduced likelihood of microbial leakage (Ng et al., 2008)

The quality of coronal restorations has also been reported as an important factor affecting the rates of success of endodontic treatment. Ray and Trope (1995) examined 1,010 teeth following root canal treatment and reported that the absence of peri-radicular inflammation was 11 times greater in teeth which had adequate coronal restorations placed, emphasising the importance of the coronal seal in the endodontic success. On the other hand, Tronstad et al. (2000) stated that the quality of endodontic treatment as judged radiographically was significantly more important than the quality of the coronal restoration when evaluating the periapical status of treated teeth.

Finally, the follow-up period appears to affect the success rate where any radiographic changes will not be evident before 6 months post-obturation. It is thought that most of the unsuccessful cases reported in the literature, were identified within two years of treatment (Basmadjian-Charles et al., 2002). On the other hand, the European Society of Endodontology Guidelines 2006 suggested that root canal treatment should be assessed at least after one year and subsequently as required (Loest, 2006).

It can be concluded that most of the studies evaluating the factors affecting the success rate of endodontic treatment were carried out on an adult population. In addition, the research to date on dental trauma has tended to focus on the factors that affect the pulpal and periodontal healing outcomes with a limited number of reports evaluating the endodontic treatment success rate following trauma in children.

1.14 Rationale of the study

The literature review conducted has shown that most of the research available looking at the factors affecting the outcome of the treatment of these injuries is of a short term nature. There is therefore a need to study the factors that have an important bearing on the treatment of these injuries, in the long term. The trauma clinic in the Leeds Dental Institute has been providing care for children with dental trauma for several years. It was felt that we should carry out research on the possible data sets that are available through the trauma clinic. Many studies have reported the effect of certain prognostic factors on various types of injuries, but there is still a need for a systematic study of these factors. New statistical models are now available which allow a better insight into the influence of trauma related factors on the long term outcome of traumatic injuries. We felt that through univariate analysis and multivariate analysis we could generate information that would add to the literature on this subject.

Limited studies have reported the final outcome of teeth that have suffered complicated crown fractures and luxation injuries, including intrusion, extrusion and lateral luxation, following root canal treatment. Also, the effect of the quality of obturation on the outcome i.e. endodontic success of traumatised teeth has seldom been reported.

Chapter Two

Aims and Hypothesis

2.1 Aims

- Identify the prognostic factors, which affect the outcome (success and failure) of four traumatic injuries of permanent teeth in children and adolescents treated at the Leeds Dental Institute (LDI) during the period of 2003-2013. The injuries included were intrusion, extrusion, lateral luxation and complicated crown fracture.
- Determine the success of traumatised permanent teeth with these four traumatic injuries.

2.2 Research Questions

The study has two defined questions that should be answered on completion. The questions are:

- What are the prognostic factors that affect the success of traumatic injuries; luxation injuries (lateral luxation, intrusion, extrusion) and complicated crown fractures?
- What is the success of teeth with these injuries?

2.3 Null Hypothesis

The null hypotheses for this study are:

- Severity of injury, stage of root development at the time of injury, time since trauma, time from trauma to tooth repositioning, method of repositioning, duration of splinting, time of pulp extirpation and quality of root canal obturation have no effect on the overall success of luxation injuries (Intrusion, lateral luxation, and extrusion).
- Time since exposure of pulp to treatment, stage of root development at time of injury, type of initial treatment provided and quality of root canal obturation have no effect on the overall success of complicated crown fractures.

Chapter Three

Materials and Methods

3.1 Ethical Approval

Full ethical approval was obtained from the local Dental Research Ethics Committee (DREC) at the Leeds School of Dentistry (Appendix 1), Faculty Sponsorship Review (Appendix 2), NHS Research Ethics Committee Service (Appendix 3) and by Research & Innovation (Appendix 4).

3.2 Methodology for Sample Selection

3.2.1 Identification of the Sample

The study sample included patients treated within the Paediatric Department of Leeds Dental Hospital, who had sustained traumatic injuries leading to luxation, intrusion, extrusion or complicated crown fracture of anterior permanent tooth/teeth.

Data collected as part of a previous research project completed at the University of Leeds, was used to identify patients who had received treatment for the specific four injuries during the period 2003-2011 (Faridoun, July 2013). In addition, clinical notes of patients who visited the trauma clinic during the period 2011-2013 were screened in order to identify those patients who had one of the four injuries. These patients were usually referred to the trauma clinic from a general dental practitioner, the community salaried services or other specialist dentists. In addition, self-referred patients who attended the casual clinic as emergency cases were included.

3.2.2 Selection Criteria

3.2.2.1 Inclusion Criteria

- Clinical dental records of patients who had sustained traumatic injuries (intrusion, luxation, extrusion and complicated crown fracture) of at least one permanent tooth and visited the Leeds Dental Institute between June 2003 and June 2013.
- The follow-up period of the patients following trauma was for at least one year.
- Dental records of children with appropriate radiographs (at presentation and at least 1 year follow up)

3.2.2.2 Exclusion Criteria

- Patients who had sustained dental trauma but the follow-up period was less than one year.
- Dental records of children with inadequate dental injury information e.g. no radiographs available or missing information from clinical notes.
- Dental records of patients who were referred late to the Leeds Dental Institute with no information about the initial management of the injury.

3.3 Methodology for Data Collection

Data was collected retrospectively from the clinical dental records of paediatric patients at Leeds Dental Institute who were included in the study. The data was recorded on a data extraction proforma (Appendix 5), which was designed especially for this study.

3.3.1 Data recording methods

The data was extracted from the clinical dental records written by the clinicians who treated the patients. The trauma details, diagnosis and emergency treatment provided were obtained from the 'Trauma Sheet', which was completed on the patient's first visit. Consecutive treatment appointments were recorded. Clinical findings of the traumatised tooth or teeth were also studied at each visit. In addition, the pre-operative and post-operative radiographs available in the clinical records were evaluated.

The radiographs studied (peri-apical, upper or lower occlusal) were either available as films or in a digital form. All radiographs were made through the use of an x-ray radiation machine (Focus by Instrumentarium Dental, Nahkelanti, Finland). The film radiographs were taken with Kodak E-speed dental films (INSIGHT, Kodac, Rochester, NY) whereas the digital radiographs were taken with VistaScan digital plates (Dürr Dental AG, Germany). The films were processed in an x-ray processor machine (Velopex Extrac, Velopex International) using Velopex dental developer and fixer whereas the digital radiographs were processed with a VistaScan image scanner (Dürr Dental AG, Germany).

The conventional films were viewed under standardised conditions using a light box with fixed light intensity. Similarly, the digital radiographs were viewed in their original form under standardised conditions on the digital computer system available at the Leeds Dental Institute (Medical Imaging, PACS).

3.3.2 Information extracted from the clinical records

The following data was identified from the clinical dental records and recorded in the extraction proforma:

Patient demographic details

- Date of birth
- Gender

Trauma details

- Type of trauma
- Affected tooth/teeth
- Severity of luxation injury
- Age at trauma
- Date of trauma

Treatment details

- Date of presentation
- Date of treatment
- Date of repositioning and splinting
- Type of splint
- Date splint removed
- Type of initial treatment for complicated enamel fractures
- Date of pulp extirpation
- Date of obturation
- Total treatment period in months
- Total review period in months

The clinical examination details during review visit include:

- Patient's symptoms if any
- Soft tissue assessment i.e. abscess/swelling
- Tenderness to percussion or palpation
- Tooth mobility
- Discolouration of tooth if applicable
- Response to sensibility tests if applicable

The findings that were identified from comparing the pre and post-operative radiographs were as follows:

- The stage of root development of the traumatised tooth at the time of trauma
- Healing complication following trauma
 - Pulp: healing, peri-apical lesion, pulp canal obliteration
 - Periodontal: healing, root resorption
 - Root fracture
- Assessment of root development in immature teeth
- Quality of obturation
- Follow-up of healing complication post-obturation#

3.4 Data variables

The data variables were categorised into demographic factors, prognostic factors and final clinical and radiographic outcomes. In the case of complicated crown fractures, in addition to the final clinical and radiographic outcomes, an initial treatment outcome of the emergency pulp treatment provided was also assessed.

3.4.1 Prognostic Factors

For the purpose of this study, the four chosen injuries were categorised into two groups, luxation (periodontal) injuries and complicated crown fractures. The reason of grouping the luxation injuries was due to the presence of small sample size within individual injuries. Therefore common prognostic factors were chosen for the group of luxation injuries and specific prognostic factors for the complicated crown fractures. These factors have been identified as the most relevant prognostic factors reported in the literature, which affect the outcome of traumatised permanent teeth with these specific injuries. The prognostic factors were divided as trauma-related factors and treatment-related factors as shown below:

3.4.1.1 Luxation Injuries (Intrusion, Extrusion, Lateral Luxation)

Trauma related factors

- Severity of luxation injury (Extrusion and lateral luxation were dependent on clinician assessment while intrusion luxation were following BSPD Guidelines:
 - Mild (0-3mm in intrusion cases)
 - Moderate (3-7mm in intrusion cases)
 - Severe (more than 7mm in intrusion cases)
- Combination injuries
- Stage of root development at time of injury

Treatment factors

- Time since trauma and repositioning
- Method of repositioning
 - Passive (for intrusions)
 - Manual repositioning
 - Surgical repositioning
 - Orthodontic repositioning
- Duration of splinting
- Time of pulp extirpation
- Quality of root canal obturation

3.4.1.2 Complicated crown fractures

Trauma related factors

- Time since exposure of pulp to treatment
- Stage of root development at time of injury

Treatment factors

- Type of initial treatment provided:
 - Pulp capping
 - Partial pulpotomy (Cvek's pulpotomy)
- Quality of root canal obturation

3.5 Methodology for the Assessment of Variables

3.5.1 Types of Trauma

The types of Trauma including the presence of combination injuries were recorded from the clinical dental records. The clinicians who assessed the patients at their first visits clearly stated the types of trauma involved on the trauma sheet, which was available in the clinical dental records. Furthermore, valuable information was also obtained from referral letters sent by patient's family dentist who might have seen and assessed the patient first.

3.5.2 Severity of Trauma

Following our departmental policy, the severity of intrusion injury was recorded as per the classification stated in the British Society of Paediatric Dentistry Guidelines (BSPD) (Albadri et al., 2010). This Guideline classifies intrusion injury as mild < 3mm, moderate 3-6mm and severe > 6mm. However, there is no clear guidance on assessing the severity of lateral luxation and extrusion injury and therefore the assessment of the severity of these two injuries was subject to clinician's judgment.

3.5.3 Stage of root development

The stage of root development of the traumatised teeth at the time of trauma was assessed radiographically based on a previously described scale by Cvek (1992). Cvek 1992 classified the stage of root development of teeth into five groups, based on the width of the apical foramen and the length of the root. Teeth in Groups A-D were considered immature where-as the teeth in Group E were classified as mature teeth.

These five categories were defined as following:

- **Stage A:** Divergent apical opening and a root length estimated to less than $\frac{1}{2}$ of final root length.
- **Stage B:** Divergent apical opening and a root length estimated to be $\frac{1}{2}$ of the final root length.
- **Stage C:** Divergent apical opening and a root length estimated to be $\frac{2}{3}$ of the final root length.
- **Stage D:** Wide apical open foramen with nearly completed root length.
- **Stage E:** Closed apical foramen with completed root development.

Figure 1 below demonstrates the classification of the stage of root development of teeth by Cvek 1992.



Figure 1: Classification of stage of root development

For the purpose of this study, the classification was modified to further categorise groups A-C as very immature teeth, group D as immature and group E as mature group of teeth.

3.5.4 Quality of apical barrier

In the case of immature teeth, an apical barrier was created with the use of either calcium hydroxide or MTA. The quality of apical barrier was assessed radiographically by evaluating the peri-apical radiographs, which had been taken following the apical barrier formation. The quality of apical barrier was classified as being adequate or inadequate, based on previously described criteria by Sarris et al. (2008).

Therefore, the placement of apical barrier was considered adequate if:

- The apical plug corresponded to the radiographic apex, did not over-extend into the peri-apical area or appear to under fill the apical 3mm of the root
- There was no space between the material and the walls of the canal
- The apical barrier did not show any signs of displacement following final obturation of the canal as compared with the radiograph taken during the initial placement of the material
- There appear to be no leakage of sealing or obturation material into the peri-apical area.

3.5.5 Quality of Root Canal Obturation

Similarly, the quality of the root canal obturation was assessed radiographically by evaluating the post-obturation radiographs. The quality of obturation was classified as being either adequate or inadequate based on previously described criteria by Sarris et al. (2008).

The quality of obturation was recorded as being adequate if:

- There was no space between the root filling and the root canal walls
- There was no canal space visible beyond the end of the root filling

On the contrary, the quality of obturation was considered inadequate if:

- There was a space evident between the root filling and the root canal walls
- The root filling was over-extended through the apex
- The root canal was under filled as evident by a space of more than 2mm from the apex or between the end of root filling and the apical barrier if present.

In the case of immature root treated teeth, both the quality of apical barrier and obturation were assessed as described above and the results were grouped as one variable, quality of obturation. This was done in order to limit the number of prognostic factors in the statistical model and for easier interpretation of results.

3.5.6 Quality of coronal seal

The quality of the coronal seal was classified as being adequate or inadequate. The seal was considered adequate if two or more restorative materials were used in the final coronal restoration following obturation. This is in accordance to our Departmental protocol. From the clinical dental records, the types of

material used and documented by the treating clinicians were abstracted and the quality of coronal seal was categorised accordingly.

3.5.7 Clinical and radiographic Outcomes

For the case of complicated crown fractures, an initial treatment outcome following pulp therapy was recorded in order to assess the success or failure of the initial treatment provided. Furthermore, a final outcome was recorded for both complicated crown fractures and periodontal (luxation) injuries at the final review visit of the patient during the period the study was carried out. The final outcomes were assessed by evaluating both the clinical information provided in the notes and the radiographs. Therefore, a final clinical and radiographic outcome was recorded as either success or failure for all traumatised teeth based on pre-determined criteria. Separate pre-determined criteria were chosen to assess the outcome of teeth following the traumatic dental injury and the endodontic outcome of traumatised teeth that received root canal treatment as part of their management.

3.5.7.1 Clinical outcome

The dental records were thoroughly inspected to identify any clinical signs and symptoms that presented at the patient's follow-up visits such as:

- Patients dental history (history of pain or use of analgesics)
- Presence of sinus tract or abscess
- Tenderness to percussion
- Tenderness to palpation of the apical area
- Pathological mobility
- Response to sensibility tests if applicable
- Discolouration of tooth

In the cases where no details related to any of the above clinical signs were mentioned in the clinical dental records, it was assumed that the signs or symptoms were not present.

3.5.7.2 Radiographic outcome

Dental radiographs were examined and compared for signs of normal healing or evidence of periodontal and pulpal complications following the traumatic injury. Specifically, radiographs were examined by assessing the periodontal ligament space, pulp canal space and root development in immature teeth.

3.5.7.2.1 Diagnosis of pulpal and periodontal healing complications

The pulpal and periodontal healing complications were examined by assessing the pre-operative and post-operative radiographs as well as taking into account the clinical details of the teeth provided in the dental notes. The healing complications were recorded according to the criteria previously published in the literature (Andreasen et al., 2011):

Pulpal healing complications

- Pulp necrosis (with possible peri-apical pathology)
- Internal pulp resorption
- Pulp canal obliteration
- Transient apical breakdown
- Bone ingrowth in pulp

Periodontal healing complications

- Surface related resorption
- Infection related resorption
- Replacement root resorption

In the case of root treated teeth, the pre and post obturation radiographs were assessed and compared, to record the endodontic treatment outcome based on the criteria described by the European Society of Endodontology (Loest, 2006).

3.5.7.2.1.1 Pulp necrosis

The diagnosis of pulp necrosis was sometimes made by the clinician based on clinical signs such as patient's symptoms, discolouration of tooth or tenderness to percussion. Radiographic examination was not always initiated by the clinician but the diagnosis of non-vitality was recorded in the dental notes. In this case, the diagnosis provided by the clinician was recorded for the study. In addition, the date of pulp necrosis identified was recorded as when the clinician decided to intervene i.e. perform pulp extirpation.

3.5.7.2.1.2 Peri-apical pathology

Peri-apical pathology was identified radiographically as a peri-apical radiolucency with loss of lamina dura. The healing of peri-apical pathology following root canal treatment was also evaluated radiographically by comparing the pre-operative and post-obturation radiograph taken at the last review visit. Cases were considered as successful when there was a decrease in the size or diminished peri-apical lesion compared to the initial radiograph. Similarly, cases with a peri-apical lesion that remained the same size as the initial lesion were also considered successful. Finally the outcome of failure was recorded when there was an increase in the size of peri-apical lesions.

3.5.7.2.1.3 Pulp canal obliteration

Pulp canal obliteration was identified radiographically as loss of canal space. Clinical presentation of a yellow crown confirmed the diagnosis of pulp canal obliteration.

3.5.7.2.1.4 Transient apical breakdown

Transient apical breakdown was also identified radiographically as a temporary apical radiolucency. Disappearance of this radiolucent area at a review radiograph together with no signs of pulp necrosis confirmed the diagnosis of transient apical breakdown as part of healing.

3.5.7.2.1.5 Surface related resorption

If radiographically visible, the surface related resorption was also identified as localised areas along the root surface, which showed superficial resorption lacunae. This radiographic defect is bordered by a normal periodontal ligament and lamina dura.

3.5.7.2.1.6 Infection related resorption

Infection related resorption was diagnosed radiographically as a bowel shaped radiolucency on root surface and adjacent bone. Clinical signs of pulp necrosis also confirmed the diagnosis. The healing of infection related root resorption following obturation was also evaluated by comparing pre-operative and post-obturation radiographs. Cases were considered as successful when there was a decrease in the size or diminished infection related resorption compared to the initial radiograph. Similarly, stable infection related resorption was also

considered successful. On the other hand, progressive infection related resorption at the final radiograph was considered a failure.

3.5.7.2.1.7 Replacement related root resorption

Similarly, replacement root resorption was diagnosed radiographically as disappearance of the periodontal ligament space with replacement of root with bone. Clinical signs of ankylosis such as high metallic percussion sound, no or decreased mobility and evidence of infra-occlusion also confirmed the diagnosis. Due to the irreversible nature of replacement resorption, its presence was classified as failure.

3.5.7.2.1.8 Root development in immature teeth

The continuation of root growth in immature teeth was also assessed radiographically. The presence of continuation of root development with same length achieved as the contra-lateral tooth was considered as healing i.e. the tooth was vital. On the contrary, arrested root development in combination with clinical signs of pulp necrosis was considered as non-healing. In addition, as a result of a luxation injury, the root growth can be disturbed with the presentation of a deformed or shorter root. This presentation together with no clinical signs of pulp necrosis was considered as part of healing.

3.6 Summary of Definition of Outcome Measures

3.6.1 Criteria for survival

- The tooth was present in patient's mouth on the last visit.

3.6.2 Complicated crown fractures

3.6.2.1 Criteria for clinical success

- i. The tooth healed following initial treatment:**
 - Pain and disease free
 - Normal sensibility reaction
 - Normal tooth colour
 - No soft tissue pathology (abscess)
 - Not tender to percussion or palpation
 - Physiological tooth mobility
 - The tooth fully functional in mouth

- ii. The tooth healed following root canal treatment:**
 - Pain and disease free since endodontic management

3.6.2.2 Criteria for radiographic success

- i. The tooth healed following initial treatment:**
 - Absence of peri-apical pathology
 - Pulp canal obliteration
 - Normal periodontal ligament healing
 - Continued root development in immature teeth

- ii. **The tooth healed following root canal treatment:**
 - Resolution/decrease/stable existing periapical lesion
 - No new periapical pathology since treatment
 - Normal periodontal healing

3.6.2.3 Criteria for clinical failure

- i. **Tooth did not heal following initial treatment**
 - Pain (tooth is symptomatic)
 - Not responding to sensibility tests
 - Soft tissue pathology (abscess)
 - Tender to percussion or palpation
 - Presence of pathological abnormal mobility
 - Discolouration as a result of non-vitality
- ii. **The tooth did not heal following root canal treatment:**
 - Tooth is symptomatic since endodontic management

3.6.2.4 Criteria for radiographic failure

- i. **The tooth did not heal following initial treatment**
 - Presence of peri-apical pathology
- ii. **The tooth did not heal following root canal treatment**
 - Increase in size of the existing periapical lesion at review
 - Evidence of new periapical pathology

3.6.3 Luxation injuries

3.6.3.1 Criteria for clinical success

iii. The tooth healed following injury:

- Pain and disease free
- Normal sensibility reaction
- Normal tooth colour
- No soft tissue pathology (abscess)
- Not TTP
- Physiological tooth mobility
- The tooth fully functional in mouth

iv. The tooth healed following root canal treatment:

- Pain and disease free since endodontic management

3.6.3.2 Criteria for radiographic success

iii. The tooth healed following injury:

- Absence of peri-apical pathology
- Pulp canal obliteration
- Normal periodontal ligament healing with no signs of external root resorption
- Continued root development in immature teeth
- Disturbed /arrested root development but evidence of PDL healing
- Evidence of bone invasion through apex as part of healing

iv. The tooth healed following root canal treatment:

- Resolution/decrease/stable existing periapical lesion over time
- Resolution/decrease/stable existing infection related resorption
- No new periapical pathology since treatment
- No new external root resorption

3.6.3.3 Criteria for clinical failure

iii. Tooth did not heal following injury

- Presence of high metallic sound (ankylosis +/- infra-occlusion)
- Tooth is symptomatic

iv. The tooth did not heal following root canal treatment:

- Tooth is symptomatic since endodontic management

3.6.3.4 Criteria for radiographic failure

iii. The tooth did not heal following injury

- Evidence of replacement root resorption in luxated teeth

iv. The tooth did not heal following root canal treatment

- Increase in size of the existing periapical lesion
- Evidence of continuing infection related root resorption
- Evidence of new periapical pathology
- Evidence of new external root resorption (infection related or replacement resorption)

3.7 Intra-examiner Reliability

The clinical dental records were coded and then randomised utilising the 'Selection of random cases' feature of the SPSS Version 22 software. A random selection of 15% of cases was chosen. This equated to 22 clinical dental records. The clinical dental records and radiographs were reviewed at two separate occasions and results were obtained. More specifically, the radiographic assessment of stage of root development and quality of obturation together with the final clinical and radiographic outcomes were re-evaluated against the indices of the study. The kappa score for agreement of intra examiner reliability for the final outcomes was $\kappa=1.0$ which suggested total agreement. On the other hand kappa score for the stage of root development was $\kappa=0.93$ and for the quality of obturation was $\kappa= 0.77$ which suggests almost perfect agreement. In the case of uncertainty or any query in the clinical dental records or radiographs reviewed, the opinion of the second investigator (MSD) was sought and a common agreement reached.

3.8 Sample Size Calculation

The sample size for this study was based on the primary aim of the study. The primary aim was to identify the factors that influenced the outcome of the four types of traumatic injuries of permanent teeth. The primary outcome of interest was the final success of traumatised teeth.

It is worth noting that the majority of the trauma studies published in the literature concentrate on reporting the outcome of traumatised teeth following initial management of dental traumatic injury. In these studies, the outcome was categorised as success or failure based on the presence or absence of healing complications. The present study aim was to assess the final outcome of the traumatised teeth either those that healed at their initial management or those that received treatment following a healing complication. To our knowledge, no similar studies have reported the final outcome of traumatised teeth in the long term; therefore it was not possible to refer to a previous study for an estimate of sample size calculation.

However, it was possible to obtain an estimate of possible sample size that could be achieved for a 10 year period data. This was based on the data obtained from the previous research project completed at the University of Leeds where the following approximate number of teeth that had sustained the four types of traumatic injuries during the period of 2003-2011 was recorded (Faridoun, July 2013): Luxation Injuries (Intrusion, Extrusion, Lateral luxation): 130 and Complicated crown fractures: 153. In addition, we were expecting these numbers to increase by 10% for the additional two-year data 2011-2013.

While taking into consideration these approximate numbers, Peduzzi et al. (1996) stated that a valid regression model should have 10 events of failures per predictor. If we therefore consider luxation injuries and assuming a success rate of pulp healing at 42% (Andreasen and Pedersen, 1985), we expect the number of successes to be approximately 60 and failures 83. Therefore, the effective sample size will be 80 and the model will allow 8 predictors.

3.9 Statistical Tests

Statistical advice was obtained with regard to the statistical tools and tests required to analyse the data of the study.

All collected data were entered into SPSS (Statistical Package for Social Science, Version 22) for Windows (SPSS Inc. Chicago, IL) software to analyse the data. Initially, a series of descriptive statistics were performed on the data. Demographic and prognostic factors were displayed using graphic descriptive statistics, such as tables, bar and pie charts. Categorical variables were summarised using frequencies and percentage proportions. On the other hand, numerical variables were summarised with maximum and minimum values as well as means and standard deviations (SD).

In order to establish an association between the different prognostic factors with the clinical and radiographic outcomes, a univariate analysis was performed for luxations and complicated crown fractures. Following which, an attempt was made to conduct a multivariable logistic regression analysis to identify which prognostic factors remained significant when analysed in combination with each other. However, it was not possible to fit a model for the complicated crown fractures, due to the small sample size of the data. Therefore, a multivariable logistic regression analysis was completed only for luxation injuries. Nevertheless, only three predictors had sufficient data to fit the model. This was because missing data was encountered within the remaining predictors resulting in small numbers.

It is also important to note that the data in this study was not independent since some individuals had multiple teeth and multiple results from an individual were likely to be similar. In order to account for the lack of independence in the data, the univariate and the multivariable logistic regression analyses were conducted with robust errors. The lack of independence could also have been accounted for using a mixed model or a multi-level modelling approach but this approach was not used in this study because the sample sizes were too small.

Chapter Four

Results

4.1 Study sample

As already described in section 3.2.1, identification of clinical records of patients who had sustained a dental injury during the period of 2003-2011, was performed by extracting information from the previous research project completed at the University of Leeds (Faridoun, July 2013). For the period of 2011-2013, all the clinical dental records of patients who attended the trauma clinic were screened in order to identify patients who had sustained a dental injury suitable for this study.

Initially, a total of 620 clinical dental records of patients who attended the trauma clinic at the Paediatric Dental Department at Leeds Dental Institute during the period of 2003 and 2013 were screened. In total, 171 clinical dental records of patients were identified who had a relevant injury, but 63 of these had to be excluded due to inadequate records.

Table 6 summarises the reasons for exclusion of clinical records. Finally, 108 clinical dental records of children with 146 traumatised teeth met the inclusion criteria. The flowchart presented in Figure 2 shows the distribution of the sample.

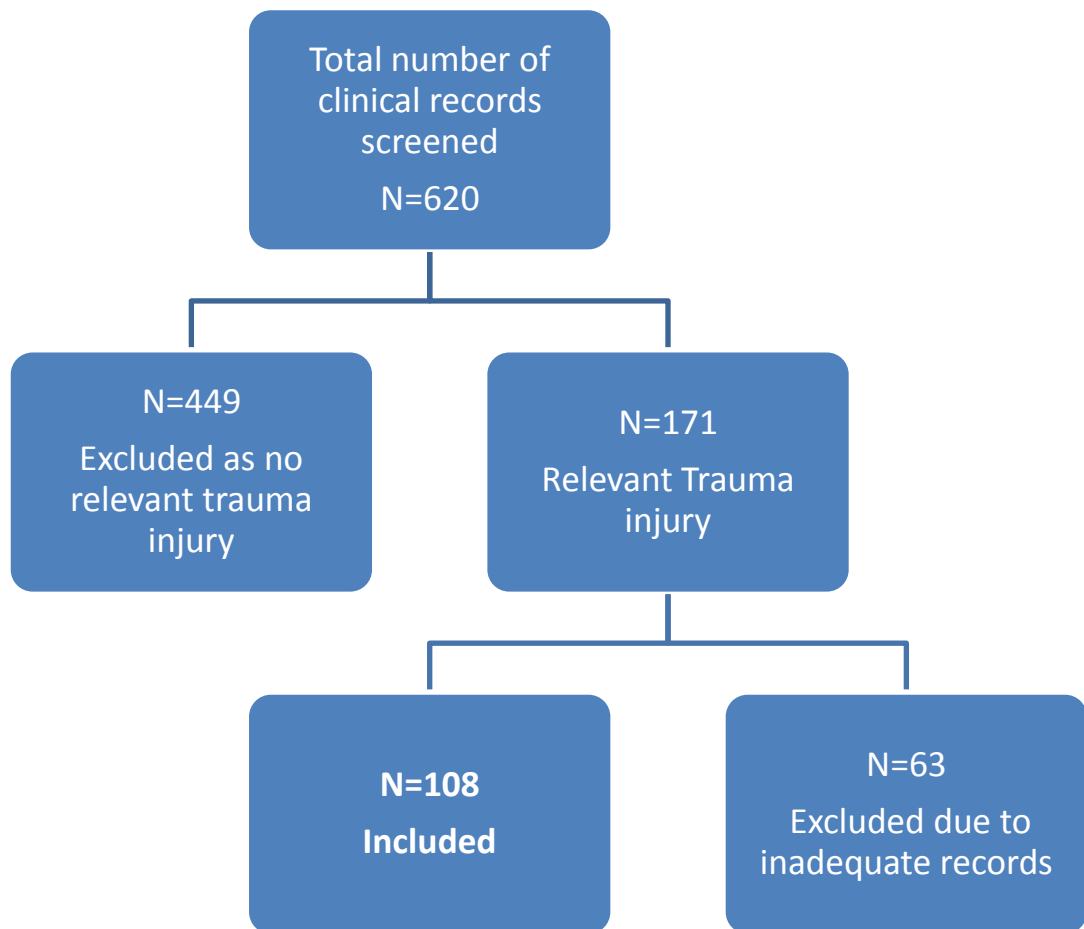


Figure 2: A flow chart showing the distribution of the sample

Table 6: Reason for exclusion of clinical records

<ul style="list-style-type: none"> • Follow-up less than 1 year
<ul style="list-style-type: none"> • No radiographs
<ul style="list-style-type: none"> • Patient presented late with no information on initial management of injury
<ul style="list-style-type: none"> • Inadequate information of the studied prognostic factors.

4.2 Descriptive Statistics

4.2.1 Demographic Factors

4.2.1.1 Gender

From the 108 patients included in this study 70 (64.8%) were males and 38 (35.2%) were females. In the group of luxation injuries, 49 (67.1%) were males and 24 (32%) were females. On the other hand in the group of complicated crown fractures, 21 (60%) were males and 14 (40%) were females.

4.2.1.2 Age at Trauma

The mean age of the patients was 10.3 years with a standard deviation of 2.6 years. The youngest patient was 6 years old and the oldest patient was 19 years old. In the group of complicated crown fractures, the mean age of patients was 10 years. Similarly, in the group of luxation injuries, the mean age was 10.32 years.

4.2.2 Trauma details

4.2.2.1 Teeth involved in Trauma

The maxillary central incisor was shown to be the most common tooth involved in both complicated crown fracture injuries and luxation injuries. The upper right central incisor accounted for 37.7% and the upper left central incisor accounted for 43.2% of the traumatised teeth. The rest of the traumatised teeth accounted individually for less than 8%. Table 7 summarises the frequency of the teeth involved in complicated crown fractures and luxation injuries.

Table 7: The frequency distribution of teeth involved in complicated crown fractures and luxation injuries

Tooth	Number	Percentage
UR2	11	7.5%
UR1	55	37.7%
UL1	63	43.2%
UL2	3	2.1%
LL2	3	2.1%
LL1	5	3.4%
LR1	2	1.4%
LR2	4	2.7%
Total	146	100.0%

4.2.2.2 Type of Trauma

Out of the four injuries which were selected for the purpose of this study, both the lateral luxation injury and complicated crown fractures were considered the most frequent injuries amongst this population, accounting for 30.8% and 29.5% of the sample respectively. The third most common injury was intrusion with a frequency of 26%. On the other hand, extrusion injury comprised only 13.7% of the sample. Table 8 shows the frequency of the four different types of trauma.

Table 8: The frequency of the four different types of trauma

Injury	Frequency	Percentage
Complicated crown fractures	43	29.5%
Lateral Luxation	45	30.8%
Extrusion	20	13.7%
Intrusion	38	26%
Total	146	100.0%

4.3 Complicated Crown Fractures

4.3.1 Time to initiation of treatment

The mean time elapsed from pulp exposure to treatment was found to be 1.44 days. The minimum time was recorded as day 0 i.e. the treatment was completed on the same day of the trauma whereas maximum time was 18 days following trauma.

4.3.2 Type of initial treatment received

It was observed that 51.2% (n=22) of teeth were treated with partial pulpotomy whereas 30.2% (n=13) of teeth were treated with pulp capping. On the other hand, 18.6% (n=8) of teeth were treated with pulpectomy as the first line of treatment at the time of the injury. Table 9 summarises the types of initial treatment performed.

Table 9: Types of initial treatment provided for complicated crown fractures

Type of treatment	Number	Percentage
Pulp capping	13	30.2%
Partial pulpotomy	22	51.2%
Pulpectomy	8	18.6%
Total	43	100.0%

4.3.3 Stage of root development

With respect to the stage of root development at the time of complicated crown fracture, it was observed that the majority of teeth comprising 58% of the sample (n=25) had a fully mature root. On the other hand, 10 teeth had a completed root with an open apical foramen (23.3%) while 7 teeth were classified as having 2/3 of root length. Only one tooth was found with less than $< \frac{1}{2}$ root length completion (2.3%) whereas none of the teeth had $\frac{1}{2}$ root length. In summary, 8 teeth (18.6%) were classified as very immature, 10 (23.3%) as immature and 25 (58.1%) as mature. Figure 3 summarises the distribution of the stages of root development for complicated crown fractures.

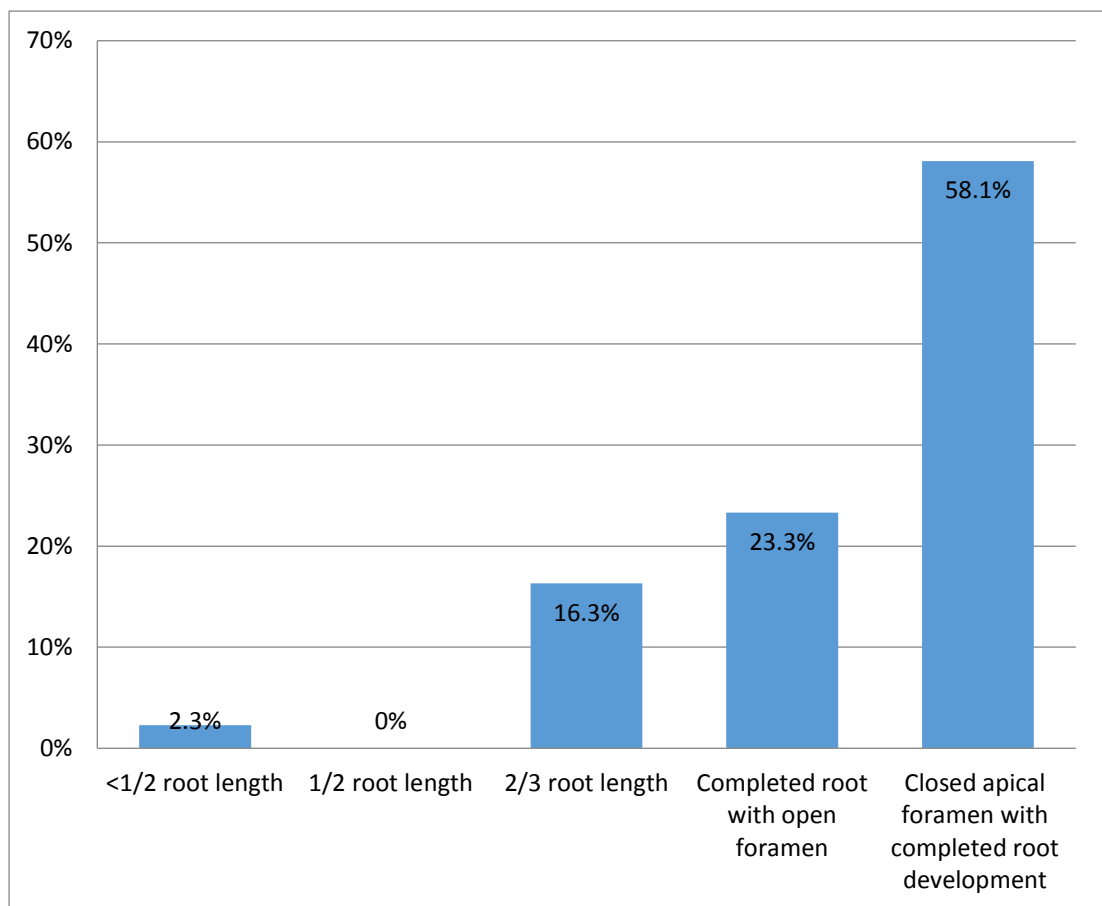


Figure 3: The distribution of the stage of root development for complicated crown fractures

4.3.4 Outcome of initial treatment provided

When pulp capping was provided as an initial treatment, only 15.4% (n=2) of the teeth were considered successful whereas the remaining 84.6% (n=11) failed requiring further treatment. On the other hand, partial pulpotomy was observed as successful in 54.5% (n=12) of teeth. Figure 4 below demonstrates the outcome of initial treatment provided for complicated crown fractures.

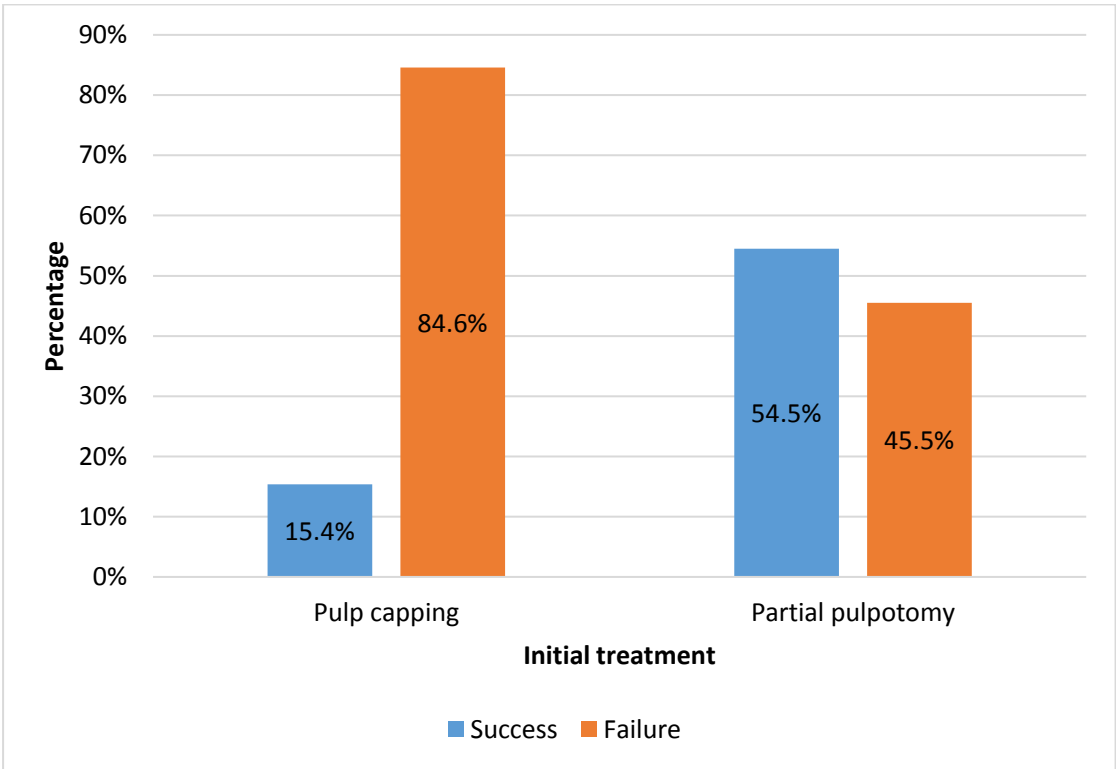


Figure 4: The outcome of initial treatment provided for complicated crown fractures

4.3.5 Root canal treatment received

Out of the 8 teeth that received pulpectomy, as an initial treatment method, 7 received completed root canal treatment as one tooth was lost prior to completion of full treatment. Together with these 7 teeth, the above 21 teeth that failed following either pulp capping or pulpotomy also received root canal treatment. Therefore in total, 28 teeth received complete root canal treatment.

4.3.5.1 Quality of obturation in root treated teeth

Results showed that quality of obturation was adequate in 67.9% (n=19) of cases. On the other hand, the quality of obturation was found to be inadequate in a third of the cases, compromising 32.1% (n=9) of the sample.

The main reason that the obturation was considered inadequate was due to the presence of obturation material beyond the apex. In addition, three teeth had short obturation material and only one case had voids and spaces between the root canal walls and obturation material. Figure 5 below demonstrates the quality of root canal obturation of complicated crown fractures.

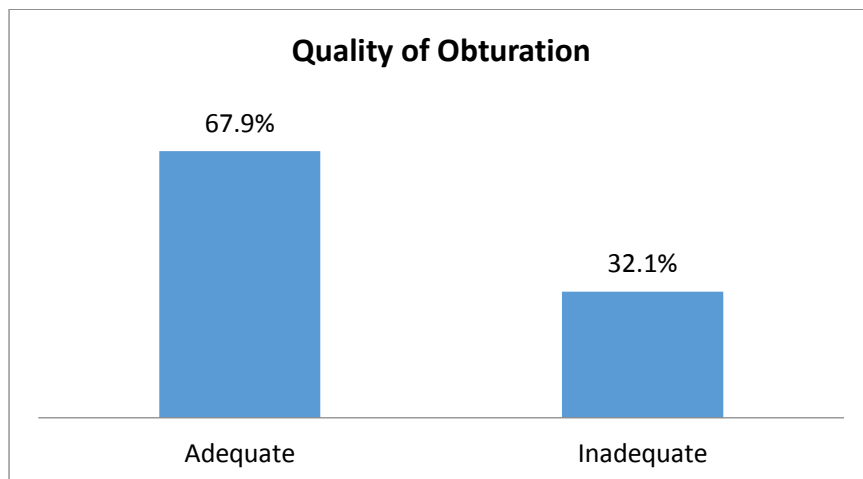


Figure 5: The quality root canal obturation of complicated crown fractures

4.3.5.2 Post-obturation clinical review period

The mean clinical review post-obturation period was 20 ± 21 months, with a minimum of 0 and a maximum of 74 months. This means that there were 8 teeth that received obturation on the last visit with no other follow-up. The median was 13 months.

4.3.5.3 Post-obturation radiographic review

Post-obturation radiographic review period was determined for 19 out of the 28 teeth that received root canal treatment. The remaining 9 teeth did not have a post-obturation radiograph. The mean period was 29 ± 28 months. The median was identified as 17 months with a minimum of 6 months and a maximum of 116 months.

4.3.6 Total treatment period since trauma

The mean treatment or review period since trauma to the last visit of the patient was 39 ± 29 months. The minimum period was 7 months and maximum 110 months. The median was identified as 28 months.

4.3.7 Final outcome

The final clinical and radiographic outcomes were classified as successful or failure according to criteria set out in Section 3.7. All 43 teeth were assessed for clinical success or failure. On the other hand, the final radiographic outcome was produced for 34 teeth. This is because 9 teeth did not have post-operative radiographs and therefore it was only possible to comment on the clinical outcome and not the radiographic outcome.

4.3.7.1 Final clinical outcome

It was found that 93% (n= 40) of the cases were considered clinically successful, whereas 7% (n=3) of teeth had failed (Figure 6).

4.3.7.2 Final radiographic outcome

It was observed that 85.3% of the 34 teeth (n=29) were radiographically successful. On the other hand, 14.7% (n=5) showed evidence of radiographic failure. The reason of radiographic failure was increased size of peri-apical radiolucency post-obturation. Figure 6 below illustrates the distribution of final clinical and radiographic outcomes for complicated crown fractures.

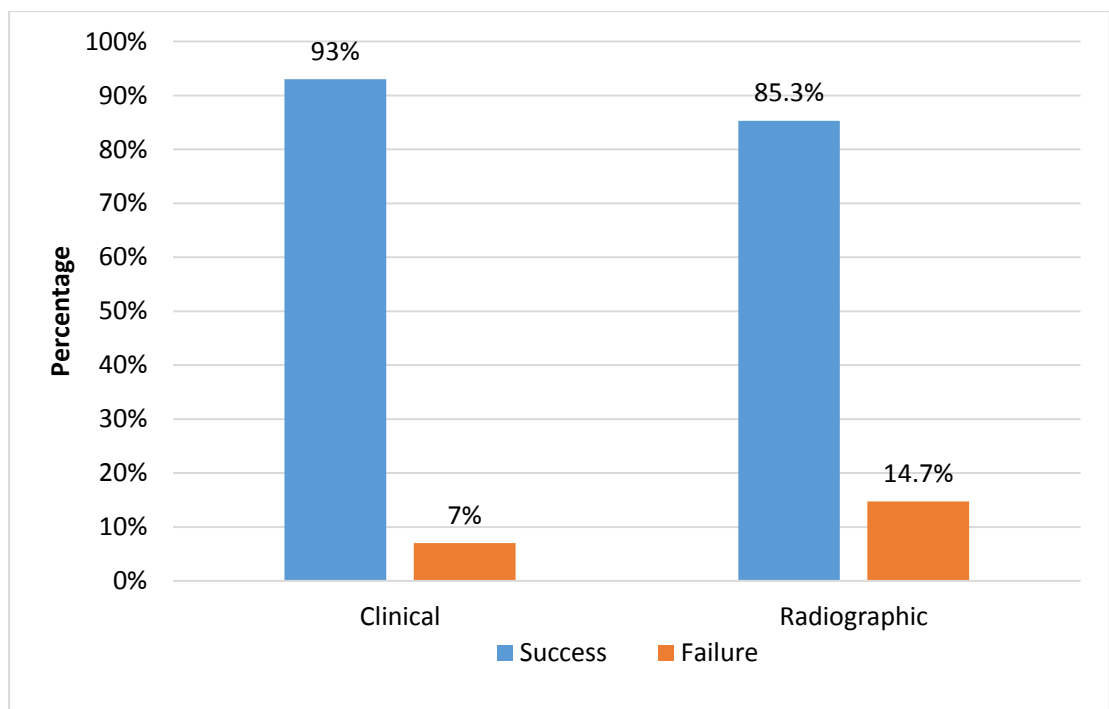


Figure 6: The distribution of final clinical and radiographic outcomes

4.3.7.3 Stage of root development and clinical outcome

The final clinical outcome for teeth with complicated crown fractures related to the stage of root development is presented below (Table 10). All the immature (Stage 4) and 96% of the mature (Stage 5) teeth were clinically successful. It was concluded that only two teeth with very immature stage of root development and only one mature tooth had signs of clinical failure.

Table 10: The final clinical outcome for teeth with complicated crown fracture in respect to the stage of root development

Stage of root development	Final clinical outcome		Total
	Failure Number (%)	Success Number (%)	
Very immature (Stage 1-3)	2 (25%)	6 (75%)	8
Immature (Stage 4)	0 (0%)	10 (100%)	10
Mature (Stage 5)	1 (4%)	24 (96%)	25
Total	3/43 (7%)	40/43 (93%)	43 (100%)

4.3.7.4 Stage of root development and radiographic outcome

When radiographic success was correlated with the stage of root development (Table 11), it can be seen that all the immature (Stage 4) and 85% of the mature teeth (Stage 5) that had suffered a complicated crown fracture were radiographically successful. In total, only five teeth showed signs of failure where 3 of these teeth were categorised as mature and the remaining two as very immature.

Table 11: The final radiographic outcome for teeth with complicated crown fracture in relation to the stage of root development

Stage of root development	Final radiographic outcome		Total
	Failure Number (%)	Success Number (%)	
Very immature (Stage 1-3)	2 (29%)	5 (71%)	7
Immature (Stage 4)	0	7 (100%)	7
Mature (Stage 5)	3 (15%)	17(85%)	20
Total	5 (15%)	29 (85%)	34

4.3.7.5 Quality of obturation and radiographic outcome

In addition, a greater proportion of teeth with adequate obturation (91%) were radiographically successful in comparison to the 62.5% of teeth with inadequate obturation (Table 12).

Table 12: The final radiographic outcome for teeth with complicated crown fracture in relation to the quality of obturation

Quality of obturation	Final Radiographic Outcome		Total
	Failure Number (%)	Success Number (%)	
Adequate	1 (9.1%)	10 (91%)	11
Inadequate	3 (37.5%)	5 (62.5%)	8
Total	4 (21.1%)	15 (78.9%)	19 (100.0%)

4.3.8 Survival

Only one tooth that sustained complicated crown fractures did not survive. In this case, the tooth was lost as a result of a root fracture.

4.4 Luxation injuries

4.4.1 Severity of injury

The severity of injury was only recorded for 34 out of the 103 teeth (33%) that sustained a luxation injury with the remaining 69 teeth (67%) not having any information on the severity of the injury.

When the severity of injury was recorded, the majority of teeth sustained a severe luxation injury accounting for the 44.1% (n=15) of the sample. On the other hand, 29.5% (n=10) of teeth were recorded as sustaining a mild luxation injury and 24.5% (n=9) of teeth had a moderate injury. Table 13 summarises the distribution of severity amongst luxation injuries.

Table 13: The distribution of the severity for luxation injuries

Luxation Injury	Severity			Total
	Mild	Moderate	Severe	
Extrusion	0	2	1	3
Intrusion	7	6	11	24
Lateral Luxation	3	1	3	7
Total	10 (29.4%)	9 (24.5%)	15 (44.1%)	34 (100.0%)

Key: Please refer to section 3.5.2

4.4.2 Stage of root development

The stage of root development at the time of the luxation injury is presented in Figure 7. It can be observed that the majority of teeth showed a fully mature root (66% of the sample (n= 68). On the other hand, 14.6% (n=15) of luxated teeth had a completed root with an open apical foramen where-as 6.8% (n=7) were categorised as having 2/3 root length. In summary, 20 teeth (19.4%) were classified as very immature, 15 teeth (14.6%) as immature and 68 teeth (66%) as mature.

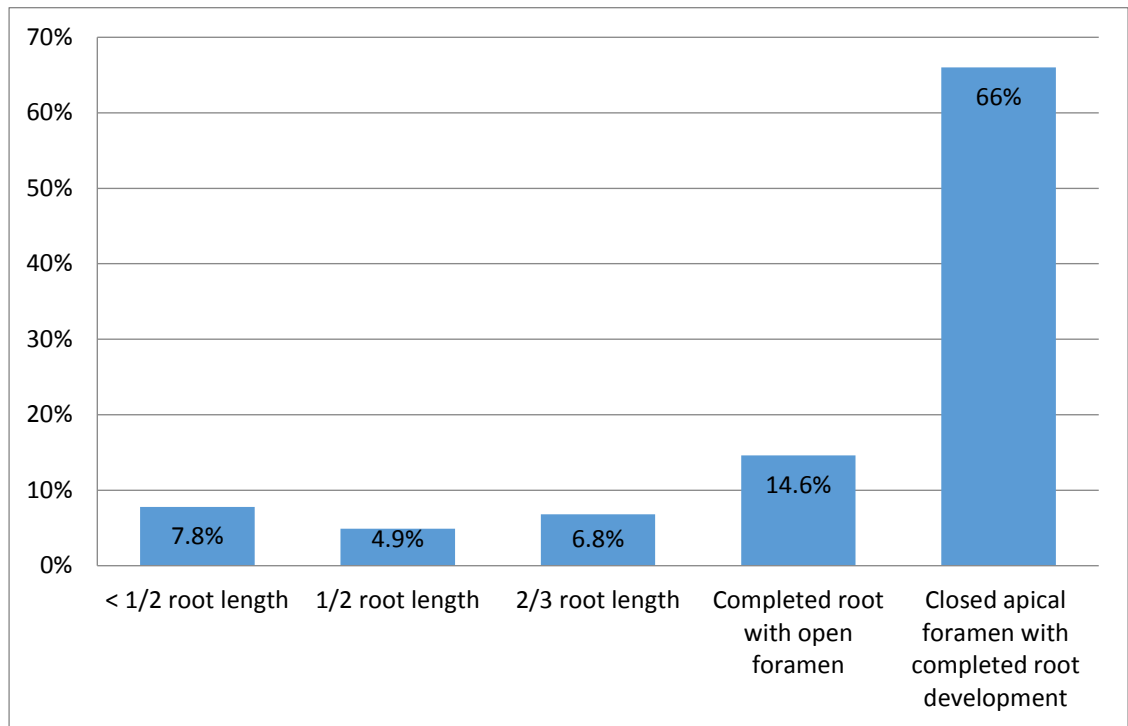


Figure 7: The distribution of the stage of root development at the time of luxation injury

4.4.3 Combination Injuries

A proportion of teeth in this sample (n=47) were affected by an associated trauma in addition to the original trauma injury. This presentation was observed in the luxation group where teeth had also sustained an associated crown fracture injury, either complicated or uncomplicated fracture. The results is summarised per luxation injury as follows:

i. Intrusion

With regards to intrusion, it was found that 71% (n=27) of intruded teeth had an associated crown fracture injury. An uncomplicated crown fracture was the most frequent crown injury accounting for the 66% (n=25) of the sample.

ii. Lateral Luxation

In the lateral luxation group, it was observed that 20% (n=9) of the injuries had an associated crown fracture injury. Similarly to intrusion, an uncomplicated crown fracture was the most frequent crown fracture compromising 11% (n=5) of the sample. However, a similar percentage of 9% (n=4) was also observed when lateral luxation was associated with a complicated crown fracture.

iii. Extrusion

With regards to extrusion, it was found that 30% (n=6) of the extrusion injuries had an associated crown fracture injury where 20% (n=4) of the teeth had an uncomplicated crown fracture and 10% (n=2) had a complicated crown fracture.

In summary, intrusion was the most common primary injury to present with an associated crown fracture injury. Figure 8 below illustrates the distribution of associated crown fracture within each luxation injury group.

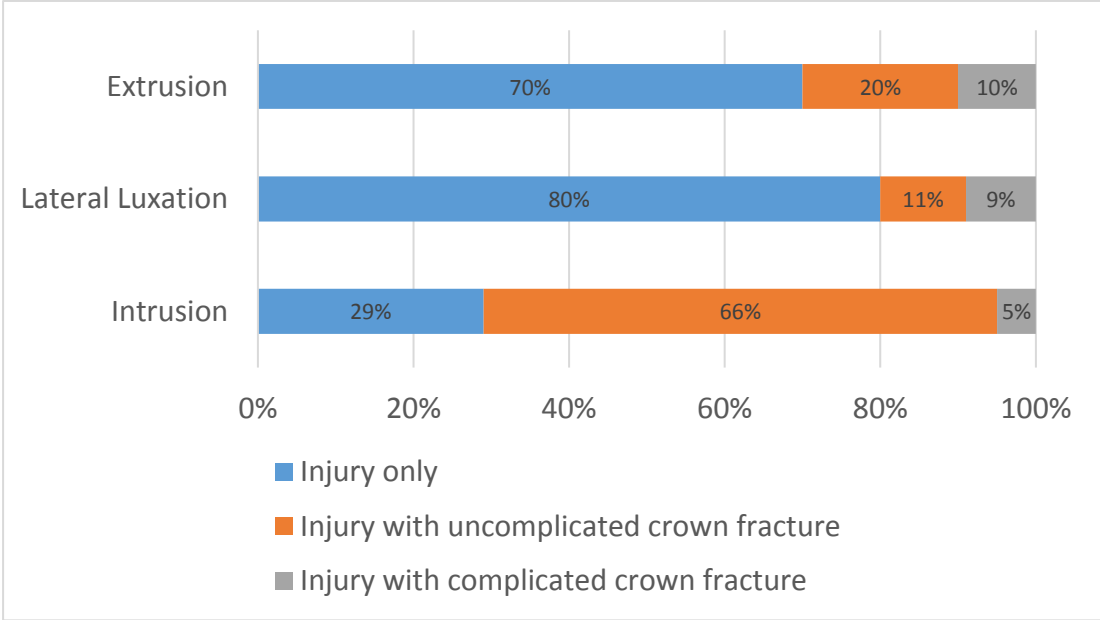


Figure 8: The distribution of associated crown fracture within each luxation injury

4.4.4 Method of repositioning

The method of repositioning for extruded teeth was solely manually (digital repositioning). On the other hand, 88% (n=29) of the laterally luxated teeth were repositioned manually, 9% (n= 3) surgically and only 3% (n=1) orthodontically. In the intrusion injury group, 42% (n= 16) of teeth received surgical repositioning whereas 24% (n=9) were repositioned orthodontically. Figure 9 illustrates the method of repositioning for the three luxation injuries.

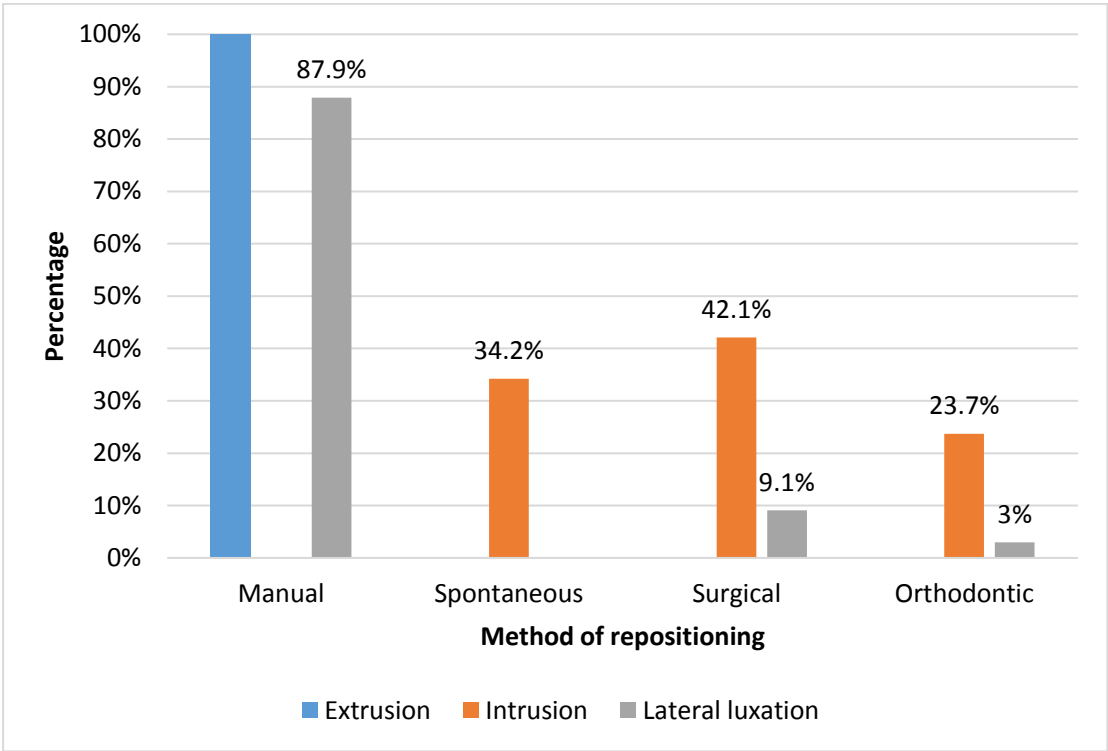


Figure 9: The method of repositioning for the three luxation injuries

It was also observed that 90% (n=18) of the 20 extruded teeth were repositioned. On the other hand, 73% (n=33) of the laterally luxated teeth were repositioned with the remaining 27% (n=12) not receiving any repositioning. In the intrusion group, awaiting re-eruption (spontaneous repositioning) was the treatment of choice in 34% of teeth (n=13) whereas active repositioning was performed in 66% (n=25) of the cases.

4.4.5 Time of repositioning

4.4.5.1 Extrusion

The minimum time since trauma to repositioning was day 0 and the maximum was 1 day following the injury. The median was day 1 where more than 55% (n=10) of the teeth were repositioned on day 1.

4.4.6.2 Lateral luxation

Similarly to extrusion, the minimum time since trauma to repositioning for luxated teeth was at day 0. The maximum was 4 days following the injury. The median was defined as day 0. More specifically, 64% (N=21) of the teeth were repositioned on the day of the injury.

4.4.6.3 Intrusion

In the group of intruded teeth, time of repositioning was on average 10 ± 32.01 days following the injury. The minimum time was on day 0 and the maximum time was 167 days following injury. The median was identified as 1 day following trauma.

4.4.7 Splinting period

4.4.7.1 Extrusion

The average splinting period was 22.6 ± 10.1 days. The median of this sample was identified to be 22 days whereas the minimum was 10 days and maximum was 49 days.

4.4.7.2 Lateral Luxation

The average splinting period was 23.6 ± 13.1 days. The median of this sample was identified as 23 days where-as the minimum period was 11 days and maximum was 83 days.

4.4.7.3 Intrusion

The average splinting period for those teeth that were surgically repositioned was 34.9 ± 20.1 days. The median of this sample was found as 30 days whereas the minimum was 14 days and the maximum 76 days.

4.4.8 Time of pulp extirpation

4.4.8.1 Extrusion

The minimum time since trauma to pulp extirpation was at day 0 whereas the maximum time found in this sample was 143 days following injury. The average time of pulp extirpation was 29 ± 43.9 days following trauma. The median was identified as 13.5 days following injury. If the reading 143 is considered as an outlier, the mean changes to 16.6 days.

4.4.8.2 Lateral Luxation

Similarly in the group of teeth with lateral luxation, the minimum time since trauma to prophylactic pulp extirpation was at day 0 whereas the maximum time was following 251 days. The median was identified as 12 days. The average time for pulp extirpation was 28 ± 62.8 days following trauma. If the reading 251 is considered as an outlier, the mean changes to 12.1 days.

4.4.8.3 Intrusion

For intruded the minimum time since trauma to do prophylactic pulp extirpation was also on day 0. The maximum time was identified 386 days following injury. The median was identified as 6 days. The mean time for pulp extirpation was 33 ± 79.8 days following trauma. If the reading 386 is considered as an outlier, the mean changes to 19.6 days.

4.4.9 Pulpal healing complications

Pulpal healing complications were categorised as pulp healing, pulp canal obliteration, transient apical breakdown and pulp necrosis.

It was observed that pulp necrosis was the most frequent pulpal complication for the intrusion group, accounting for 81.6% (n=31) of the sample. On the other hand, pulpal healing most commonly occurred in the lateral luxation group comprising 66.6% (n=30) of the sample with either signs of pulp healing, pulp canal obliteration or transient apical breakdown. An interesting finding was the fact that 50% of the extruded teeth showed signs of pulpal healing including pulp canal obliteration whereas the remaining 50% showed signs of pulp necrosis. Finally, only one tooth that sustained lateral luxation showed signs of transient apical breakdown, which subsequently healed. Figure 10 below illustrates the distribution of pulpal healing complications between the three luxation injuries.

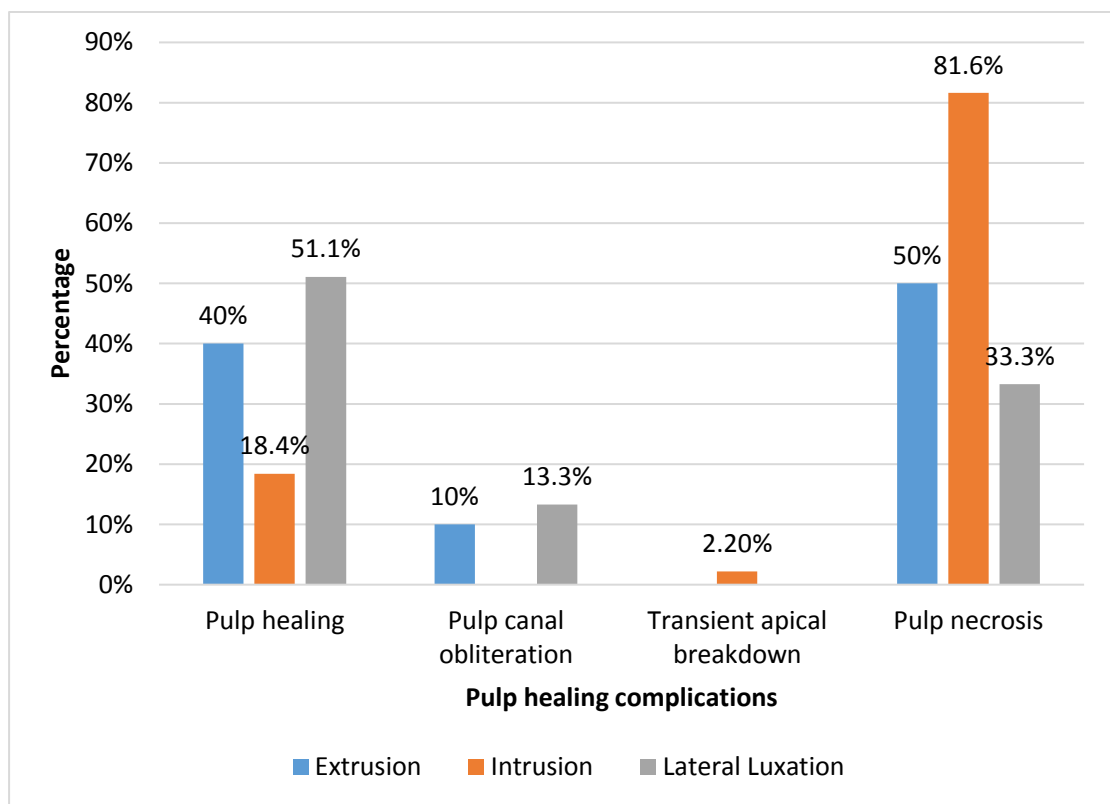


Figure 10: The distribution of pulpal healing complications of luxation injuries

4.4.10 Periodontal healing complications

Periodontal healing complications were categorised as healing, repair related resorption, infection related resorption and replacement root resorption.

As described earlier, healing was the most common finding in the lateral luxation group where 66.6% (n=30) of the sample showed evidence of both pulp revitalisation and healed periodontal condition. Similarly, 50% (n=10) of the extruded teeth healed. On the other hand, infection related root resorption presented most frequently in the intrusion group. More specifically, 23.7% (n=9) of intruded teeth showed evidence of infection related root resorption in comparison to the 6.7% (n=3) and 5% (n=1) of lateral luxated and extruded teeth respectively. Replacement root resorption was only observed in the intrusion group compromising 26.3% (n=10) of the sample. Figure 11 below summarises the distribution of periodontal healing complications between the three luxation injuries.

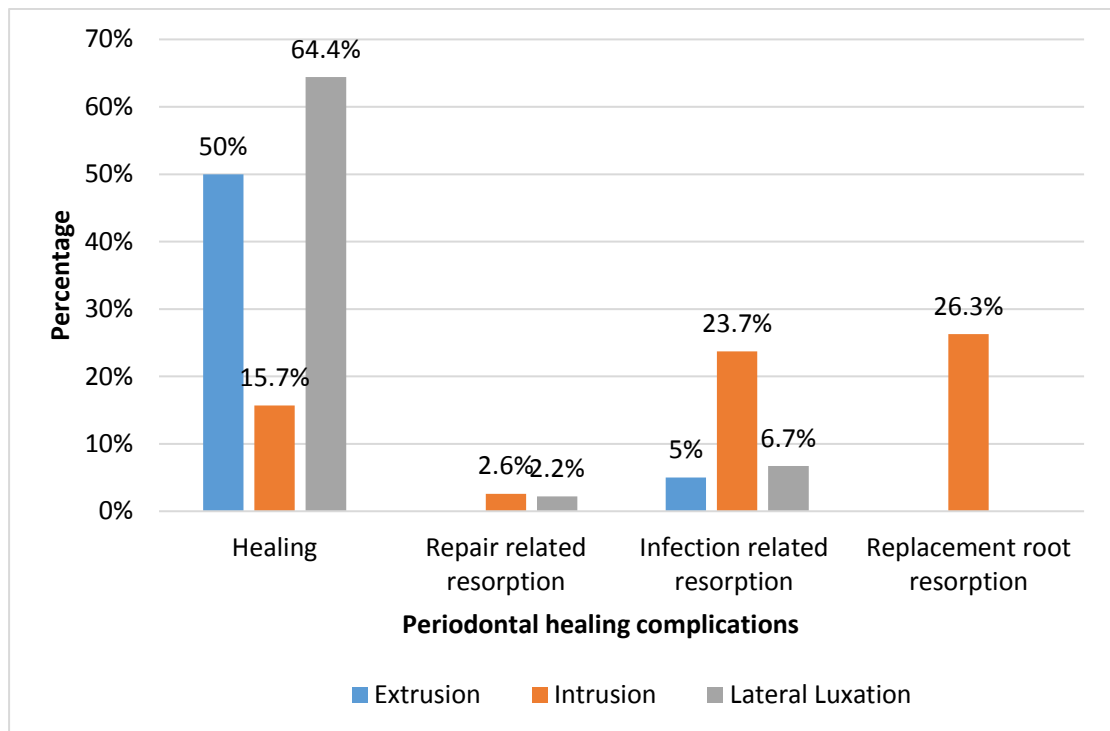


Figure 11: The distribution of periodontal healing complications of luxation injuries

4.4.11 Root canal treatment

In total 41 out of the 103 luxated teeth received root canal treatment.

4.4.11.1 Quality of Obturation

The quality of obturation was found to be adequate in 73% (n=30) of the cases. On the other hand, the quality of obturation was found to be inadequate in 27% (n=11) of the cases. Figure 12 below shows a bar chart demonstrating the results on the quality of obturation.

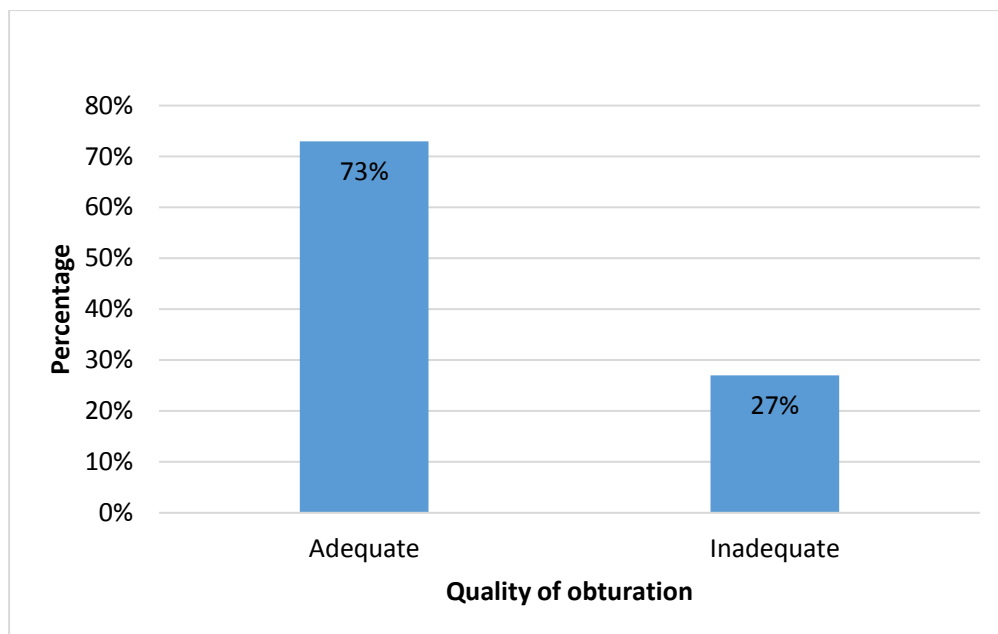


Figure 12: The quality of obturation of luxation injuries

The main reason that the obturation was considered inadequate was due to the presence of voids and spaces between root canal walls and the obturation material compromising 45.5% (n=5) of the sample. The remaining teeth either had long or short obturation material (equally 27.3%). Table 14 summarises the main reasons of inadequate obturation.

Table 14: The main reasons for inadequate obturation

Reason for inadequate obturation	Number	Percentage
Long	3	27.3%
Short	3	27.3%
Poor condensation	5	45.5%

4.4.11.2 Post-obturation clinical review

The post-obturation clinical review period was found to have a mean of 27 ± 23 months. The median was identified as 24 months whereas the minimum review time was 0 months and the maximum was 98 months.

4.4.11.3 Post-obturation radiographic review

The post-obturation radiographic review period was found to have a mean of 23 ± 19.8 months. The median was 15 months whereas the minimum was 2 months and the maximum was 87 months.

4.4.12 Total treatment/review time

The mean treatment or review period since trauma to the last visit of the patient was 38.5 ± 27.5 months. The minimum period was 1 month and the maximum 87 months. The median was identified as 31 months.

4.4.13 Final clinical outcome

In summary, 81.5% (n=84) of luxated teeth were considered clinically successful. More specifically, all the teeth that sustained traumatic extrusion were clinically successful. Similarly, almost all the laterally luxated teeth were clinically successful accounting for 97.7% (n=44) of the sample. On the other hand, 52.6% (n=20) of intruded teeth were successful and 47.6% (n=18) had signs of clinical failure. In particular, 16 teeth out of the 18 that failed, had sustained a combination injury with a crown fracture. The results of the final clinical outcome are summarised in Table 15 below.

Table 15: The final clinical outcome for the luxation injuries

Injury	Success	Failure	Total
Extrusion	14	0	
Extrusion with crown fracture	6	0	
	20 (100%)		20
Lateral luxation	35	1	
Lateral luxation with crown fracture	9	0	
	44 (97.7%)	1 (2.2%)	45
Intrusion	9	2	
Intrusion luxation with crown fracture	11	16	
	20 (52.6%)	18 (47.4%)	38
Total	84 (81.5%)	19 (18.5%)	103

4.4.13.1 Severity of Injury

The final clinical outcome for teeth with luxation injury related to the severity of injury is presented in Table 16 below. It can be summarised that all luxated teeth with moderate injury and 90% of those with mild injury were clinically successful. On the other hand, 60% of teeth with severe injury were clinically successful.

Table 16: The final clinical outcome for teeth with luxation injury related to the severity of injury

Severity of Injury	Final Clinical Outcome		Total
	Failure Number (%)	Success Number (%)	
Mild	1 (10%)	9 (90%)	10
Moderate	0	9 (100%)	9
Severe	6 (40%)	9 (60%)	15
Total	7 (20.6%)	27 (79.4%)	34 (100.0%)

4.4.13.2 Method of repositioning

In addition, the final clinical outcome for teeth with luxation injury in relation to the method of repositioning is described in Table 17 below. It was found that all teeth that were repositioned manually were clinically successful. On the other hand, 70% of teeth that were repositioned orthodontically and 69% of those that were allowed to re-erupt were clinically successful. More failures were encountered in the group of surgical repositioning accounting for 58% (n=11) of the sample.

Table 17: The final clinical outcome for teeth with luxation injury in relation to the method of repositioning

Method of repositioning	Final Clinical Outcome		Total
	Failure Number (%)	Success Number (%)	
Manual	0	47 (100%)	47
Passive	4 (31%)	9 (69%)	13
Surgical	11(58%)	8 (42%)	19
Orthodontic	3 (30%)	7 (70%)	10
Total	28 (20.2%)	72 (79.8%)	89 (100.0%)

4.4.14 Final radiographic outcome

Radiographic assessment was possible for 95 out of the 103 teeth as these teeth had adequate radiographic records. In summary, 72.6% (n=69) of luxated teeth were successful compared to the 27.4% (n=26) of teeth that failed.

In comparison to the result of clinical outcome where all the extruded teeth were found to be clinically successful, 88.2% of extruded teeth were radiographically successful. In particular, there were two teeth that showed signs of radiographic failure. In addition, similar to the clinical outcome, intrusion had the highest percentage of failure compromising 61.1% (n=22) of the sample. However, fewer teeth (n=14) were found to be radiographically successful when compared to the number of teeth (n=20) that were assessed as clinically successful. Table 18 below describes the final radiographic outcome of the three luxation injuries.

Table 18: The final radiographic outcome of luxation injuries

Injury	Success	Failure	Total
Extrusion	11	1	
Extrusion with crown fracture	4	1	
	15 (88.2%)	2 (11.8%)	17
Lateral luxation	32	1	
Lateral luxation with crown fracture	8	1	
	40 (95.2%)	2 (4.8%)	42
Intrusion	7	3	
Intrusion with crown fracture	7	19	
	14 (38.9%)	22 (61.1%)	36
Total	69 (72.6%)	26 (27.4%)	95

The most common reason of radiographic failure was the presence of replacement resorption accounting for 61.5% of the sample that failed. The remaining teeth failed due to progressive or new infection related resorption (27%) and as a result of an increase in the size of peri-apical pathology (11.5%) following treatment. The reasons for radiographic failure are summarised in Table 19 below.

Table 19: The reasons for final radiographic failure

Reason for radiographic failure	Number	Percentage
Periapical pathology increased in size	3	11.5%
Progressive infection related root resorption	6	27%
New infection related root resorption	1	
Presence of replacement root resorption	16	61.5%
Total	26	100.0%

4.4.14.1 Severity of Injury

Table 20 shows the final radiographic outcome for teeth with luxation injury in relation to the severity of injury. It can be concluded that radiographic failure occurred more frequently in teeth with a severe luxation injury. More specifically, 64% (n=9) of the severe cases showed signs of radiographic failure whereas only one tooth with either mild or moderate injury failed.

Table 20: The final radiographic outcome for teeth with luxation injury in relation to the severity of injury

Severity of Injury	Final Radiographic Outcome		Total
	Failure Number (%)	Success Number (%)	
Mild	1 (11%)	8 (89%)	9
Moderate	1 (11%)	8 (89%)	9
Severe	9 (64%)	5 (36%)	14
Total	11 (34.4%)	21 (65.6%)	32 (100.0%)

4.4.14.2 Method of repositioning

In addition, more failures were encountered in teeth that received surgical repositioning (74%) in comparison to those that were repositioned manually, orthodontically or passively. The results of the final radiographic outcome in respect to the method of repositioning are summarised in Table 21.

Table 21: The final radiographic outcome for teeth with luxation injury in respect to the method of repositioning

Method of repositioning	Final Radiographic Outcome		Total
	Failure Number (%)	Success Number (%)	
Manual	2 (5%)	40 (95%)	42
Passive	4 (33%)	8 (67%)	12
Surgical	14 (74%)	5 (26%)	19
Orthodontic	4 (44%)	5 (56%)	9
Total	24	58	82 (100.0%)

4.4.15 Survival

In summary, 83.5% (n=86) of teeth with a luxation injury survived whereas 16.5% (n=17) of teeth were lost. In particular, all extruded teeth survived whereas only one tooth with a history of lateral luxation injury did not survive. On the other hand, 42% (n=16) of teeth with intrusion injury did not survive at the end of the study. It was noted that out of the 16 intruded teeth, 14 of these had an associated crown fracture injury. Table 22 below summarises the survival for the 4 luxation injuries.

Table 22: The survival of the 4 luxation injuries

Injury	Survival		Total
	Yes	No	
Extrusion	14	0	20
Extrusion with crown fracture	6	0	
	20 (100%)		
Lateral Luxation	35	1	45
Lateral Luxation with crown fracture	9	0	
	44 (98%)	1 (2%)	
Intrusion only	9	2	38
Intrusion with crown fracture	13	14	
	22 (58%)	16 (42%)	
Total	86 (83.5%)	17 (16.5%)	103

The most common reason of the tooth being lost or extracted was as a result of progressive replacement resorption where the tooth was clinically mobile and non-functional, comprising 41.2% of the sample. On the other hand, 35% of the teeth were extracted for premolar transplant planning. Table 23 below summarises the reasons of tooth loss.

Table 23: The reasons for tooth loss

Reason for tooth lost	Number	Percentage
Extracted as mobile	7	41.2%
Root fracture	2	12%
Planning for premolar transplant	6	35%
Persistent infection	2	12%
Total	17	100%

4.5 Association between the outcome and prognostic factors

The following set of results focus upon the association between the variables of interest, the prognostic factors chosen for the two injury groups, and the outcomes. The outcomes have been previously described as the initial treatment outcome for complicated crown fractures and the final clinical and radiographic outcome for both injury groups. In order to determine the associations, a univariate analysis using a logistic regression model was conducted, while accounting for the clustered nature of the data using robust errors. Following this, a multivariable logistic regression model was fitted in order to identify the independent predictors of the outcome while adjusting for the factors that might influence the outcomes. To avoid model overfitting the multivariable logistic regression model was only fitted for three predictors due to the small sample size of the data.

4.5.1 Results from Univariate Analysis for Complicated Crown Fractures

4.5.1.1 Initial treatment outcome

A significant association was found between the initial type of treatment provided and the initial treatment outcome -1.89 ($-3.61, -0.16$), $p=0.03$. Pulp capping was more likely to have reduced chance of success compared to partial pulpotomy .i.e. partial pulpotomy can be considered more successful than pulp capping. On the other hand, even though there was a trend for very immature teeth and immature teeth to have an increased likelihood of success compared to mature, this association was not found to be statistically significant. Similarly, the time since pulp exposure (days) to treatment did not significantly affect the success of the initial treatment provided. Table 24 summarises the results of the univariate analysis.

Table 24: The regression coefficients (B) and corresponding 95% confidence intervals from the univariate analyses of factors associated with initial outcome in the complicated crown fractures

Predictors	Univariate analysis	
	B (95% CI)	p-value
Time since pulp exposure to treatment (days)	0.27 (-0.03, 0.57)	0.08
Stage of root development		0.37
Very immature	1.26 (-0.78, 3.23)	0.23
Immature	0.85 (-0.72, 2.41)	0.29
Mature	0	
Initial type of treatment		
Pulp capping	-1.89 (-3.61,-0.16)	0.03
Partial pulpotomy	0	

4.5.1.2 Final clinical outcome

With regards to the factors analysed for their effect on the final clinical outcome, only the stage of root development was found to have a significant association with this outcome as shown in Table 25. Even though there was a trend of decreased success in the final outcome of very immature teeth compared to mature teeth, this was not significant. Instead, there was a significant increased likelihood of success in the final clinical outcome of immature teeth compared to mature teeth 19.39 (95% CI: 17.29, 21.48), $p < 0.001$. On the other hand, the univariate analysis suggested that the quality of obturation was not associated with the final clinical outcome ($p = 0.58$). However, there was a trend of increased chance of success for the teeth that had adequate obturation in comparison to those that were considered inadequate.

Table 25: The regression coefficients and corresponding 95% confidence intervals from the univariate analyses of factors associated with final clinical outcome in the complicated crown fractures

Predictors	Univariate analysis	
	B (95% CI)	p-value
Stage of root development		0.001
Very immature	-2.08 (-4.64, 0.48)	0.11
Immature	19.39 (17.29, 21.48)	0.001
Mature	0	
Quality of obturation		
Adequate	0.81 (-2.08, 3.71)	0.58
Inadequate	0	

4.5.1.3 Final radiographic outcome

Similar to the result for the final clinical outcome, the stage of root development was found to have a significant association with the final radiographic outcome as shown in Table 26. There was an increased likelihood of success in the final radiographic outcome for the immature teeth compared to the mature teeth 20.83 (95% CI: 19.40, 22.27), $p < 0.001$. On the other hand, the univariate analyses suggested that the quality of obturation was not associated with the final radiographic outcome.

Table 26: The regression coefficients and corresponding 95% confidence intervals from the univariate analysis of factors associated with final radiographic outcome in the complicated crown fractures

Predictors	Univariate analysis	
	B (95% CI)	p-value
Stage of root development		0.001
Very immature	-0.82 (-2.87, 1.23)	0.43
Immature	20.83 (19.40,22.27)	0.001
Mature	0	
Quality of obturation		
Adequate	1.79 (-0.71,4.30)	0.16
Inadequate	0	

4.5.2 Results from univariate and multivariable analyses for luxation injuries

4.5.2.1 Final Clinical Outcome

Table 27 shows the regression coefficients and corresponding 95% confidence intervals from the univariate and multivariate analyses of factors associated with the final clinical outcome.

Overall, the univariate analysis has shown that the prognostic factors which did not have a significant association with the final clinical outcome for luxation injuries were the stage of root development, time of pulp extirpation and quality of obturation. On the other hand, there was evidence to suggest that the severity of injury, the presence of combination injury, the method of repositioning and the duration of splinting (days) were significantly associated with the final clinical success.

With regards to the severity of injury, the univariate analysis suggested that there was an increased chance of success for the moderately affected teeth in comparison to those that were severely injured 22.16 (20.94, 23.38) $p < 0.001$. On the other hand, even though there was a trend of increased success for the mild group compared to the severe group, this was not found to be significant.

In addition, the presence of crown fracture in the extrusion group was found to have an increased likelihood of success compared to the intrusion group with an associated crown fracture 22.94 (21.83, 24.05) $p < 0.001$. Similarly, lateral luxation associated with a crown fracture had an increased likelihood of success when compared with the more severely injured group of intrusion with crown fracture 22.94 (21.93, 23.95) $p < 0.001$.

Furthermore, the univariate analysis revealed that luxated teeth that were repositioned manually had an increased likelihood of success compared to those that were surgically repositioned 22.89 (21.93, 23.84) $p < 0.001$.

Finally, the duration of splinting (days) was found to have a negative impact on clinical success, implying that the longer period of splinting the lower the chance of clinical success -0.04 ($-0.08, -0.005$) $p=0.03$.

The multivariable analysis was based on a model with three chosen predictors namely stage of root development, method of repositioning and time since trauma to repositioning. When these three factors were considered together in the logistic regression model, the stage of root development did not have a significant association with the final clinical outcome as had been also observed in the univariate analysis. On the other hand, the multivariable logistic analysis suggested that the method of repositioning and time since trauma to repositioning (days) had a significant association with the final clinical outcome.

With regards to the method of repositioning, there was evidence to suggest that this predictor remained to have a significant association with the final clinical outcome in the multivariate analysis as had also been observed in the univariate analysis. It was found that manual repositioning, passive repositioning as well as orthodontic repositioning had an increased likelihood of success when compared individually to surgical repositioning 22.91 ($21.79, 24.03$) $p<0.001$, 23.44 ($20.40, 26.50$) $p<0.001$ and 2.02 ($0.08, 3.95$) $p=0.04$ respectively.

Furthermore, the time since trauma to repositioning (days) was found to reduce the chances of clinical success -0.03 ($-0.05, -0.01$) $p=0.02$.

Table 27: The regression coefficients and corresponding 95% confidence intervals from the univariate and multivariable analyses of factors associated with the final clinical outcome in the luxation injuries

Predictors	Univariate analysis		Multivariable analysis Based on 3 predictors	
	B (95% CI)	p-value	B (95% CI)	p-value
Severity		0.001		
Mild	1.792 (-0.52, 4.10)	0.13		
Moderate	22.16 (20.94,23.38)	0.001		
Severe	0			
Stage of root development		0.96		0.74
Very immature	-0.15 (-1.42, 1.11)	0.81	-0.78 (-3.53,1.98)	0.58
Immature	-0.15 (-1.57, 1.26)	0.83	-0.67 (-2.80,1.46)	0.54
Mature	0			
Combination Injury		0.001		
Extrusion & crown fracture	22.94 (21.83,24.05)	0.001		
Lateral Luxation & crown fracture	22.94 (21.93,23.95)	0.001		
Intrusion & crown fracture	0			
Method of repositioning		0.001		0.001
Manual	22.89 (21.93,23.84)	0.001	22.91 (21.79, 24.03)	0.001
Passive	1.13 (-0.36,2.62)	0.18	23.44 (20.40, 26.50)	0.001
Orthodontic	1.17 (-0.47,2.80)	0.16	2.02 (0.08, 3.95)	0.04
Surgical	0			
Time since trauma to repositioning (days)	-0.03 (-0.07,0.002)	0.06	-0.03 (-0.05, -0.01)	0.02
Duration of splinting (days)	-0.04 (-0.08,-0.005)	0.03		
Time of pulp extirpation (days)	0.001 (0.000, 0.002)	0.14		
Quality of obturation				
Adequate	1.135 (-0.96,3.23)	0.29		
Inadequate	0			

4.5.2.2 Final radiographic outcome

Table 28 presents the regression coefficients and corresponding 95% confidence intervals from the univariate and multivariate analyses of factors associated with the final radiographic outcome.

The univariate analysis showed that the stage of root development, time since trauma to repositioning (in days), time of pulp extirpation and the quality of obturation were not significantly associated with the final radiographic outcome. However, there was evidence to suggest that the severity of injury, the presence of combination injuries, the method of repositioning and the duration of splinting had a significant effect upon the final radiographic outcome.

With regards to the severity of the injury, it was found that a mild injury had an increased likelihood of success compared to a severely injured tooth 2.67 (0.32, 5.02) $p=0.03$. Similarly, a moderate injury was found to have increased chance of success when compared to a severe injury 2.67 (0.32, 5.02) $p=0.02$.

In addition, the presence of a combination injury in the extrusion group was found to have increased likelihood of success when compared to a more severely affected injury such as intrusion associated with crown fracture 2.39 (0.03, 4.74) $p=0.05$. This association was also found when the group of lateral luxation associated with crown fracture was shown to have increased chance of success when compared to the group of intrusion combined with crown fracture 3.08 (0.83, 5.33) $p=0.01$.

Furthermore, there was evidence to suggest that the teeth repositioned manually had an increased likelihood of success when compared to surgical repositioning 4.03 (2.28, 5.77) $p<0.001$. Similarly, teeth that were left for spontaneous re-eruption (passive repositioning) showed an increased likelihood of success compared to those teeth that had surgical repositioning 1.72 (0.15, 3.30) $p=0.03$. Teeth that were repositioned orthodontically also showed an increased chance of success when compared to those that were repositioned surgically 1.25 (-0.41, 2.92) $p=0.14$.

Finally, the univariate analysis also revealed that the longer duration of splinting (days) was associated with a reduced chance of radiographic success -0.04 ($-0.08, 5.178E-5$) $p=0.05$.

Similar to the clinical outcome, a multivariable analysis for the radiographic outcome was based on the chosen three predictors. When the three chosen predictors were fitted into the model, the stage of root development and the time since trauma to repositioning remained as not having a significant association with the final radiographic outcome, an observation also found in the univariate analysis.

On the other hand, the multivariable analysis suggested that the method of repositioning continued to have a significant association with the final radiographic outcome when the three predictors were analysed together, as observed in the univariate analysis. In particular, when the method of repositioning was studied individually the manual, passive and orthodontic repositioning all had an increased likelihood of success when compared to a more invasive procedure such as surgical repositioning.

Table 28: The regression coefficients and corresponding 95% confidence intervals from the univariate and multivariable analyses of factors associated with the final radiographic outcome in the luxation injuries

Predictors	Univariate analysis		Multivariable analysis Based on 3 predictors	
	B (95% CI)	p-value	B (95% CI)	p-value
Severity		0.02		
Mild	2.67 (0.32, 5.02)	0.03		
Moderate	2.67 (0.32, 5.02)	0.03		
Severe	0			
Stage of root development		0.84		0.21
Very immature	-0.10 (-1.28, 1.08)	0.87	-1.06 (-3.91, 1.80)	0.47
Immature	-0.36 (-1.58, 0.85)	0.56	-1.41 (-2.99, 0.16)	0.08
Mature	0			
Combination Injury		0.01		
Extrusion & crown fracture	2.39 (0.03, 4.74)	0.05		
Lateral Luxation & crown fracture	3.08 (0.83, 5.33)	0.01		
Intrusion & crown fracture	0			
Method of repositioning		0.001		0.001
Manual	4.03 (2.28, 5.77)	0.001	4.16 (2.17, 6.15)	0.001
Passive	1.72 (0.15, 3.30)	0.03	24.28 (20.97, 27.59)	0.001
Orthodontic	1.25 (-0.412, 2.92)	0.14	2.96 (0.66, 5.26)	0.01
Surgical	0			
Time since trauma to repositioning (days)	-0.11 (-0.23, 0.004)	0.06	-0.08 (-0.21, 0.04)	0.19
Duration of splinting (days)	-0.04 (-0.08, 5.18E-5)	0.05		
Time of pulp extirpation (days)	0.001 (-0.001, 0.003)	0.23		
Quality of obturation				
Adequate	1.66 (-0.04, 3.36)	0.06		
Inadequate	0			

Chapter Five

Discussion

5.1 Introduction

The current study has provided the opportunity to investigate the prognostic factors, which affect the final clinical and radiographic outcomes of traumatised teeth in the long term. In addition, it allowed us to evaluate the success of traumatised teeth with four particular injuries; intrusion, extrusion, lateral luxation and complicated crown fractures.

A comprehensive discussion of the methodology and the results of the current study and their comparison to studies published previously in the literature are detailed in this chapter.

5.2 Study Aims Appraisal

The aim of conducting this research was centred on analysing the effect of specific prognostic factors on the long term clinical and radiographic success of traumatised teeth. In addition, the research had a secondary aim of evaluating the clinical and radiographic success of two groups of traumatic injuries of permanent teeth (luxation injuries and complicated crown fractures).

Although some studies were found in the literature that had evaluated the effect of prognostic factors on the success of traumatised teeth, these studies had limitations such as small sample size, unclear methodology of outcome assessments, completion of statistical analysis without adjusting for confounders as well as restricted to short follow-up of traumatised teeth. In addition, there was a limited number of published studies reporting the final outcome of traumatised teeth following root canal treatment in children.

Following the completion of an in-depth literature review, it was recognised that it was important to conduct a study evaluating the factors which affect the final clinical and radiographic outcomes of traumatised teeth in children, with histories of intrusion, extrusion, lateral luxation and complicated crown fractures. To achieve this, univariate and multivariate statistical analyses were employed.

Although the aim of the present study was to obtain a large number of data with long term follow up, this was not achieved as a result of the retrospective design of this study as well as due to inadequate clinical records. Therefore this study did not manage to address the limitations of previously reported trauma studies.

5.3 Appraisal of Methodology

5.3.1 Obtaining Ethical Approval

When conducting a study dealing with data derived from humans, it is essential to maintain high scientific accuracy and evidence. In addition, it is equally important to ensure that the study follows and maintains ethical standards. The World Medical Association Declaration of Helsinki clearly states that medical research involving human subjects, including research on identifiable human material and data must conform to the ethical principles where all research protocols should be submitted for ethical approval before the study begins (Association, 2013). Accordingly, prior to conducting the current study, ethical approval was obtained from the Dental Research Ethics Committee (DREC) at the School of Dentistry. In addition, the study gained approval from the National Research Ethics Service (NRES) and Research & Innovation (Appendices 1-4).

5.3.2 Study design

After obtaining expert's opinion, it was considered important that a study should be conducted to identify the prognostic factors which affect the final clinical and radiographic outcomes of traumatised teeth that sustained any of the four chosen injuries (intrusion, extrusion, lateral luxation and complicated crown fractures). In addition, it was also important to evaluate the success of these traumatised teeth.

It has been shown that carrying out a retrospective study in the field of dental trauma is valuable. Most of the studies available in the literature concerning the prevalence, prognostic factors and treatment outcomes of TDIs are of retrospective design. With this noted, the study was designed as a retrospective study and therefore the clinical dental records and peri-apical radiographs of paediatric patients from 2003 up to 2013 were evaluated.

5.3.3 Sample Identification

The Paediatric Dental Department at the Leeds Dental Institute has a well-known trauma centre where for years it has been providing emergency dental treatment and specialist care to patients that had suffered dental trauma.

The available trauma database includes details of patients that had visited the trauma clinic at the Leeds Dental Institute since 2003. For the period of 2003-2011, it was possible to identify patients that had sustained one of the four chosen injuries as per the inclusion criteria of this study (intrusion, extrusion, lateral luxation and complicated crown fractures), through information retained from a previous research project conducted at the University of Leeds (Faridoun, July 2013). To complete a follow-up period of 10 years, patients that visited the trauma clinic up to the year of 2013 were also included. For the additional 2 year period, all the files of patients that had attended the trauma clinic were screened in order to identify those that had sustained one of the chosen injuries.

5.3.4 Classifications and Evaluation Criteria

5.3.4.1 Stage of root development

In this study, the pre-operative peri-apical radiographs were evaluated with the objective to determine the stage of root development of traumatised teeth at the time of trauma. The scale described by Cvek (1992) in their study of calcium hydroxide apexification in non-vital immature luxated teeth was adopted for this study. After evaluating several scales, this particular scale was selected as it was easy to use and provided reproducible measures when used by the investigator to determine the stage of root development radiographically. For further simplification of the scale, it was decided to group Stages A-C as very immature teeth. Similarly, teeth classified as Stage D root development were considered as immature and those classified as Stage E were considered as mature. This simplification of the scale was suggested recently by Tsilingaridis et al. (2016). Due to the presence of small numbers within the categories of Stage A-C, it was decided that having three main groups will allow easier interpretation of the results in the statistical analyses.

To ensure that the stage of root development was recorded accurately and consistently, intra-examiner reliability was assessed at the beginning of the data collection process, which showed an almost total agreement when 15% of the peri-apical radiographs were re-assessed.

5.3.4.2 Criteria for Success and Failure

Over the years, several studies have followed different criteria for evaluating the outcome of traumatised teeth. However, the outcomes were commonly evaluated through analysing the radiographic findings and the presence or absence of clinical signs or symptoms.

For the purpose of this study, the outcomes were based on specific criteria chosen for the two groups of traumatic dental injuries, whether the tooth had sustained a complicated crown fracture or a periodontal (luxation) injury. It was important to set different criteria for the two groups of traumatic dental injuries as different healing complications were expected following a periodontal and pulpal injuries. In addition, on the last review visit, teeth were assessed both clinically and radiographically and were classified as failure/success according to whether the tooth healed following the injury or if further treatment was completed, following root canal obturation.

It was important to use a wide range of parameters in order to evaluate the clinical success as one parameter cannot describe comprehensively the clinical picture. The information about the clinical presentation of the tooth was extracted from the clinical notes.

In addition, radiographic evaluation was completed in order to confirm the clinical findings and identify the presence of pulpal or periodontal healing complications following the injury or the root canal treatment. The cases were assessed based on the aforementioned criteria in Sections 3.6 and 3.7. In the group of luxation injuries, root resorption was the most common sequelae following periodontal injury. In the present study, the presence of replacement root resorption was considered a failure due to the irreversible nature of this resorption entity as it could not be treated.

Furthermore, in order to investigate accurately the endodontic outcome of obturated teeth, validated and tested criteria set by the European Society of Endodontology were followed (Loest, 2006). These guidelines categorise the endodontic treatment outcome as favourable, unfavourable or uncertain. An uncertain outcome was described for the lesions that remained the same or

diminished in size during a 4 year review period. However, if the lesions persisted after the 4 year period, the outcome was considered as unfavourable with associated post-treatment disease. While taking into account these guidelines, our evaluation criteria were simplified as either success or failure for easier interpretation of the results in the statistical regression analysis. Therefore, the lesions that remained the same or reduced in size were considered successful and this was justified by considering that the lesions could take up to four years to resolve or heal. In the present study, teeth that had sustained complicated crown fractures had a mean follow-up period of 23 months and teeth with a periodontal (luxation) injury were followed-up on average for 29 months.

Finally, in order to ensure the accuracy and reliability of the radiographic evaluations of the outcomes, 15% of the cases were re-evaluated by the main investigator on a separate occasion. Total agreement for the intra-examiner reliability was determined suggesting that the outcomes were reported consistently throughout the data collection period.

5.3.5 Statistical Analyses of the data

5.3.5.1 Study Sample

Initially, 620 clinical dental records of children who attended the trauma clinic at the Paediatric Dentistry Department at Leeds Dental Institute were screened. Only 171 out of the 620 patient's clinical records were identified to have a history of a relevant traumatic injury meeting the inclusion criteria of this study. The remaining 449 clinical notes either did not have a relevant traumatic injury or as a result of late presentation there was unconfirmed trauma diagnosis. Out of these 171 clinical notes, 63 were excluded due to inadequate records or the follow-up was less than one year. Finally, 108 clinical notes with a sample size of 146 teeth met the inclusion criteria.

The present study sample size estimation was based on the primary aim of the study, which was to identify the factors, which affected the final outcome of teeth. However, there were no similar published studies in the literature; therefore no estimate could be used to determine the sample size. The previous trauma database contained the numbers of luxation injuries and complicated crown fractures during the period of 2003-2011 and this provided valuable information about the possible sample size that could be reached. In addition, Peduzzi et al. (1996) stated that a valid regression model required 10 events for each predictor. Based on this assumption, the effective sample size for the luxation injuries was 80 based on 8 predictors.

The final sample included 48 teeth with complicated crown fractures and 103 teeth that sustained luxation injuries, which were lower numbers than had been expected. This was because a number of files which were initially recorded in the trauma database as having one of the relevant traumatic injuries were patients who presented late and the initial trauma diagnosis was not confirmed in the clinical notes. In addition, there was little or no information about the initial management of the injury. These clinical notes did not meet the inclusion criteria of the study.

5.3.5.2 Statistical Tests

Statistical advice was obtained with regards to the statistical tools and tests required to analyse the data of the current study. In order to fulfil the aims of the study, several tests were implemented.

Initially, a series of descriptive statistics were conducted on the data including percentages, tables and charts. The small sample size of the four individual injuries (intrusion, lateral luxation, extrusion and complicated crown fractures) was noted during the data collection of the study. Secondly, a univariate analysis using a logistic regression model was conducted in order to determine whether or not significant associations existed between the predictors of interest and the clinical and radiographic outcomes, while adjusting for the clustered nature of the data. Finally, a multivariable logistic regression model was conducted in order to identify the independent predictors of the outcomes while adjusting for the factors that might influence the outcomes. This was only possible for the luxation injuries, as the sample size for the complicated crown fractures was small (n=48). However, in an attempt to complete the multivariable analysis, the model could only fit three predictors. The presence of missing data within certain predictors such as the severity of injury meant that not all factors could fit into the model. The best combination resulted with three chosen predictors namely the stage of root development, method of repositioning and time since trauma to repositioning (days). However, this method could be considered as selection bias and it is acknowledged as one of the limitations of this study.

5.4 Appraisal of Results

5.4.1 Demographic Factors

Discussion is presented on the demographic characteristics of the sample in this study.

5.4.2 Gender

Gender has been reported by several studies to be a well-recognised risk variable of TDIs (Andreasen et al., 2013). Boys have been reported to suffer more TDIs than girls with a ratio of 2:1 (Glendor, 2008). This is explained mainly by the higher participation of boys in leisure activities and contact sports. In this study, boys were found to suffer more TDIs with a percentage of 64.8% compared to girls (35.2%) where this ratio was not equal to 2:1 but quite close to this (1.8:1). However, it is important to mention that this study was retrospective and the inclusion criteria were adhered to strictly. It might well be that the sample was not representative of the true gender distribution of trauma that is otherwise found in the population.

5.4.3 Age at Trauma

It has been reported in the literature that the peak incidence of TDIs in permanent teeth varies between 9-10 years (Andreasen et al., 2013). In this study, the mean age at the time of trauma was 10.3 years, which is similar to that reported by other studies. This may be due to the fact that children, at this age, are participating more in sports and physical activities and therefore more prone to TDIs. The minimum age in the current study was 6 years old and the maximum age was 19 years.

5.4.4 Teeth involved in Trauma

In this study, the upper left central incisor was the tooth most commonly involved in TDIs accounting for 43.2% of the sample followed by the upper right central incisor (37.7%). This finding is comparable to what is highlighted in the literature, where the maxillary central incisors are the teeth more susceptible to TDIs (Glendor, 2009). This is justified by the fact that upper central incisors are more likely to sustain damage due to their vulnerable position.

5.4.5 Complicated crown fractures

5.4.5.1 Prognostic factors and initial treatment outcome

In this study, complicated crown fractures were initially treated with either pulp capping or partial pulpotomy, whereas cervical pulpotomy was not considered as a treatment option. In particular, 13 teeth received pulp capping and 22 had partial pulpotomy. Pulp capping was only successful to 2 teeth (15.4%) where the remaining 11 teeth (84.6%) failed and required root canal treatment. The success of pulp capping in the present study was much lower to that reported in the literature which ranged from 72-88% (Fuks et al., 1982, Ravn, 1982). On the other hand, more than half of the teeth treated with partial pulpotomy were successful (54.5%). Similarly, the success of partial pulpotomy was much lower than that reported in published studies and ranged from 94-100% (Cvek, 1978, Cvek, 1993, de Blanco, 1996). This inconsistency may have been due to the presence of a small sample size, and therefore, not representing the overall population. In addition, the variation in the clinical skills of different dentists providing this type of treatment should also be considered as a possible reason for this low success rate.

In addition, the current study found that the type of initial treatment had a significant effect upon pulp healing of complicated crown fractures i.e. initial treatment success ($p=0.03$). It can be suggested that teeth treated with pulp capping will have a reduced chance of success compared to those treated with partial pulpotomy. This finding is in agreement with previous published studies, which reported higher success rates for partial pulpotomy compared to pulp capping. Partial pulpotomy is considered a more successful procedure because it results in better wound control thus allowing healing.

With regards to the time since trauma to treatment, It was reported that the majority of complicated crown fractures $n=28$ (80%) were treated during the first day or the day after (Day 0-1). However, this predictor was not found to have a significant effect upon the overall pulp healing ($p=0.08$). Similarly, the stage of root development at the time of treatment was not found to have a significant association with the initial outcome ($p=0.37$). It is important to note that these two factors were investigated individually for a possible association with the initial outcome (pulp healing) irrespective to the type of initial treatment received for the traumatised teeth. It is known that both the stage of root development and time since pulp exposure to treatment can influence the clinician's choice of treatment. It is also well documented in the literature that these two factors can affect the success of initial treatment. The time since trauma is important for the success of pulp capping whereas high success rates have been observed with partial pulpotomy irrespective of the time interval (Cvek, 1993). Similarly, partial pulpotomy can be successful irrespective of the stage of root development whereas pulp capping appeared to provide better healing in immature teeth (de Blanco, 1996, Ravn, 1982).

5.4.5.2 Prognostic factors and final outcomes

The final clinical and radiographic outcomes were assessed for 42 teeth in total. Out of the 42, 14 had healed following initial treatment (pulp capping/partial pulpotomy) whereas the remaining 28 of these teeth received root canal treatment.

A relatively high clinical (93%) and radiographic (85.3%) success was reported for complicated crown fractures. In addition, only one very immature tooth did not survive as a result of root fracture. These results suggest that complicated crown fractures can be clinically and radiographically successful in the long run, based on a mean follow-up period of 39 months following trauma.

In the current study, the quality of obturation was not found to have a significant association with the final radiographic ($p=0.16$) and clinical outcomes ($p=0.58$). On the other hand, there is evidence to suggest that the stage of root development had an effect on the final outcome ($p<0.001$). In particular, the univariate analysis suggested that immature teeth had an increased chance of success compared to mature teeth. In total, 10 teeth were classified as immature teeth where 5 of these teeth were root treated. It was important to note that all immature teeth were 100% successful. This finding might suggest that the slight open apex may increase the chance of pulp healing compared to the fully mature teeth. However, it is difficult to comment on the result for the root treated teeth as the effect of root canal treatment on traumatised teeth with different stages of root development, has not yet been evaluated in the literature. In addition, the small sample size obtained for the root treated teeth should also be acknowledged.

5.4.6 Luxation injuries

5.4.6.1 Pulpal healing complications

The incidence of pulp necrosis for the luxation injuries was 54% overall, a similar percentage to those found in previous published studies (Andreasen, 1970, Andreasen and Pedersen, 1985). The greatest frequency of pulp necrosis was encountered among intrusions (81.6%) followed by extrusion (50.0%) and lateral luxation (33.3%). Intrusion injury is considered the most severe periodontal injury and it was therefore expected to have a higher frequency on pulp necrosis compared to the other two periodontal injuries, as already observed in other studies (Andreasen and Pedersen, 1985). On the other hand, the present study found that more teeth with extrusion injuries had signs of pulp necrosis compared to those that had sustained a lateral luxation injury. This finding is not consistent with previous studies on luxation injuries (Andreasen and Pedersen, 1985). However the data must be interpreted with caution as the sample size was different for the three groups of injuries and extrusion had the lowest number of teeth (n=20). In addition, the stage of root development can also have had an impact on the outcome of pulp healing where a large number of the luxated teeth were fully mature teeth (n=68) and 59% of these teeth were diagnosed with pulp necrosis.

Furthermore, pulp canal obliteration (PCO) was also observed in the sample of luxated teeth at a frequency of 8%. This percentage was slightly lower to that reported in previous studies that investigated the occurrence of pulp canal obliteration in luxated teeth (Andreasen, 1970, Andreasen et al., 1987). In the present study, PCO was only found in laterally luxated and extruded teeth and this was in accordance to previous studies which explained that PCO is more commonly seen in severely mobile or luxated teeth, a clinical finding mostly found in extrusion and lateral luxation and rarely in intrusion (Andreasen et al., 1987).

5.4.6.2 Periodontal healing complications

In the present study, root resorption was found in 24% of luxated teeth, a similar finding to what was previously reported in the literature (Oikarinen et al., 1987, Crona-Larsson et al., 1991). More specifically, infection related resorption was more frequently encountered in the intrusion group (23.7%) compared to lateral luxation (6.7%) and extrusion (5%). In addition, replacement root resorption was only observed in the intrusion group at a frequency of 26.3%. The higher frequency of the two resorption entities in the intrusion group has also been observed in previous studies (Andreasen and Pedersen, 1985). This is because intrusion is considered a severe form of luxation injury causing greater damage to the periodontium, compared to an extrusion and lateral luxation injury.

5.4.6.3 Final outcomes

The final clinical outcome was assessed in 103 teeth where 81.5% (n=81) of these teeth were clinically successful. On the other hand, radiographic outcome was reported in 95 teeth concluding that 72.6% of the luxated teeth were radiographically successful. Overall, a lower success rate was observed in the luxation group compared to the complicated crown fractures. The findings add to our understanding that a lower success rate is expected in a luxation injury as it involves damage to both pulp and periodontal ligament with high frequency of healing complications, compared to a pulpal injury only, such as complicated crown fractures.

In addition, a higher frequency of failure was observed in the intrusion group compared to the other two luxation injuries. As already described, the higher prevalence of periodontal and pulpal healing complications in the intrusion group, such as infection related and replacement root resorption had an impact on the final outcome. In particular, 61.1% of intruded teeth failed radiographically, compared to extrusion (11.8%) and lateral luxation (4.8%). These findings confirm previous studies in the literature reporting the high

frequency of healing complications in intrusion injuries (Humphrey et al., 2003, Andreassen et al., 2006c, Wigen et al., 2008).

Furthermore, of the 95 teeth which had a final radiographic outcome reported, 33 of these were root treated. It was found that 11 root treated teeth (33%) failed as a result of progressive infection or presence of new resorption following root canal treatment. However, it is difficult to comment on the final outcome of root treated luxated teeth, as this treatment modality has not been investigated thoroughly in the trauma studies carried out in children. One study completed by Cvek (1992), treated 885 non-vital luxated teeth with calcium hydroxide and gutta-percha and reported healing in 91% of the cases, at the four year follow-up. In addition, a pilot study performed by Sarris et al. (2008) treated 17 non-vital incisors with MTA apexification and obturation with gutta-percha, and reported a radiographic success of 76.5%. However, this study did not give details of the original trauma injury and also referred solely to the MTA apexification technique.

5.4.6.4 Prognostic factors and final outcomes

The severity of luxation injury represents the degree of displacement of the luxation injury, which is a clinical measure of the extent of periodontal injury suffered. In the current study, the severity of luxation injury was found to have a significant association with the final clinical ($p < 0.001$) and radiographic outcomes ($p = 0.02$). This finding is in agreement with previous studies which concluded that the more severe the luxation injury, the higher the risk of pulpal and periodontal healing complications (Lee et al., 2003, Tsilingaridis et al., 2016). However, it must be noted that this variable was only recorded in 43 out of the 103 luxated teeth. In addition, the degree of displacement was recorded more commonly in teeth that had sustained intrusive luxation ($n = 25$). This finding also raises the issue that the severity of injury might not have been taken into account in the overall management of the injured tooth.

In addition, the presence of an associated crown fracture in a luxation injury had a significant effect upon the final clinical ($p < 0.001$) and radiographic outcome ($p = 0.01$). This is in agreement with previous studies which concluded that a crown fracture may represent a way for bacterial invasion into the injured pulp, increasing the risk of pulp necrosis (Lauridsen et al., 2012a). It can also be noted that the univariate analysis suggested that a combination injury in the extrusion or lateral luxation group had an increased chance of radiographic and clinical success compared to the intrusion group. This finding confirms with our understanding that intrusion injury is a more severe form of luxation injury compared to the other two luxation injuries (Andreasen et al., 2013). However, it is important to mention that in the present study both enamel dentine and enamel dentine pulp fractures were combined in one group for the purpose of statistical analysis, and this might have affected the overall result.

Furthermore, the method of repositioning was found to have a significant association with the final and radiographic outcome ($p < 0.001$). When the individual repositioning methods were compared with each other, it was found that the manual and passive repositioning (spontaneous re-eruption) had an increased likelihood of radiographic success compared to surgical repositioning. This result is consistent with previous studies completed in intruded teeth, which suggested that passive repositioning appeared to result in the fewest healing complications (Wigen et al., 2008, Tsilingaridis et al., 2012, AlKhalifa and AlAzemi, 2014). In addition, although, there was an increased likelihood of success when orthodontic repositioning was used compared to surgical, this was not found to be significant. This result is in accordance to previous studies reported in the literature which suggested no significant differences in the healing outcomes between orthodontic and surgical repositioning (Andreasen et al., 2006b, Wigen et al., 2008).

The univariate analysis also revealed that the duration of splinting (days) had a significant association with the final radiographic and clinical outcomes, where the longer the duration of splinting the reduced chance of success. This finding is in contrast to data reported in previous studies which concluded that neither the type nor duration of splinting affected the healing outcome of teeth (Kahler and Heithersay, 2008).

When the stage of root development, method of repositioning and time since trauma to repositioning were analysed together in the multivariable regression model, the method of repositioning remained to have a significant effect upon both radiographic and clinical outcomes ($p < 0.001$). This suggests that after adjusting for two possible confounders, the method of repositioning was still considered an important factor for the final outcome of the tooth.

In the present study, although there was a trend of increased likelihood of success for teeth with adequate obturation compared to inadequate obturation, this predictor was not found to have a significant association with the final clinical and radiographic outcomes ($p = 0.06$). The results showed that adequate obturation was observed in 73% of the sample where radiographic success was more common in this group, compared to the group with inadequate obturation. On the other hand, clinical success was almost equally observed in both groups. It is well established in the literature that the quality of obturation is considered an important factor influencing the success rate of endodontic treatment (Ng et al., 2011). A possible explanation could be due to the fact that all the root canal treatments completed at the Leeds Dental Institute were performed at a specialist level with proper use of endodontic materials, rubber dam and effective chemo-mechanical preparation of the root canal. Therefore, even though the obturation was inadequate, there was evidence of healing of the lesion. Furthermore, all root canal treated teeth were considered to have adequate coronal seal, as it was recorded that two or more restorative materials were used, following our departmental protocol. It is also important to mention that the post-obturation follow-up period ranged from 2-87 months with a mean of 23 months, where in some cases a longer follow-up period may have been required to assess post-obturation healing.

5.5 Study Limitations and Challenges Encountered

One of the main problems encountered in the present study was the variable quality of record keeping included in the clinical dental notes. Although there is a specially designed trauma sheet available in the clinical dental record, some of these records were not completed and specific research information was difficult to extract. In addition, the referral letters included in the dental notes, which were received from general dental practitioners, often lacked information on the initial presentation and management of the injury. This resulted in inadequate patient notes where 63 patients that had to be excluded from the study. In addition, only 43 out of the 103 included patient's notes recorded the severity of the luxation injury, an important predictor for the final outcome of the tooth. It is inevitable that clinical dental records would be completed to varying degrees of accuracy as different clinicians were involved in the patient's care. In addition, it is important to highlight that these records were documented by different clinicians with a range of clinical experience, ranging from postgraduate students to consultants.

5.6 Future Research

Dental trauma has been studied extensively in the literature. However, more scientific evidence is required concerning the possible factors, which affect the outcome of traumatic dental injuries. Most of the current research is of a retrospective design and the limitations encountered with this type design are acknowledged.

The present study highlighted the important factors, which can affect the outcome of traumatised teeth with histories of intrusion, lateral luxation, extrusion and complicated crown fractures. However, due to the small sample size of the data it was not possible to adjust for all the confounders in the multivariable logistic regression model.

It will therefore be beneficial to design long term clinical studies, possibly by combining data from different trauma centres to give a sufficiently large sample size to conduct a good statistical model where certain confounders can be taken into account.

Chapter Six

Conclusion

Firstly, the final clinical and radiographic success of complicated crown fractures was found to be higher in comparison to the luxation injuries. More specifically, the final clinical success in the group of complicated crown fractures was 93% and in the group of luxation injuries was 81.5%. Furthermore, the final radiographic success in the group of complicated crown fractures was 85.3% and in the group of luxation injuries was 72.6%.

Based on the univariate regression analysis for the complicated crown fractures, the predictor that was found to significantly affect the initial treatment success was the type of initial treatment where pulp capping was found to have a reduced chance of success compared to partial pulpotomy. Therefore we reject the null hypothesis for the type of initial treatment as a predicting factor while accepting the null hypothesis for the other factors' as predictors of initial success. In addition, the predictor which significantly affected the final radiographic and clinical success was the stage of root development. Therefore we reject the null hypothesis for stage of root development as a predicting factor for final success while accepting the null hypothesis for the other factors' as predictors of final success.

On the other hand, in the group of luxation injuries the univariate regression analysis suggested that the predictors that may affect the final clinical and radiographic success were the severity of injury, combination injury, method of repositioning and duration of splinting (days).

Based on the multivariable regression model, the method of repositioning was found to significantly affect the clinical and radiographic success while the time since trauma to repositioning (days) was found to affect the clinical success. Therefore we reject the null hypothesis for the method of repositioning on clinical and radiographic success and the time since trauma to repositioning (days) on the clinical success as predictors of success for luxation injuries.

References

- ABBOTT, P. 1991. Recognition and prevention of failures in clinical dentistry. Endodontics. *Annals of the Royal Australasian College of Dental Surgeons*, 11, 150-166.
- ACTON, C. H., NIXON, J. W. & CLARK, R. C. 1996. Bicycle riding and oral/maxillofacial trauma in young children. *The Medical journal of Australia*, 165, 249-251.
- AL-BADRI, S., KINIRONS, M., COLE, B. & WELBURY, R. 2002. Factors affecting resorption in traumatically intruded permanent incisors in children. *Dental Traumatology*, 18, 73-76.
- AL ANSARY, M. A., DAY, P. F., DUGGAL, M. S. & BRUNTON, P. A. 2009. Interventions for treating traumatized necrotic immature permanent anterior teeth: inducing a calcific barrier & root strengthening. *Dental Traumatology*, 25, 367-379.
- 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*.
- ALKHALIFA, J. D. & ALAZEMI, A. A. 2014. Intrusive luxation of permanent teeth: a systematic review of factors important for treatment decision-making. *Dental Traumatology*, 30, 169-175.
- ANDREASEN, F., ZHIJIE, Y. & THOMSEN, B. L. 1986. Relationship between pulp dimensions and development of pulp necrosis after luxation injuries in the permanent dentition. *Dental Traumatology*, 2, 90-98.
- ANDREASEN, F. M. 1986. Transient apical breakdown and its relation to color and sensibility changes after luxation injuries to teeth. *Dental Traumatology*, 2, 9-19.
- ANDREASEN, F. M. & ANDREASEN, J. O. 1985. Diagnosis of luxation injuries: the importance of standardized clinical, radiographic and photographic techniques in clinical investigations. *Dental Traumatology*, 1, 160-169.
- ANDREASEN, F. M. & PEDERSEN, B. V. 1985. Prognosis of luxated permanent teeth—the development of pulp necrosis. *Dental Traumatology*, 1, 207-220.
- ANDREASEN, F. M., ZHIJIE, Y., THOMSEN, B. L. & ANDERSEN, P. K. 1987. Occurrence of pulp canal obliteration after luxation injuries in the permanent dentition. *Dental Traumatology*, 3, 103-115.
- ANDREASEN, J. 1970. A clinical and radiographic follow-up study of 189 injured teeth. *Scand. J. Dent. Res*, 78, 273-286.
- ANDREASEN, J. 1985. Challenges in clinical dental traumatology. *Dental Traumatology*, 1, 45-55.

- ANDREASEN, J., ANDREASEN, F., SKEIE, A., HJØRTING-HANSEN, E. & SCHWARTZ, O. 2002. Effect of treatment delay upon pulp and periodontal healing of traumatic dental injuries—a review article. *Dental traumatology*, 18, 116-128.
- ANDREASEN, J. O., ANDREASEN, F. M. & ANDERSSON, L. 2013. *Textbook and color atlas of traumatic injuries to the teeth*, John Wiley & Sons.
- ANDREASEN, J. O., BAKLAND, L. K. & ANDREASEN, F. M. 2006a. Traumatic intrusion of permanent teeth. Part 2. A clinical study of the effect of preinjury and injury factors, such as sex, age, stage of root development, tooth location, and extent of injury including number of intruded teeth on 140 intruded permanent teeth. *Dental Traumatology*, 22, 90-98.
- ANDREASEN, J. O., BAKLAND, L. K. & ANDREASEN, F. M. 2006b. Traumatic intrusion of permanent teeth. Part 3. A clinical study of the effect of treatment variables such as treatment delay, method of repositioning, type of splint, length of splinting and antibiotics on 140 teeth. *Dental Traumatology*, 22, 99-111.
- ANDREASEN, J. O., BAKLAND, L. K., FLORES, M. T., ANDREASEN, F. M. & ANDERSSON, L. 2011. *Traumatic dental injuries: a manual*, John Wiley & Sons.
- ANDREASEN, J. O., BAKLAND, L. K., MATRAS, R. C. & ANDREASEN, F. M. 2006c. Traumatic intrusion of permanent teeth. Part 1. An epidemiological study of 216 intruded permanent teeth. *Dental Traumatology*, 22, 83-89.
- ASSOCIATION, W. M. 2013. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Jama*, 310, 2191.
- BAKLAND, L. K. & ANDREASEN, J. O. 2012. Will mineral trioxide aggregate replace calcium hydroxide in treating pulpal and periodontal healing complications subsequent to dental trauma? A review. *Dental Traumatology*, 28, 25-32.
- BARNETT, F. 2002. The role of endodontics in the treatment of luxated permanent teeth. *Dental Traumatology*, 18, 47-56.
- BASMADJIAN-CHARLES, C., FARGE, P., BOURGEOIS, D. & LEBRUN, T. 2002. Factors influencing the long-term results of endodontic treatment: a review of the literature. *International Dental Journal*, 52, 81-86.
- BECKER, D. B., NEEDLEMAN, H. L. & KOTELCHUCK, M. 1978. Child abuse and dentistry: orofacial trauma and its recognition by dentists. *The Journal of the American Dental Association*, 97, 24-28.
- BENDO, C. B., SCARPELLI, A. C., VALE, M. P. P., ZARZAR, A. & PEREIRA, P. M. 2009. Correlation between socioeconomic indicators and traumatic dental injuries: a qualitative critical literature review. *Dental traumatology*, 25, 420-425.

- BERGER, T. D., KENNY, D. J., CASAS, M. J., BARRETT, E. J. & LAWRENCE, H. P. 2009. Effects of severe dentoalveolar trauma on the quality-of-life of children and parents. *Dental Traumatology*, 25, 462-469.
- BIMSTEIN, E. & ROTSTEIN, I. 2016. Cvek pulpotomy—revisited. *Dental Traumatology*, 32, 438-442.
- BONTE, E., BESLOT, A., BOUKPESSI, T. & LASFARGUES, J.-J. 2015. MTA versus Ca (OH) 2 in apexification of non-vital immature permanent teeth: a randomized clinical trial comparison. *Clinical oral investigations*, 19, 1381-1388.
- BORSSÉN, E. & HOLM, A. K. 2000. Treatment of traumatic dental injuries in a cohort of 16-year-olds in northern Sweden. *Dental Traumatology*, 16, 276-281.
- BORUM, M. K. & ANDREASEN, J. O. 2001. Therapeutic and economic implications of traumatic dental injuries in Denmark: an estimate based on 7549 patients treated at a major trauma centre. *International Journal of Paediatric Dentistry*, 11, 249-258.
- BURDEN, D. 1995. An investigation of the association between overjet size, lip coverage, and traumatic injury to maxillary incisors. *The European Journal of Orthodontics*, 17, 513-517.
- ÇAĖŞKAN, M. & ŞEN, B. 1996. Endodontic treatment of teeth with apical periodontitis using calcium hydroxide: a long-term study. *Dental Traumatology*, 12, 215-221.
- CAIRNS, A., MOK, J. Y. & WELBURY, R. 2005. Injuries to the head, face, mouth and neck in physically abused children in a community setting. *International Journal of Paediatric Dentistry*, 15, 310-318.
- CHALA, S., ABOUQAL, R. & RIDA, S. 2011. Apexification of immature teeth with calcium hydroxide or mineral trioxide aggregate: systematic review and meta-analysis. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology*, 112, e36-e42.
- CHANDRA, A. 2009. Discuss the factors that affect the outcome of endodontic treatment. *Australian Endodontic Journal*, 35, 98-107.
- COX, C. F., BERGENHOLTZ, G., FITZGERALD, M., HEYS, D. R., HEYS, R. J., AVERY, J. K. & BAKER, J. A. 1982. Capping of the dental pulp mechanically exposed to the oral microflora—a 5 week observation of wound healing in the monkey. *Journal of Oral Pathology & Medicine*, 11, 327-339.
- CRONA-LARSSON, G., BJARNASON, S. & NORÉN, J. G. 1991. Effect of luxation injuries on permanent teeth. *Dental Traumatology*, 7, 199-206.
- CVEK, M. 1978. A clinical report on partial pulpotomy and capping with calcium hydroxide in permanent incisors with complicated crown fracture. *Journal of endodontics*, 4, 232-237.

- CVEK, M. 1992. Prognosis of luxated non-vital maxillary incisors treated with calcium hydroxide and filled with gutta-percha. A retrospective clinical study. *Dental Traumatology*, 8, 45-55.
- CVEK, M. 1993. Results after partial pulpotomy in crown fractured teeth 3-15 years after treatment. *Acta Stomatol Croat*, 27, 167-173.
- CVEK, M., CLEATON-JONES, P. E., AUSTIN, J. C. & ANDREASEN, J. O. 1982. Pulp reactions to exposure after experimental crown fractures or grinding in adult monkeys. *Journal of endodontics*, 8, 391-397.
- DA FONSECA, M. A., FEIGAL, R. & TEN BENDEL, R. 1992. Dental aspects of 1248 cases of child maltreatment on file at a major county hospital. *Pediatric Dentistry*, 14, 152-7.
- DE BLANCO, L. P. 1996. Treatment of crown fractures with pulp exposure. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology*, 82, 564-568.
- 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.
- DIMITROULIS, G. & EYRE, J. 1991. A 7-year review of maxillofacial trauma in a central London hospital. *British dental journal*, 170, 300-302.
- EKLUND, G., STALHANE, I. & HEDEGARD, B. 1975. A study of traumatized permanent teeth in children aged 7-15 years. Part III. A multivariate analysis of post-traumatic complications of subluxated and luxated teeth. *Svensk tandlakare tidskrift. Swedish dental journal*, 69, 179-189.
- 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. *Dental traumatology*, 24, 309-313.
- FARIDOUN, A. July 2013. *A study of the clinical and radiographic outcomes of root canal obturation with Obtura-II System using Thermoplasticised Guta-percha in Traumatized and Autotransplanted Teeth* D.CLIN.DENT, University of Leeds.
- FERRAZZINI POZZI, E. C. & VON ARX, T. 2008. Pulp and periodontal healing of laterally luxated permanent teeth: results after 4 years. *Dental Traumatology*, 24, 658-662.
- FONG, C. D. & DAVIS, M. J. 2002. Partial pulpotomy for immature permanent teeth, its present and future. *Pediatric dentistry*, 24, 29-32.
- FRANK, A. L. 1966. Therapy for the divergent pulpless tooth by continued apical formation. *The Journal of the American Dental Association*, 72, 87-93.

- FRANSSON, H., WOLF, E. & PETERSSON, K. 2015. Formation of a hard tissue barrier after experimental pulp capping or partial pulpotomy in humans: an updated systematic review. *International endodontic journal*, 49, 533-542.
- FUKS, A., BIELAK, S. & CHOSAK, A. 1982. Clinical and radiographic assessment of direct pulp capping and pulpotomy in young permanent teeth. *Pediatric dentistry*, 4, 240-244.
- FUKS, A. B., CHOSACK, A., KLEIN, H. & EIDELMAN, E. 1987. Partial pulpotomy as a treatment alternative for exposed pulps in crown-fractured permanent incisors. *Dental Traumatology*, 3, 100-102.
- GELBIER, M. & WINTER, G. 1988. Traumatized incisors treated by vital pulpotomy: a retrospective study. *British dental journal*, 164, 319.
- GLENDOR, U. 2008. Epidemiology of traumatic dental injuries—a 12 year review of the literature. *Dental traumatology*, 24, 603-611.
- GLENDOR, U. 2009. Aetiology and risk factors related to traumatic dental injuries—a review of the literature. *Dental Traumatology*, 25, 19-31.
- GÜNGÖR, H. C. 2014. Management of crown-related fractures in children: an update review. *Dental Traumatology*, 30, 88-99.
- HALLETT, G. & PORTEOUS, J. 1963. Fractured incisors treated by vital pulpotomy. A report on 100 consecutive cases. *British Dental Journal*, 115, 279-87.
- HELING, I., SLUTZKY-GOLDBERG, I., LUSTMANN, J., EHRLICH, Y. & BECKER, A. 2000. Bone-like tissue growth in the root canal of immature permanent teeth after traumatic injuries. *Dental Traumatology*, 16, 298-303.
- HERMANN, N. V., LAURIDSEN, E., AHRENSBURG, S. S., GERDS, T. A. & ANDREASEN, J. O. 2012. Periodontal healing complications following extrusive and lateral luxation in the permanent dentition: a longitudinal cohort study. *Dental Traumatology*, 28, 394-402.
- HUMPHREY, J. M., KENNY, D. J. & BARRETT, E. J. 2003. Clinical outcomes for permanent incisor luxations in a pediatric population. I. Intrusions. *Dental traumatology*, 19, 266-273.
- HUMPHREYS, K., BADRI, S., KINIRONS, M., WELBURY, R., COLE, B., BRYAN, R., CAMPBELL, O. & FUNG, D. 2003. Factors affecting outcomes of traumatically extruded permanent teeth in children. *Pediatric dentistry*, 25, 475-478.
- ILMA DE SOUZA CORTES, M., 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.
- KAHLER, B. & HEITHERSAY, G. S. 2008. An evidence-based appraisal of splinting luxated, avulsed and root-fractured teeth. *Dental Traumatology*, 24, 2-10.

- KASTE, L., GIFT, H., BHAT, M. & SWANGO, P. 1996. Prevalence of incisor trauma in persons 6-50 years of age: United States, 1988-1991. *Journal of dental research*, 75, 696-705.
- KINIRONS, M., SRINIVASAN, V., WELBURY, R. & FINUCANE, D. 2001. A study in two centres of variations in the time of apical barrier detection and barrier position in nonvital immature permanent incisors. *International Journal of Paediatric Dentistry*, 11, 447-451.
- KINIRONS, M. & SUTCLIFFE, J. 1991. Traumatically intruded permanent incisors: a study of treatment and outcome. *British dental journal*, 170, 144-146.
- LAURIDSEN, E., HERMANN, N. V., GERDS, T. A., AHRENSBURG, S. S., KREIBORG, S. & ANDREASEN, J. O. 2012a. Combination injuries 3. The risk of pulp necrosis in permanent teeth with extrusion or lateral luxation and concomitant crown fractures without pulp exposure. *Dental Traumatology*, 28, 379-385.
- LAURIDSEN, E., HERMANN, N. V., GERDS, T. A., KREIBORG, S. & ANDREASEN, J. O. 2012b. Pattern of traumatic dental injuries in the permanent dentition among children, adolescents, and adults. *Dental Traumatology*, 28, 358-363.
- LEE, R., BARRETT, E. J. & KENNY, D. J. 2003. Clinical outcomes for permanent incisor luxations in a pediatric population. II. Extrusions. *Dental traumatology*, 19, 274-279.
- LEE, S.-J., MONSEF, M. & TORABINEJAD, M. 1993. Sealing ability of a mineral trioxide aggregate for repair of lateral root perforations. *Journal of endodontics*, 19, 541-544.
- LIM, K. C. & KIRK, E. E. J. 1987. Direct pulp capping: a review. *Dental Traumatology*, 3, 213-219.
- LOEST, C. 2006. Quality guidelines for endodontic treatment: consensus report of the European Society of Endodontology. *International Endodontic Journal*, 39, 921-930.
- MACKIE, I. 1998. UK National Clinical Guidelines in Paediatric Dentistry. Management and root canal treatment of non-vital immature permanent incisor teeth. Faculty of Dental Surgery, Royal College of Surgeons. *International journal of paediatric dentistry/the British Paedodontic Society [and] the International Association of Dentistry for Children*, 8, 289-293.
- MACKIE, I., BENTLEY, E. & WORTHINGTON, H. 1988. The closure of open apices in non-vital immature incisor teeth. *British dental journal*, 165, 169-173.
- MARCENES, W. & MURRAY, S. 2001. Social deprivation and traumatic dental injuries among 14-year-old schoolchildren in Newham, London. *Dental Traumatology*, 17, 17-21.

- MARCENES, W., ZABOT, N. & TRAEBERT, J. 2001. Socio-economic correlates of traumatic injuries to the permanent incisors in schoolchildren aged 12 years in Blumenau, Brazil. *Dental Traumatology*, 17, 218-222.
- MORFIS, A. & SISKOS, G. 1990. Apexification with the use of calcium hydroxide: a clinical study. *The Journal of clinical pediatric dentistry*, 16, 13-19.
- NG, Y. L., MANN, V. & GULABIVALA, K. 2011. A prospective study of the factors affecting outcomes of nonsurgical root canal treatment: part 1: periapical health. *International endodontic journal*, 44, 583-609.
- NG, Y. L., MANN, V., RAHBARAN, S., LEWSEY, J. & GULABIVALA, K. 2008. Outcome of primary root canal treatment: systematic review of the literature—Part 2. Influence of clinical factors. *International endodontic journal*, 41, 6-31.
- NGUYEN, Q., BEZEMER, P., HABETS, L. & PRAHL-ANDERSEN, B. 1999. A systematic review of the relationship between overjet size and traumatic dental injuries. *The European Journal of Orthodontics*, 21, 503-515.
- NIK-HUSSEIN, N. N. 2001. Traumatic injuries to anterior teeth among schoolchildren in Malaysia. *Dental Traumatology*, 17, 149-152.
- NIKOUI, M., KENNY, D. J. & BARRETT, E. J. 2003. Clinical outcomes for permanent incisor luxations in a pediatric population. III. Lateral luxations. *Dental traumatology*, 19, 280-285.
- OIKARINEN, K., GUNDLACH, K. K. & PFEIFER, G. 1987. Late complications of luxation injuries to teeth. *Dental Traumatology*, 3, 296-303.
- PARIROKH, M. & TORABINEJAD, M. 2010a. Mineral trioxide aggregate: a comprehensive literature review—part I: chemical, physical, and antibacterial properties. *Journal of endodontics*, 36, 16-27.
- PARIROKH, M. & TORABINEJAD, M. 2010b. Mineral trioxide aggregate: a comprehensive literature review—part III: clinical applications, drawbacks, and mechanism of action. *Journal of endodontics*, 36, 400-413.
- PEDUZZI, P., CONCATO, J., KEMPER, E., HOLFORD, T. R. & FEINSTEIN, A. R. 1996. A simulation study of the number of events per variable in logistic regression analysis. *Journal of clinical epidemiology*, 49, 1373-1379.
- PETERSSON, E., ANDERSSON, L. & SÖRENSEN, S. 1996. Traumatic oral vs non-oral injuries. *Swedish dental journal*, 21, 55-68.
- PITTS, N., CHADWICK, B. & ANDERSON, T. 2015. Children's Dental Health Survey 2013. Report 2: dental disease and damage in children. HSCIC England, Wales and Northern Ireland.
- PORRITT, J. M., RODD, H. D. & BAKER, S. R. 2013. Parental quality-of-life impacts following children's dento-alveolar trauma. *Dental Traumatology*, 29, 92-98.

- PORRITT, J. M., RODD, H. D. & RUTH BAKER, S. 2011. Quality of life impacts following childhood dento-alveolar trauma. *Dental Traumatology*, 27, 2-9.
- RAFTER, M. 2005. Apexification: a review. *Dental Traumatology*, 21, 1-8.
- RAVN, J. 1982. Follow-up study of permanent incisors with complicated crown fractures after acute trauma. *European Journal of Oral Sciences*, 90, 363-372.
- RAY, H. & TROPE, M. 1995. Periapical status of endodontically treated teeth in relation to the technical quality of the root filling and the coronal restoration. *International endodontic journal*, 28, 12-18.
- ROBERTSON, A., ANDREASEN, F., ANDREASEN, J. & NOREN, J. 2000. Long-term prognosis of crown-fractured permanent incisors. The effect of stage of root development and associated luxation injury. *International Journal of Paediatric Dentistry*, 10, 191-199.
- ROBERTSON, A., ANDREASEN, F. M., BERGENHOLTZ, G., ANDREASEN, J. O. & NORÉN, J. G. 1996. Incidence of pulp necrosis subsequent to pulp canal obliteration from trauma of permanent incisors. *Journal of endodontics*, 22, 557-560.
- SARRIS, S., TAHMASSEBI, J. F., DUGGAL, M. S. & CROSS, I. A. 2008. A clinical evaluation of mineral trioxide aggregate for root-end closure of non-vital immature permanent incisors in children—a pilot study. *Dental Traumatology*, 24, 79-85.
- 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.
- SIMON, S., RILLIARD, F., BERDAL, A. & MACHTOU, P. 2007. The use of mineral trioxide aggregate in one-visit apexification treatment: a prospective study. *International Endodontic Journal*, 40, 186-197.
- STEWART, C., DAWSON, M., PHILLIPS, J., SHAFI, I., KINIRONS, M. & WELBURY, R. 2009. A study of the management of 55 traumatically intruded permanent incisor teeth in children. *European Archives of Paediatric Dentistry*, 10, 25-28.
- TORABINEJAD, M., HONG, C., MCDONALD, F. & FORD, T. P. 1995. Physical and chemical properties of a new root-end filling material. *Journal of endodontics*, 21, 349-353.
- TRONSTAD, L. 1988. Root resorption—etiology, terminology and clinical manifestations. *Dental Traumatology*, 4, 241-252.
- TRONSTAD, L., ASBJØRNSEN, K., DØVING, L., PEDERSEN, I. & ERIKSEN, H. 2000. Influence of coronal restorations on the periapical health of endodontically treated teeth. *Dental Traumatology*, 16, 218-221.
- TROPE, M. 2002. Root resorption due to dental trauma. *Endodontic topics*, 1, 79-100.

- TSILINGARIDIS, G., MALMGREN, B., ANDREASEN, J. O. & MALMGREN, O. 2012. Intrusive luxation of 60 permanent incisors: a retrospective study of treatment and outcome. *Dental Traumatology*, 28, 416-422.
- TSILINGARIDIS, G., MALMGREN, B., ANDREASEN, J. O., WIGEN, T. I., MASENG AAS, A. L. & MALMGREN, O. 2016. Scandinavian multicenter study on the treatment of 168 patients with 230 intruded permanent teeth—a retrospective cohort study. *Dental Traumatology*, 32, 353-360.
- TWATI, W., WOOD, D., LISKIEWICZ, T., WILLMOTT, N. & DUGGAL, M. 2009. An evaluation of the effect of non-setting calcium hydroxide on human dentine: a pilot study. *European archives of paediatric dentistry*, 10, 104-109.
- VOJINOVIĆ, O. 1981. The endodontic method of treatment of apical periodontitis in immature and young permanent teeth. *Journal of the International Association of Dentistry for Children*, 12, 65-72.
- WELBURY, R., DUGGAL, M. S. & HOSEY, M. T. 2012. *Paediatric dentistry*, Oxford university press.
- WHITE, J. D., LACEFIELD, W. R., CHAVERS, L. & ELEAZER, P. D. 2002. The effect of three commonly used endodontic materials on the strength and hardness of root dentin. *Journal of endodontics*, 28, 828-830.
- WIGEN, T. I., AGNALT, R. & JACOBSEN, I. 2008. Intrusive luxation of permanent incisors in Norwegians aged 6–17 years: a retrospective study of treatment and outcome. *Dental Traumatology*, 24, 612-618.
- WONG, F. S. & KOLOKOTSA, K. 2004. The cost of treating children and adolescents with injuries to their permanent incisors at a dental hospital in the United Kingdom. *Dental Traumatology*, 20, 327-333.
- YASSEN, G. & PLATT, J. 2013. The effect of nonsetting calcium hydroxide on root fracture and mechanical properties of radicular dentine: a systematic review. *International endodontic journal*, 46, 112-118.
- YASSEN, G. H., CHIN, J., MOHAMMEDSHARIF, A. G., ALSOUFY, S. S., OTHMAN, S. S. & ECKERT, G. 2012. The effect of frequency of calcium hydroxide dressing change and various pre-and inter-operative factors on the endodontic treatment of traumatized immature permanent incisors. *Dental Traumatology*, 28, 296-301.

APPENDIX 1: E-mail confirming DREC approval of the study

From: Julie McDermott

Sent: 06 November 2014 10:12

To: Eliana Hadjiantonis

Cc: David Wood; Monty Duggal; Medicine and Health Research Governance

Subject: Ethics application 'A Retrospective study on the outcome of traumatic injuries of teeth'

Dear Eliana

Thank you for re-submitting the above Ethics application to the Dental Research Ethics Committee.

Your application has been reviewed and I am pleased to inform you that DREC are happy for you to proceed and apply for full NHS Research Ethics Committee approval.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, signed consent forms, participant information sheets and all other documents relating to the study. This should be kept in your study file, and may be subject to an audit inspection.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

With best wishes for the success of your project.

For and on behalf of

Professor David Wood

DREC Chair

APPENDIX 2: Letter confirming University of Leeds sponsorship

HENDERSON
INSURANCE BROKERS

Henderson Insurance Brokers Limited
Trueman House
Capitol Park
Leeds
LS27 0TS

17 September 2014

Tel 0113 393 6300
Fax 0113 393 6363

www.hibl.co.uk

To Whom it May Concern

Dear Sirs,

EVIDENCE OF INSURANCE – The University of Leeds &/or Subsidiary Companies

We are writing to confirm that we act as Insurance Brokers to the above client and that we have arranged liability insurance on their behalf as detailed below:

EMPLOYERS LIABILITY

Cover in respect of indemnity for claims made for death, injury or disease to any person arising out of and in the course of their employment.

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0013
PERIOD OF INSURANCE	:	29 th September 2014 – 28 th September 2015
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence including costs and expenses

PUBLIC/PRODUCTS LIABILITY

Indemnity in respect of claims made for death, injury or disease to persons (other than employees) or loss or damage to third party property arising out of and in the course of the business.

INSURER	:	Zurich Municipal
POLICY NUMBER	:	NHE-03CA02-0013
PERIOD OF INSURANCE	:	29 th September 2014 – 28 th September 2015
LIMIT OF INDEMNITY	:	£40,000,000 each occurrence (and in the aggregate in respect of Products)

PROFESSIONAL INDEMNITY

Indemnity in respect of the Legal Liability to Third Parties for breach of professional duty due to negligent act, error or omission in connection with your business.

INSURER	:	Royal & Sun Alliance
POLICY NUMBER	:	RKK665002
PERIOD OF INSURANCE	:	29 th September 2014 – 28 th September 2015
LIMIT OF INDEMNITY	:	£10,000,000 each occurrence and in the aggregate

Subject to the policy terms, conditions, limitations, exclusions and cancellation provisions.

This document is issued as a matter of information only and confers no rights upon the document holder other than those provided by the policy. This document does not amend, extend or alter the coverage afforded by the policy or policies as described herein.

/Continued.....

Notwithstanding any requirement, term or condition of any contract or other document with respect to which this document may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions or exclusions of such policy (policies). Limits shown may have been reduced by paid claims.

If you should require any further information or the above please do not hesitate to contact us.

Yours faithfully,



David Galey
Brcking Manager

Direct Dial: 0113 393 6825
Email: david.galey@hibl.co.uk



APPENDIX 3: Letter from NRES confirming favourable opinion



Health Research Authority

NRES Committee London - City Road & Hampstead

Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0117 342 1339

20 January 2015

Dr Eliana Hadjiantonis
Paediatric Dentistry Department
Clarendon way
Leeds
LS29LU

Dear Dr Hadjiantonis

Study title: A Retrospective study on the outcome and the prognostic factors affecting the success of traumatic injuries of permanent teeth.
REC reference: 15/LO/0131
IRAS project ID: 154293

The Proportionate Review Sub-committee of the NRES Committee London - City Road & Hampstead reviewed the above application on 14 January 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Miss Maeve Groot Bluemink, nrescommittee.london-cityroadandhampstead@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

The Committee has considered and reviewed the project as research and given the ethical opinion detailed below.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

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.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study 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 a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra_studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

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).

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").

Approved documents

The documents reviewed and approved were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Sponsor Insurance or Indemnity]	Version 1	17 September 2014
IRAS Checklist XML [Checklist_09012015]		09 January 2015
Letter from sponsor [Letter/E-mail from sponsor]	Version 1	17 September 2014
Other [CV for Academic Supervisor - Ms Munyonbwe]	Version 2 (Short version)	25 November 2014
Other [CV for Academic Supervisor - Prof Toumba]	Version 1	25 November 2014
Other [Email: Response to request for further info during validation]		09 January 2015
REC Application Form [REC_Form_09012015]		09 January 2015
Research protocol or project proposal	2	31 October 2014
Summary CV for Chief Investigator (CI) [Chief Investigator CV - Dr Hadjantonis]	Version 1	28 November 2014
Summary CV for supervisor (student research) [Supervisor CV - Prof Duggal]	Version 1	28 November 2014

Membership of the Proportionate Review Sub-Committee

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

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.

After ethical review

Reporting requirements

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
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

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

15/LO/0131

Please quote this number on all correspondence

Yours sincerely



pp
Dr David Slovic
Chair


Email: nrescommittee.london-cityroadandhampstead@nhs.net

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

"After ethical review – guidance for researchers" [SL-AR2]

*Copy to: Faculty Research Ethics and Governance Administrator
Ms Ann Gowing, Leeds R&D LTHT*

APPENDIX 4: Letter of approval by Research & Innovation

The Leeds Teaching Hospitals 
NHS Trust

Josephine Cuxton

Research & Innovation

03/03/2015

Leeds Teaching Hospitals NHS Trust

34 Hyde Terrace
Leeds
LS2 9LN

Dr Eliana Hadjiantonis
Paediatric Dentistry Department
Clarendon way
Leeds
LS2 9LU

Tel: 0113 392 0162
Fax: 0113 392 0146

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

Dear Dr Eliana Hadjiantonis

Re: NHS Permission at LTHT for: A Retrospective study on the outcome and the prognostic factors affecting the success of traumatic injuries of permanent teeth
LTHT R&I Number: DT14/11399:
REC: 15/LO/0131

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&I Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at <http://www.leedsth.nhs.uk/research/>

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet Conditions of Approval.

If you have any queries about this approval please do not hesitate to contact the R&I Department on telephone 0113 392 0162.

Indemnity Arrangements

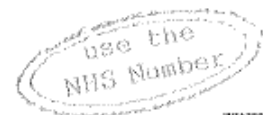
The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority "Clinical Negligence Scheme for NHS Trusts" for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the R&I Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as investigator and the researchers listed on the Site Specific Information form. Should there be any changes to the research team please ensure that you

Chair Dr Linda Pollard CBE JP DL Chief Executive Julian Hartley

The Leeds Teaching Hospitals incorporating:

Chapel Allerton Hospital Leeds Dental Institute Seacroft Hospital Leeds Children's Hospital
St James's University Hospital Leeds General Infirmary Wharfedale Hospital Leeds Cancer Centre



WTA280

inform the R&I Department and that s/he obtains an appropriate contract, or letter of access, with the Trust if required.

Yours sincerely



Dr D R Norfolk
Associate Director of R&I

Approved documents

The documents reviewed and approved are listed as follows:-

<i>Document</i>	<i>Version</i>	<i>Date of document</i>
NHS R&D Form	3.5	04/02/15
CSU Approval		26/02/15
REC Letter confirming favourable opinion		20/01/15
Protocol	2	10/2014
Evidence of Insurance		17/09/14

\

Conditions of NHS Permission for Research:

Permission from your Directorate must be obtained before starting the study.

Favourable Opinion of the appropriate Research Ethics Committee, where necessary, must be obtained before starting the study.

Arrangements must be made to ensure that all members of the research team, where applicable, have appropriate employment contracts or letter of agreement to carry out their work in the Trust.

Agreements must be in place with appropriate support departments regarding the services required to undertake the project and arrangements must be in place to recompense them for the costs of their services.

Arrangements must be in place for the management of financial and other resources provided for the study, including intellectual property arising from the work.

Priority should be given at all times to the dignity, rights, safety and well being of participants in the study

Healthcare staff should be suitably informed about the research their patients are taking part in and information specifically relevant to their care arising from the study should be communicated promptly.

Each member of the research team must be qualified by education, training and experience to discharge his/her role in the study. Students and new researchers must have adequate supervision, support and training.

The research must follow the protocol approved by the relevant research ethics committee. Any proposed amendments to or deviations from the protocol must be submitted for review by the Research Ethics Committee, the Research Sponsor, regulatory authority and any other appropriate body. The R&I Department should be informed where the amendment has resource implications within the Directorate and the Directorate research lead/clinical director notified.

Adverse Events in clinical trials of investigational medicinal products must be reported in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Complete and return Study Status Reports, when requested, to the R&I Department within 28 days of receipt as requested. (NB Failure to comply to such request with the requirement will lead to suspension of NHS Permission.)

Procedures should be in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.

Arrangements must be made for the appropriate archiving of data when the research has finished. Records must normally be kept for 15 years.

All data and documentation associated with the study must be available for audit at the request of the appropriate auditing authority. Projects are randomly selected for audit by the R&I Department. You will be informed by letter if your study is selected.

Findings from the study should be disseminated promptly and fed back as agreed to research participants.

Findings from the study should be exposed to critical review through accepted scientific and professional channels.

All members of the research team must ensure that the process of informed consent adheres to the standards GCP outlined in the UK Clinical Trials Regulations. Investigators are directed to the R&I website for further information and training availability.

Where applicable, this NHS Permission includes aspects of the study previously covered by the NRES Site Specific Assessment (SSA) process.

Appropriate permissions must be in place for studies which are covered by the Human Tissue Act.

Patient Information Sheet and Consent form must be on The Leeds Teaching Hospitals headed paper and include local contact details.

NIHR Benchmarks for Performance in Initiating & Delivering Clinical Research

Provide recruitment information when requested by R&I on the Clinical Trial Tracker (available on Trust Sharepoint)

Work with R&I to resolve blocks and delays on trials to ensure that LTHT meets the NIHR benchmarks.

If you are not able to comply with these requirements, NHS permission to conduct the research in LTHT will be suspended.

Commercially Sponsored Trials

If the study is commercially sponsored, NHS Permission is given subject to provision of the following documents.

Clinical Trials Agreement - agreed and signed off by the R&I Department (on behalf of the Leeds Teaching Hospitals NHS Trust) and the Sponsor. Investigators do not have the authority to sign contract on behalf of the Trust.

Indemnity agreement, if not included in the Clinical Trials Agreement- (standard ABPI no fault arrangements apply) signed by the R&I Department and the Sponsor

It is essential that all the responsibilities set out in the Research Governance Framework, including those outlined above are fulfilled. The Trust reserves the right to withdraw NHS Permission where the above criteria are not being met. The Trust will not accept liability for any activity where NHS Permission has not been granted.

NEW Condition of Approval NEW

Clinical Trials Performance Management

NIHR Benchmarks for Performance in Initiating & Delivering Clinical Research

LTHT clinical trial performance is now measured against 2 national benchmarks to improve the initiation and delivery of clinical trials approved by the Trust. Since April 2013 NIHR funding to the Trust has been conditional on meeting these benchmarks.

Initiation – it should take no more than 70 days from receipt of a valid research application (signed SSI form) by the R&I Department to the recruitment of (ie consenting) the 1st patient to the trial

Delivery – for all commercial trials hosted by the Trust the agreed number of patients must be recruited within the agreed recruitment period

The Trust now has to submit quarterly performance reports to the Department of Health setting out our performance.

NHS permission for this project to be carried out in the Trust is therefore granted on the understanding that you:

Provide recruitment information when requested by R&I on the Clinical Trial Tracker (available on Trust Sharepoint)

Work with R&I to resolve blocks and delays on trials to ensure that LTHT meets the NIHR benchmarks.

If you are not able to comply with these requirements, NHS permission to conduct the research in LTHT will be suspended. These new conditions of approval are in addition to the Conditions of approval listed in the attached NHS permission letter.

For more information about the new benchmarks and the work we are doing to support clinical trial management please see the R&I website.
<http://www.leedsth.nhs.uk/research/>

APPENDIX 5: Data Extraction Proforma

Patient Demographics

Serial Number	
Date of Birth	
Gender	<input type="radio"/> 1 Male <input type="radio"/> 2 Female
Medical History	<input type="radio"/>
Referral	<input type="radio"/> 1 General Dental Practitioner <input type="radio"/> 2 Community Dental Services <input type="radio"/> 3 Specialist Paediatric Dentist <input type="radio"/> 4 Self-referral <input type="radio"/> 5 Emergency

Trauma Details

Type of Trauma	<p>Luxation injury</p> <ul style="list-style-type: none"> <input type="radio"/> 1 Concussion <input type="radio"/> 2 Subluxation <input type="radio"/> 3 Extrusion Mild <input type="radio"/> 4 Extrusion Moderate <input type="radio"/> 5 Extrusion Severe <input type="radio"/> 6 Extrusion <input type="radio"/> 7 Lateral Luxation Mild <input type="radio"/> 8 Lateral Luxation Moderate <input type="radio"/> 9 Lateral Luxation Severe <input type="radio"/> 10 Lateral Luxation <input type="radio"/> 11 Intrusion Mild <input type="radio"/> 12 Intrusion Moderate <input type="radio"/> 13 Intrusion Severe <input type="radio"/> 14 Intrusion <p>Hard tissue injury</p> <ul style="list-style-type: none"> <input type="radio"/> 15 Infraction <input type="radio"/> 16 Enamel fracture <input type="radio"/> 17 Enamel/dentine fracture <input type="radio"/> 18 Enamel/dentine/pulp fracture <input type="radio"/> 19 Uncomplicated Crown/root fracture <input type="radio"/> 20 Complicated crown/root fracture <input type="radio"/> 21 Root fracture
Affected tooth (FDI)	
Date of Trauma	
Date of presentation	
Age at Trauma	
Stage of Root Development	<ul style="list-style-type: none"> <input type="radio"/> 1 < ½ root length <input type="radio"/> 2 ½ root length <input type="radio"/> 3 2/3 root length <input type="radio"/> 4 Completed root with open foramen <input type="radio"/> 5 closed apical foramen and completed root development

Treatment Details (Luxation Injuries)

Date of repositioning	
Method of repositioning chosen	<ul style="list-style-type: none"> ○ 1 Manual ○ 2 Passive ○ 3 Surgical ○ 4 Orthodontic
Type of splint	
Duration of splinting	

Treatment Details (Complicated crown fractures)

Start Date	
Time since exposure of pulp	
Type of treatment	<ul style="list-style-type: none"> • 1 Pulp capping <ul style="list-style-type: none"> ○ Material: 1 Dycal CaOH • 2 Partial pulpotomy (Cvek's pulpotomy) <ul style="list-style-type: none"> Material: ○ 1 Non setting Ca (OH) ○ 2 MTA ○ • 3 Pulpectomy
Date of build up with Composite	

Treatment Details (Other injuries)

Start Date	
Type of treatment	

Clinical assessment

Date	Visit Symptoms 1 Yes 2 No	Soft Tissue (Abscess) 1 Present 2 Absent	Mobility 1 Normal 2 Grade I 3 Grade II 4 Grade III 5 No mobility	TTP 1 Yes 2 No 3 Not recorded	Colour 1 Normal 2 Yellow 3 Greyish 4 Not recorded	Sensibility tests 1 +ve 2 -ve	Sound 1 Normal 2 Ankylosis 3 Not recorded	Infraocclusion 1 Yes 2 No	Clinical outcome 1.Success 2.Failure

Radiographic assessment

Date	Radiographic Pulp 1.Healing 2.PCO 3.Periodontal widening 4.Periapical pathology	Radiographic PDL 1.Healing 2.RRR 3.IRR 4.RRR	Follow up Root development immature teeth 1.Yes 2.No 3.N/A	Radiographic outcome 1.Success 2.Failure	Follow up Periapical pathology 1.Resolution 2.Decrease 3.Same 4.Increased	Follow up IRR 1.Resolution 2.Decrease 3.Same 4.Increased 5.New	Follow up RRR 1.Resolution 2.Decrease 3.Same 4.Increased 5.New	Follow up Root Fracture 1.Yes 2.No	Follow up Post-RCT x-ray outcome

Root canal treatment details if relevant

Tooth		
Date of pulp extirpation		
Apical barrier	<ul style="list-style-type: none"> ○ 1 Yes ○ 2 No Material <ul style="list-style-type: none"> ○ 1 MTA ○ 2 Calcium hydroxide ○ 3 None Quality of apical barrier	
Date of obturation		
Length of Obturation	<ul style="list-style-type: none"> ○ 1 Good ○ 2 Long ○ 3 Short 	
Quality coronal seal (Adequate >2 materials in canal)	<ul style="list-style-type: none"> ○ 1 Adequate ○ 2 Inadequate 	
Quality of condensation	<ul style="list-style-type: none"> ○ 1 Adequate ○ 2 Inadequate Describe: 1 Voids 2 Gap	
Overall quality of Obturation according to above	<ul style="list-style-type: none"> ○ 1 Adequate ○ 2 Inadequate 	
Date of final coronal restoration with composite		

Follow up duration

Total follow up period at LDI (Injury- Discharge)	
---	--