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Vertical root fractures in root canal-treated teeth



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Vertical root fractures (VRF) are longitudinally orientated, complete or incomplete cracks that can occur on the tooth root at any level and usually initiate from the internal root canal wall. VRFs commonly occur in root canal-filled teeth and may result in the loss of the affected tooth. A PubMed search to April 2017 was completed using the key words “vertical root fractures”, “endodontic treatment” and “root-filled teeth”. Abstracts were read to identify relevant articles before retrieval. A search of reference lists identified further studies and 62 articles were selected. Diagnosis of VRFs can often be challenging. The combined use of history taking, periodontal probing and periapical radiographs is essential. The aetiology is multifaceted and includes predisposing factors such as tooth type, root canal morphology, and iatrogenic factors involving materials and devices used in root canal treatment and for post space preparation. Emerging risk factors such as implant-associated VRF have recently been identified. Prevention of VRF includes conservation of dentine during root canal instrumentation, appropriate choices of materials for preparation, irrigation and disinfection and avoiding excessive forces during lateral and vertical condensation of gutta-percha (GP). Cracks formed during root-end preparations in apical surgery may also lead to VRF, and teeth with the “butterfly effect” seem to be more at risk. Traditionally, treatment of VRFs has been tooth extraction. Alternative treatments such as bonding of separated root fragments followed by intentional replantation have gained some momentum.

■ Introduction

A vertical root fracture (VRF) is defined as a longitudinally orientated complete or incomplete crack originating from the root at any level¹. The fracture most likely initiates internally from the canal wall and develops outwards to the root surface^{1,2}. It is usually directed bucco-lingually and may involve one surface (buccal or lingual) or both^{3,4}. The fracture is located in the root portion of the tooth only, however it may extend apically or coronally toward the cervical periodontal attachment. A VRF may span the length of the root or occur as a shorter crack at any level along the root¹.

VRFs arguably represent some of the most frustrating cases in endodontic practice. Diagnosis can be difficult and they can be devastating for patients who have invested time and finances to undergo root canal treatment (RCT) only to have the tooth extracted⁵. They can also be a source of stress for practitioners, as the occurrence of a VRF following RCT is a potential medico legal problem⁶. An in-depth knowledge of how to accurately diagnose and successfully manage VRFs is essential to avoid inappropriate treatment and subsequent complaints.

■ Prevalence

Although VRFs in previously unrestored teeth have been described, this is uncommon and has mainly been reported in patients of Chinese descent or following trauma^{7,8}. A recent study reported that unrestored teeth that develop VRFs usually exhibit attrition and occlusal wear⁹. It is well documented that the majority of VRFs occur in root canal-filled teeth⁴.

Studies investigating the prevalence of VRFs in extracted root canal-filled teeth use different and sometimes vague definitions. This limits their comparability, and could explain the wide range (8.8 to 31%) reported. Sjögren et al (1990) reported the highest recorded prevalence of 31% of "root fractures" in 68 teeth extracted after RCT¹⁰. Although this figure is often quoted in the literature, the study provides no definition of root fracture and so a contribution from horizontal root fractures cannot be excluded. Their findings contrast with more conservative results reported in subsequent studies. Vire et al (1991) examined 116 extracted root canal-filled teeth and reported a VRF prevalence of 13%¹¹. A more recent study by Toure et al (2011) reported a comparable prevalence of 13.4%⁵. Fuss and co-workers (1999) examined 564 extracted teeth and reported a lower prevalence of 11%, whereas Zadik et al (2008) studied 547 extracted root canal-treated teeth and reported an even lower prevalence of 8.8%^{12,13}.

The literature is also divided on the susceptibility of tooth types to developing a VRF. Some studies report a higher prevalence in mandibular molars than maxillary molars, particularly the mesial root of mandibular molars^{9,13}. Another study reports a higher prevalence in maxillary premolars⁵. Cohen et al (2006) found that maxillary premolars and mandibular molars both had a significantly higher prevalence of VRFs compared with anterior teeth¹⁴. Occurrence of VRFs has also been reported to be significantly higher in females and among older patients^{14,15}.

■ Diagnosis

An accurate diagnosis is paramount to the correct and timely management of VRFs, however the diagnosis is often very challenging. In contrast to

horizontal fractures, VRFs tend to propagate and this makes diagnosis more difficult, especially in the early stages. An important first step is to differentiate VRFs from other longitudinal fractures and cracks that occur in teeth.

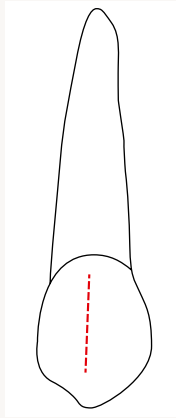
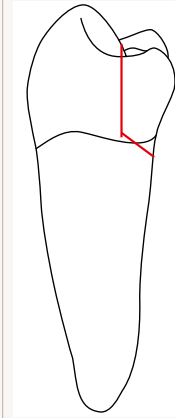
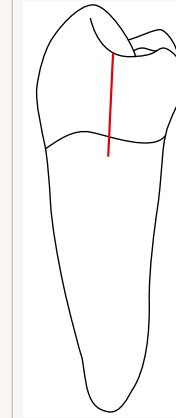
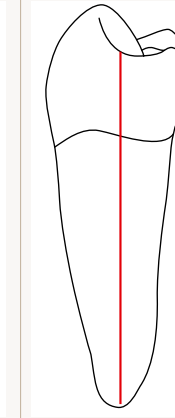
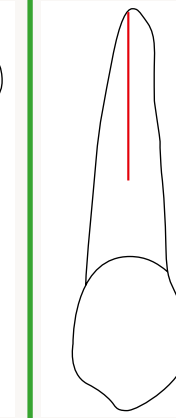
After excluding tooth fracture caused by sudden impact trauma, five classes of longitudinal tooth fracture have been identified; enamel craze lines, fractured cusps, cracked tooth, split tooth and VRF¹. These five categories have been devised to provide universal definitions that researchers and clinicians can use to avoid ambiguity. Rivera and Walton (2009) provide a comprehensive overview of the five classes, and a summary is provided in Table 1¹. For the purposes of this review, diagnosis will primarily focus on VRFs of root canal-treated teeth.

It is important to note that the clinical signs and symptoms of VRFs, as well as their radiographic presentations, are often similar to those associated with non-healing lesions following RCT and also certain manifestations of periodontal disease^{2,15}. The presence of a VRF may coincide with a recurrent periodontal abscess¹⁵. Poor quality root canal fillings further complicate the diagnosis of VRF, which, in turn, extends the time to achieve an accurate diagnosis and increases medico legal risk⁶. When a poor-quality root canal filling is present, the most obvious reason for the failure is the RCT. Unless the clinician actively seeks to rule out a VRF the possibility of misdiagnosis exists. A variety of diagnostic aids are available.

■ History and clinical examination

Unfortunately, there are no typical hallmark signs or symptoms associated with VRFs. Some retrospective studies reported that the majority of patients (55 to 66%) will present with mild pain or dull discomfort, which may be accompanied by tenderness on mastication^{15,16}. On the other hand it has also been reported that almost one-third of patients present with no obvious symptoms or pain history¹⁵. The presence of a draining sinus may indicate a VRF, and this has been reported in 13 to 42% of cases^{15,16}. A distinct feature of a sinus tract associated with VRF is its frequent location at mid-root level or close to the gingival margin, as opposed to more apically, as expected with persistent periapical

Table 1 Classification of longitudinal fractures (adapted from Rivera & Walton 2009)¹.

	Craze line	Fractured cusp	Cracked tooth	Split tooth	Vertical root fracture
					
Location	Enamel only	Crown & cervical margin of root	Crown only or crown to root	Crown & root; to proximal surfaces	Root only
Direction	Occluso-gingival	Mesio-distal & bucco-lingual	Mesio-distal	Mesio-distal	Bucco-lingual

disease². The presence of two sinus tracts at both the buccal and lingual aspects is highly indicative of VRF^{2,17}.

Transillumination using a fibre-optic light has been described as a useful aid to detect a VRF¹⁷. Placement of the light at various points on the crown or root surface may reveal a fracture line. Transillumination is particularly useful when performed after restorations are removed, but may not be feasible when a prosthetic crown or root canal posts are present.

The majority of late-stage VRFs present with a deep, vertical step, osseous defect that can be detected using a periodontal probe (Fig 1)^{15,18}. The probe can usually be inserted into a narrow pocket that extends to the deepest point of the fracture line¹⁵. A non-metallic periodontal probe (e.g. Perio-Wise, Premier Dental Products, Plymouth Meeting, PA, USA) is valuable for the detection of these periodontal defects. It is important for clinicians to distinguish between pocket probing depths in VRF and periodontal disease. In VRFs, the pocket is usually isolated and limited to the site of the fracture, whereas in a patient with periodontitis more sites and multiple teeth with generalised pocketing are expected. In the early stages of a VRF, there may be insufficient time for an osseous defect to occur








**Fig 1** PerioWise probe exploring for presence of a VRF.

and thus probing can give a false-negative result. Although probing patterns are helpful, they are not totally diagnostic and should be used in conjunction with other aids.

■ Conventional radiography

The radiographic appearance of VRFs has been extensively studied^{15,17,19,20}. In the majority of cases the appearance is a diffuse widening of the periodontal ligament space^{9,15}. External root resorption may sometimes occur along the line of fracture, and this may be seen as an irregular radiolucent zone

Table 2 Radiographic appearances of VRF

Description	Radiographic appearance
Halo shaped radiolucency is a combined periapical and perilateral radiolucency on one or both sides of the root. May extend to the mid or coronal root level ^{16,18,19} .	
Isolated perilateral radiolucency along the proximal side of the root (mesial or distal), but not involving the coronal or periapical part of the root ^{16,19} .	
Periodontal radiolucency. A lateral radiolucency on the proximal root surface (mesially, distally or both) extending from the crestal bone apically. Does not usually involve the apical portion of the root. The level to which the radiolucency extends often coincides with the level of the VRF ^{2,16,18} .	
Vertical bone loss/angular radiolucency extending from the crestal interproximal bone and terminating along the root surface (mesially and or distally) ^{2,18} .	
Periapical radiolucency confined to the apical region and not extending coronally. This can be confused with persistent disease following RCT ^{14,19} .	
Bifurcation radiolucency – commonly found in VRFs of mandibular molars. Large or small radiolucency in the bifurcation area, without involving other regions around the root ¹⁹ .	
Root displacement – the root fracture is clearly visible. Proliferation of granulation tissue results in rapid movement of the separated fragment away from the remaining root, often until it comes into contact with an adjacent tooth ^{2,14,16} .	

adjacent to and overlying the root canal filling¹⁷. Studies have reported a number of radiographic appearances that are suggestive of a VRF, and a summary is provided in Table 2.

Rud and Omnell (1970) stated that a fracture on the lingual and buccal sides of the root (the usual sites) would require some time before bone destruction extends interproximally to be seen on a radiograph²¹. Therefore, radiographs may appear normal and are limited when bone resorption is narrow or lies solely on the buccal or lingual aspects. Furthermore, conventional radiographs will only detect a VRF if the X-ray beam is parallel to the plane of fracture. Angled radiographs to the distal or mesial may help to reveal bony defects¹⁷. Because it is difficult to make a diagnosis from conventional radiographs alone, they should be used only as an adjunct.

■ Cone beam computed tomography (CBCT)

The use of CBCT in the diagnosis of VRFs is controversial. CBCT allows visualisation of the fracture line from multiple planes at a very high contrast while eliminating superimposition of surrounding structures. However, there is no agreement on the accuracy of CBCT in detecting VRFs. Some studies have found that CBCT imaging is more accurate than conventional radiography^{22,23}, while another reports no differences²⁴, and yet others have concluded that CBCT is not a reliable method to detect VRFs^{25,26}.

The reproducibility and accuracy in VRF detection has been found to vary between different CBCT systems²⁷. Artefacts caused by the presence of root canal filling materials such as gutta-percha or metal posts may hinder the identification of fracture lines on CBCT²⁶. Nonetheless, according to the European Society of Endodontology (2014)²⁸, and the American Association of Endodontists and Academy of Oral and Maxillofacial Radiology (2015/2016)²⁹, CBCT should be used only if conventional periapical radiographs do not provide enough information for VRF diagnosis.

■ Surgical exploration

Historically, studies have suggested that the only way to definitively confirm the presence of a VRF is by

visual inspection^{15,17,18}. This often entails raising a full thickness mucoperiosteal flap to locate a fracture line (Fig 2). Lustig et al (2000) carried out surgical exploratory procedures on 110 teeth to study the pattern of bone resorption associated with VRFs¹⁸. They reported two main types of buccal alveolar bone resorption: dehiscence and fenestration. Dehiscence was described as a triangular V-shaped defect, which pointed apically and occurred in 91% of the teeth studied. Fenestration only occurred in 9% of the teeth and was described as an oval-shaped defect with an intact bridge of coronal bone. Fenestration bone resorption is said to occur when the VRF is located along the root, but does not extend to the cemento-enamel junction or apex¹⁸.

Surgery does not always reveal a VRF. Meister et al (1980) described a case of VRF where the radiograph of a root canal-treated tooth was essentially normal and probing revealed no osseous defect. When a full thickness flap was raised, no bone loss was evident. Only on extraction was the fracture line revealed, extending the length of the root¹⁵. Today the use of CBCT may identify such early cases of VRF without exposing the patient to invasive surgical procedures²².

■ Pathogenesis

VRFs occur when excessive forces on radicular dentine (often from within the root canal) surpass the binding strength of dentine^{1,3,4,30}. A VRF, whether incomplete or complete, usually extends to the periodontal ligament. Soft tissue may grow into the fracture space increasing the separation of the root segments. On communication with the oral cavity through the gingival sulcus, foreign material, food debris and bacteria obtain access to the fracture area. An inflammatory process is induced in the adjacent periodontium, resulting in breakdown of the periodontal ligament, alveolar bone loss and granulation tissue formation³⁰. The osseous defect usually propagates apically. In VRFs confined to the apical root portion without communication with the oral cavity, the inflammatory process in the surrounding tissues will depend on the release of any existing irritants in the root canal, including bacteria and canal sealer material^{2,30}.



Fig 2 Intraoral photograph of a surgical site showing VRF (arrow), loss of buccal bone, and associated soft tissue lesion.

■ Aetiology and prevention

The aetiology of VRFs in root canal-treated teeth is multifactorial and can be divided into predisposing and iatrogenic factors. Predisposing factors include tooth type and morphology (maxillary premolars and mesial roots of mandibular molars), loss of healthy tooth structure (such as from trauma, root resorption or caries), and loss of periodontal and alveolar bone support^{2,14}.

Parafunctional habits such as bruxism have also been described as contributing to the formation of VRFs⁷. Although this has been reported to be statistically insignificant¹⁴, patients should still be questioned about parafunctional habits as this may give clinicians an indication of unfavourable forces on teeth.

Iatrogenic factors refer to VRFs resulting from dental procedures and materials used during RCT. These include excessive chemomechanical preparation and overzealous widening of the root canal space during post space preparation or root-end cavity preparations.

■ Root canal instrumentation

Excessive application of forces on to radicular dentine during RCT has been shown to increase the risk of VRF. Cracks often initiate during instrumentation of canals and existing cracks propagate during obturation³¹. It has been reported that rotary instrumentation may cause more crack formation compared with traditional hand filing^{32,33}. However, it is important to note that tooth type, the presence of oval canals and thin canal walls all significantly increase the risk of VRF during instrumentation². It is critical that caution is applied regardless of the preparation system being used to avoid excessive instrumentation and reduce the risk of VRF.

Interestingly, teeth instrumented with the Self-Adjusting File (SAF; ReDent Nova, Ra'anana, Israel) may exhibit better fracture resistance than those instrumented with other rotary or reciprocating systems³⁴. The SAF is a hollow and flexible file that adapts itself to the shape of the root canal. Its abrasive surface removes circumferential and equal amounts of radicular dentine, reducing the chance of over preparation while maintaining canal anatomy³⁵. The SAF system may help to avoid VRFs.

■ Root canal irrigants and medicaments

The prolonged use of calcium hydroxide (CH) has been found to adversely affect the biomechanics of dentine by reducing its microhardness, rendering it more brittle and prone to fracture^{36,37}. The long-term use of CH for the apexification of immature teeth resulted in a 40% incidence of root fracture³⁶. Interestingly however, sheep teeth obturated with mineral trioxide aggregate (MTA) after 1 month of CH showed no significant reduction in fracture resistance³⁷. To reduce the risk of VRF, clinicians should avoid prolonged use of CH.

Likewise, ethylenediaminetetraacetic acid (EDTA) and sodium hypochlorite, commonly used for smear layer removal, have also been found to significantly decrease the microhardness of dentine when high concentrations are used for prolonged periods³⁸. Clinicians should avoid their excessive use during chemomechanical debridement of the root canal system.

■ Root canal obturation

Excessive forces applied to the root canal wall during lateral or vertical condensation of gutta-percha have been identified as a major contributor to VRF formation^{3,15}. In some cases a sharp cracking sound may be heard or bleeding around the gutta-percha points can be seen, both of which are diagnostic of VRF¹⁵. The force exerted on dentine during lateral condensation has been reported to be between 1 to 3 kg³. Forces generated by finger spreaders are significantly lower than those from hand spreaders³. Clinicians should be cautious not to apply excessive force when using spreaders and pluggers during obturation.

A variety of obturation materials have recently become available, with some claiming to have superior properties, such as the ability to strengthen teeth and minimise VRF. Literature on this subject remains divided. One study reported that obturation with the Resilon (Resilon Research, Madison, CT, USA) and EndoREZ (Ultradent, South Jordan, UT, USA) "mono-block" system provided a significantly higher resistance to VRF compared with gutta-percha³⁹. Conversely, another study reported no significant difference between these materials⁴⁰. This shows that practitioners should be cautious when using new products, especially if their benefits have not been adequately proven by scientific studies.

Teeth with root canals filled with MTA have demonstrated a higher resistance to VRF than teeth whose canals were filled with gutta-percha and sealer⁴¹. Recently, MTA has been reported to induce mineralisation within dentinal tubules⁴². This could potentially strengthen roots and protect against crack and VRF formation. Further research is required.

■ Intraradicular restorations and posts

VRFs can also be caused by restorative procedures carried out after root canal treatment. The compaction and condensation of amalgam into the canal space when constructing a core exerts unfavourable forces on root dentine which may lead to VRF formation^{1,15}. Furthermore, once hardened, amalgam packed into the canal has the potential to create wedging stresses that may promote cracks. Clinicians may consider using bonded resin composite restorations instead of amalgam to reduce the need for intraradicular retention.

The selection of an appropriate post and correct preparation of the post space are important in the prevention of VRF¹⁵. The ideal post should be parallel sided, serrated and fit passively into the canal space so as to minimise unfavourable wedging stresses. Posts should also have at least a 1:1 ratio with crown length, and their diameter should be kept to a minimum so as not to cause excessive removal of dentine⁴³. Custom-made metallic posts do not increase the strength of root canal-filled teeth⁴⁴ and so their use should be limited to teeth that require retention of a core of restorative material⁶. Corrosion of some metallic posts has been reported to promote the formation of VRFs²¹.

Interestingly, a study on immature bovine teeth reported that the use of MTA reinforced by a metallic post significantly increased fracture resistance. This might be indicated where the post is not essential for retention of a restoration, but is important to strengthen the root⁴⁵. Use of prefabricated fibre-reinforced posts is becoming popular. These posts have a similar elastic modulus to root dentine and are thought to be associated with a decreased risk of root fractures. Fibre posts are also associated with non-catastrophic failures; that is, the post fractures preferentially to root dentine. A six-year follow-up study reported compelling evidence in support of the use of fibre posts when restoring root canal-filled premolars⁴⁶. Prefabricated fibre posts significantly improved tooth survival (more so than custom-fitted posts) and the root fracture risk decreased with an increasing number of remaining coronal walls.

The preservation of tooth structure is important in maximizing resistance to fracture. A ferrule is a collar of dentine extending coronally from the crown margin, which after being encircled by a crown has a protective function (the ferrule effect) by reducing stresses within the tooth. The ideal amount of dentine required for a ferrule has been widely debated, however most studies recommend at least 1.5 mm to 2.0 mm⁴⁴. The ferrule effect can significantly enhance the fracture resistance of restored teeth, regardless of the use of a post⁴⁴. When a ferrule can be preserved, a post seems unnecessary and it might even decrease the strength of the restored tooth⁴⁴. Teeth with a 2 mm ferrule and restored without a post obtained the highest fracture resistance and this was not significantly different from teeth with a ferrule and post. Teeth with no ferrule and no post had the lowest fracture resistance⁴⁴. The ferrule effect is an important concept that clinicians should be aware of, as it may facilitate the prevention of VRFs.

■ Implant-associated VRF

The study by Rosen et al (2016) was the first to report a series of cases in which VRFs in root canal-filled teeth were diagnosed after adjacent implant placement⁴⁷. Dental implants have no periodontal ligament and thus no proprioceptive mechanisms to signal excessive force. To prevent occlusal overloading (which can adversely affect the osseointegration

of the implant), the implant crown is often fitted so there is minimal force on the implant. Instead, occlusal forces are distributed to adjacent teeth. However, when this tooth is root canal-filled, the increased loading may be catastrophic. It has been reported that non-vital teeth have lower nociceptive and proprioceptive ability and are therefore less able to warn the patient of increased load⁴⁸. It is suggested that proprioception is reduced by 30% following RCT due to the removal of pulpal nerves, which would otherwise be involved in regulating masticatory loads⁴⁸. The combination of excessive occlusal load and reduced proprioceptive ability potentially increases the risk of VRF in root canal-filled teeth adjacent to implants⁴⁷.

■ Apical surgery and the butterfly effect

Use of ultrasonic retrotips for root-end cavity preparation can lead to increased formation of micro-cracks in radicular dentine⁴⁹⁻⁵¹. These could propagate to form VRFs^{52,53}. Cracking of root-ends was first noted as an incidental finding in a scanning electron microscope (SEM) study⁴⁹. However, the teeth were dehydrated prior to evaluation, so it is impossible to conclude whether ultrasonic instrumentation or dehydration artefacts were involved.

A subsequent study overcame the problem by taking silicone impressions of the prepared root-ends and using resin replicas and SEM to examine cracking⁵⁰. It found that ultrasonics caused significantly more cracks than burs. Investigations into the contribution of ultrasonic power settings to crack formation have produced conflicting results. One study reported more cracks with higher settings⁵¹ whereas another found that lowering the power setting produced a greater number of cracks⁵⁴.

Importantly, studies exploring why VRFs develop predominantly in the bucco-lingual direction are limited. It has been hypothesized that teeth with the “butterfly effect” are more prone to developing cracks and VRFs in the bucco-lingual direction due to their significantly higher dentine hardness mesio-distally⁵⁵. The butterfly effect is an optical phenomenon which occurs in some cross-sections of tooth roots. A decrease in the number of dentinal tubules results in greater light transmission to give a translucent appearance⁵⁶. Teeth with the butterfly effect

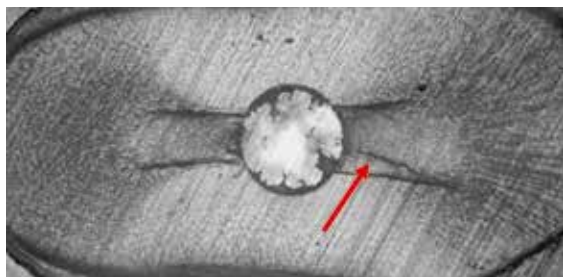


Fig 3 Root section under light microscope ($\times 10$) showing the butterfly effect.

have a significantly higher density of dentinal tubules bucco-lingually compared to mesio-distally⁵⁷ giving the characteristic butterfly appearance (Fig 3). The effect can be seen clinically when resected root-ends are viewed with an operating microscope or an endoscope⁵⁸. Use of an operating microscope or an endoscope and staining of the root-end with dyes, such as methylene blue, may help detect cracks^{17,58}.

■ Treatment of VRF

A common misconception among clinicians is that teeth with VRFs are doomed to be problematic and must therefore be extracted. Although extraction is indicated in cases where there is extensive destruction of the periodontium and supporting tissues, there are a number of case reports with alternative treatments that report success^{2,17,59,60}.

Extraoral bonding of the separated fragments of VRF teeth with adhesive resin material and intentional replantation of the reconstructed tooth has been described⁵⁹. At a three-year follow-up, successful healing (clinically and radiographically) was reported⁵⁹. Bonding and intentional replantation procedures are ideal for incisor teeth, but have limited long-term success in premolars and molars⁶⁰⁻⁶². Higher occlusal forces on posterior teeth may cause debonding and re-fracture⁶⁰. For multi-rooted teeth, treatment options may include root resection, amputation of the affected root or hemisection¹⁷.

Incomplete buccal VRFs that are confined to the coronal part of the root may be successfully managed by surgical intervention. Taschieri and colleagues (2010) described a procedure in which a mucoperiosteal flap was raised to visualise the fracture, a groove was prepared following the fracture line using ultrasonically powered retro tips and the

defect sealed with MTA. The study reported a 100% survival rate at 1 year, which reduced to 70% at the 33-month follow-up⁶³.

It is important to note that careful case selection and informed consent are essential prior to commencing treatment of VRFs. Patients should be made aware of the risks and complications. Root resorption might be expected to occur if replanted teeth are held in dry conditions during reconstruction and if the extraoral time is excessive⁶⁰. Replacement resorption/ankylosis is another complication. Patients should also be advised of the guarded long-term prognosis of teeth with a VRF and be provided with alternative treatment options should extraction eventuate.

■ Conclusions

Clinicians should have a good understanding of how to correctly diagnose and manage VRFs. They require a sound understanding of the different clinical and radiographic presentations of VRFs to avoid misdiagnosis. There are predisposing and iatrogenic causes of VRF and conservation of radicular dentine during instrumentation and post space preparations are examples of simple steps for prevention. Root canal-filled teeth adjacent to implants may have a higher susceptibility to developing VRFs. Where apical surgery is indicated, prepared root-ends should be inspected carefully to detect cracks. Treatment options vary, and some are worth exploring for the motivated patient who understands that a good long-term prognosis cannot be guaranteed.

■ Conflict of interest/funding statement

We affirm that we have no financial affiliation (e.g. employment, direct payment, stock holdings, retainers, consultancies, patent licensing arrangements or honoraria), or involvement with any commercial organisation with direct financial interest in the subject or materials discussed in this manuscript, nor have any such arrangements existed in the past 3 years. Any other potential conflict of interest is disclosed. The authors deny any conflict of interest related to this study.

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