A clinical evaluation of all-ceramic bridges placed in UK general dental practices: three-year results

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Abstract

Purpose: To report the results at year three of an evaluation of the performance of fixed-fixed all-ceramic bridges, constructed with a yttrium tetragonal zirconia polycrystal substructure, placed in adult patients in UK general dental practices and cemented using a self-adhesive resin-based cement

Methods: Ethical approval was obtained. Four UK general dental practitioners were asked to recruit patients in accordance with the trial criteria and protocol. After obtaining informed written consent, appropriate vitality and radiographic assessments were completed and the pre-operative status of the gingival tissues noted. The teeth were prepared and bridges constructed the technical and laboratory procedures in accordance with the manufacturer’s instructions. Each bridge was reviewed annually within 3 months of the anniversary of its placement by a calibrated examiner, together with the clinician who had placed the restoration. The examiners evaluated the integrity of the restoration, its anatomic form, marginal adaptation, surface quality, sensitivity, the condition of the adjacent gingivae, and the presence or absence of secondary caries. The first-year results were published in 2008.

Results: Bridges which were examined at the third-year review (n= 34) were present, intact and performing well, though a further veneering porcelain chip was detected at the year-two review (one reported at year-one) and a further abutment tooth had been successfully endodontically treated, through an occlusal access cavity, in addition to the two already reported at year 1.

Conclusion: At year 3 the Lava bridges placed in this trial and reviewed to date were continuing to perform satisfactorily.

INTRODUCTION

The paper reporting the first-year results of this evaluation of fixed-fixed all-ceramic bridges in general practice was published in 2008[1]. That paper also discussed the value of research in general practice, with particular reference to the UK-wide practice based research group The PREP (Product Research and Evaluation by Practitioners) panel, of which the four general dental practitioners (GDPs) involved in this evaluation were members. In late 2008 the value of practice-based research was further recognised in Europe by the establishment of the Pan European Region Practice-based Research Network[2], part of the worldwide Practice-Based Research Network Group of the International Association for Dental Research, inaugurated in 2007.

Following discussion with the manufacturer, and after obtaining Ethics Committee approval, it was agreed to extend the original three-year evaluation to five years to provide more long-term information.

Yttrium tetragonal zirconia crystals (Y-TZP) and CAD-CAM technology

Zirconia ceramic (ZrO_2) is produced from zircon ($ZrSiO_4$) mined primarily in Australia and South Africa, but also in the USA and Indonesia. Pure ZrO_2 has a monoclinic crystal structure at room temperature and transitions to tetragonal and cubic phases at increasing temperatures. On cooling from high temperatures the volume expansion caused by transformation back to the monoclinic phase induces very large stresses and can cause pure ZrO_2 to fracture. The addition of 3% yttrium oxide (Y_2O_3) stabilises the tetragonal phase ceramic, and the material is then known as yttrium tetragonal zirconia polycrystals (Y-TZP). This material also has the advantage of enhanced fracture toughness due to transformation toughening, since when stress is applied it is magnified by stress concentration at the crack tip causing the tetragonal phase to change phase. The associated volume expansion places the crack tip in compression, retarding its growth. The use of yttrium tetragonal zirconia polycrystal (Y-TZP) ceramic material for CAD–CAM constructed restorations in dentistry is now well documented[3,4,5,6,7,8,9].

In order to overcome the opacity of pure white zirconia in the material under investigation (Lava, 3M ESPE, Seefeld, Germany) the milled framework is stained, after the milling stage and prior to sintering, with a dye available in seven different shades to match the final overlay ceramic.

For reasons explained in the first paper of this series[1] the self-adhesive resin-based luting material RelyX Unicem (3M ESPE, Seefeld, Germany) was used to place the fixed-fixed bridges with no additional surface treatment of the zirconia framework fitting surface.

Objective

The purpose of this practice-based multi-centre observational study was to evaluate the five-year performance of all-ceramic fixed-fixed bridges, constructed with a Lava substructure, placed in adult patients in 4 UK general dental practices and cemented using a self-adhesive resin based cement. This paper reports the three-year results. As detailed previously, the primary end points of this investigation were retention of the restoration, lack of fracture of the restoration, margin integrity, secondary caries status and post-operative sensitivity. Secondary end points were the health of gingival tissues surrounding the restored teeth, colour match, stain resistance and surface quality.

Ethical standards

The study was conducted in accordance with the Declaration of Helsinki (1964) as revised in Venice in 1983. Ethics Committee and site-specific approval was obtained prior to commencing the study, and also when the decision was made to extend the study to five-years. Informed written consent was obtained from all patients prior to registration for participation in the evaluation. Implicit in giving informed written consent was the right of patients to withdraw from the study at any time.

The investigators

Six investigators took part in this study – 4 UK general practitioners, and two staff members of the University of Birmingham School of Dentistry.

MATERIALS AND METHODS

Four general dental practitioner members of the PREP panel (mean time since graduation of 24 years) with practices in Alness (Scotland), Buxton and Liverpool (England), and Coleraine (Northern Ireland) were each asked to recruit ten patients requiring a fixed-fixed bridge, and complying with the criteria set out in Table 1.

Having had an opportunity to read and consider the patient's information sheet and having received satisfactory answers to any questions concerning the evaluation, each patient was asked to complete and sign a consent form.

The pre-operative status of the gingival tissues adjacent to the tooth / teeth to be restored was assessed using codes and criteria set out in Table 2. Appropriate vitality and radiographic assessments were completed where indicated, and the outcome recorded.

The Operative procedures

The preparation of the teeth was carried out to the manufacturer's specification with rounded line and point angles, a shoulder of 1mm at the gingival margin and a minimum of 2mm occlusal clearance.

The tooth shade was selected using the Vitapan (Vita Zahnfabrik, Germany) classical shade guide. The impression was taken in vinyl polysiloxane (VPS) material, with an opposing arch impression in alginate and bite registration as indicated. A temporary bridge was constructed and placed. Impressions were then sent to the designated laboratory for the study (Castle Ceramics, Tamworth, Staffs, UK).

The laboratory procedures for the construction of Lava bridges.

As detailed previously[1], the dies and models were mailed to 3M ESPE, Seefeld, Germany, for the construction of the zirconia substructure using the digitised information obtained by the non-contact photo-optical scanning system of the casts, dies and bite registration wafers. The bridge frameworks were designed using the custom CAD-CAM system with the parameters of the system setting the minimum thickness of the framework (0.5mm) and the square area of the bridge connectors ($9mm^2$). The design was then produced on milling machines pre-loaded with appropriately sized lightly pre-sintered blocks of the Lava Y-TZP. Prior to sintering, the milled frameworks were trimmed and stained with one of seven dies to match the chosen shade(s) of the final restoration. The completed frameworks were then returned to the UK laboratory for the addition to full contour of the special overlaying veneering ceramic, LavaCeram, which has a co-efficient of thermal expansion matched to the Y-TZP material[4]. The completed bridges were delivered to the clinicians for placement on average 17 days after the original preparation and impressioning.

Placement of the Lava bridges.

All the bridges were placed in accordance to the manufacturer's instructions using the same self-adhesive resin-based luting system (RelyX Unicem, 3M ESPE, Seefeld, Germany). When the luting material was polymerised, the occlusion was checked and maintenance instructions given to the patient. Before discharging the patient baseline assessment forms were completed (Table 2).

Annual review of the restorations

Each bridge was reviewed within 3 months of the anniversary of its placement by the trained and calibrated examiner together with the clinician who had placed the restoration. The examiners completed the assessment form which was based on criteria laid down by Ryge[10] (Table 3) to evaluate the integrity of the restoration, its anatomic form, marginal adaptation, surface quality, sensitivity, the condition of the adjacent gingivae, and the presence or absence of secondary caries. Before the patient was dismissed a consensus opinion was agreed if the examiners ratings had differed. Photographic records of the restorations were also taken at the annual reviews. If any restoration was found to be defective, an adverse event form was completed and the necessary remedial work completed.

RESULTS

At baseline, a total of 41 fixed-fixed bridges were placed in 36 patients (24 Female and 12 Male) Thirty-eight of the bridges (93%) were three-units, with the remainder four-units. The distribution of the bridges at baseline and those reviewed at the annual reviews to year-three, are as shown in Table 4.

Thirty-four Lava bridges (of mean age 35.6 months) in 29 patients (19 Female, 10 Male) from the four participating practices have now been reviewed at three-years. Twelve (35%) of the bridges (all 3-units) replaced anterior teeth (Incisors or canines) and the remaining 22, including two 4-unit bridges, replaced premolars or molars.

All (100%) of the bridges examined were present and 94% (n=32) of the bridges were intact. In addition to the small chip which was detected in the veneering porcelain on the palatal surface of a upper premolar retainer reported in the year-one paper[1], a further larger chip on the buccal surface of an upper premolar pontic was detected at two-years[11]. This chip extended to the veneering porcelain/zirconia framework interface and though the patient was quite happy with the aesthetic appearance it was decided, in conjunction with the chief investigator and the manufacturer, to recommend repair using a micro-blasting device and composite. On review at year-three the repair had been lost and the patient was offered a replacement bridge at no cost. The patient declined as he stated he was quite happy with the polished buccal surface of the pontic (Fig 1).

By year-three, a total of two molar and one premolar abutments (4% of the total at baseline) had been endodontically treated successfully after investigation of symptoms. Access cavities had been prepared in the occlusal surface of the retainers, and the final composite restorations were optimal when examined using the same Ryge criteria (Fig 2). The Lava bridges involved were otherwise intact and continued to perform well. 91% (n=31) of the Lava bridges were scored as optimal for marginal adaptation with no unacceptable scores recorded and no secondary caries was detected.

At the three-year review the gingival tissues (when examined facially, mesially and distally) continued to follow the trend of improved gingival health scores demonstrated in the previous reports[1,11] (Table 5).

One bridge examined at three-years showed a slight shade mismatch but, as reported previously, it was of no concern to the patient.

At three-years no surface staining of the bridges was noted and no change in the anatomic form of the bridges was recorded.

DISCUSSION

The development of CAD-CAM techniques for the production of dental restorations, especially using ceramic materials such as yttrium tetragonal zirconia polycrystals (Y-TZP), in the last decade has been rapid. Long term clinical data are required to ensure that these techniques produce satisfactory results for fixed-fixed bridges both from the patients' and the clinicians' viewpoint. The current benchmark for fixed-fixed bridgwork is the survival rate for bridges constructed in metal-ceramic materials, which have a reported survival rate of at least 84% at 10-years[12], and a reported 79% at 18 to 23 years[13]. Prior to the advent of zirconia based frameworks two manufacturers did recommend the use of 1) a slip-cast glass-infiltrated alumina (In-Ceram Alumina, Vita-Zahnfabrik) and 2) a hot pressed lithium disilicate-based glass ceramic (IPS Empress 2 [now IPS e.Max Press] for anterior 3-unit fixed-fixed prostheses. The survival rates for anterior fixed-fixed bridges of glass infiltrated alumina has been reported as 74%[14] at five-years, with very variable results reported so far when this and the hot pressed material are used in the posterior region[15]. The success rate for posterior bridges using zirconia-based CAD-CAM all-ceramic systems is, however, looking more promising, though with few five-year results with large numbers of restorations having been published to date in peer-reviewed journals[15,8,9].

Though CAD-CAM is currently the favoured method of producing zirconia-based restorations it should perhaps be noted that a possible disadvantage of this technique is the removal of relatively large amounts of expensive high purity material and efforts are now being made to recycle the waste. Other methods of producing zirconia restorations currently under investigation include the use of rapid-prototyping gel-casting techniques involving aqueous suspensions of Y-TZP to produce a direct casting of the restoration substructure. This has the potential to be a more agile production method with minimal waste compared with the current CAD/CAM methods[16,17].

Though all the bridges examined at the third-year review were present and intact mention has been made of previously detected chipping of the veneering porcelain in two cases. The first case, reported at year-one[1], was a small chip approximately 1mm in diameter, wholly within the veneering porcelain and unnoticed by the patient. This was smoothed and re-polished and the bridge has continued to perform satisfactorily. The second larger chip reported at year-two was on the buccal surface of an upper premolar pontic was approximately 5mm in diameter, with the veneering porcelain/zirconia framework just exposed at the deepest central part. Repair of the defect was attempted using a micro-blasting device (CoJet Intraoral Repair System, 3M ESPE, Seefeld, Germany)[18,19]. This system uses silica-coated alumina particles delivered under pressure (nozzle pressure of 5 bars for 10s at 10mm distance) to form a micro-roughened silicatised layer on both the chipped veneering porcelain and the exposed Y-TZP material. Without this silicatised layer on the non-silica based Y-TZP there would be no chemical adhesion to the applied silane (3-methacryloxyprophytrimethoxy silane). It has been demonstrated that this system significantly improves the bond strength of resin-based materials to zirconium-based ceramics[20]. However, as reported, on this occasion the repair failed and though offered a replacement bridge the patient was very satisfied both with functionality and appearance of the smoothed and polished fractured surface (Fig 1). The acceptability of the shade-matched exposed zirconia framework suggests the possibility of using this material just with a surface glaze, with anecdotal information having been received that some practitioners are using this rather than a full ceramic veneer (perhaps in posterior regions until a translucent zirconia is available) though it has been shown that the overlayed ceramic veneer does contribute to the overall strength of the restoration[21,22].

Many of the papers reporting clinical trials of zirconia all-ceramic restorations do report varying incidences of veneering porcelain chipping of up to 25%[23] but it is difficult to compare the data when the chipping can vary from very minor chipping to catastrophic loss of veneering porcelain in a critical area. Also it is not always clearly stated that the overlying veneering porcelain is the framework manufacturer recommended co-efficient of thermal expansion matched material, which is critical[24], as is the minimalisation of stress, both in the zirconia framework and the veneering porcelain by following the prescribed sintering and firing regime specified for the specific material[25]. It is now recognized also that the zirconia framework needs to provide adequate support to an even depth of veneering porcelain, for example in the mesial and distal contact areas, rather than just be virtually designed in the CAD/CAM process to be of uniform thickness[26]. In this respect, the bridges constructed for this study used early software which did not include the ‘digital wax knife’ which allowed technicians to increase the thickness of the underlying zirconia to allow a more even thickness of veneering ceramic. It could be postulated that this later software might have reduced the potential for these fractures that have been observed in the veneering ceramic. However, the incidence of chipping (5.9%) at three-years would appear to be compare well to the incidence of chipping reported in the literature for both conventional fixed partial dentures and other all-ceramic fixed partial denture systems[26].

Attempts have been made to classify chipping. Yu et al (2009)[9] used a simple Alpha, Beta and Charlie rating where Alpha was no chipping, Beta = minor chipping and Charlie = major chipping. The authors would like to propose a more detailed classification where the first two grades are within the veneering porcelain:

A. A minor chip <1mm in diameter – may be left alone or polished.
B. A larger chip >1mm but still within the veneering porcelain
C. A repairable chip involving the framework interface
D. A catastrophic loss of veneering porcelain requiring restoration replacement.

In the current study the two chips described earlier would thus be classified as one Grade A and one Grade C. The overall rate of chipped restorations in the current study is 6% at three-years which compares well with rate reported in similar studies of between 3% and 25% over a similar time period[7,23,28].

It was noted at the three-year assessments that an access cavity for successful endodontic treatment had been prepared & restored in the occlusal surface of a pre-molar retainer (Fig 2). The endodontic treatment of two heavily-filled molar abutments was reported at in the first-year paper[1] and these two bridges continue to perform well. A total of 3 (4% of the 68 abutments examined at 3 years) of the abutments in this trial have now been endodontically treated with the bridges were otherwise intact and performing well. This is similar to other reported rates of endodontic intervention in studies of all-ceramic zirconia fixed-fixed bridges over a similar time period[23,29]. The final composite restorations placed in the access cavities were optimal when examined using the same Ryge criteria as the Lava bridges.

As discussed in the previous paper[1], Berganholtz[29] in his literature review has shown that iatrogenic injury to the dental pulp occurs with a frequency of 10-15% over a period of 5-10 years while Jackson et al[30] in their review of 603 crowned teeth in 103 patients with crowns or bridges found that 5.7% required root canal treatment (RCT) over the 4-year observational period. The incidence of RCT in the present study would appear to be in line with these findings. However, as pointed out by Burke & Lucarotti[31] in their paper reviewing the outcomes of re-intervention in over 47,000 crowns placed in the National Health Service in England and Wales over a period of ten years in which 3% of the total had an endodontic re-intervention, this figure does not necessarily represent the incidence of pulp death, as a radiographic investigation was not part of the annual review process.

The gingival tissue health scores adjacent to Lava bridges evaluated at the three-year review (Table 4) continue the trend of improving scores already reported[1,11] confirming that the zirconia-based material is well tolerated by the soft-tissues and with no allergic reactions reported.

The continued satisfactory results for all the criteria evaluated confirm the results already published for similar clinical trials of this all-ceramic material and the five-year reviews of the first bridges placed in this trial will commence shortly.

Conclusion

At three-years the Lava bridges placed in this trial and reviewed to date were continuing to perform satisfactorily.

ACKNOWLEDGMENTS

The support, and construction of the Lava frameworks, by 3M ESPE, Seefeld, Germany is acknowledged. Thanks are due to Castle Ceramics, Tamworth, for the completion of the construction of all the Lava bridges.

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Table 1. : Patient inclusion and exclusion criteria

To be considered appropriate for **inclusion** in the study a patient was:

- Over 18 years of age
- Had a molar supported permanent dentition free of any clinically significant occlusal interferences
- Had well maintained dentitions free of any active, untreated periodontal disease
- Had a maximum of two three or four-unit fixed/fixed bridges requiring placement
- Was a regular dental attender who agreed to return for assessments.

Patients were **excluded** from participating in the study if:

- There is a history of any adverse reaction to clinical materials of the type to be used in the study
- There was evidence of occlusal parafunction and/ or pathological tooth wear
- They were pregnant or had medical and/or dental histories which could possibly have complicated the provision of the proposed restoration and/or influenced the behaviour and performance of the restorations in clinical service
- They were irregular dental attenders.

The abutment teeth included were in occlusal function and there was a valid reason for the placement of a bridge to replace the missing unit(s). The abutment teeth were free of signs and symptoms of periapical pathology both clinically and radiographically

Table 2: Criteria for baseline evaluation

Margin adaptation O=Optimal, 1=slight deficiency

Colour match O=Optimal, 1=Slight mismatch, 2=Gross mismatch

Gingival health

Facial	1	2	3	4
Mesial	1	2	3	4
Distal	1	2	3	4

Gingival status codes:

1. Healthy gingivae
2. Mild inflammation – slight color change, slight edema, no bleeding on probing
3. Moderate inflammation – redness, oedema and glazing, bleeding on probing.
4. Severe inflammation – marked redness and edema, tendency to spontaneous bleeding

Table 3: Modified Ryge criteria

Anatomical form
0 = Restoration continuous with tooth anatomy
1 = Slightly under- or over- contoured restoration

Secondary caries
0 = No visible evidence of caries contiguous with the margin of the restoration
1*= Caries is evident contiguous with the margin of the restoration

Marginal adaptation
0 = Restoration is contiguous with existing anatomic form, sharp explorer does not catch
1 = Explorer catches, no crevice is visible into which the explorer will penetrate
2*= Obvious crevice at margin, dentine or lute exposed

Surface roughness
0 = Smooth surface
1 = Slightly rough or pitted
2 = Rough, cannot be refinished

Colour match
0 = Very good/good colour match, restoration almost invisible
1 = Slight mismatch in colour, shade or translucency
2*= Obvious/gross mismatch, outside the normal range

Gingival health: To be assessed adjacent to the restoration
1= Healthy gingivae
2= Mild inflammation – slight color change, slight edema, no bleeding on probing
3 =Moderate inflammation – redness, edema and glazing, bleeding on probing.
4 =Severe inflammation – marked redness and edema, tendency to spontaneous bleeding

(*= unacceptable)

Table 4: Distribution of the bridges reviewed at one, two and three-years

Tooth replaced *(3-unit)*		**Baseline**	**Year 1**	**Year 2**	**Year 3**
Upper	Central Incisor	6	5	3	4
	Lateral Incisor	7	7	6	7
	Canine	1	1	1	1
	Ist Premolar	8	6	7	8
	2nd Premolar	4	4	2	3
	Ist Molar	7	7	5	5
Lower	2nd Premolar	1	1	1	1
	Ist Molar	4	4	3	3
Teeth replaced *(4-unit)*					
Upper	1st & 2nd Premolars	3	3	2	2
TOTAL		41	38	30	34

Table 5: Comparison of gingival health at Baseline, One, two and Three-years.

	Baseline	One-year	Two-years	Three-years
Facial	1 85% 2 15%	1 95% 2 5%	1 92% 2 4% 3 4%	1 94& 2 6%
Mesial	1 82% 2 18%	1 100%	1 100%	1 100%
Distal	1 85% 2 15%	1 95% 2 5%	1 96% 2 4%	1 100%

LEGENDS FOR ILLUSTRATIONS

Figure 1: Chipping buccal surface of UR4 pontic (3 unit bridge).

Figure 2: Two views of the endodontically treated UR5 abutment (3-unit bridge).

Figure 3: Two anterior 3-unit bridges at three-years (pontics UR2 and UL2)

Figure 4; A molar 3-unit bridge at three-years (pontic UR6)

Fig 1

Fig. 2

Fig.3

Fig. 4