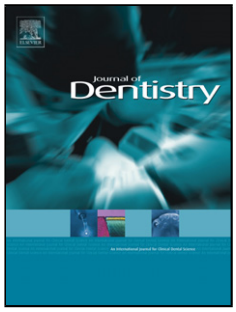

Title: The crushing truth about glass ionomer restoratives: exposing the standard of the standard.

Authors: Garry JP Fleming, Adam H Dowling, Owen Addison

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Abstract: Objectives: The compressive fracture strength (CFS) test is the only strength test for glass ionomers (GIs) in ISO 9917-1: 2003. The CFS test was the subject of much controversy in 1990 and has been challenged over its appropriateness and reproducibility and the study aimed to revisit the suitability of the CFS test for GIs.
Methods: Groups of 20 (four batches of n=5) cylinders (6.0±0.1 mm height, 4.0 ±0.1 mm diameter) of three encapsulated GIs were prepared for CFS testing using two mechanical mixing regimes and two operators. The CFS data for each GI restorative were pooled, three-, two- and one-way analyses of variance (ANOVAs) were conducted (p=0.05) for operator, mixing regime and batch to assess reliability. The data was also analysed according to ISO 9917-1: 2003.
Results: The three-way ANOVAs showed a significant interaction of operator × mixing regime × batch ($p<0.017$) for two of the three encapsulated GIs. However, no significant effects of operator × mixing regime ($p>0.042$), operator × batch ($p>0.332$), mixing regime × batch ($p>0.056$), operator ($p>0.094$), mixing regime ($p>0.118$) or batch ($p>0.054$) were evident. When examined in batches of five (or ten where appropriate) as specified in ISO 9917-1: 2003, inter- and intra-operator variability were evident.
Conclusions: The use of batch-censoring in accordance with ISO 9917-1: 2003 is unsafe when the data scatter reflects a homogenous flaw distribution as it misidentifies operative variability. Despite demonstrating that the CFS test can be performed reliably, the validity of the CFS test for GIs remains under scrutiny.

The crushing truth about glass ionomer restoratives: exposing the standard of the standard.

Garry JP Fleming[1], Adam H Dowling[1] and Owen Addison[2].

[1]Materials Science Unit, Division of Oral Biosciences, Dublin Dental University Hospital, Trinity College Dublin, Lincoln Place, Dublin 2, Ireland and [2]Biomaterials Unit, University of Birmingham School of Dentistry, St Chads Queensway, Birmingham B4 6NN, UK

Short Title: Glass ionomer restoratives - exposing the standard of the standard.

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Corresponding Author: Garry JP Fleming,
Materials Science Unit,
Division of Oral Biosciences,
Dublin Dental School & Hospital,
Trinity College Dublin,
Lincoln Place,
Dublin 2.

Telephone: 00 353 1 612 7371

Fax: 00 353 1 612 7297

E-Mail: garry.fleming@dental.tcd.ie

Introduction

The International Organisation for Standardisation (ISO) provides guidance for the evaluation of dental materials with the intention of ensuring reproducibility of test results for selected testing methodologies between different test centres under standard conditions. The compressive fracture strength (CFS) is the only strength test specified for inclusion in ISO 9917-1: 2003 - the international standard for powder/liquid acid-base cements and restoratives [1]. The selection of CFS for assessing powder/liquid acid-base cements and restoratives has previously been justified as a relevant indicator of applied service performance [2,3]. Investigators have suggested that loading during masticatory function results in stressing patterns analogous to those observed during CFS testing [2] and proposed that a high CFS was necessary to tolerate the functional forces routinely encountered in the posterior region of the mouth [3].

In a comprehensive review of uniaxial compression testing [4], the types of specimen failure during uniaxial compression tests for a range of materials were reported [4]. Most interesting, from a dental perspective, was the failure mode of uniaxially compressed gypsum cylinders which varied [4] from ‘vertical split slabbing mode’ when tested dry or wetted with alcohol, to failure on the ‘diagonal planes running from top left to bottom right’ when wet with water [5]. Therefore a major criticism of the CFS testing methodology was the stress at failure calculation does not take account of the failure mechanism [4]. The interpretation of the CFS data was considered inherently difficult even when employed for ‘comparative purposes’ to determine ‘service performance’ [4] and the CFS was suggested to be a measure of

the ‘quality of the cement’ rather than a ‘predictive value’ [6]. The civil engineering terminology of ‘bearing capacity’ [7] was suggested to be a more practical description of CFS than the ‘crushing strength’ of the material [4,8] as uniaxially compressed cylinders collapse due to ‘some unresolved combination of tension and shear’ [4] stresses.

In addition to the concerns regarding the validity of the CFS test [4,6], the reliability of the prescribed method has also been challenged [9]. In 1990, an investigation of ‘test-house variability’ reported differences in the CFS of 30 Ketac Fil (ESPE, Seefeld, Germany) glass ionomer (GI) cement specimens (6 mm height, 4 mm diameter) prepared at each of three different test centres [9]. The GI specimens were prepared in accordance with ISO DP 9917: 1987 (Harmonization of Test Methods for Dental Cements) [10] - the forerunner to ISO 9917-1: 2003 [1]. The CFS test outlined in ISO DP 9917 [10] required that five cylindrical specimens were prepared and tested. If four specimens had a CFS ≥ 130 MPa - the material passed the test and the mean CFS was reported [10]. However, if three specimens had a CFS ≥ 130 MPa, a further five specimens had to be prepared and tested and at least eight of the ten specimens needed a CFS ≥ 130 MPa for the material to pass the CFS test [10]. When the ISO DP 9917 [10] pass/fail criteria was followed stringently by dividing the 30 specimens into six batches (n=5), a clear fail was evident for all six batches in the first test centre, two batches passed and four batches failed the pass/fail criteria in the second test centre and a clear pass was identified for all six batches in the third test centre [9]. The mean CFS and associated standard deviation for the 30 specimens were 114 ± 16 MPa, 137 ± 19 MPa and 161 ± 28 MPa for the first, second and third test centres, respectively [9]. In a subsequent updated standard ISO 9917-1: 2003 [1]

the only significant change was a reduction in the minimum CFS requirement for the pass/fail criteria from 130 to 100 MPa. This reduction could suggest an acknowledgement by the ISO panel at the time that a discrete threshold value for CFS is a somewhat flawed parameter for the predictive performance modelling of GI restoratives.

While the 'test-house variability' study [9] identified that inter-operator variability was considerable - manifested as the variability between different test centres, the CFS data also highlighted individual intra-operator variability - emphasised by the results for the second test centre where a pass and fail was evident in two and four of the six batches, respectively. McCabe et al. [9] concluded that due to the variation in CFS results achieved in the 'test-house variability' study, the CFS testing methodology was 'inappropriate' for inclusion in the standard [10] and suggested an 'alternative means of evaluating dental cements' should be identified. More than 20 years on, the CFS test remains the only strength test described in the specification for powder/liquid acid-base cements [1]. During this time only a limited number of investigators have adopted alternative and potentially more valid strength determination methods for GIs in which the failure mode is reproducible [11-19]. In contrast, a significant body of evidence has been presented for GIs [20-33] which could account for the lack of reliability of the CFS test method observed in the 1990 test-house variability study [8]. It has been demonstrated that the proportioning of constituents [20-22,24,37-38], mixing technique [20-21,23-24] and mould design [20-24,26-33] all impact on the recorded strength data. These factors combined with the frequently uncontrolled variables such as laboratory environmental conditions,

operator experience [25] and fatigue could account for the previously observed variability.

The aim of the study was to revisit the reliability of the CFS testing methodology, outlined in ISO 9917-1: 2003, for assessing the performance of GI restoratives both in the context of intra- and inter-operator reproducibility. Encapsulated GI restoratives were employed in the current study as they offer significant advantages over their hand-mixed equivalents [20-21], by eliminating operator induced variability in the powder to liquid mixing ratios [22] and by standardising the mixing regime [20-21,23-24].

Materials and Methods

CFS test cylindrical (6.0 ± 0.1 mm height, 4.0 ± 0.1 mm diameter) specimens of three encapsulated posterior GI restoratives (Ketac Molar Aplicap (3M ESPE, Seefeld Germany; LOT 276540, shade A3), Fuji IX_{GP} Fast Capsule (GC Europe, Leuven, Belgium; LOT 0610204, shade A3) and ChemFlex in Caps (Dentsply DeTrey, Konstanz, Germany; LOT 0602002448, shade A3)) were prepared [1] by two operators that received the same level of training. Both operators had no experience of mixing encapsulated GIs or applying encapsulated GIs to cylindrical moulds to prepare CFS specimens. Each operator was taught how to activate, mechanically mix and extrude an encapsulated GIs by an operator with six years experience using GIs. Prior to the commencement of testing, each operator manufactured and tested ten preliminary batches of five specimens to learn the specimen preparation technique. Specimen manufacture was performed in a temperature (21±1°C) and humidity (50±5%) controlled laboratory.

The powder in the capsules was aerated by tumbling the capsules for 5 s, prior to 2 s activation to rupture the membrane separating the constituents in accordance with the manufacturers' instructions for usage [34-36]. The capsule was then placed into the holder of a Capmix (3M ESPE, Seefeld, Germany) or a Rotomix (3M ESPE, Seefeld, Germany) mechanical mixing device. In accordance with manufacturers' instructions, the Ketac Molar Aplicap capsules were vibratory mixed for 15 s (Capmix) or 10 s with 3 s of centrifuging (Rotomix) [34]. The Fuji IX_{GP} Fast Capsule [35] and ChemFlex in Caps capsules [36] were vibratory mixed for 10 s (Capmix) or 8 s with 3 s of centrifuging (Rotomix). The capsules were placed in the appropriate applicator to

extrude the plastic mass into the polytetrafluoroethylene (PTFE) split-mould [37-38].

The base of a PTFE split-mould was covered with an acetate strip and the PTFE split-mould (capable of holding eight specimens) was aligned with nylon wedges and a locating pin to ensure equal pressure was applied along the length of the mould [37-38]. To minimise air entrapment the nozzle of the capsule was positioned to one side of the unfilled cylindrical split-mould and the plastic mass extruded slowly to provide laminar flow [20-21]. The filled mould was covered with a second acetate strip and isolated from the surrounding environment with a glass slab. One specimen was produced from a single capsule and the procedure was repeated until five specimens (one batch) were made. The split-mould assembly was clamped to ensure that an equal pressure was applied to all specimens. The clamped mould assembly was transferred to a water-bath maintained at 37±1°C for 1 h. The split-mould was disassembled, the individual specimens removed and checked for visual defects [1]. The flash was removed through hand-lapping using water as a lubricant on P600 silicon carbide (SiC) abrasive paper (Beuhler, Lake Bluff, Illinois, USA) to ensure parallelism of ends [39]. The GI specimens were stored in 50 mL of distilled water maintained at 37 ± 1°C for a further 23 h prior to testing. Groups of 20 nominally identical cylindrical specimens (four batches of five specimens) were manufactured for each encapsulated GI restorative (Ketac Molar Aplicap, Fuji IX_{GP} Fast Capsule and ChemFlex in Caps) and mixing regime (Capmix or Rotomix) investigated.

The average diameter of each specimen prior to compressive loading was determined with a digital micrometer screw gauge reading to 1 μm (Mitutoyo, Kawasaki, Japan) from three points along the length of the specimen. A piece of wet filter paper

(Whatman No. 1, Whatman International Ltd., Maidstone, England) was placed on the flat ends of the long axis of each specimen [1] and subjected to CFS testing in a tensile testing machine (Instron Model 5565, High Wycombe, England). A compressive load, at a loading rate of 1 mm/min, was applied to the long axis of the specimen and the load to failure recorded for each encapsulated GI restorative group for the mixing regimes investigated.

The CFS (σ_1) was calculated using equation 1 [1]

$$\sigma_1 = \frac{4F_f}{\pi d^2} \qquad \text{Equation 1}$$

where F_f is load at fracture (N) and d the mean diameter of the specimen (mm).

Statistical analysis

Statistical analyses (three-, two- and one-way analyses of variance (ANOVAs) and Independent Sample Students t-tests) were made in software (SPSS 12.0.1; SPSS Inc., Chicago, IL, USA) at a significance value of p=0.05. Decisions for further analyses and post-hoc tests (where applicable) were made based on the results of the ANOVAs and Independent Sample Students t-test statistical analyses.

Results

The overall mean CFS and associated standard deviations for the three GI restorative materials, mechanically mixed using either the Capmix or Rotomix machines by the two operators, are shown in Tables 1 and 2. The variances of the CFS data for each GI restorative group under investigation were checked using Levene's test of homogeneity and all groups investigated were identified to be homogeneous ($p>0.05$). Additionally, all groups passed the Shapiro-Wilk test for normality ($p>0.05$).

Statistical Approach

The four factors influencing the CFS data were material (GI restorative), operator (1 and 2), mixing regime (Capmix or Rotomix) and batch (four batches of n=5 specimens). In the current statistical analysis the differences in the CFS data between the three GI restoratives was not of interest, as the reported CFS for GI restoratives vary in accordance with the dental literature [20-33]. As a result, the CFS data for each GI restorative was analysed individually, using three three-way ANOVAs (operator × mixing regime × batch) such that differences between the materials would not influence the analyses. There was a significant interaction of operator × mixing regime × batch for Fuji IX_{GP} Fast Capsule ($p<0.0001$) and ChemFlex in Caps ($p=0.017$), but no significant effect for Ketac Molar Aplicap ($p=0.091$) was evident (Table 3). Additionally, there was no significant effect of operator × mixing regime ($p>0.420$), operator × batch ($p>0.332$) or mixing regime × batch ($p>0.056$) for each GI restorative. Also no significant differences between the operators ($p>0.094$), mixing regimes ($p>0.116$) or batches ($p>0.054$) were evident for each GI restorative (Table 3).

Since the three-way ANOVAs showed no significant effect of mixing regime for each GI restorative, the mixing regime data was pooled for each GI restorative and the analyses reduced to three two-way ANOVAs (operator × batch). The two-way ANOVAs showed no significant effect of operator × batch ($p>0.369$) for all GIs (Table 4). In addition, no significant differences between operators ($p>0.122$) or batch ($p>0.061$) on the CFS data were evident for each GI (Table 4).

Given that the purpose of the study was to test for inter- and intra-operator variability further statistical analyses were employed. To test for inter-operator variability the CFS data for each GI restorative and the mixing regime data were pooled and one Independent Sample Students t-test was conducted for each GI restorative. No significant inter-operator variability was evident for Ketac Molar Aplicap ($p=0.223$), Fuji IX_{GP} Fast Capsule ($p=0.606$) and ChemFlex in Caps ($p=0.452$). To test for intra-operator variability, one-way ANOVAs were performed using the dependent variable batch for the 20 CFS data points for each operator and mixing regime independently. For the three GI restoratives each batch of five specimens were analysed using two one-way ANOVAs for mixing regime (Capmix and Rotomix) and two one-way ANOVAs for operator (1 and 2). Two of the twelve one-way ANOVAs (Fuji IX_{GP} Fast Capsule (Rotomix × Operator 1; $p=0.001$ and Capmix × Operator 2; $p=0.003$)) were significant when the dependent variable was batch.

ISO Approach

The CFS results from both operators were also treated in accordance with the protocols of ISO DP 9917 [10] to allow comparison with previous studies and with ISO 9917-1: 2003 [1]. Specimen numbers 1-5 and 11-15 were analysed individually and the material passed the test if four from a batch had a CFS ≥ 130 MPa [10] or 100 MPa [1]. If three specimens had a CFS ≥ 130 MPa [10] or 100 MPa [1], specimen numbers 6-10 and 16-20, respectively were further analysed. At least eight of the ten specimens needed a CFS ≥ 130 MPa [10] or 100 MPa [1] for the material to pass.

For operator 1, one Ketac Molar Aplicap (Capmix) group passed [10] and one group failed [10] while one Ketac Molar Aplicap (Rotomix) group passed [10] and one group failed [10] when the minimum CFS threshold outlined in ISO DP 9917 [10] (130 MPa) was employed highlighting intra-operator variability. Interestingly, all Fuji IX_{GP} Fast Capsule (Capmix and Rotomix) and ChemFlex in Caps (Capmix and Rotomix) groups failed [10]. A clear pass was evident for all materials when the lower CFS criteria in ISO 9917-1: 2003 [1] (100 MPa) was used (Table 1). For operator 2, both Ketac Molar Aplicap (Capmix) groups failed [10] while one Ketac Molar Aplicap (Rotomix) group passed [10] and one group failed [10] highlighting intra-operator variability when the CFS criteria in ISO DP 9917 [10] was used. All Fuji IX_{GP} Fast Capsule (Capmix and Rotomix) and ChemFlex in Caps (Capmix) groups failed [10] while one ChemFlex in Caps (Rotomix) group passed [10] and one group failed [10] again highlighting intra-operator variability. A clear pass was evident for all materials when the lower CFS criteria in ISO 9917-1: 2003 [1] was employed with the exception of one Fuji IX_{GP} Fast Capsule (Rotomix) group [1] further emphasising intra-operator variability (Table 2).

Further examination of the batches of five specimens in Tables 1 and 2 clearly showed inter- and intra-operator variability for all three GI restoratives investigated when the more stringent pass/fail criteria (130 MPa) outlined in ISO DP 9917 [10] was followed. When the less stringent CFS criteria in ISO 9917-1: 2003 [1] was employed (100 MPa) two of the three GI restoratives (Fuji IX_{GP} Fast Capsule and ChemFlex in Caps) showed evidence of inter- and intra-operator variability (Tables 1 and 2).

Discussion

The protocols [1,10] for determining the CFS of powder/liquid acid-base cements and restoratives have been challenged over their validity [4,6] and reproducibility [9]. Although the validity of CFS testing will continue to be a controversial point of academic discussion, there appears to be little interest in considering its removal as reflected by the consistency of the ISO standard over the past 20 years. However, the evidence of a lack of reproducibility manifested as inter- and intra-operative variability brings into question major inferences from the analysis of CFS data hereto reported in the dental literature. The current study examines whether such variability is systemic to the CFS test for powder/liquid acid-base cements or is a reflection of widespread inadequate control in experimental execution. GI restoratives are brittle materials [40] such that a distribution of CFSs is inevitable [41] given the likelihood of pore inclusion during restorative mixing or placement into the mould [22-24,37]. It has been suggested that a minimum of 20 nominally identical specimens is required to determine statistically significant differences when assessing the CFS of brittle dental materials [42] although higher sample sizes (n=60) have also been advocated for ceramics [43]. For GI restoratives the reported standard deviation of the mean CFS is routinely 15% or less [20-24]. Employing power law statistics [44-45] (at a 95% power level) informs us that 20 or more samples is sufficient to show statistically significant CFS differences where standard deviations of groups are similar and the differences between groups is 15% (or more) of the mean CFS [20-24].

Statistical Approach

The three-way ANOVA statistical analyses identified no inter-operator variability

(operator; $p>0.094$) or intra-operator variability (batch; $p>0.054$) for all GI restoratives. While the numbers of specimens in each batch was five (in accordance with the protocols [1,10] employed), the three-way ANOVA analysed two operators and two mixing regimes such that the pooled sample size was 20 and therefore confidence in the statistical analyses was confirmed. Similarly, the two-way ANOVAs highlighted no inter-operator variability (operator; $p>0.122$) or intra-operator variability (batch; $p>0.061$) for all GI restoratives where the mixing regime data was pooled ($n=10$) for the two operators so that the sample size was 20 and confidence in the statistical analyses could again be confirmed. The Independent Sample Students t-test also showed no inter-operator variability ($p>0.223$ for $n=20$). However, the one-way ANOVAs did show intra-operator variability for two of the twelve groups but the sample size used was $n=5$ and statistical confidence in the accurate prediction of the dependent variable (batch) could not be confirmed. Furthermore, given the probabilistic nature of the critical flaw distribution in a brittle material [41] such as a GI, it would be unsafe to over interpret the observed inter-batch variability for such small sample sizes.

ISO Approach

In contrast, using the ISO approach of batch-censoring, inter- and intra-operator variability were evident for all three GI restoratives investigated when the 130 MPa pass/fail CFS threshold [10] was followed. Inter- and intra-operator variability were evident in only two of the three GI restoratives when the updated (100 MPa) CFS threshold was used [1]. The use of a discrete strength value to identify operator variability is questionable given that the values prescribed by previous and current ISOs appear to be completely arbitrary. Earlier the authors proposed that the

generation of a discrete value for CFS had been accepted as a flawed parameter for the predictive performance modelling of GI restoratives. However, the reduction in the 'predictive value' [6] from 130 to 100 MPa coincided with the increased clinical use of encapsulated GI restoratives which are weaker than their hand-mixed equivalents when mixed under the conditions recommended by the manufacturers [20-21]. Therefore it would appear that the decision of the ISO panel could simply have been a reaction to prevent a situation, where the recently marketed encapsulated GI restoratives would ultimately fail the ISO inclusion criteria.

Inter-operator variability

Close adherence to the CFS testing methodology protocol outlined in ISO 9917-1: 2003 [1] in combination with increased care in the experimental design to control a number of variable factors (proportioning of the components, mechanical mixing regime, mixing time, training and environmental conditions) did achieve inter-operator consistency ($p=0.094$) for groups of 20 specimens for all GI restoratives investigated. This finding is contrary to the large body of the published information available on GI restoratives in the dental literature [20-33] which includes results of investigations undertaken in the same test centre using the same laboratory protocols [20-24]. The results are also in contrast to the variability identified by the ISO approach using batch-censoring.

Intra-operator variability

Although test samples are reported as being 'nominally identical' it is recognisable to all concerned that the skill of the operator [25] will improve over the course of time. In addition it is rarely, if ever, discussed in the literature that operator boredom,

fatigue and motivation have the capacity to have a profound influence on experimental sample preparation and handling. The comprehensive statistical approach undertaken (three- and two-way ANOVAs) did provide results in which the authors had statistical confidence. However, pooling of the CFSs prevented testing for statistical differences between individual batches (n=5) in the groups of 20 specimens. Accordingly, twelve individual one-way ANOVAs were used and identified statistical differences but confidence in the findings is undermined by the low associated power [44-45].

The rather crude ISO approach of using the pass/fail criteria [1,10] was adopted and intra-operator variability between groups was evident for all GI restoratives using 130 MPa [10] and two of the three GI restoratives using 100 MPa [1]. The result appears to confirm the finding by Wasson and Nicholson [25] that the skill of the operator is important. However, in the current study no significant improvement over the course of time (from batch 1 to 4) was evident from regression analyses ($p>0.103$; data not shown) and the observation is not consistent with the statistical analyses of the entire data set. This would suggest that the variability observed between batches (n=5) is likely to be due to the probabilistic nature of the flaw distribution in the brittle specimens [40-41] rather than significant operator induced variability. The aim of batch-censoring is to remove grossly defective specimens (caused by poor experimental technique) that will skew the data distribution. When applied, as in the current situation, where considerable effort has been made to control all variables influencing the quality of specimens, batch-censoring acts as a ‘fudge’ to remove low strength data points from a continuous data distribution resulting in an artificially elevated and unrepresentative average CFS value.

Conclusions

The standard of the standard

In the current study, when CFS testing was performed by two independent operators for three GI restoratives in accordance with ISO 9917-1: 2003 [1], the resultant data sets demonstrated no statistically significant inter- or intra-operative variability. The findings demonstrate that the CFS testing protocol is reliable but conflicts with previously reported data [20-33]. Considerable efforts were made to standardise techniques and laboratory conditions, however, the large variability in the CFS data reported in the dental literature for GI materials suggests that this level of control is infrequently applied. The use of batch-censoring in accordance with ISO 9917-1: 2003 [1] is unsafe when the data scatter reflects a homogenous flaw distribution as it misidentifies operative variability. Despite demonstrating that the CFS test can be performed reliably, the validity of the CFS test remains under scrutiny. The most obvious alternative strength tests to CFS for GI restoratives are the three-point flexure strength test [13-16,29] and the bi-axial flexure strength test [16-19,30]. The next manuscript in this two part series (Improving the standard of the standard for glass ionomers: an alternative to the compressive fracture strength test for consideration? [46]) examines the alternative strength tests for GIs. The aim is to identify the most appropriate strength test, in terms of validity and reliability, for GI restoratives.

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Operator 1	Ketac Molar Aplicap		Fuji IX_{GP} Fast Capsule		ChemFlex in Caps	
Specimen Number	**Capmix**	**Rotomix**	**Capmix**	**Rotomix**	**Capmix**	**Rotomix**
1	174.1	169.3	114.3	134.2	107.5	160.5
2	134.8	125.1	91.8	122.8	144.8	129.4
3	157.1	141.8	119.1	124.0	113.0	156.1
4	122.3	124.5	107.1	129.8	118.4	108.6
5	156.3	142.2	107.4	119.7	138.2	144.8
Mean±SD	148.9±20.4	140.6±18.2	107.9±10.3	126.1±5.8	124.4±16.3	139.9±21.2
	P [10], P [1]	**P [1]**	**F [10], P [1]**	**F [10], P [1]**	**F [10], P [1]**	**P [1]**
6	133.6	131.0	114.6	85.0	124.6	128.2
7	148.7	177.2	120.2	107.6	135.5	143.5
8	111.0	145.8	115.5	94.3	122.3	83.5
9	123.8	155.6	121.3	104.6	113.7	115.5
10	121.2	143.3	108.3	88.2	151.3	95.2
Mean±SD	127.7±14.2	150.6±17.3	116.0±5.2	95.9±9.9	129.5±14.5	113.2±24.3
		P [10]				**F [10]**
11	123.5	127.2	143.6	123.6	114.2	109.8
12	106.3	152.2	113.6	126.0	109.4	79.0
13	131.8	139.3	122.1	105.8	118.7	118.4
14	124.5	116.1	132.3	103.0	110.8	117.2
15	145.8	116.3	98.5	135.3	134.9	140.9
Mean±SD	126.4±14.3	130.2±15.6	122.0±17.3	118.7±13.8	117.6±10.3	113.1±22.3
	F [10], P [1]	**F [10], P [1]**	**F [10], P [1]**	**F [10], P [1]**	**F [10], P [1]**	**F [10], P [1]**
16	166.1	138.8	115.3	107.2	146.4	158.4
17	143.5	155.3	95.8	117.2	116.4	135.5
18	119.5	129.4	106.4	110.6	112.2	88.6
19	147.7	147.7	111.7	118.4	142.6	141.2
20	132.1	136.6	115.6	116.4	161.4	128.0
Mean±SD	141.8±17.5	141.6±10.1	109.0±8.2	114.0±4.8	135.8±20.9	130.3±25.9
Total Mean±SD	136.2±18.2	140.7±16.1	113.7±11.8	113.7±14.3	126.8±16.2	124.1±24.6

Table 1: The mean CFS ± standard deviation (SD) for the three encapsulated GI restoratives mechanically mixed in the Capmix or Rotomix by operator 1.

P: pass, F: fail, [10]: ISO DP 9917 (130 MPa) and [1]: ISO 9917-1: 2003 (100 MPa).

Operator 2	Ketac Molar Aplicap		Fuji IX_{GP} Fast Capsule		ChemFlex in Caps	
Specimen Number	**Capmix**	**Rotomix**	**Capmix**	**Rotomix**	**Capmix**	**Rotomix**
1	157.1	138.6	150.0	138.7	117.7	130.3
2	110.8	144.4	124.2	99.0	81.1	129.4
3	129.1	111.0	129.6	117.3	128.4	124.6
4	105.5	144.0	145.7	98.4	97.1	125.0
5	131.8	112.2	121.2	119.4	109.6	125.6
Mean±SD	126.9±20.4	130.0±17.0	134.1±13.0	114.6±16.7	106.8±18.4	127.0±2.7
	F [10], P [1]	**P [1]**	**F [10], P [1]**	**F [10]**	**F [10]**	**P [1]**
6	119.2	152.1	87.9	101.9	121.1	134.2
7	176.9	141.6	104.5	147.2	130.7	133.5
8	138.3	128.1	96.5	124.6	126.9	118.4
9	149.4	137.1	99.6	134.9	131.6	114.7
10	136.7	125.0	95.9	121.1	114.1	135.8
Mean±SD	144.1±21.3	136.8±10.9	96.9±6.1	125.9±16.8	124.9±7.3	127.3±9.9
		F [10]		**P [1]**	**P [1]**	**F [10]**
11	116.3	146.0	127.3	99.9	151.1	136.0
12	143.7	130.0	131.9	129.7	116.9	134.8
13	125.2	105.6	102.9	113.0	134.4	165.4
14	104.6	143.3	97.9	90.5	138.3	119.2
15	104.7	143.7	150.7	95.1	96.5	115.6
Mean±SD	118.9±16.3	133.7±16.9	122.1±21.8	105.6±15.9	127.4±21.2	134.2±19.7
	F [10], P [1]	**P [10], P [1]**	**F [10], P [1]**	**F [10], F [1]**	**P [1]**	**P [1], P[10]**
16	124.4	166.5	103.1	111.4	124.7	127.4
17	148.1	133.0	112.3	131.2	81.4	107.9
18	116.8	149.6	106.2	100.1	96.7	122.6
19	140.3	129.5	120.1	129.5	116.1	127.2
20	121.2	164.5	107.1	101.9	127.9	123.3
Mean±SD	130.2±13.4	148.6±17.2	109.8±6.7	114.8±14.8	109.4±19.8	121.7±8.0
					F [10]	
Total Mean±SD	130.0±19.1	137.3±16.1	115.7±18.8	115.2±16.5	117.1±18.6	127.1±11.8

Table 2: The mean CFS ± standard deviation (SD) for the three encapsulated GI restoratives mechanically mixed in the Capmix or Rotomix by operator 2.

P: pass, F: fail, [10]: ISO DP 9917 (130 MPa) and [1]: ISO 9917-1: 2003 (100 MPa).

	Ketac Molar Aplicap	Fuji IX_{GP} Fast Capsule	ChemFlex in Caps
Operator	0.200	0.535	0.094
Mixing regime	0.116	0.926	0.320
Batch	0.054	0.060	0.817
Operator × mixing regime	0.714	0.937	0.420
Operator × batch	0.350	0.332	0.599
Mixing regime × batch	0.622	0.232	0.056
Operator × mixing regime × batch	0.091	<0.0001	0.017

Table 3 Significance values determined from the three-way ANOVAs of operator × mixing regime × batch (degrees of freedom = 80) of the CFS data for the three encapsulated GI restoratives investigated.

	Ketac Molar Aplicap	Fuji IX_{GP} Fast Capsule	ChemFlex in Caps
Operator	0.210	0.597	0.122
Batch	0.061	0.062	0.851
Operator × batch	0.369	0.475	0.660

Table 4 Significance values determined from the two-way ANOVAs of operator × batch (degrees of freedom = 80) of the CFS data for the three encapsulated GI restoratives investigated.