

Active CEM Fluoride Ions Release Test – Internal Report - Jun – 2024

1. Rational:

The aim of this outsourced (Arni Miller Laboratories Ltd., ISRAEL) evaluation was to ensure, measure the Fluoride ions release from Active CEM Resin Modified Glass Ionomer Cement (RMGIC) and compared to a client (SPS, South Korea) outsourced evaluation (Yonsei University, South Korea).

The test was conducted since one of the important properties of glass ionomers of both types (conventional and resin modified) is the ability to release fluoride. This property has been widely studied and much is known about it. In principle, it is beneficial, because fluoride at low concentrations helps promote remineralization of the hydroxyapatite component of the tooth, and thereby to reverse the damage caused by caries.

2. Materials:

- Active CEM RMGIC (B.J.M. Laboratories Ltd.)
 - Lot. 5100ACRMGIC, Exp. 01-2026
- GC FujiCEM 2 (GC Corporation, Tokyo, Japan)
 - Lot. 2301112, Exp. 01-2025
- RelyX Luting Plus (3M ESPE, St. Paul, MA, USA)
 - Lot. 10870064, Exp. 03-2026

3. Equipment:

- Ionic Chromograph – Metrohm Advanced Compact IC - 861.

4. Test Methods:

4.1. Determination of strong Anions in aqueous solution by Ion Chromatograph:

- 4.1.1. In accordance with experimental methods found in the literature[1]-[5], specimens were prepared by hand mixing base/catalyst pastes of Active CEM on a mixing pad using a metal spatula in accordance with the IFU. Individually mixed samples of cement were placed in a silicon mold (2.7 mm thick X 5.6 mm in diameter) and



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inserted into an incubator at 37°C to complete the chemical setting curing mechanism. Afterwards, the specimens were “finished” with light curing to remove the inhibited layer.

- 4.1.2. Individual specimens of Active CEM were placed in 10 cm³ volumes of deionized water in a clean plastic 25 cm³ flask and placed into a shaking incubator maintained at 37°C with speed of 120 rpm. Total time of shaking in incubator was 21 working days.
- 4.1.3. After 1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 14, 15, 18, 19, 20, 21, 22, 25, 26, 27, 28 days from the start of equilibration an extract of the water was taken from the flask for IC analysis. The equilibrated solution was filtrated through a nylon syringe filter of 0.45µm before and analyzed for fluoride using an IC.
- 4.1.4. Specimens of the competitive RMGICs (FujiCEM 2 and RelyX) were prepared and evaluated the same way, as described in 4.1.1. – 4.1.3.



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5. Results:

Figure 1 below shows the mean fluoride release profile and the corresponding standard deviation of the amount of fluoride released for Active CEM, FujiCEM 2 and RelyX. This figure corroborates the heterogeneity of the variance of the amount of fluoride released and that the results are function of the elution time.

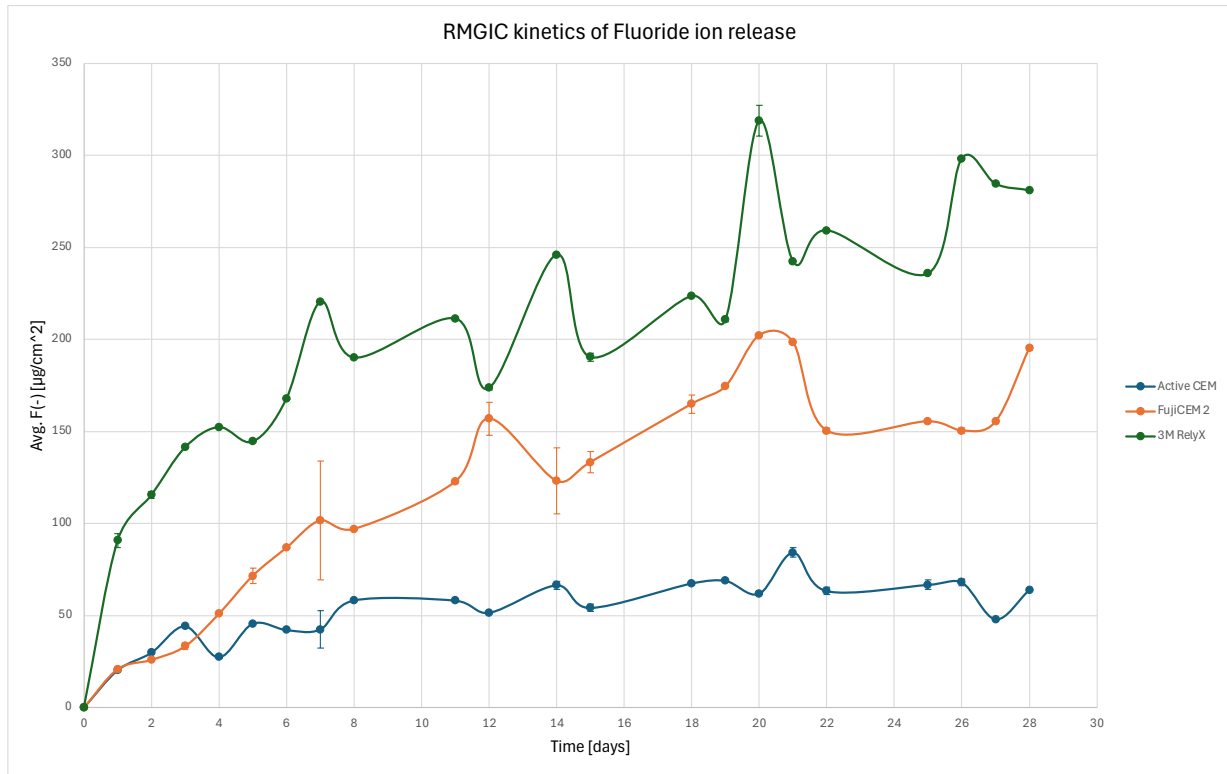


Figure 1: Active CEM, FujiCEM2 and RelyX fluoride release profile in $\mu\text{g}/\text{cm}^2$ for 28 days.

It can be seen from Figure 1 above that Active CEM had a more moderate release rate than FujiCEM 2 and RelyX. Active CEM release less $\text{F}(-)$ ions per each day but it can not be concluded from the literature as a disadvantage.

The cumulative amount of fluoride release, $[\text{F}]_c$ was calculated and fitted as a function of elution time, as revealed in Figure 2.



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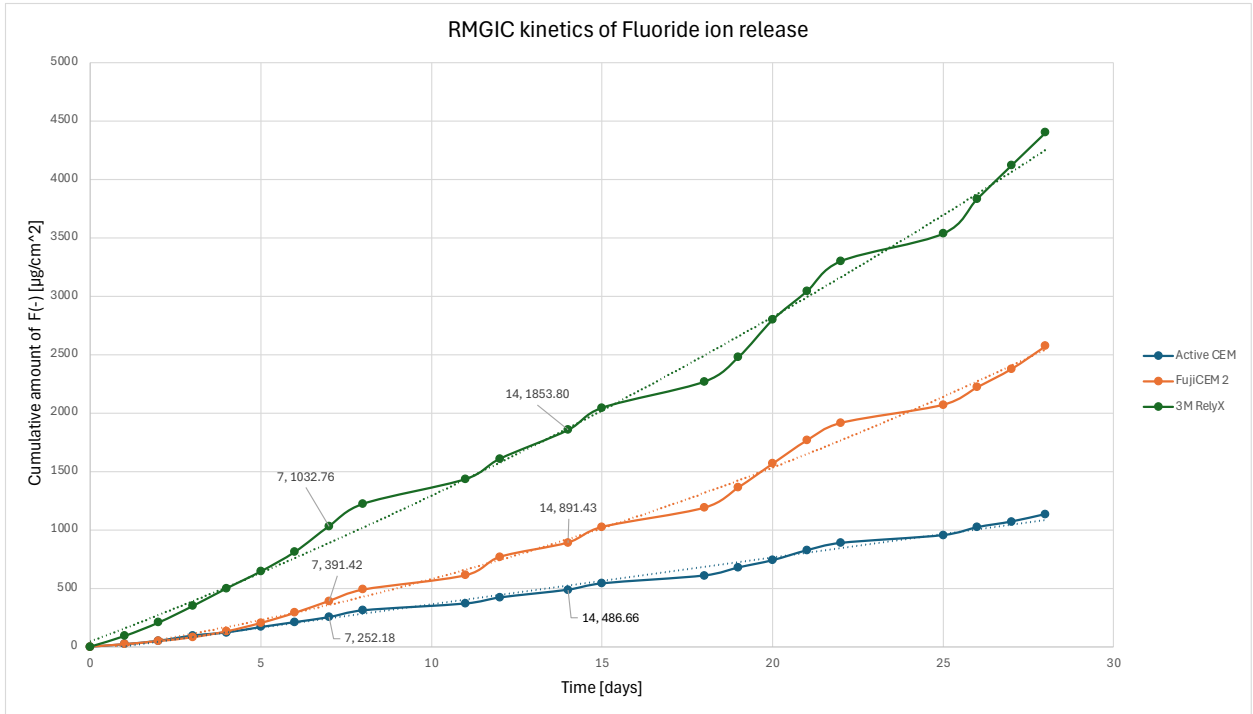


Figure 2: Cumulative amount of fluoride release of Active CEM, FujiCEM2 and RelyX.

Although the analysis demonstrate almost a linear trend for Active CEM, it was found in the literature that the cumulative fluoride release profile is described most adequately as a two steps process. The first of these is sometimes referred to as early washout, and is a first-order dissolution stage that ceases after some time. It accounted for by the first term in the equation. The second stage is a longer term, slower process that is diffusion based. This process is held to be responsible for the ability of glass ionomer cements to release fluoride for extended periods of time.

The cumulative fluoride release of FujiCEM2 and RelyX was fitted with 2nd order polynomial curve ($y=ax^2+bx+c$). Both had higher cumulative amount of F(-) release than Active CEM during all testing period.



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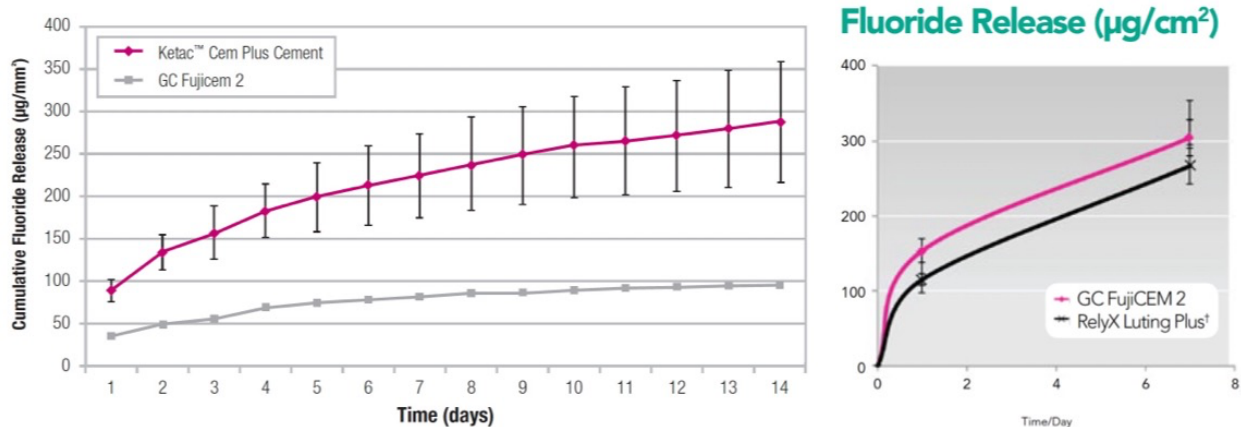


Figure 3: Cumulative Fluoride release of two main RMGIC competitors – left: 3M Ketac Cem Plus Cement, right: GC FujiCEM2.

Comparing to the competitors RMGIC cumulative fluoride release curves in the technical data sheets of the products, it can be seen that B.J.M.'s Active CEM had almost the same values range after 7 days (like GC test results) and higher value after 14 days (3M test results). The linear trend of the curve shows a steady release rate. The results of F(-) release evaluation of FujiCEM2 and RelyX performed for B.J.M. at Arnie Miller Laboratories Ltd. didn't fit the GC and 3M figures from their literature.



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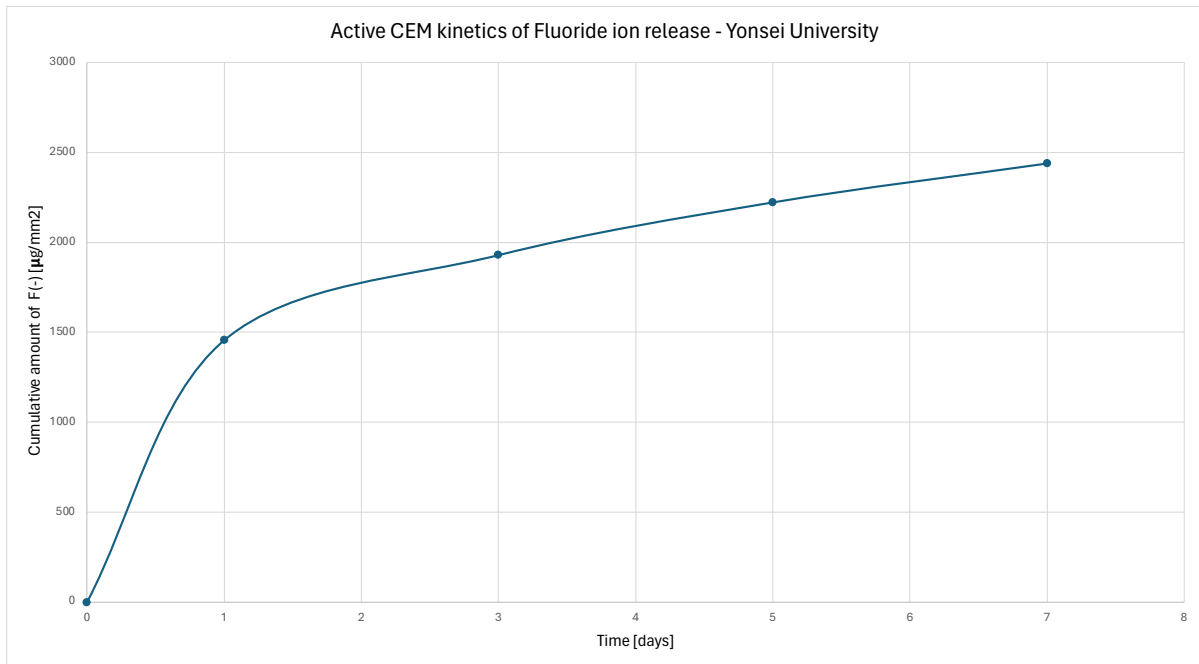


Figure 4: Cumulative Fluoride release of Active CEM performed by Yonsei University

The results received from the study in Yonsei University shows a trend similar to the competitors although numerically the results are much higher which may have been caused by different sampling method.

6. Conclusions:

The fluoride release profile (Figure 1) of Active CEM shows a quick release up to 8 days (early washout) and afterwards the release is more moderate and controlled (long-term release). FujiCEM2 and RelyX seems to continue releasing in high rate through all test period with “big jumps” between days.

The almost linear trend of the cumulative amount of fluoride released from Active CEM (Figure 2) shows that the release is increasing with a steady rate during the test period (28 days).

All the above results, confirms with high confidence that the fluoride ion release process is present in Active CEM.



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7. Reference test reports:

7.1. AML Report No. 27820, 27664, 27632, 27668, 27669 and 27670.

7.2. Yonsei University Report No. 24-02-3033 - C11040.01.

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8. Literature references:

- [1] P. Francois, V. Fouquet, J. P. Attal, and E. Dursun, "Commercially available fluoride-releasing restorative materials: A review and a proposal for classification," *Materials*, vol. 13, no. 10. MDPI AG, May 01, 2020. doi: 10.3390/ma13102313.
- [2] A. Wiegand, W. Buchalla, and T. Attin, "Review on fluoride-releasing restorative materials- Fluoride release and uptake characteristics, antibacterial activity and influence on caries formation," *Dental Materials*, vol. 23, no. 3. pp. 343–362, Mar. 2007. doi: 10.1016/j.dental.2006.01.022.
- [3] J. W. Nicholson, N. J. Coleman, and S. K. Sidhu, "Kinetics of ion release from a conventional glass-ionomer cement," *J Mater Sci Mater Med*, vol. 32, no. 4, Apr. 2021, doi: 10.1007/s10856-021-06501-1.
- [4] R. J. G. De Moor, R. M. H. Verbeeck, and E. A. P. De Maeyer, "Fluoride release profiles of restorative glass ionomer formulations," 1996.
- [5] L. Forsten, "Resin-modified glass ionomer cements: fluoride release and uptake," *ACTA ODONTOL SCAND*, no. 53, pp. 222–225, 1995.



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