# The ‘Flash’ adhesive study: A randomised cross over trial using an additional adhesive patch to prolong Freestyle Libre sensor life among youth

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## Introduction

Continuous glucose monitoring (CGM) and flash glucose monitoring (FGM) systems for the management of type 1 diabetes mellitus (T1DM) are an increasingly used alternative to traditional self-monitored capillary blood glucose (SMBG) [1, 2]. CGM and FGM systems measure interstitial glucose values, and have a range of potential advantages in comparison with SMBG, including for glycaemic control [3-10], especially when used consistently [11-13].

One of the downsides of this technology is the need to frequently replace sensors, which require subcutaneous placement and a cutaneous adhesive to secure sensors for durations of up to two weeks. This need for external sensor adhesives has led to increasingly reported cutaneous adverse events (AE) [9, 14-17]. While common, the emerging literature specific to FGM suggests cutaneous AEs are predominantly rated as mild [10, 18-21], and rarely result in the cessation of use [3, 10, 18]. Currently, measures used to prevent and mitigate cutaneous AEs include education on good hygiene regarding site preparation and sensor insertion; barrier sprays, creams and tapes; and hydrocortisone cream [22, 23]. Newer alternatives for the management of cutaneous AEs include fluticasone spray, of which research is ongoing [24].

While data concerning the epidemiology and prevention of AEs is expanding, literature discussing sensor duration and methods to optimise comfort and duration are limited. One study among adolescents with unhealthy glycaemic control found that, while the majority of users experienced at least one episode of premature sensor loss, the majority were due to adhesive issues and not AEs [21]. In addition, sensor duration has recently been raised as one of the key barriers to adolescent use and success with FGM [25]. Particular concerns arise among children and adolescents engaged in activities such as contact sport, physical work, and even the action of changing clothes, which all present opportunities for sensor adhesive to become compromised, and may contribute to reduced sensor life [18, 23, 26].

Given the substantial costs to patients and health systems of funding sensors, strategies to optimise sensor adhesion and sensor life could be of considerable benefit. Therefore, this study aimed to evaluate whether adding an additional adhesive patch to FGM sensors among adolescents with T1DM: 1) reduces the frequency of premature sensor loss; and 2) does not contribute to additional cutaneous AEs.

## Methods

### Participants and study design

All participants, at completion of the *‘Managing Diabetes in a Flash’* randomised controlled trial (RCT) were invited to be included in this adhesive sub-study. In brief, participants were aged 13-20 years at the commencement of the RCT, with T1DM duration ≥ 12 months, and high-risk glycaemic control (mean pre-study HbA1c ≥ 75 mmol/mol [≥9%] over the previous 6 months) [25]. For this sub-study there were no additional inclusion or exclusion criteria. Participants who consented to the adhesive sub-study were randomised into two groups by an offsite biostatistician. For the first three months of this study, group one were allocated to receive the intervention phase first, and were provided with a three-month supply of adhesive patches to place over the sensor. Group two were allocated to the control phase first and instructed not to use any additional adhesive products to prevent sensor loss. For the second three-month portion of this study, each group crossed over [Figure 1].

When participants were scheduled to receive the intervention, a variety of coloured RockaDex adhesive patches (<https://www.rockadex.co.nz>, RockaDex, New Zealand) were provided. RockaDex adhesive patches are kinesiology tape pre-cut for the FGM sensor and do not obscure the sensor nor the hole for ventilation. The adhesive patch is made from cotton, nylon and acrylic and contains no latex or zinc oxide in the material. Prior to the commencement of FGM, all participants were advised on good hygiene regarding site preparation and sensor insertion (as recommended by the manufacturer) to help prevent adverse AEs. Adhesive removal wipes and education on patch removal were provided to all participants to allow patches to be replaced if required during an ongoing FGM sensor session. Alternatively, participants were able to apply an additional RockaDex patch over top of the existing patch.

Ethics approval was granted by the Southern Health and Disability Ethics Committee (17/STH/240) and conforms to the provisions of the Declaration of Helsinki. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12618000320257p; http://www.anzctr.org.au/ACTRN12618000320257p.aspx and was issued a Universal Trial Number (U1111–1205-5784) by the World Health Organization International Clinical Trials Registry.

### Data collection

Data were collected from April 2018 to November 2019. Basic demographic and clinical participant data were collected during the first RCT study visit. Additional HbA1c, height and weight data were collected and updated during the six-month study visit. During this sub-study, participants were sent an identical safety questionnaire every 14 days which were timed to coincide with the day each sensor change was due. Each participant received 6 questionnaires per intervention phase and 6 questionnaires per control phase, totalling 12 questionnaires over the 6-month (24 week) period. After the first three-month phase of this study, questionnaire timing was adjusted to account for previous sensor loss and changes to the scheduled study visit time. Each safety questionnaire included questions regarding use or non-use of an adhesive patch (i.e. adherence to the study protocol), if the participant experienced a sensor loss before the expected 14 days, and any cutaneous AEs the participant may have experienced. Information was collected electronically and managed using REDCap™ (Research Electronic Data Capture) survey administration tool [27, 28]. Up to three contact attempts were made to non-responders. Participants were also asked to send photos of cutaneous AEs to research staff to aid in documenting and describing AEs.

### Statistical analyses

Appropriate summary statistics were calculated for all variables of interest (means and standard deviations for normally distributed continuous variables, medians and 25th and 75th percentiles for non-normally distributed continuous variables, and counts and percentages for categorical variables). Baseline demographic and clinical characteristics statistical analyses were performed using Stata® v15.1 (StataCorp LLC, TX, USA). version 3.6.0

We fitted a linear mixed binomial model with sensor loss as the response variable. For the intention to treat analysis, the predictor of interest was patch allocation. For the Per Protocol analysis, we removed all questionnaires where patch use differed from patch allocation. We also fitted a model with patch use as a predictor (using all 314 questionnaires). We included factors sex, the NZ deprivation index, and the study phase as fixed effects, plus a random intercept for each participant. We estimated odds ratios for all coefficients, none of which turned out significantly different from the value one. All confidence intervals are 95%.

## Results

### Demographics

A total of 34 out if 64 participants exiting the *‘Managing Diabetes in a Flash’* study were recruited into this study. 17 participants were randomised to receive the adhesive patches and 17 were randomised to the control before crossing over after 3-months. Baseline demographic and clinical data were similar between participants who accepted inclusion into this study and those who declined [Table 1].

### Intention to treat analysis

The response rate of completed questionnaires was 77% (314/408). There was no significant difference in response rate between the first 3-month phase and the cross-over phase of this study. Overall, premature sensor loss was reported in 18% (58/314) of questionnaires, involving 67% (22/34) of participants. Sensor loss was reported in 17% (26/152) of questionnaires from participants allocated to control and 20% (32/162) of questionnaires from participants allocated to intervention (Fisher’s exact test, OR=1.20, CI=0.65,2.21, P=0.56) [Table 2]. With regards to actual use of the adhesive patch, regardless of allocation, 21% (23/112) of questionnaires that used a patch reported sensor loss, whereas 17% (35/202) of questionnaires which did not use the patch reported sensor loss. Although, there was a higher percentage of premature sensor loss from participants that reported using an adhesive patch, there was no significant difference of sensor loss between these two groups (Fisher’s exact test, OR=1.23, CI=0.65-2.30, P=0.54).

The linear mixed model shows that the unadjusted estimate of the odds ratio for patch loss, under intention to treat, is 1.28 (CI=0.66-2.47, P=0.46). This is not statistically significant. These figures do not materially alter if we adjust for the factors mentioned above (OR=1.04, CI=0.31-3.45, P=0.26), or if we use patch use (rather than allocation) as a predictor (OR=1.04, CI=0.32-3.43, P=0.79)

### Per protocol analysis

Overall, 38% (118/314) questionnaires were non-compliant to the allocation of use or non-use of an adhesive patch. 22% (34/152) of questionnaires of participants who were allocated to not use a patch, reported using a patch. Comparatively, 52% (84/162) questionnaires of participants who were allocated to the intervention, did not actually use the adhesive patch. As a result per protocol analysis was completed.

For the per protocol analysis, all questionnaires that were non-compliant with allocation and adhesive use or non-use were excluded, leaving 196 questionnaires available for analysis. Premature sensor loss was reported in 15% (18/118) of questionnaires compliant with no adhesive patch use and 19% (15/78) of questionnaires compliant with the adhesive patch use (OR=1.49, CI=0.60-3.75, P=0.38) [Table 2]. When controlled for sex, deprivation and study phase this comparison was also not statistically significant (OR=1.49,CI= 0.48-4.62, P=0.26).

Overall, regardless of allocation, 11/34 participants had the same proportion of premature sensor loss with and without patch use, 6/34 participants had a higher proportion of premature sensor loss with patch use and 5/34 participants had a lower proportion of premature sensor loss with patch use compared to no patch. Of these 5 participants, the percentage of premature sensor loss was reduced by 20-100% with patch use. Among these 5 participants, 1 participant reported a cutaneous AE in 1/4 of their questionnaires (1/1 questionnaire when using patch) and 1 participant reported a cutaneous AE in 10/10 of their questionnaires (9/9 questionnaires when using patch and 1/1 questionnaires when not using patch), the latter of which was the only participant of the 5 who showed a benefit from patch to report a previous skin issue prior to the study.

### Cutaneous AEs

There was no significance between reports of cutaneous AEs between the control and intervention group allocation (7% [10/152] and 6% [9/162] respectively, P=0.81) nor for the per protocol analysis between the control and intervention group allocation when participants reported being compliant (3% [3/118] and 6% [5/78] respectively, P=0.27).

## Discussion

While simple in design, this is the first randomised trial to evaluate if FGM sensor life can be prolonged by adding an additional adhesive patch. The main finding is that, for the overall study, there appears to be no difference in rate of premature sensor loss before the expected 14-day sensor session end, whether or not an adhesive patch is used. Reassuringly, for this population of youth, overall premature sensor loss was reported in 18% of sensor sessions. In addition, minimal cutaneous AEs were experienced by both groups, suggesting the use of additional adhesive patches is not harmful, and does not appear to contribute to cutaneous AE burden.

Premature sensor loss is an important issue. Previous data has suggested premature loss occurs in and 7-32% of CGM sensors [29] and 24% of FGM sensors [21]. Importantly, one observational study found when all FGM sensors are secured by an additional plaster, premature sensor loss was numerically lower, and occurred in 20% of sensors [30]. As sensors are a considerable cost to healthcare, a simple cheap patch (approximately 1 USD) is an attractive concept to prolong sensor life. Although, the overall percentage of FGM sensors which ended prematurely in this study was reduced compared to previous studies [21, 30], the data from this study was not supportive of routine use of additional adhesive patches. However, this study found that at an individual level, some people may have experienced a benefit. Notably, of the participants that benefited from patch use, the majority reported no premature sensor loss with patch use, suggesting that it remains possible there is a cost-benefit for certain individuals.

Importantly, cutaneous AEs were minimal and similar between groups. These have been studied previously and show FGM associated cutaneous AEs are common [10, 18-21]. Although a recent study reported a rate of 1 cutaneous AE per 18 weeks of FGM use [21], the rate of AEs in this study was lower, at a rate of 1 cutaneous AE per 33 weeks of FGM use. Previous studies have shown that the adhesive component of the sensor, which contains isobornyl acrylate [31], has been identified as the probable cause for some FGM-associated cutaneous AEs [16-18, 31, 32]. Thus, given there is a clear need for measures to prevent premature sensor loss and adhesive patches may benefit some individuals, safety is important, especially regarding the use of additional adhesives. The additional adhesive patches used in this study do not contain isobornyl acrylate which may provide a possible reason why an increase in cutaneous AEs was not associated with patch use. In addition, study participants were actively managed and recommendations for the prevention and management of cutaneous AEs, associated with either the FGM sensor or the additional adhesive patch, which could also suggest a reason for the minimal cutaneous AEs reported. However, it is possible if participants experienced a FGM-associated AE they chose not to use or continue to use an adhesive path when allocated.

The key strength of this study is data collected from an independent, non-industry sponsored trail, which has a systematic methodology and approach to data collection. The adjustment of questionnaire timing prior to cross over, enabled previous sensor loss to be accounted for, and ensured questionnaire were timed to coincide with each 14-day sensor and consistent throughout the trail. The novel comparison between the use of an additional patch when compared to no additional measures of prolonging sensor life is also important. However, as this study focused on a small group of youth from a wider study with high-risk glycaemic control, the generalisability of these findings remains unclear. Past studies have found youth have reduced adherence to T1DM management [33, 34], including misreporting of SMBG [35, 36]. As premature sensor loss and adhesive patch use data were self-reported by participants, it is possible that participants falsely reported sensor loss or patch use, which could suggest why similar rates of sensor loss were reported with and without patch use. This may provide a reason for the non-adherence seen, but also it is reassuring that the premature sensor loss rate was only 18% in this highly complex patient population. In addition, the exact duration of each sensor was not collected in this trial. Thus, it is possible that the use of an additional adhesive patch prolonged sensor life, but not for the entire 14-day period, but this hypothesis was unable to be confirmed by the data from this study.

In conclusion, this randomised cross over trial provides no evidence that an additional adhesive patch has any significant advantage for the prevention of premature FGM sensor loss compared to no additional adhesive. Importantly, this study also found the use of an additional adhesive patch did not contribute to additional cutaneous AEs. Ultimately, while the results of this trial suggest additional patches should not be routinely recommended, given the low risk and low cost of these patches, and some possible benefits in some individuals, an individualised approach to their use is warranted.

## Tables and Figures

#### Figure 1: Adhesive study CONSORT flow diagram

n represents of individuals unless otherwise stated.

Diabetes clinic visits.   
Received study overview (n=140)

Assessed for eligibility (n=77)

Recruited and completed 6-months in the *‘Managing Diabetes in a Flash’* study and invited into this adhesive study (n=64)

Recruited into adhesive study and randomised (n=34)

**Phase 1**

Questionnaires sent

(n=204 questionnaires)

**Phase 2**

Questionnaires sent

(n=204 questionnaires)

**Analysis**

Questionnaires returned

(n=408 questionnaires)

Questionnaires included in **intention to treat analysis**

(n=314 questionnaires)

Questionnaires included in

**per protocol analysis**

(n=196 questionnaires)

Allocated to intervention (adhesive) first (n=17)

Allocated to control

(no adhesive) second (n=17)

Allocated to control

(no adhesive) first (n=17)

Allocated to intervention

(adhesive) second (n=17)

Declined (n=43)

Unable to contact (n=20)

Not meeting inclusion criteria (n=13)

Declined adhesive study (n=30)

Excluded questionnaires due to incomplete response (n=6 questionnaires):

* Did not report adhesive use or non-use AND did not report sensor loss or non-loss (n=5 questionnaires)
* Did not report sensor loss or non-loss (n=1 questionnaires)

Questionnaires excluded due to non-compliance with allocation protocol (n=118 questionnaires)

#### Table 1: Demographic and clinical characteristics of participants

|  |  |
| --- | --- |
| **Variable, n (%)** | **Participants (n=34)** |
| Age (years) | 17.0 (2.2) |
| Male, n (%) |  |
| Prioritised ethnicity, n (%) |  |
| NZ European/European | 21 (62) |
| Māori | 8 (24) |
| Pacific Islander | 5 (15) |
| Indian | 0 |
| Deprivation (NZDep2013), n (%) |  |
| Low deprivation (score: 1-3) | 11 (32) |
| Medium deprivation (score: 4-7) | 16 (47) |
| High deprivation (score: 8-10) | 7 (21) |
| BMI (kg/m2) | 24.5 (4.6) |
| BMI z-scorea, median (IQR) | 0.81 (0.04-1.44) |
| BMI status, n (%) |  |
| Underweight (BMI percentile ≤5) | 0 |
| Healthy weight (BMI percentile >5 and <85) | 22 (65) |
| Overweight (BMI percentile ≥85 and <95) | 5 (15) |
| Obese (BMI percentile ≥95) | 7 (21) |
| Duration of diabetes (years) | 8.8 (3.6) |
| HbA1c (mmol/mol) | 89 (16) |
| Insulin therapy, n (%) |  |
| MDI | 29 (85) |
| CSII | 5 (15) |
| Previous skin problem, n (%) | 8 (24) |
| Eczema | 1 (13) |
| Dermatitis | 1 (13) |
| Acne | 1 (13) |
| Other | 2 (25) |

*Variables presented as mean (± SD) unless otherwise stated.*

*aBMI z-score calculated using Centre for Disease Control Guidelines and two participants from each group unable to generate BMI z-score as over 20 years of age.*

*1Paired t-test 2Pearsons’ chi squared and 3Mann-Whitney-Wilcox tests used to p value.*

*NZDep2013, New Zealand deprivation index 2013; BMI, Body mass index; HbA1c, Glycated haemoglobin; NZ, New Zealand; MDI, Multiple daily injections; CSII, Continuous subcutaneous insulin infusion.*

#### Table 2: Comparison of premature sensor loss and cutaneous adverse event reports

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Analysis** | **Variable, n (%)** | **Questionnaires from no patch group** | **Questionnaires from patch group** | **P value** |
| Intention to treat | Premature sensor loss | 26/152 (17) | 32/162 (20) | 0.56 |
|  | Cutaneous adverse event | 10/152 (7) | 9/162 (6) | 0.81 |
| Per protocol | Premature sensor loss | 18/118 (15) | 15/78 (19) | 0.38 |
|  | Cutaneous adverse event | 3/118 (3) | 5/78 (6) | 0.27 |

*Fisher’s exact test used to calculate P-value.*

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