

## Scientific Research Report

## Silver Diamine Fluoride Staining With Potassium Iodide: A Prospective Cohort Study

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## ARTICLE INFO

## Article history:

Received 23 April 2023

Received in revised form

11 July 2023

Accepted 14 July 2023

Available online xxx

## Key words:

Silver diamine fluoride staining

Shade

Carious lesions

Children

## ABSTRACT

**Background:** Staining after silver diamine fluoride (SDF) treatment limits treatment acceptability but is also used as a clinical indicator of lesion stability. Potassium iodide (KI) has been postulated to modify SDF staining. Understanding the natural history and resultant shade of SDF/KI-treated lesions will inform clinical decision-making. This study describes the change in colour of carious lesions in primary teeth treated with SDF and KI.

**Methods:** One hundred carious lesions in primary teeth were treated with SDF + KI (Riva Star, SDI) and followed up over 6 months. Lesion shade was determined using standardised intraoral photography and broadly categorised into 4 shades: yellow, light brown, dark brown, and black. Lesions were digitally isolated, and colour was evaluated using CIELAB (L\*: lightness, a\*/b\*: hue) and perceptible colour change ( $\Delta E$ ).

**Results:** One hundred valid observations were analysed on 129 lesions included in the study. Lesions were excluded if subsequently restored (n = 15), teeth exfoliated (n = 2), exhibited pulpal exposure (n = 1), or failed to attend at follow-up visits (n = 11). At baseline, the shade of carious lesions was yellow (n = 22), light brown (n = 19), dark brown (n = 29), or black (n = 30). The changes in shade between baseline and 6 months were clinically perceptible to the human eye, with the mean  $\Delta E$  being 12.2 (SD = 6.9). Neither tooth type, lesion severity, nor baseline shade was statistically associated with the degree of perceptible change at 6 months.

**Conclusions:** Carious lesions exhibited clinically significant changes in colour after application of SDF + KI, primarily attributed to differences in L\* of lesions over the 6 months.

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## Background

There has been a global increase in the interest, use, and research of silver diamine fluoride (SDF) in the past 5 years.<sup>1</sup> The onset of COVID-19 has heightened its clinical application,

especially in minimising aerosol-generating procedures.<sup>2</sup> SDF is up to 89% more effective in arresting dentine caries than other modalities.<sup>3,4</sup> The mechanisms behind SDF efficacy in promoting caries arrest include the remineralisation effects of fluoride, formation of calcium fluoride reservoirs and fluorohydroxyapatite, combined with the antimicrobial effects of silver and inhibition of collagen degradation.<sup>5</sup> Also, SDF use is cost-effective and has a good safety profile in caries management in high-risk children.<sup>6,7</sup> Despite its many benefits, the black staining, due to forming a layer of silver phosphate and silver sulphide precipitates on the carious dentine<sup>8</sup> following SDF application, is a significant adverse effect limiting

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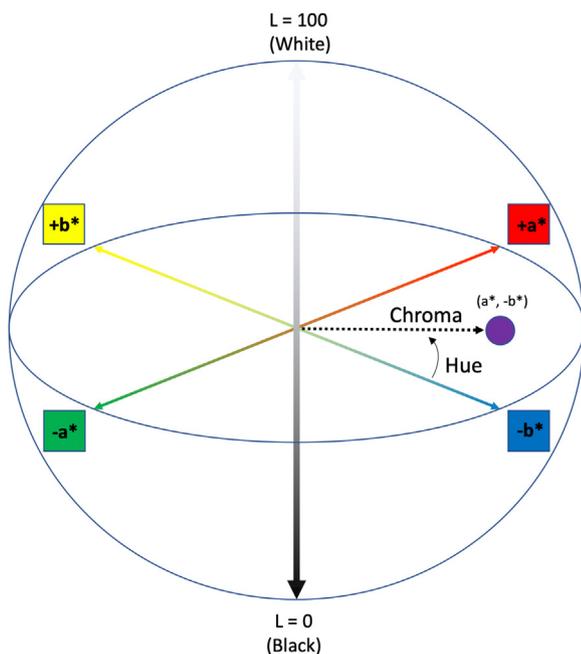
<https://doi.org/10.1016/j.identj.2023.07.006>

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its acceptability and use.<sup>9</sup> Therefore, potassium iodide (KI) following SDF application facilitates the precipitation of free silver ions to minimise untoward black staining and sequelae.<sup>10</sup> However, only *in vitro* studies<sup>11</sup> support the ability of KI to mitigate staining, and limited clinical evidence reinforces this perspective.<sup>12</sup>

Tooth shade and its perception are fundamental to dental aesthetics and underpin visual caries detection. Given its simplicity and cost-effectiveness, direct visual examination and comparison with standardised shade guides are used widely to determine the shade. Previously, the Munsell colour space ( $L^*C^*h^*$ : lightness, chroma, hue) was used for visual examination.<sup>13</sup> Recently, the CIELAB colour space ( $L^*a^*b^*$ : lightness, red-green axis, yellow-blue axis), illustrated in Figure 1, an internationally recognised measurement of colour designed to approximate human vision, has been used as an industry standard to measure shade as it more closely represents the human perception of color.<sup>14,15</sup> Notably, the eye's perception of colour is limited and strongly influenced by some aspects of shade, such as the value and external factors ranging from fatigue to metamerism.

The use of DSLR photography has gained popularity, as it has shown to have good colour accuracy, aids in clinical documentation, and has been integrated into telehealth practice.<sup>17,18</sup> A carious lesion's natural presentation and history vary depending on severity, activity, and surface.<sup>19</sup> Therefore, clinicians often use the shade of a carious lesion as a critical diagnostic indicator.<sup>20</sup> This study aims to describe the baseline shade and examine differences in the shade of carious lesions of different severity following treatment with SDF + KI over 6 months. The null hypothesis was that no significant shade changes would occur over time.



**Fig. 1 – The CIELAB colour space. CIELAB is a colour model used to represent colours in a 3-dimensional space,  $a^*b^*$  axis representing the colour axes and the  $L^*$  axis representing lightness.<sup>16</sup>**

## Methods

Ethical approval for this study was received by the Child and Adolescent Health Service Human Research and Ethics Committee (Ref 2016117EP) and the University of Western Australia Human Research and Ethics Committee (Ref RA/4/1/8973), which is nested within a larger phase IV randomised clinical trial evaluating the use of SDF in arresting caries amongst refugee children.<sup>21</sup> Newly arriving refugee children between the ages of 12 months and 12 years presenting to the tertiary paediatric hospital with at least 1 carious lesion in their primary teeth (International Caries Detection and Assessment System [ICDAS]  $\geq 3$ )<sup>22</sup> were invited to participate in this study. Children who were caries-free; had a history of bronchial asthma; presented with ulcerative gingivitis; or were allergic to silver, fluoride, potassium, iodine, ammonia, or methacrylates and nonvital teeth were excluded from this study. Professional interpreters assisted in obtaining consent and provision of clinical care. A sequential, random allocation sequence was used to group children in either the control group (5% sodium fluoride varnish) or the interventional group (38% SDF + KI). This study reports on the first 100 carious lesions treated with SDF+KI after 6 months. During treatment the soft tissues were isolated with cotton wool rolls and Vaseline (Unilever) was applied to the lips and surrounding skin. SDF followed by KI (Riva Star, SDI) was applied per the manufacturer's instructions, using a micro-brush on the carious lesions to leave the surrounding tooth structure untouched. Then, KI was applied to the same site until the reactionary white precipitate turned clear. Children were instructed not to eat or drink for 30 minutes after application. Clinical examination and intraoral photography were completed at baseline and the 6-month review.

### Digital photography and shade assessment

All children in the study had a series of standardised intraoral clinical photographs taken at baseline (before SDF + KI application) and 6 months after SDF + KI application. The children in the trial received no other dental intervention in the interim period. Photographs were taken using a DSLR camera, Canon EOS 70D (Canon Inc.), a macro lens 60-mm f2.8 macro and a MR-14EX II ring flash (both Canon, Canon Inc.) under the same lighting conditions in the hospital clinic. The camera settings were as follows: shutter speed 1/200 second; aperture value f/22; focal length 100 mm. Frontal, maxillary, and mandibular occlusal photographs were taken for all children. Standardised pictures for comparison were generated by trained dentists using a single calibrated camera with the aforementioned settings, under the same lighting and room conditions with consistent patient positioning governed by a fixed focal length. This protocol was maintained to ensure consistent image acquisition.

The photographs were then imported into Image J software (US National Institutes of Health) for digital shade analysis.<sup>23</sup> The boundary of each carious lesion was manually identified using Image J, as shown in Figure 2. The average shade of each carious lesion was recorded using the colour histogram plugin and subsequently converted from sRGB into the CIELAB colour space. It is expressed by  $L^*a^*b^*$ , with the  $L^*$



**Fig. 2 – Carious lesion isolation and digital shade analysis: Intraoral photographs were uploaded to Image J software<sup>23</sup> (US National Institutes of Health), where the boundary of each carious lesion was manually identified as shown. The average shade of each carious lesion was subsequently analysed and recorded using the colour histogram plugin.**

component representing perceptual lightness, whilst a\* represents the green-red axis and b\* represents the blue-yellow axis (Figure 1). Based on Lynch and Beighton's (1994)

classification, the colour of carious lesions were assigned according to its nearest CIELAB colour shade representing "yellow," "light brown," "dark brown," and "black" lesions (Table 1).<sup>24</sup> The change in visual perception (Delta E,  $\Delta E$ ) between shade at baseline and 6 months was calculated using the following equation:  $\Delta E^* = (\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2 / 2$ .<sup>27</sup> Delta E is a metric used to calculate perceptible differences between colours. The human threshold distinguishing 2 colours was considered  $\Delta E$  1-2, with higher  $\Delta E$  values representing greater perceptible differences.<sup>25</sup>

#### Statistical analysis

Carious lesions were categorised descriptively by surface and severity based on ICDAS scores and tooth type. Assessors undertook an hourlong training session covering ICDAS scoring and shade selection using a standardised shade guide and digital shade analysis. Assessors were retrained every 14 days throughout the study period. Subsequently, each lesion's shade was assessed by 2 assessors to mutual agreement. The differences in means amongst subgroups were analysed using analysis of variance, whilst differences in proportions by group membership were examined using Chi-square tests.

**Table 1 – Carious lesions were first categorised by clinically observed colour (yellow, light brown, dark brown and black).**

No. of carious lesions by clinically observed colour	Clinically observed colour converted to CIELAB	Digitally analysed colour at baseline	Digitally analysed colour at 6-month follow-up after SDF + KI application
Yellow n = 22	L – 74.3	L – 51.6 (SD 11.4)	L – 52.3 (SD 9.1)
	A – 1.0	A – 9.7 (SD 4.5)	A – 9.3 (SD 3.3)
	B – 26.1	B – 14.3 (SD 4.2)	B – 13.9 (SD 4.4)
Light brown n = 19	L – 45.1	L – 43.7 (SD 9.0)	L – 44.0 (SD 13.2)
	A – 11.8	A – 16.7 (SD 6.2)	A – 15.4 (SD 6.4)
	B – 33.7	B – 14.3 (SD 4.2)	B – 20.6 (SD 5.5)
Dark brown n = 29	L – 29.8	L – 36.5 (SD 7.6)	L – 37.2 (SD 15.3)
	A – 5.7	A – 15.2 (SD 4.8)	A – 15.3 (SD 4.9)
	B – 11.7	B – 18.8 (SD 5.5)	B – 19.4 (SD 5.9)
Black n = 30	L – 2.5	L – 25.4 (SD 9.5)	L – 30.8 (SD 11.7)
	A – 2.1	A – 16.8 (SD 2.7)	A – 13.7 (SD 5.4)
	B – 0.8	B – 12.7 (SD 4.1)	B – 15.3 (SD 5.7)

Column 1 shows the corresponding CIELAB parameters of the observed colour, and this is reflected by the shading of each cell. The lesions in each colour category were then digitally analysed at baseline and at 6-month follow-up (after SDF application) with the mean CIELAB parameters and standard deviation (SD) shown, the shading of each cell reflects the mean CIELAB value.

SDF, silver diamine fluoride; KI, potassium iodide.

\*CIELAB colour space where A, B represents the hue and its saturation, whilst L represents lightness.<sup>16</sup>

## Results

A total of 129 lesions were followed up yielding 100 valid observations in the final analysis. Lesions were excluded due to exfoliation ( $n = 2$ ), restoration ( $n = 15$ ), pulp exposure ( $n = 1$ ), or being unable to observe in the case of children who were uncooperative for clinical photography ( $n = 11$ ). The 100 lesions belonged to 14 children (mean age = 4.9 years; youngest = 2 years; oldest = 8 years), of whom half ( $n = 7$ ) were female. Most lesions were observed on primary molars (62%) with ICDAS scores of 3 to 4 (65%). Notably, the shade of carious lesions at baseline varied, with 30% of lesions initially classified as black. The diversity in the natural presentation of carious lesions is reflected by the significant differences in the severity of the lesions, the affected surfaces, and the different tooth types (Table 2).

The change in lesion shade according to colour category and CIELAB values at baseline and 6 months is shown in Table 1. The perceived lesion colour, represented by the broader colour categories, was observed to be different from the digitally calculated shade. Nevertheless, a consistent reduction in  $L^*$  values from yellow to black was observed at baseline and follow-up, corresponding to the changes across the 4 colour groups. Furthermore, the perceptible differences between the lesion's clinical characteristics at baseline and follow-up ( $\Delta E$ ) are listed in Table 2. However, tooth type, lesion size, or baseline shade was not a significant indicator for the degree of perceptible colour change at 6 months (Table 2).

## Discussion

SDF has quickly become an increasingly popular adjunctive modality in arresting caries amongst high-risk populations, particularly with the global impact of COVID-19 on dental practice.<sup>1,2</sup> Also, the World Health Organisation recently added 38% SDF into the model list of essential medicines.<sup>26</sup> However, the unsightly black staining after SDF application remains the primary drawback, limiting patient acceptability and use.<sup>9</sup> SDF reacts with hydroxyapatite, and the by-product—silver phosphate—is produced, which is responsible mainly for black staining. Applying a saturated solution of KI immediately after SDF leads to the formation of silver iodide (AgI) and tripotassium phosphate ( $K_3PO_4$ ), thus reducing the free silver ions and potential staining.<sup>11,12</sup>

Few clinical studies have investigated the degree of staining of SDF in detail, and limited longitudinal data exist assessing the impact of KI on staining exploring factors such as tooth type, surface, and caries severity.<sup>12</sup> Therefore, the present study findings are valuable as it illustrates the colour changes, including the above factors, following SDF + KI application over time. Also, to the author's knowledge, this study is the first to objectively measure shade changes associated with SDF + KI in a clinical setting. However, a recent randomised clinical trial found SDF + KI application to be associated with lower odds of caries arrest but higher odds of avoiding black discolouration.<sup>27</sup>

Visual inspection of dental materials to ascertain their colour stability in vitro is adequate according to the ISO

7491:20001 standard.<sup>28</sup> This standard specifies the method by which colour stability of dental materials is determined and includes aspects such as placing the material on a white background.<sup>28</sup> However, there is no ISO standard for the clinical evaluation of the colour of dental hard tissues. Therefore, using both the CIELAB colour space and Lynch and Beighton's classification system strengthens the study findings, as it best reflects a human perception of colour.<sup>14,25</sup> CIELAB has shown to be an objective and appropriate means of assessing colour coherence in both in vitro and clinical settings.<sup>29,30</sup> Employing a horizontal plane where  $a^*$  represents a green-red axis and  $b^*$  a blue-yellow axis, the angle between  $a^*$  and  $b^*$  on this plane denotes the hue (colour tone, eg, red). In contrast, the chroma (saturation, eg, dark red) is the distance from the central axis, illustrated in Figure 1. The z plane, perpendicular to the a-b plane, thus represents  $L^*$  or the value of the shade. In this study, the null hypothesis was rejected as significant change was observed in  $L^*$  values, as expected by the darkening effect of the SDF application. Notably, the chroma of lesions mainly appeared unaffected. However, differences were found when comparing the lesions' colour across shade categories, for example, yellow, black, and brown, with the actual measured CIELAB values. As shown in Table 1, the mean shade of carious lesions, whether at baseline or follow-up, mostly took on varying degrees of brown. Furthermore, the lesions' colour shade categories were found reliable as a means of classification, as demonstrated by the negligible difference between CIELAB values at baseline and follow-up for each colour category.

A difference of 1  $\Delta E$  unit can be distinguished in laboratory settings by human observers.<sup>25</sup> However, this may extend up to 3.7 $\Delta E$  units in the oral cavity for perceptible changes to be observed.<sup>30</sup> The present study showed no statistically significant differences between baseline and follow-up across the CIELAB domains within each colour category (Table 1). However, as shown in Table 2, the  $\Delta E$  units suggest the changes that occur are clinically perceptible at follow-up, emphasising that the value, hue, and chroma must be considered together when interpreting shade. Also, lighter lesions at baseline did not exhibit a greater degree of change at follow-up in this study.

Similarly, no significant differences in  $\Delta E$  were seen amongst the colour groups when comparing the 2 time points. Therefore, this study's findings support the concept that the SDF + KI application may not show significant changes when individually considering the domains of colour. Nonetheless, the overall change is clinically perceptible to the human eye. It is assumed that the degree of change across all categories would likely be more significant if KI was not applied. Although this could not be definitively explored in this study as no control group—SDF alone without KI application—was included, it has been reported by Turton et al<sup>27</sup> in a clinical trial setting.

Lesions with baseline yellow/light brown shades exhibited the most significant change in shade at 6 months. A possible explanation may be the smooth surface and surface area involved when applying SDF to incisors is compounded by the noticeable impact that a change in value can have over domains such as hue and chroma. Therefore, the lesion value may have the most pronounced effect and hence is classically

**Table 2 – Colour of carious lesions 6 months after SDF + KI application and  $\Delta E$  characterised by lesion size and tooth-type.**

	-2 SD	Mean	+2SD	$\Delta E^a$	P value <sup>b</sup>
Tooth type					
Incisor/canine	L - 40.8	L - 44.9	L - 48.9	13.4 (SD 7.7)	.177
	A - 11.8	A - 13.9	A - 16.1		
	B - 14.8	B - 17.3	B - 19.8		
Molar	L - 30.7	L - 33.8	L - 36.8	11.4 (SD 6.4)	
	A - 12.3	A - 13.5	A - 14.7		
	B - 15.5	B - 16.7	B - 17.9		
Lesion severity					
ICDAS 3-4	L - 37.6	L - 40.9	L - 44.1	11.9 (SD 6.7)	.658
	A - 11.3	A - 12.6	A - 1.4		
	B - 15.6	B - 17.0	B - 6.8		
ICDAS 5-6	L - 28.4	L - 32.6	L - 36.8	12.6 (SD 6.9)	
	A - 13.8	A - 15.7	A - 17.7		
	B - 14.4	B - 16.9	B - 19.4		
Baseline shade					
Yellow	L - 46.6	L - 51.6	L - 56.7	11.9 (SD 6.4)	.159
	A - 7.7	A - 9.7	A - 11.7		
	B - 12.5	B - 14.3	B - 16.1		
Light brown	L - 39.3	L - 43.7	L - 48.1	15.1 (SD 8.3)	
	A - 13.7	A - 16.7	A - 19.7		
	B - 19.2	B - 22.0	B - 24.8		
Dark brown	L - 33.6	L - 36.5	L - 39.4	11.4 (SD 6.4)	
	A - 17.7	A - 15.2	A - 17.1		
	B - 16.7	B - 18.3	B - 20.8		
Black	L - 21.5	L - 25.4	L - 29.2	12.0 (SD 6.7)	
	A - 10.7	A - 12.6	A - 14.5		
	B - 11.0	B - 12.7	B - 14.4		
Overall	L - 35.3	L - 13.2	L - 40.6	12.2 (SD 6.9)	
	A - 12.6	A - 5.5	A - 14.8		
	B - 15.7	B - 16.9	B - 18.1		

Delta E ( $\Delta E$ ) represents the perceptible differences between colour at baseline and at 6 months after SDF + KI. The human threshold to distinguish 2 colours is considered to be a difference of 1  $\Delta E$  unit, with higher  $\Delta E$  values representing greater perceptible differences.<sup>25</sup> The shading of each cell represents the colour coded by the CIELAB\* parameters (L, A, B).

SDF, silver diamine fluoride; KI, potassium iodide.

\*CIELAB colour space where A, B represents the hue and its saturation, whilst L represents lightness.<sup>16</sup>

<sup>a</sup> $\Delta E^* = (\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2)^{1/2}$ .

<sup>b</sup>Chi-squared test.



**Fig. 3 – Changes in the shade (A) baseline and (B) 6 months after applying silver diamine fluoride and potassium iodide to the carious lesions. For example, tooth 75 (mandibular left primary second molar) demonstrates speckling with various shades within the same lesion, teeth 74 and 84 (mandibular left and right primary first molars) exhibit darkening, and tooth 85 (mandibular right primary second molar) shows stability over time.**

referred to as the most critical parameter in the shade-taking.<sup>31</sup> However, as illustrated in this study, the shade of a lesion is complex, and variations in chroma can exist within a single lesion (Figure 3).

The clinical relevance of shade assessment extends to its use as an indicator of caries activity. For example, reflective black lesions are more likely to be associated with caries arrest when compared with yellow/brown lesions.<sup>32</sup> This finding is supported by the colourimetric study by Iwami et al,<sup>33</sup> who found bacterial presence to be decreased as the L\* of dentine lesions increased. However, associations between lesion colour and activity are beyond this study's scope, which future studies should investigate. In addition, a 6-month time point is insufficient to determine caries arrest, as reported in previous studies.<sup>27</sup>

Using standardised photography in a pragmatic context of high-risk children with an appropriate follow-up period strengthens this study's clinical relevance. The findings can therefore assist clinicians' judgement on the expected effect of SDF + KI application and better inform the consent process with patients and/or their caregivers. Although KI application may mitigate the severity of staining *in vitro*,<sup>11</sup> the findings of this *in vivo* study suggest that staining is still likely to occur. Oral health-related quality of life measures, including appearance, are captured as part of the larger clinical trial but not reported in this paper. The study limitations include its small sample size of 14 children; however, this is tempered by the unit of measurement being carious surfaces assessed at a lesion level. Furthermore, this study did not include any controls treated with SDF only, which could have provided a means of assessing the influence of KI on shade. This was, however, explored in a recent clinical trial that found that the use of KI resulted in 6 times lower odds of lesions turning black compared with SDF alone, although this was based on visual assessment only.<sup>27</sup> Finally, this study did not use a spectrophotometer, which is likely to produce the highest accuracy and precision for shade analysis.<sup>34</sup> Although spectrophotometers are accurate and reliable in shade matching, they are expensive, can be challenging to use, and are primarily used to diagnose the shade of intact tooth surface rather than the irregular surface topography and characteristics of carious lesions.<sup>34</sup> In contrast, digital

photography has shown to be a reliable method in shade selection and for the purposes of this study was a more feasible approach given the study cohort and number of lesions requiring evaluation.<sup>35,36</sup> Nevertheless, the science of shade is complex and is influenced by factors such as translucency, surface texture, and metamerism. Therefore, images were standardised where possible to reduce the impact of environmental factors such as fluorescence on the shade. However, the numerous variations in carious lesion presentation likely may indirectly contribute to final shade classification. Hence, the study's limitations should be considered whilst extrapolating the findings.

## Conclusions

The following conclusions can be made based on our results:

- 1) There is a significant diversity in the shade, severity, and surface involvement of carious lesions in primary teeth. Despite this diversity, none of these factors had any impact on the change in the shade of the lesions over time.
- 2) Application of KI following SDF does not completely mitigate staining and leads to a consistent reduction in L\*(perpetual lightness) values that is perceptible to the human eye ( $E > 1$ ).

## Author contributions

JP: conceived and designed the analysis, collected the data, performed the analysis, writing and editing of the manuscript. BT: performed the analysis, writing and editing of the manuscript. SC: supported data collection and clinical supervision, provided critical feedback and helped shaped the research, editing of the manuscript. RA: conceived and designed the analysis, writing and editing of the manuscript, supervision of the project. All authors discussed the results and contributed to writing the manuscript.

## Conflict of interest

None disclosed.

## Acknowledgements

This project was supported by a Research Seeding Grant from the Perth Children's Hospital Foundation (Grant 9769).

## Supplementary materials

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.identj.2023.07.006](https://doi.org/10.1016/j.identj.2023.07.006).

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