Clinical effectiveness report

# Tube placement using 'IRIS': A pilot assessment of its utility and safety

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## ARTICLE INFO

## ABSTRACT

*Introduction:* Most critically ill patients have a feeding tube placed blindly, but 0.5% result in a major lung complication because misplacement is only detected at the end of procedure. Real-time guided tube placement may pre-empt such complications. This clinical effectiveness study examined the ability to visualise anatomy using Kangaroo™ feeding tubes with IRIS technology ('IRIS' tube).
*Methods:* In a single centre, gastric or intestinal integrated real-time imaging system (IRIS) tubes were prospectively placed in critically ill patients noting the anatomical visualisation.
*Results:* Of 15 placements, 13 were successful gastric placements and used for feeding but one gastric and one intestinal placement failed because of signal loss and inability to find the pylorus, respectively; both tubes were removed. Air insufflation and fluid aspiration were possible with all tubes. Respiratory misplacement was clearly differentiated, prior to reaching the main carina, from gastrointestinal (GI) anatomical markers, permitting removal before causing trauma. Furthermore, non-traumatic placement was visualised in high-risk cases including during advancement through a nostril with a base of skull fracture and into a stomach with a recently haemorrhaging gastric polyp. Individually assessed, direct vision may offer greater safety. X-ray or pH of aspirated fluid confirmed the position of GI tube placements. One adverse event occurred during placement, reversible bradycardia, in a patient previously having bradycardia. Vision was intermittently obscured by bile, mucus or impaction with mucosa.
*Conclusion:* 'IRIS' tubes offer real-time guidance regarding anatomical position. Larger studies are needed to establish the best techniques of deploying this equipment and over-coming the difficulties observed.
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## Implications for clinical practice

- Because IRIS clearly differentiates respiratory from GI anatomical features and when respiratory placement does occur it can be detected pre-carina, operators should be able to achieve two vital outcomes: a) By the end of tube placement, the tube should be safely sited; and b) Respiratory placement will be detected before deep penetration, making pneumothorax unlikely.
- Use of specific techniques can overcome intermittent obscuration of vision, difficulty achieving placement into the oesophagus and moving from the upper to lower stomach.
- To date there are insufficient data to recommend that IRIS tubes can be used to confirm safe tube position alone. However, if larger studies support this study's findings, real time, guide tube placement using direct vision may offer a safer and quicker route to feeding and drug administration.

## Introduction

Early enteral nutrition in critically ill patients, predominantly delivered by nasogastric (NG) or nasointestinal (NI) tube, is associated with a significant reduction in infection and a trend to

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reduced mortality (Heyland et al., 2021), as well as facilitating drug delivery. Unfortunately, tube misplacement into the lung is more common in critically ill patients, possibly due to decreased consciousness and the presence of artificial airways (Sparks et al., 2011). About 10% of feeding tubes enter the lung (Taylor et al., 2017b). In general patient populations most tubes are removed during the procedure, but 1.5% are only detected post-placement, too late to prevent 0.5% resulting in pneumonia or pneumothorax [Adapted from (Krenitsky, 2011)]. These complications could only be reduced by, mid-procedure, $CO_2$ detection or X-ray at the level of the main bronchi. Alternatively, real-time, bedside guided-placement could pre-empt complications without delays or further irradiation. Expert-operated bedside electromagnetic-guided placement (EMGP) warns of lung placement (McCutcheon et al., 2018). The disadvantage with EMGP is that it only gives a trace of the tube path, not the actual internal anatomy. In addition, official guidance is only about 70% accurate in determining gastric position and is therefore potentially unsafe (Taylor et al., 2017a, b, 2019).

The Kangaroo™ feeding tube with integrated real-time imaging system (IRIS) (Cardinal Health, Mansfield, MA USA), hereafter the 'IRIS tube', is a relatively new CE-marked method of bedside guided tube placement using 'endoscope-like' direct vision. This may enable safer tube placement by showing respiratory misplacement before damage is done and confirm position through visualisation of oesophageal, gastric and intestinal mucosa.

Two studies have examined the clinical effectiveness of the first-generation IRIS tube. In 20 ICU patients, 'IRIS' visualised the trachea in 7 (35%) patients permitting repositioning to pre-empt trauma. 'IRIS' allowed recognition of the gastric mucosa in 18 (90%) patients, confirmed by contrast-enhanced X-ray. In the second study of 45 subjects, one tube was initially misplaced with, ultimately, 42 successful gastric and three intestinal placements. Clinicians correctly identified the stomach in 44 of 45 placements at a median depth of 60.0 cm (range 45.0–85.0 cm) (Wischmeyer et al., 2018). Agreement between camera image and radiographic confirmation of placement was 93% ($p = 0.014$) with small deviations in recognizing stomach vs small bowel. No device-related adverse events occurred. We used the IRIS-2 tube with improved optics: Depth of field 10–80 mm and field of view 80° compared to IRIS-1 with 20–50 mm and 59°, respectively.

This preliminary, clinical effectiveness study, reviews the ability to insufflate air, aspirate fluid and visualise anatomy via the IRIS-2 tube, in intenisve care unit (ICU) patients requiring gastric or intestinal tube placement, using standard hospital practice. Specific comment is made on what safety advantages direct vision may have regarding lung misplacement or during high-risk tube placements.

## Methods

### Preparation

The first author, already experienced in electromagnet-guided tube placement, underwent training including supervised tube placement by Cardinal Health and received feedback from Dr Terlevich, a consultant gastroenterologist, in the accuracy of interpretation of anatomical images.

### Equipment

The IRIS tube consists of a standard enteral feeding tube with a 3 mm camera integrated into the tip (Fig. 1). With real-time imaging, key anatomical markers can be identified during placement. The equipment consists of a console that displays an endoscope-

like image via a cable-link to the tube. The cable-link includes a button to capture still images. The tube has a Y-port for attachment of an enteral syringe or 30 mL insufflation bulb.

The tube tip was warmed in water to activate hydromer lubricant and placed in a standard manner via the nostril or mouth. Where necessary and safe the head was tilted forward or a jaw thrust performed to enable the tube to move into the oesophagus. Placement was by slow insertion, using occasional air insufflation and slight tube withdrawal, as needed, to clear the camera lens. Images were saved at noted tube lengths and advancement based upon recognition of GI markers and the absence of respiratory markers. We attempted to reach duodenum part-1 then withdraw into the stomach to maximise recognition of anatomy and chance of aspirating fluid for a pH test.

### Patients

The IRIS tube was placed in a convenience sample of 15 patients. Inclusion criteria were any patient ≥18 years who required gastric or intestinal tube placement. An ICU consultant decided that the risk–benefit of NG tube placement was warranted for two high risk patients (base of skull fracture [n = 1], recently bleeding gastric polyps [n = 1]) but that it was safer the place the tube under direct vision (IRIS) than blindly. Exclusion criteria were contraindication to enteral tube placement (no anatomical access, clinical instability, moribund, consent refusal) or study staff unavailable.

### Aim, objectives, data collection and analysis

To assess the safety and utility of the IRIS tube, this study determined:

1. Visualisation of anatomy using the IRIS-2 tube. Accuracy of real-time, direct vision of the anatomy by ST (research dietitian) is commented upon in relation to image checks by AT (consultant gastroenterologist) and definitive confirmation of tube position by the pH of aspirated fluid of ≤4.0 or, failing this, X-ray, as per North Bristol NHS Trust policy (2020).
2. IRIS tube radio-opacity.
3. Ability to aspirate fluid and insufflate air.

Data collected included patient demography and clinical status, tube characteristics, visual clarity and anatomical points, placement techniques used and any problems or adverse events. Analysis was only intended to be descriptive but will inform future studies on how operators can best apply the IRIS system.

### Statistics

Parameters were tested for normal distribution using the Shapiro-Wilk test using 'R Studio Version 1.1.463'. Most continuous variables did not have a normal distribution, therefore, descriptive statistics are presented as a median (inter-quartile range, IQR) or number (%).

### Ethics

North Bristol NHS Trust Clinical Audit department assigned this project as a clinical effectiveness study (CE10413) and as such not requiring formal ethics approval.
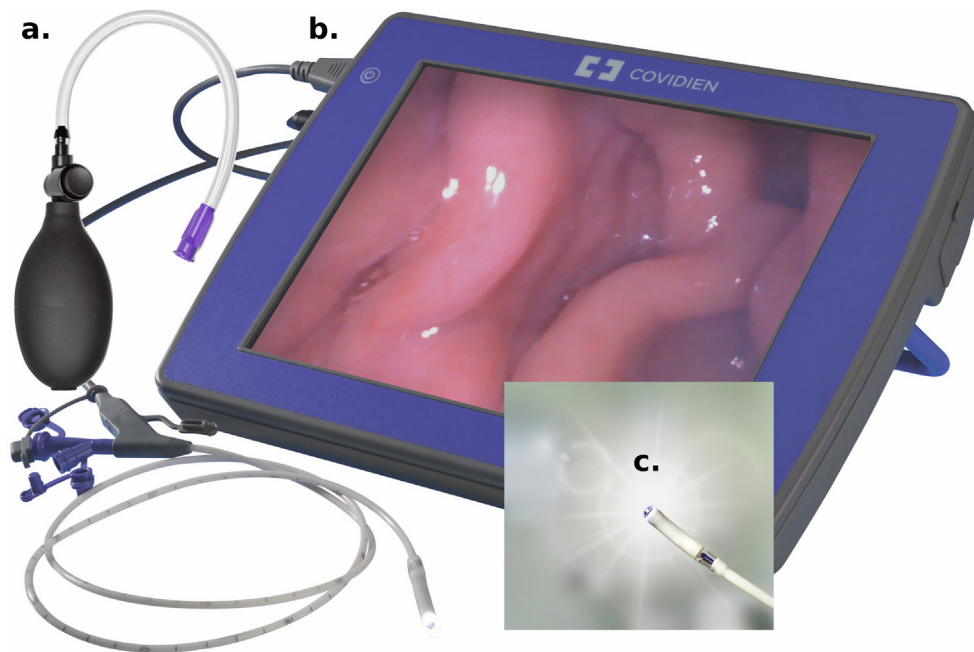
**Fig. 1.** IRIS: a) Insufflation bulb, b) Console, cable link, tube, c) Tube tip and camera.

## Results

### Baseline characteristics

In this pilot clinical effectiveness study, tube placement was observed in 15 patients (Table 1). Most patients were infected medical patients, mechanically ventilated via an artificial airway and sedated.

### Tube and position

Most placements were done on day 1 of ICU admission (IQR: 1–4.5), via the nose (n = 14) or mouth (n = 1) using 12 Fr, 109 cm (n = 14) or 10 Fr, 140 cm (n = 1) tubes. Four tubes initially entered the respiratory tract in the presence of an endotracheal tube (ETT, n = 3) or tracheostomy (n = 1). The deepest tip position reached was the nasopharynx (n = 1), upper stomach (n = 6) or duodenum part-1 (n = 8). Tubes were removed due to loss of image signal and

failure to enter the oesophagus (n = 1) or intestine (n = 1). During the intestinal placement that failed the patient was on 10 mg IV metoclopramide three doses per day to aid gastric emptying; no other prokinetic agents were used. However, some patients already on sedation were given a small (1–2 mL) bolus of Propofol at the beginning of tube placement. Of 13 tubes left in situ 5 remained in the upper stomach and 8 were pulled back into the lower stomach. Fluid was aspirated from all tubes but pH failed to meet the ≤4.0 threshold in 6 of 7 patients on concurrent feed, H2-blockers or proton-pump inhibitors (pH 5.8 [5.5–6]). In contrast, pH was always ≤4.0 in the 6 patients without acid suppression (pH 2 [2–2]). All tubes remaining in situ were confirmed to be within the GI tract on X-ray.

### Anatomical visualisation

Identification was done at placement by ST (dietitian) and confirmed by AT (gastroenterologist) either at placement or from recorded images. All tubes were positively identified within the nose/mouth, respiratory tract (n = 4), oesophagus, stomach and intestine in those that reached these points (Table 2) (Fig. 2). Differentiation between respiratory versus GI tract and oesophagus versus stomach were always possible. However, when examining three views the dietitian's (ST) identification was corrected by

**Table 1**
Patient demography and clinical state.

| Parameter | Detail | Median or n | *IQR or % |
|---|---|---|---|
| Number | (n) | 15 | – |
| Age | years | 51 | 29.5–63.5 |
| Sex | male | 8 | 53.3 |
| BMI | kg/m² | 24.8 | 22.5–28.7 |
| Height | cm | 175.5 | 164–180 |
| Weight | kg | 79 | 61.8–89.5 |
| APACHE 2 | score | 11 | 14–15 |
| Disease | Medical | 7* | 46.7 |
| | Neurosurgical (non-trauma) | 2 | 13.3 |
| | Surgery (general) | 1 | 6.7 |
| | Trauma | 5 | 33.3 |
| Consciousness | Awake | 2 | 13.3 |
| | Sedated | 13 | 86.7 |
| Airway | Normal | 0 | 0 |
| | Endotracheal tube (ETT) | 13 | 86.7 |
| | Tracheostomy | 2 | 6.7 |

* 3 COVID-19 pneumonia.

**Table 2**
Accuracy of non-endoscopist (ST) in identifying anatomy.

| Confirmation | Anatomy | N | % |
|---|---|---|---|
| Positive identification | Nose/mouth | 15 | 100 |
| | Lung | 4 | 100 |
| | Oesophagus | 14 | 100 |
| | Stomach | 14 | 100 |
| | Intestine | 8 | 100 |
| Differentiation | Lung vs GI | 4 | 100 |
| | Oesophagus vs stomach | 14 | 100 |
| | Stomach vs intestine | 7 | 87.5* |

* In 1 patient an initial image of the stomach was correctly interpreted, but a duplicate 'stomach' image was thought by the gastroenterologist to be duodenal.
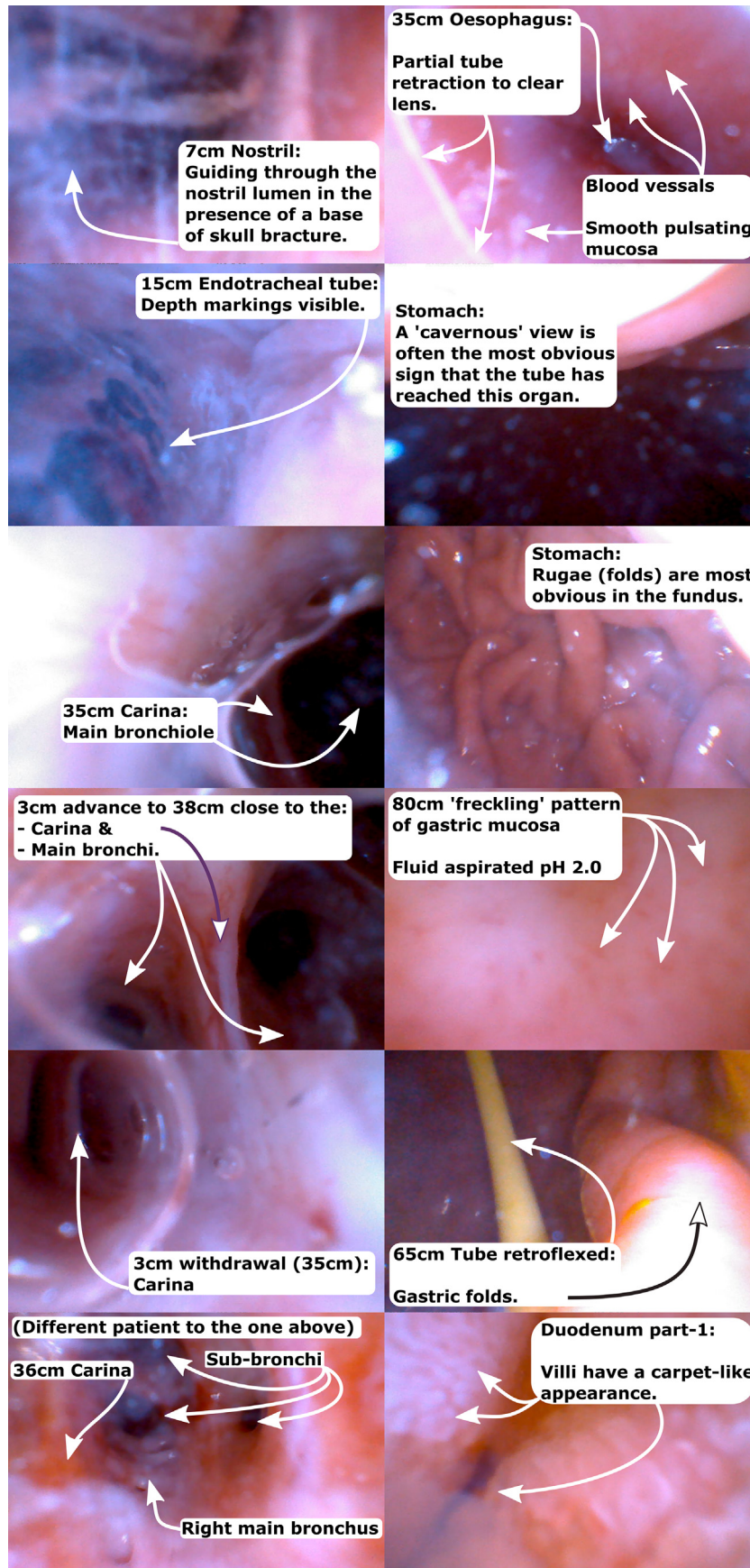
**Fig. 2.** IRIS images from nostril to duodenum.

the gastroenterologist (AT): a) In duodenum part-1, ST cited a 'retroflex view of the pylorus' when it was probably the superior flexure; b) An 'antral view' was thought by AT to be duodenum part-2; and c) When ST was withdrawing a tube due to uncertainty about tube position AT glimpsed tracheal cartilage. Although tracheal cartilage rings were not initially identified on 3 of 4 occasions that tubes entered the respiratory tract, the carina and bronchi beyond, were clearly visible and warned of the need to withdraw. Oesophageal markers were more difficult to identify until an 'insufflate and slight withdrawal technique' was employed, then, the collapsible, fluted nature of the oesophagus was noted. On entering the stomach, the lens commonly passes along the surface of the greater curvature visualising gastric pits. The cavernous nature of the stomach, gastric rugae and folds were better identified on partial withdrawal and/or with air insufflation or when the tube coiled anti-clockwise and became retroflex.

Duodenal placement, when it occurred, usually happened so quickly that the pylorus was only seen on very slow withdrawal. Duodenal villi were clearly visible. Some tubes failed to advance beyond the upper stomach as evidenced by 'black out' caused by the tube coiling back towards the oesophagus. Air insufflation and withdrawal of ~10 cm of the guide-wire to create a flexible tip were not always successful in permitting forward advance, partly because the guide-wire lubricant was not activated with water, which would have otherwise prevented pH checks. However, retracting the guide-wire 20 cm to create a long flexible tip permitted two of these tubes to reach the lower stomach then duodenum.

Direct visualisation was a specific advantage in permitting:

- Navigation of a nostril when there was a known base of skull fracture (n = 1);
- Avoiding damage to previously haemorrhaging gastric polyps (n = 1);
- Rotation of the tube to orientate the tip away from the endotracheal tube (ETT) and towards the oesophagus (n = 3), in two cases after bending the guide-wire to 30°, 3 cm from the tip; and
- Pre-carina withdrawal when entering the trachea (n = 4).

### Adverse events and problems

One patient who had bradycardic episodes pre-tube placement experienced reversible bradycardia during the initial stage of placement. Obtaining visual clarity often required tube rotation or partial withdrawal with or without air insufflation. Pictures obtained were sometimes out of focus due to a delay between visualisation and capture. Advancing through the nose was difficult in only one patient but occurred in 67% when trying to enter the oesophagus and requiring a head tilt (54%) and/or jaw thrust (27%) to permit advance. In the one failure to enter the oesophagus there was no-one available to provide a jaw thrust to aid tube advancement.

## Discussion

### Main findings

In this preliminary clinical effectiveness study, IRIS tubes, typical of modern polyurethane tubes, permitted air insufflation, GI fluid aspiration and manoeuvres of both guide-wire and tube. All tubes that were X-rayed could be clearly visualised. Direct visualisation of internal anatomy facilitated definite identification and differentiation of respiratory versus GI tract in all cases. Similar to previous study, (Wischmeyer et al., 2018) differentiation of gastric from intestinal placement was sometimes more difficult. The most obvious differentiating characteristics noted by organ were: Respiratory tract: Carina and bronchi; Oesophagus: Collapsible fluted tube; Stomach: Cavernous space, folded mucosa and gastric pits; Intestine: Finger-like villi.

### Visualisation

The IRIS tube lacks the ability to steer, provide constant air insufflation or water flushing or focus adjustment. This led to anatomy sometimes being obscured by mucus, bile or 'red out' due to tip impaction against the mucosa. Specifically, during the four respiratory misplacements, tracheal cartilage rings were not initially observed because mucus covered the lens, presumably because the tube was sliding between the tracheal wall and ETT. This precluded earlier tube withdrawal. However, on these occasions, as soon as the lens moved beyond the ETT cuff it was possible to visualise the main carina and bronchi distally. In addition, in a patient with a base of skull fracture, the tube clearly remained within the nasal orifice and later the tube was orientated away from the ETT towards the oesophagus. In a patient with recently bleeding gastric polyps, the polyps could be seen as tube entered the stomach and trauma avoided. In these situations, the IRIS tube provided early warning to avoid or minimize risk.

Of 15 placements, four entered the trachea, two without clinical signs, all immediately withdrawn. Previous study also detected a relatively high proportion (35%) of tubes entering the trachea (Mizzi et al., 2017). This compares with up to 3.2% from blind misplacements found at end of procedure X-ray or 10% detected during EMGP placement (de Aguilar-Nascimento and Kudsk, 2007; Taylor et al., 2017b). It is unclear whether the IRIS tube is misdirected more often or simply detects mis-direction into the trachea earlier or both (Mizzi et al., 2017; Wischmeyer et al., 2018). The large tip may contribute to the difficulty entering the oesophagus past endotracheal tubes or tracheostomies and sometimes deflect towards the trachea. Conversely, during insertion of non-IRIS tubes, coughing usually prompts tube withdrawal. Such withdrawals may have been from a tracheal placement. Thus IRIS tubes may be detecting an under-reported problem.

## Limitations

This clinical effectiveness study has several limitations. First, the patient number was small, all ICU and mostly sedated. Both individuals performing the placements were already well-trained in other guided-tube placement techniques. The generalisability of the success in this study and training needs for competence in IRIS tube placement are yet to be determined.

## Conclusions

In this small series a non-endoscopist could accurately identify major respiratory or GI anatomy. However, standard training needs to be expanded to include more structures (e.g. artificial airways) and more subtle and partial views that may only be seen briefly. In addition, manoeuvres designed to reorient direction of advancement and movement of the tube tip from upper to lower stomach should be further investigated in a larger sample of patients. Direct vision appears to offer an advantage over other methods in differentiating points of transition between the nose, pharynx, respiratory tract, oesophagus, stomach and intestine. IRIS may be less effective in determining point-position or tube tip orientation within the stomach or intestine, but this needs to be tested in future study.

## Ethical statement

North Bristol NHS Trust Clinical Audit department assigned this project as a clinical effectiveness study (CE10413) and as such not requiring formal ethics approval.

## Acknowledgements

We thank the nursing, medical and dietetic ICU staff for making this study possible.

## Conflict of interest

Consultancy for Cortrak (ST, 2007). An audit sponsored by Cortrak 2013-14 (ST, KA). See 'Financial Support'. Other authors: None.

## Financial support

Cardinal Health awarded a grant to cover staff and equipment costs but had no part in preparing the plan, execution or publication of the project.

## Authorship contributions

- Conception and design of the study (ST), the acquisition of data (ST, KA), interpretation of IRIS images (ST, AT) and X-rays (DC) and interpretation of the data (All).
- Drafted or provided critical revision of the article (All).
- Provided final approval of the version submitted for publication (All).

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