RESEARCH PAPER

Formulation and Characterisation of *Hylocereus undatus* (Dragon Fruit) Extract-Loaded Floating Microballoons: A Gastroretentive Approach

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ABSTRACT
Background: *Hylocereus undatus* (white pitaya) is rich in phenolics, flavonoids and betalains, and floating microballoons can prolong gastric residence. **Objective:** To prepare and characterise *H. undatus* extract-loaded floating microballoons using hydroxypropyl methylcellulose (HPMC) and ethyl cellulose (EC). **Methods:** An aqueous extract of whole fruit was prepared by maceration, freeze-dried and screened qualitatively; quercetin and kaempferol were docked against Keap1 (PDB 4IQK). Five batches (F1–F5) were prepared by solvent evaporation (ethanol–dichloromethane 1:1, 0.01% Tween 80) and the F2 batch was characterised by FTIR, optical microscopy, SEM, micromeritics, in-vitro buoyancy, in-vitro release in 0.1 N HCl and the DPPH assay. **Results:** The extract showed alkaloids, carbohydrates, flavonoids, phenols and tannins; saponins were absent. Docking affinities were −9.0 (quercetin) and −9.3 kcal/mol (kaempferol). Batch F2 (HPMC:EC 1:1) gave a yield of 91.67%. Mean particle diameter was 144.63 µm (n = 100), and SEM showed porous, cavity-bearing shell structures. Bulk and tapped densities were 0.294 and 0.385 g/cm^3 (Hausner ratio 1.31, passable flow), and buoyancy after 8 h in simulated gastric fluid was 64.26%. The DPPH IC_{50} was 94.29 µg/mL versus 6.717 µg/mL for ascorbic acid. Release absorbance data could not be used for kinetic modelling. **Conclusion:** Floating microballoons of *H. undatus* extract were prepared and showed in-vitro buoyancy and antioxidant activity. These are preliminary results; entrapment efficiency, quantitative release, stability and anti-ulcer efficacy remain to be established.
Keywords: *Hylocereus undatus*; Dragon fruit; Microballoons; Gastroretentive drug delivery system; Floating microspheres; Antioxidant activity; Solvent evaporation.
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1. INTRODUCTION

Peptic ulcer disease arises when the balance between aggressive factors (gastric acid, pepsin) and mucosal defences (mucus, bicarbonate) is disturbed, with *Helicobacter pylori* infection and use of non-steroidal anti-inflammatory drugs as the principal risk factors.[1,2] Standard therapy combines antisecretory agents, antibiotics and antacids. These relieve symptoms but carry adverse effects, and conventional oral dosage forms add problems of frequent dosing, fluctuating plasma levels and poor adherence.[2,3] Natural products that act beyond acid suppression are therefore of continuing interest as gastroprotective agents.[4]

Gastroretentive drug delivery systems (GRDDS) prolong residence in the stomach and suit sustained or site-specific release in the upper gastrointestinal tract.[5,6] Floating drug delivery systems (FDDS) achieve this because their density is lower than that of gastric fluid; non-effervescent FDDS include hollow microspheres, or microballoons.[6,7] Microballoons are free-flowing, spherical particles with a polymeric shell and a hollow core, generally smaller than 200 µm. On contact with gastric fluid they hydrate to form a gel layer that regulates fluid ingress and drug release, while entrapped air maintains buoyancy.[8,9] The solvent evaporation technique is widely used to prepare them and is suited to thermolabile materials.[10]

Hylocereus undatus (white pitaya; Cactaceae) contains flavonoids (e.g., quercetin, kaempferol, isorhamnetin), betalains, other phenolic compounds and vitamin C, and its extracts show antioxidant and anti-inflammatory properties.[11–13] In rodent models, *H. undatus* pulp protected against ethanol- and indomethacin-induced gastric ulcers,[14] and *H. polyrhizus* extract attenuated indomethacin-induced gastric injury.[15] Plant extracts have been formulated as floating microballoons, for example *Rhynchosia densiflora* leaf extract[16] and tulsi extract,[17] as have anti-ulcer drugs such as famotidine.[18] To the best of our knowledge, *H. undatus* extract has not previously been reported in floating microballoons.

The present study therefore aimed to prepare HPMC/ethyl cellulose microballoons loaded with an aqueous extract of whole *H. undatus* fruit and to characterise them in vitro (FTIR, particle size, SEM, yield, micromeritics, buoyancy, release behaviour and DPPH radical scavenging), supported by a docking analysis of two fruit flavonoids against Keap1.

2. MATERIALS AND METHODS

2.1 Materials. HPMC, ethyl cellulose (EC), ethanol, dichloromethane, Tween 80 and distilled water were used.

2.2 Plant material. Fruits were purchased from a local market in Bengaluru and authenticated by Navashakti Herbal Labs, Bengaluru (authentication certificate, batch DF-2025-004; macroscopy, microscopy and TLC fingerprint complied).

2.3 Extraction. Fresh ripe fruit (750 g) was washed, cut, and the peel and pulp were crushed together with a mortar and pestle. The mass was macerated in 100 mL

distilled water for three days at room temperature with occasional stirring, filtered through muslin cloth, freeze-dried and stored airtight under refrigeration (Fig. 1).[19]

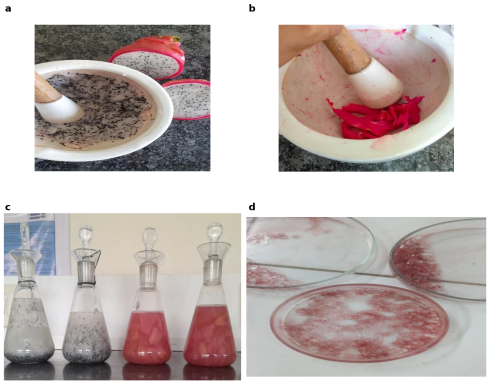


Fig. 1. Preparation of the extract: (a) crushed pulp, (b) crushed peel, (c) macerates of pulp and peel in distilled water, (d) freeze-dried extract.

2.4 Preliminary phytochemical screening. The extract (diluted in 10 mL distilled water) was tested by standard qualitative methods:[20] alkaloids (Dragendorff's and Wagner's tests), carbohydrates (Molisch and Fehling's tests), flavonoids (alkaline reagent test), phenols and tannins (ferric chloride test) and saponins (foam test).

2.5 Molecular docking. Quercetin and kaempferol were docked against the Kelch domain of Keap1 (PDB ID 4IQK, from RCSB). The protein was prepared in Swiss-PdbViewer (co-crystallised ligands removed), the highest-ranked pocket from PrankWeb was used as the binding site, ligands were converted with Open Babel, and docking was run in AutoDock Vina through PyRx. Interactions were visualised in PyMOL and BIOVIA Discovery Studio.

2.6 Preparation of microballoons. Microballoons were prepared by solvent evaporation.[10,21] HPMC and EC (Table 1) were dissolved in ethanol–dichloromethane (1:1) and added dropwise to 250 mL distilled water containing 0.01% Tween 80 and 1.5 mg extract. The dispersion was stirred with a magnetic stirrer at 500 rpm and 40 °C for 1 h to evaporate the solvents. The particles were filtered, washed with distilled water, dried in a hot-air oven and stored at room temperature (Fig. 2).

Table 1. Composition and yield of the *H. undatus* extract-loaded microballoon formulations

Batch	HPMC (mg)	EC (mg)	Total polymer (mg)	Dried yield (g)	Yield (%)
F1	250	350	600	0.47	78.33
F2	300	300	600	0.55	91.67
F3	450	600	1050	0.50	47.62
F4	350	650	1000	0.46	46.00
F5	650	250	900	0.52	57.78

Constant for all batches: ethanol:dichloromethane 1:1, Tween 80 0.01% in 250 mL water, extract 1.5 mg. Yield (%) = dried yield ÷ total polymer mass × 100. No statistical optimisation or design of experiments was performed.

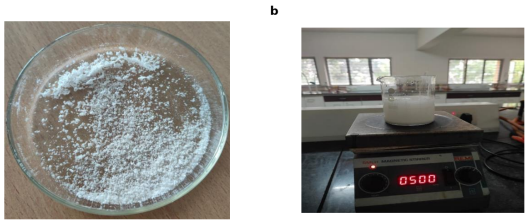


Fig. 2. (a) Preparation of microballoons by solvent evaporation (magnetic stirrer, 500 rpm); (b) dried *H. undatus* extract-loaded microballoons.

2.7 FTIR. Spectra of the extract, excipient mixture and microballoons were recorded on a Bruker Alpha II ATR (ZnSe crystal) at 4000–400 cm^{-1}, 32 scans, resolution 4 cm^{-1}, at 25.0 ± 0.5 °C, without sample preparation.

2.8 Particle size. Microballoons were spread on a glass slide under a coverslip, and the diameters of 100 randomly selected particles were measured at 10× with an eyepiece micrometre calibrated against a stage micrometre.[22] Particle size = projected diameter (divisions) × calibration factor; mean size = Σ(size)/100.

2.9 SEM. Dried microballoons were sprinkled on double-sided adhesive tape on an aluminium stub, coated with Au–Pd and imaged (backscattered-electron detector, 5 kV, 60 Pa, as shown on the micrographs).[23]

2.10 Percentage yield.[24] Yield (%) = (weight of dried microballoons ÷ initial weight of non-volatile ingredients) × 100.

2.11 Micromeritics.[25,26] Accurately weighed 1 g of microballoons was placed in a 10 mL measuring cylinder. Bulk density = mass ÷ bulk volume; tapped density = mass ÷ volume after tapping (100 taps); Hausner ratio = tapped density ÷ bulk density; Carr's index = (tapped density − bulk density) ÷ tapped density × 100.

2.12 In-vitro buoyancy.[27] Microballoons (50 mg) were placed in 100 mL simulated gastric fluid (pH 1.2) containing 0.02% Tween 20 at 37 °C and stirred at 100 rpm. After 8 h, buoyant and settled particles were collected separately, dried at 40 °C and weighed. Buoyancy (%) = $W_{buoyant} \div (W_{buoyant} + W_{settled}) \times 100$.

2.13 In-vitro drug release.[27] Microballoons (50 mg) were tested in USP type II apparatus with 900 mL 0.1 N HCl (pH 1.2) containing 0.02% Tween 20, at 50 rpm and 38 °C, sampled hourly for 8 h and read at 262 nm. Zero-order, first-order, Higuchi and Korsmeyer–Peppas plots were drawn from the absorbance values.

2.14 DPPH assay. DPPH (0.1 mM; 3.94 mg in 100 mL methanol) was mixed 1:1 (2 mL + 2 mL) with samples (10–640 µg/mL in methanol) or ascorbic acid (1–32 µg/mL), vortexed, incubated in the dark for 30 min and read at 517 nm. Inhibition (%) = $(A_{control} - A_{sample}) \div A_{control} \times 100$. IC_{50} values were obtained by nonlinear regression of inhibition against log concentration in GraphPad Prism; the concentration giving 50% inhibition was also read by linear interpolation between adjacent points. The tested sample was the extract-loaded microballoon preparation.

3. RESULTS AND DISCUSSION

3.1 Extraction. Aqueous maceration of whole fruit gave a pink-red filtrate that, after freeze-drying, yielded a pink-red solid (Fig. 1). The extract yield was not recorded, so extraction efficiency cannot be reported.

3.2 Preliminary phytochemical screening. The extract gave positive tests for alkaloids, carbohydrates, flavonoids, phenols and tannins, and a negative foam test for saponins. The tests are qualitative; the intensely pigmented aqueous extract (betalains) may mask or mimic colour reactions, so the results indicate the presence of these classes only and not their amounts.

3.3 Molecular docking. Quercetin and kaempferol, flavonoids reported from *H. undatus*,[11] bound the Keap1 Kelch domain with affinities of −9.0 and −9.3 kcal/mol (Table 2, Fig. 3), both forming five hydrogen bonds. Keap1 is the negative regulator of the Nrf2 antioxidant pathway, so this is an in-silico indication of possible antioxidant-pathway interaction only. The presence of these compounds in the present extract was not confirmed analytically, and no reference ligand or re-docking validation was reported; the result is hypothesis-generating.

Table 2. Docking of quercetin and kaempferol with Keap1 (PDB 4IQK)

Compound	Binding affinity (kcal/mol)	Hydrogen-bond residues	Other interacting residues
Quercetin	−9.0	A:463, A:418, A:465, A:606, A:365	A:417, A:464, A:416, A:367, A:364, A:607, A:604, A:366
Kaempferol	−9.3	A:512, A:465, A:463, A:606, A:367	A:464, A:559, A:513, A:510, A:509, A:605, A:462, A:416

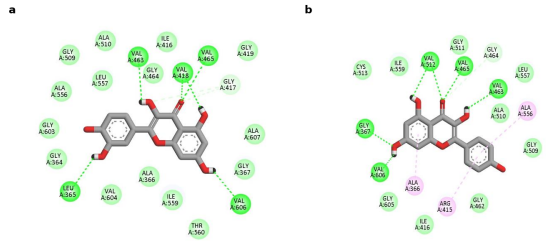


Fig. 3. Two-dimensional interactions of (a) quercetin and (b) kaempferol with Keap1 (PDB ID 4IQK).

3.4 Formulation development. Five batches with HPMC:EC ratios from 0.54:1 (F4) to 2.6:1 (F5) were prepared (Table 1). The product was a white, free-flowing powder (Fig. 2). The hydrophilic HPMC and hydrophobic EC combination is consistent with published floating microballoons,[17,21] but because only one batch (F2, the batch with the highest yield) was characterised, no formulation-dependent conclusions can be drawn.

3.5 FTIR. The extract showed a broad O–H band at 3328 cm^{-1}, C–H bands at 2984/2935 cm^{-1}, a carbonyl band at 1716 cm^{-1} and C–O bands at 1229–1041 cm^{-1}, consistent with phenolic, carbohydrate and carboxylic functionalities (Table 3, Fig. 4). The microballoon spectrum was dominated by a strong band at 1052 cm^{-1} (C–O–C, cellulose ethers) with weak O–H (3454 cm^{-1}) and C–H bands (2972–2871 cm^{-1}); the broad extract O–H band was not evident. Weak bands at 1833–1689 cm^{-1} in the formulation are not seen in the excipient spectrum and were not assigned. Two limitations apply: (i) the excipient mixture was recorded as a semi-liquid, and its strong bands near 734 and 703 cm^{-1} may reflect residual solvent rather than dry HPMC, EC and Tween; and (ii) the extract is only about 0.25% w/w of the polymer (1.5 mg in about 600 mg), too little to be expected in a bulk ATR spectrum. FTIR therefore cannot be taken to demonstrate compatibility or interaction; a physical mixture of extract and polymers should be scanned for that purpose.

Table 3. Principal FTIR bands (cm^{-1}) and tentative assignments

Sample	Observed bands	Tentative assignment
Extract (semi-solid)	3328; 2984, 2935; 1716; 1642, 1621, 1585; 1454–1372; 1308, 1229; 1122, 1080, 1041	O–H; C–H; C=O; C=O/C=C, N–H; C–H bending; C–O; C–O/C–O–C
Excipient mixture (semi-liquid)	3354; 3055; 2974, 2927, 2895; 1640; 1449, 1416, 1379; 1266; 1086, 1046; 880; 734, 703	O–H; =C–H; C–H; C=O/H–O–H; C–H bending; C–O; fingerprint
Microballoons (solid)	3454; 2972, 2918, 2871; 1833–1689; 1354–1203; 1052; 948–529	O–H; C–H; carbonyl region (unassigned); C–O; C–O–C; fingerprint

Bruker Alpha II, ATR (ZnSe), 4000–400 cm^{-1}, 32 scans, resolution 4 cm^{-1}.

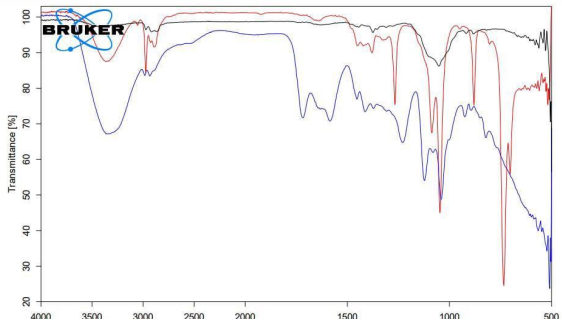


Fig. 4. Overlaid FTIR spectra of the formulation (black), extract (blue) and excipient mixture (red); ATR, 4000–400 cm^{-1}.

3.6 Particle size. The mean diameter of 100 particles was 144.63 µm (calibration factor 13.16 µm per division; range about 79–250 µm; Table 4, Fig. 5a), within the <200 µm range usually quoted for microballoons.[8,9] The 200–300 µm sometimes quoted for plant-extract microballoons[16] was not obtained: only

8% of particles exceeded 200 µm. The size distribution (SD, span) was not calculated.

Table 4. Physicochemical characterisation of the microballoons (batch F2, single determination)

Parameter	Value
Mean particle diameter (n = 100)	144.63 µm
Bulk volume of 1 g / tapped volume (100 taps)	3.4 mL / 2.6 mL
Bulk density / tapped density	0.294 g/cm^3 / 0.385 g/cm^3
Hausner ratio / Carr's index	1.31 / 23.5%
Buoyant / settled mass after 8 h	30.2 mg / 16.8 mg (47.0 mg of 50 mg recovered)
Buoyancy	64.26%

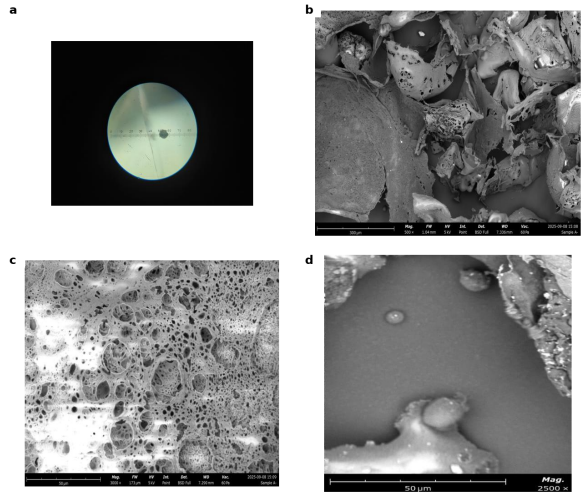


Fig. 5. (a) Optical micrograph of microballoons (10×, eyepiece scale visible); (b–d) SEM images: (b) 500×, scale bar 300 µm; (c) 3000×, scale bar 50 µm; (d) 2500×, scale bar 50 µm.

3.7 SEM. SEM images (Fig. 5b–d) showed thin, porous shell-like structures with numerous cavities, consistent with a hollow or porous matrix formed by solvent evaporation and ethanol diffusion. Many particles appeared broken or collapsed, exposing cavities, and small rounded bodies a few micrometres in diameter were seen on a smooth film. Uniform, smooth, intact spheres were therefore not conclusively shown; images of intact particles and fractured cross-sections are needed to confirm the hollow-sphere morphology.

3.8 Percentage yield. F2 gave the highest yield (91.67%; 0.55 g from 0.60 g polymer), followed by F1 (78.33%); the yields of F3–F5 were 47.62, 46.00 and 57.78%, calculated on the total polymer mass of each batch (Table 1). The extract (1.5 mg) contributes less than 0.3% of the non-volatile solids and does not alter these values.

3.9 Micromeritic properties. Bulk density (0.294 g/cm^3) and tapped density (0.385 g/cm^3) were below that of gastric fluid (about 1.004 g/cm^3), but powder densities include inter-particle air and do not by themselves prove buoyancy. The Hausner ratio (1.31) and Carr's index (23.5%) correspond to passable flow, so flow improvement (e.g., a glidant) may be needed for capsule filling.

3.10 In-vitro buoyancy. After 8 h in simulated gastric fluid, 64.26% of the microballoons remained buoyant (Table 4, Fig. 6). This is lower than the 72.01% reported for famotidine microballoons[18] and shows that about a third of the particles settled, possibly because of broken or non-hollow particles (Section 3.7). The 3.0 mg of unrecovered mass should be accounted for in future work, and floating lag time and total floating duration were not recorded.

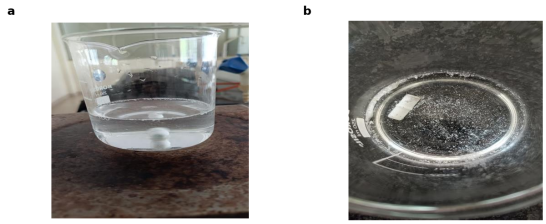


Fig. 6. In-vitro buoyancy test of the microballoons in simulated gastric fluid (pH 1.2): (a) side view and (b) top view of the beaker.

3.11 In-vitro drug release. Absorbance of the release-medium samples at 262 nm fell from 0.118 (1 h) to 0.008 (8 h) but not monotonically (0.065 at 2 h, 0.102 at 3 h, then 0.068, 0.055, 0.049 and 0.041 at 4–7 h). Because cumulative release should rise with time, and because no calibration curve or marker compound was available, these values were not converted into percentage release. Model fitting to the absorbance data gave R^2 of 0.370 (zero-order), 0.686 (first-order), 0.786 (Higuchi) and 0.517 (Korsmeyer–Peppas); no model fitted well and no release mechanism can be assigned. Release from the microballoons is therefore not established by this study.

3.12 Antioxidant activity. DPPH scavenging increased with concentration for both ascorbic acid and the sample (Table 5, Fig. 7). The IC_{50} of the sample (94.29 µg/mL) was about 14-fold higher than that of ascorbic acid (6.717 µg/mL); by linear interpolation the concentrations giving 50% inhibition were 100.1 and 10.8 µg/mL, respectively (about 9-fold). The sample was therefore a weaker radical scavenger than the standard. The two series covered different ranges (1–32 versus 10–640 µg/mL), so percentage inhibition at equal concentration should not be compared. Because the extract is about 0.25% of the microballoon mass and its content per unit mass of microballoons was not determined, the activity cannot be attributed to a defined extract concentration. Antioxidant activity is not evidence of anti-ulcer efficacy and supports further investigation only.

Table 5. DPPH radical scavenging activity of ascorbic acid and the sample

Ascorbic acid (µg/mL)	A at 517 nm	Inhibition (%)	Sample (µg/mL)	A at 517 nm	Inhibition (%)
1	0.563	9.19	10	0.498	19.42
2	0.444	28.39	20	0.478	22.65
4	0.399	35.65	40	0.443	28.32
8	0.363	41.45	80	0.329	46.76

Ascorbic acid (µg/mL)	A at 517 nm	Inhibition (%)	Sample (µg/mL)	A at 517 nm	Inhibition (%)
16	0.241	61.13	160	0.267	56.80
32	0.179	71.13	320	0.189	69.42
–	–	–	640	0.167	72.98
IC_{50} (curve fit)	6.717 µg/mL		IC_{50} (curve fit)	94.29 µg/mL	

Control absorbance: 0.620 (ascorbic acid series) and 0.618 (sample series). IC_{50} by linear interpolation: 10.8 µg/mL (ascorbic acid) and 100.1 µg/mL (sample).

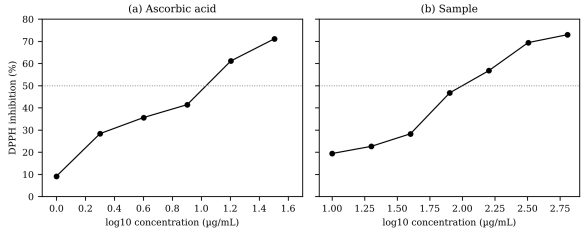


Fig. 7. DPPH radical scavenging (%) versus log_{10} concentration for (a) ascorbic acid and (b) the sample. Points are the measured values in Table 5.

3.13 Limitations. The study was entirely in vitro, with single determinations, no standard deviations and one characterised batch. Entrapment efficiency, quantitative release, floating lag time, stability and anti-ulcer activity were not studied, and no claim of therapeutic efficacy, improved bioavailability or stability is made.

4. CONCLUSION

An aqueous extract of whole *H. undatus* fruit was incorporated into HPMC/ethyl cellulose microballoons by solvent evaporation. The F2 batch gave a 91.67% yield, particles of mean diameter 144.63 µm with porous, cavity-bearing morphology, passable powder flow and 64.26% buoyancy after 8 h in simulated gastric fluid. The sample showed DPPH scavenging activity (IC_{50} 94.29 µg/mL) weaker than that of ascorbic acid. These findings support further development, but entrapment efficiency, validated drug release, stability and in-vivo anti-ulcer evaluation are required before any therapeutic potential can be claimed.

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Nil.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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