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A next-generation antimicrobial wound dressing: a real-life clinical evaluation in the UK and Ireland

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A next-generation antimicrobial wound dressing: a real-life clinical evaluation in the UK and Ireland

• **Objective:** To assess the effectiveness of a new, next-generation antimicrobial dressing (NGAD; AQUACEL Ag+ EXTRA dressing) in managing wound exudate, infection and biofilm, and facilitating progression toward healing.

• **Method:** Clinicians from the UK and Ireland selected stalled or deteriorating wounds that were considered to be compromised by infection and/or biofilm. Only the primary dressing was replaced by the NGAD, for up to 4 weeks or as deemed clinically appropriate; otherwise, standard protocols of care were used. Evaluation forms captured the baseline and final assessment characteristics of wound status, exudate levels, skin health, wound bed appearance, signs of infection and biofilm, and wound dimensions.

• **Results:** In all, 29 wounds were suitable for inclusion in the final analysis. Following the NGAD evaluation, wound statuses were shifted from stagnant/deteriorating to mainly improved, exudate levels were shifted from moderate/high to moderate/low, and skin health was improved in 20 wounds (69%). Wound bed tissue types were shifted from largely suspected biofilm/sloughy tissue (76%) to largely granulation tissue (53%). All signs of clinical infection were reduced in average frequency, with biofilm suspicion falling from 76% to 45% of the cases. The median management period with the NGAD was 4.5 weeks, after which 26 wounds (90%) became smaller in size and 10 wounds (34%) completely healed.

• **Conclusion:** This real-life clinical evaluation of the NGAD suggests that its successful management of exudate, infection and biofilm is generally accompanied by notable improvements in wound health and size, and in some cases, complete healing.

• **Declaration of interest:** The authors are all employed by ConvaTec Ltd. but have no other conflict of interest to declare. Dressings were provided to the clinicians free of charge.

AQUACEL Ag+ EXTRA, biofilm, exudate, healing, infection

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Microbial biofilm is increasingly implicated in wounds that fail to heal.[1] In addition to wound recalcitrance, the presence of surface slime, recurrent infections and poor response to antimicrobial agents are all indicators of wound biofilm.[2,3] It has been reported that approximately two-thirds of patients with non healing wounds are treated with systemic antibiotics,[4–6] and their frequent ineffectiveness may in part be attributed to biofilm involvement. Although clinical indicators of wound biofilm are evident, treatment strategies are currently uncertain. In the absence of specific antibiofilm devices, good wound bed preparation, involving physical removal of superficial tissue and use of both antimicrobial cleansers and antimicrobial dressings, provides the best approach to wound biofilm control.

Physical disruption of wound biofilm (debridement) has been known to facilitate effectiveness of antibiotics and antiseptics by creating a therapeutic period (24–72 hours) during which associated bacteria are more suspectible.[7] In addition, combining antibiofilm and antimicrobial strategies has been shown to improve wound healing outcomes.[8]

In recent years, AQUACEL Ag+ EXTRA dressing—a next-generation antimicrobial dressing (NGAD)—has been developed and approved; it comprises both antibiofilm and antimicrobial agents.[9] On the basis that antibiotics and antiseptics have limited effectiveness against biofilm-encased microorganisms, this combination enables biofilm disruption and subsequent exposure of associated organisms to the antimicrobial agent. Synergy between the three antibiofilm/antimicrobial agents in the NGAD has been demonstrated *in vitro* with subsequent enhanced antimicrobial activity when compared against the same dressing without the antibiofilm components.[10] In a real-life clinical evaluation of the NGAD in 113 patients with non-healing wounds of varied aetiology across Europe and Canada, 17% of wounds completely healed and 42% achieved at least 90% wound closure over an average evaluation period of 4.1 weeks.[11]

The current clinical user evaluation is an extension of the previous clinical evaluation and was conducted in the UK and Ireland. The aim was to further assess the performance of this new primary dressing with regard to its ability to manage exudate, infection, biofilm and improve the wound and skin health.

Methods

Patient inclusion

The dressing was evaluated on patients with challenging wounds from eight health-care facilities across the UK and Ireland between February and September 2014. The evaluating clinicians were all experienced in tissue viability or podiatry, and had previous experience with Hydrofiber wound dressings. While there were no strict inclusion or exclusion criteria, the clinicians were asked to use their discretion in the selection of patients with particularly challenging wounds, with regard to high levels of exudate, signs of clinical infection, and/or suspicion of biofilm, as well as wounds that were failing to demonstrate timely progression toward healing.

As the NGAD had gained regulatory clearance for clinical use in the UK and Ireland via CE Marking, no ethical committee approval was required.[12] Since this was a clinical user evaluation, written informed consent was not essential, but verbal consent was obtained between clinician and patient before starting the evaluation. Product safety has previously been demonstrated in a 42-patient, non-comparative clinical study in non-healing, chronic venous leg ulcers.[13]

Dressing usage

Clinicians were requested to continue managing their patients with their own standard protocol of wound care but to replace the primary dressing with the NGAD for up to 4 weeks, or beyond that if deemed appropriate. It is acknowledged that variations in protocols of care would be expected in clinical settings. However, each clinician was primarily requested to evaluate each wound before and after use of the NGAD.

Baseline assessment

An evaluation form was used for each clinician to record basic patient demographic information, relevant medical history, and the following baseline wound information:

- Wound type (clinician's own description)
- Size (length, wide, depth; cm)
- Duration (months)
- Healing status (stagnant; deteriorating)
- Signs and symptoms of infection[14] (pain; erythema; oedema; heat/warmth; foul odour; purulent exudate; discolouration of granulation tissue; friable granulation tissue; suspected biofilm)[2,3]
- Approximate % of tissue types present in the wound bed (necrotic; sloughy; suspected biofilm; granulation)
- Exudate level (low; moderate; high)
- Condition of surrounding skin (healthy; macerated; dry/eczematous).

Table 1. Patients wound type, age and duration of wound

Wound type	No. of wounds	Mean patient age (range) years	Wound duration months	
			Median	Mean (range)
Mixed aetiology	6	70 (43–84)	26	28 (4–60)
Venous ulcer	4	69 (59–75)	54	120 (11–360)
Diabetic foot ulcer	3	57 (52–67)	3	14 (1.8–36)
Pressure ulcer	2	26, nr	–	14 (3–24)
Arterial ulcer	2	57, nr	–	44 (3–84)
Leg ulcer	2	57, nr	–	5 (3–6)
Traumatic	1	90	nr	–
Cyst	1	45	–	10 (10)
Other	7	65 (40–80)	4	12 (0.3–36)
Not given	1	37	nr	–
ALL	**29**	**61 (26–90)**	**10**	**34 (0.3–360)**

nr–not recorded

Final assessment

At final assessment, the following information was recorded on the evaluation form to assess progress:

- Evaluation period (weeks)
- Size (length, wide, depth; cm)
- Overall healing status (healed; improved; same; deteriorated)
- Signs and symptoms of infection[14] (pain; erythema; oedema; heat/warmth; foul odour; purulent exudate; discolouration of granulation tissue; friable granulation tissue; suspected biofilm)[2,3]
- Approximate % of tissue types present on the wound bed (necrotic; sloughy; granulation; epithelialisation; suspected biofilm)
- Exudate level (low; moderate; high)
- Change in surrounding skin condition (improved; same; deteriorated)
- Frequency of dressing changes compared with previous dressing used (less; same; more)
- Overall performance of NGAD when compared with previous dressing (less effective; same; more effective)
- Whether the clinician would continue to use NGAD (yes; no)
- Whether they would recommend NGAD to a colleague (yes; no).

Results

Sample

A total of 33 patients were evaluated. This was reduced to 28 patients as five were withdrawn due to notably incomplete data sets (evaluation forms that were missing baseline and/or final assessment data on more than one of the following characteristics: exudate levels, skin health, signs of infection,

Table 2. Wound status, exudate levels and skin health at baseline and after use of next-generation antimicrobial dressing evaluations

	Wound status*				Exudate levels†			Skin health‡		
	Deteriorating	Stagnant/same	Improved	Healed	High	Moderate	Low	Healthy	Macerated	Dry/ eczematous
Baseline	7	21			10	16	3	7	9	9
								Deteriorating	Same	Improved
After evaluation	4	2	13	10	2	12	10	2	5	20

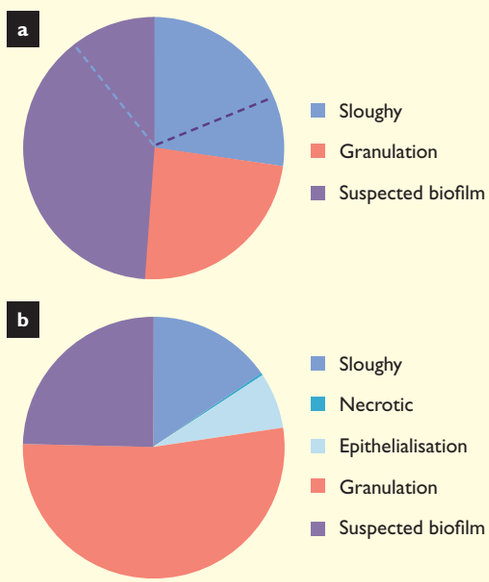
*Information not given at baseline for one patient; †‡Information was not given for 5 wounds after evaluation;‡Information not given for four wounds at baseline, and two wounds after evaluation

suspected biofilm, wound dimensions). One patient had two wounds that were included, bringing the sample size to 29.

Patients

The final sample (n=29) consisted of 19 males and 9 females, with a median age of 59 years (mean: 61 years; range: 26–90 years; Table 1). Wounds were further categorised by duration, with the median duration at baseline being 10 months (Table 1). Moreover, 7 (24%) wounds were judged to be infected, 10 (34%) were judged not to be infected, and 12 (41%) were not classified on infection status (data not shown). For all evaluations, the NGAD assessment period ranged from 1–16 weeks (median: 4.5 weeks), and the average evaluation duration was 5.4 weeks (data not shown).

Fig 1. Wound bed coverage as a % of different tissue types before (a) and after NGAD application (b). Dashed lines represent the judged extent of overlap between sloughy tissue (- - -) and suspected biofilm (- - -)



Wound health

Table 2 shows wound status, exudate levels and skin health, before and after the NGAD evaluations. At baseline, 7 wounds (24%) were judged to be deteriorating, while 21 (72%) were judged to be stagnant. Although 4 wounds (14%) were judged to have remained deteriorating and 2 stagnant, the remainder of the wounds were judged to have shifted to an improving (13 wounds; 45%) or healed (10 wounds; 34%) state at final assessment. Exudate levels shifted from a predominantly moderate (55%) or high level (34%), to a predominantly moderate (41%) or low level (34%). Skin health was also judged to have improved in 20 wounds (69%).

Fig 1 shows the types and approximate coverage of different tissue types observed in the wound bed before (Fig 1a) and after use of the NGAD (Fig 1b). There was a shift from mainly sloughy tissue/suspected biofilm (on average, 76% of wound bed coverage at baseline) to mainly granulation/epithelialisation (57%) after the NGAD evaluations. Sloughy tissue/suspected biofilm coverage was almost halved to an average of 40% after the evaluations, while granulation tissue coverage was more than doubled from 24% to 53%. Note that several clinicians appeared to classify sloughy tissue and suspected biofilm as the same thing. Hence, the actual independent average baseline figures were 68% for suspected biofilm and 38% for sloughy tissue (Fig 1a, dashed lines).

Infection and biofilm

The % of wounds with clinical signs of infection[14] before and after use of NGAD are shown in Fig 2. Each of the eight clinical signs of infection was reduced in frequency after evaluation (mean number of signs 1.4) compared with baseline (2.4). Suspected biofilm[2,3] was more frequently reported than any of the classic signs of infection, with suspicion in 22 wounds (76%) at baseline compared with 13 wounds (45%) after evaluation.

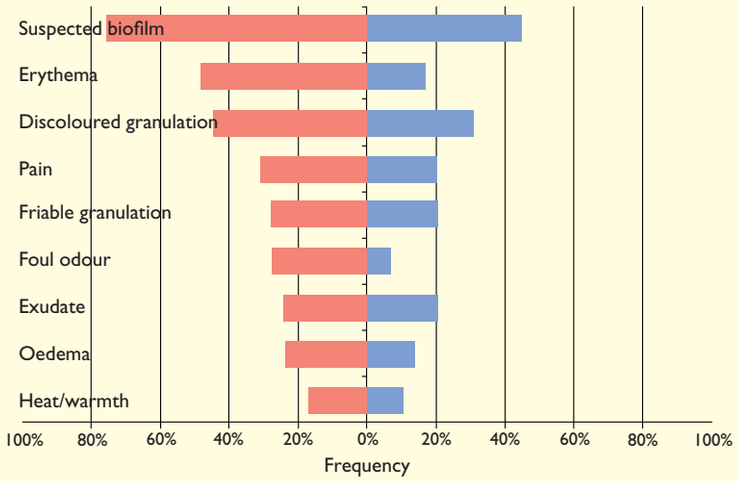
Wound closure

Of the 29 wounds included, 26 (90%) reduced in size or completely healed (100% re-epithelialisation with

no wound volume) by the end of the evaluation, and average wound closure reported was 62%, as judged by the change in wound volume/area calculated from the length, width and depth measurements (Fig 3). There was no correlation between prior wound duration or size and wound closure achieved. There were 10 wounds (34%) that healed completely, and 16 (55%) achieved at least 75% closure. The average previous duration of the 10 wounds that healed was 14.2 months, while the average time to healing for these 10 wounds was 6.7 weeks with NGAD. Of the chronic wounds that healed three were least 2 years old and a further three that were 5, 7 and 8 years old, closed 77%, 98% and 78% respectively.

There were three wounds that failed to progress; two of these belonged to the same patient who was treated with flucoxacillin throughout the evaluation, possibly suggesting a deeper infection problem. The other patient had a 7-year leg ulcer and with peripheral vascular disease, which the evaluating clinician noted may have contributed to the lack of progression.

Fig 2. Percentage of patients with clinical signs of wound infection, plus suspected biofilm, before (■) and after (■) the NGAD application



Dressing usage

The average number of NGAD used per evaluation was 9.7 (range: 2–21), which equates to an average of 1.8 dressing per week for the average 5.4 week evaluation period (data not shown). Clinicians judged the NGAD to be more effective than their previously used primary dressing in 75% of cases (Table 3). There were three instances (two clinicians) where the dressing was judged to be less effective; these involved the same three wounds that did not progress (Fig 3). When asked 23/28 clinicians (82%) said they would continue to use the NGAD, while all clinicians who responded said they would recommend the dressing to a colleague (Table 3).

Discussion

The results of this real-life clinical user evaluation of the NGAD in the UK and Ireland concur with those in other international clinical evaluations conducted in 2013 using the same antibiofilm/antimicrobial technology.[11,13] In the present evaluation, the complete healing of 34% compares favourably with 12%[13] and 17%[11] reported in the 2013 international evaluations. Of particular note in the present evaluations were the prior durations of some of the wounds which went on to heal or progress well toward healing. As described by the participating clinicians, many of these long-standing wounds showed multiple signs of infection,[14] and contained suspected biofilm based on visible and indirect clinical signs.[2,3] It is likely that biofilm or developing/established infection was contributing significantly to the recalcitrant nature of many of these wounds.

Use of the NGAD on previously stagnant or deteriorating, long-standing wounds resulted in a number of important changes in wound health. Excess exudate, exacerbated by inflammation and infection, is widely acknowledged as a cause of delayed healing. Symptomatic management of exudate has been the target of absorptive wound management products since the advent of modern wound care. The sodium carboxymethylcellulose (Na-CMC) component of the NGAD is known to effectively manage exudate, owing to its ability to rapidly gel when in contact with fluid and to intimately contact the wound bed.[15] Bacterial immobilisation within the dressing has also been demonstrated *in vitro*[16–18] and *in vivo*.[19] These current clinical evaluations demonstrate that, by addressing

Table 3. NGAD dressing usage

	Less effective	Same	More effective
Overall performance of the NGAD compared with previous dressing	3	4	21
	Yes		**No**
Will you continue to use the NGAD?*	23		5
Would you recommend the NGAD to a colleague?‡	25		0

*information not given by one clinician. ‡information not given by four clinicians

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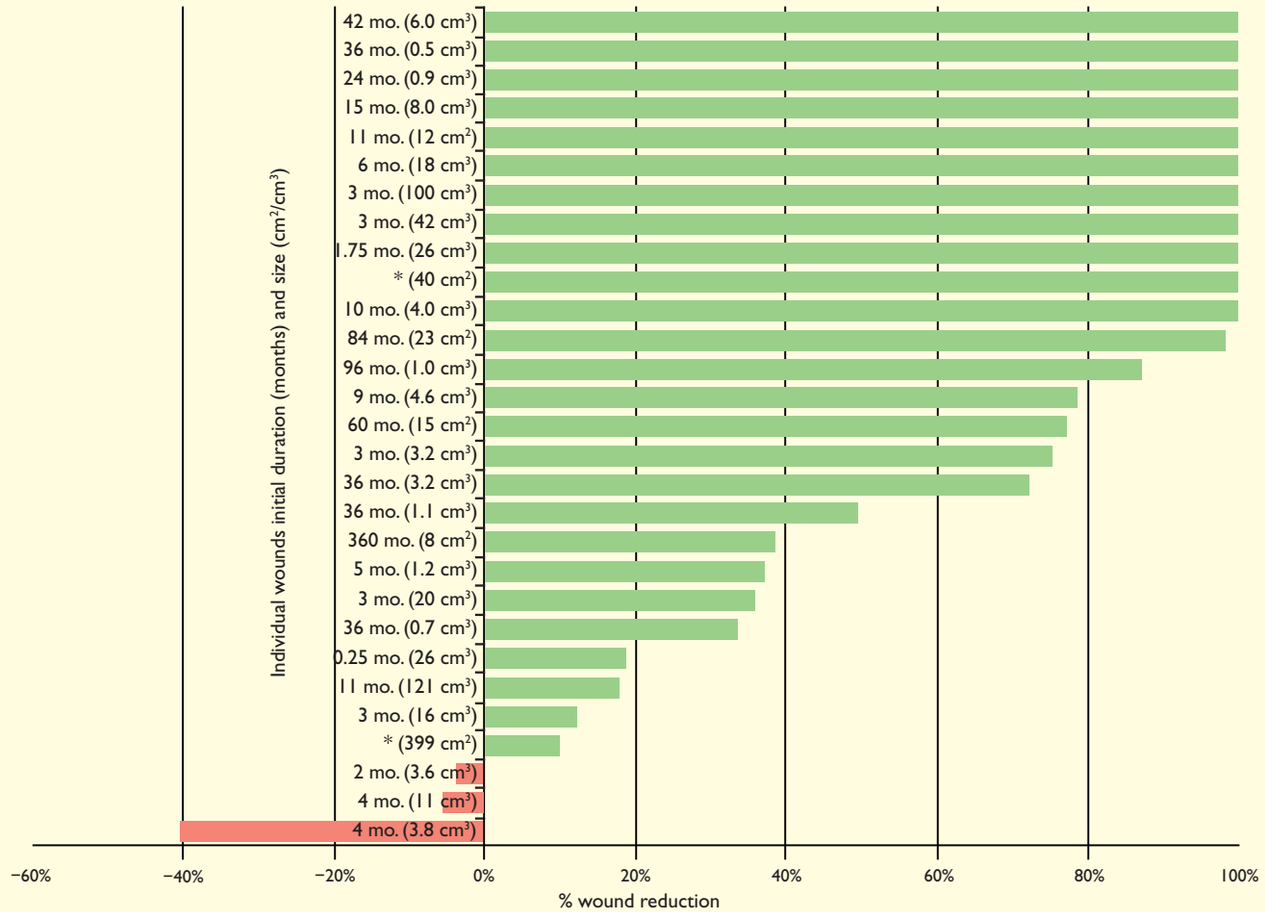
Fig 3. Percentage decrease (■) or increase (■) in wound size for each wound in the evaluation, as judged by change in wound volume/area. Note that each wound is labelled with its initial duration (months) and size (cm^2 or cm^3)



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both excess exudate and wound bioburden (both planktonic and biofilm microorganisms), the NGAD addresses management of both the symptomatic and causative elements of excessive exudate. One direct corollary of reducing exudate levels by dressing with the NGAD may be the observation of improvements in peri-wound skin health in the majority of cases.

Infection is also well-recognised as being a primary cause of delayed wound healing.[14] The ionic silver component of the NGAD is able to efficiently manage wound bioburden, with a broad-spectrum *in vitro* microbicidal activity against wound microorganisms,[20,21] including multidrug-resistant organisms (MDR).[22] Unfortunately, most topical antimicrobial wound therapies available today were developed for efficacy against planktonic microorganisms. Only dressings with combined and proven antibiofilm and antimicrobial capability can hope to be effective against microorganisms in both planktonic and biofilm forms. Following the NGAD clinical evaluations, signs of clinical infection and suspected biofilm were reduced for every characteristic.

Accompanying these reductions in exudate and signs of infection were shifts in the predominant wound bed tissue types, from suspected biofilm/sloughy tissue to granulation and epithelialisation. While the combination of the Na-CMC and ionic silver components of the NGAD have been reported to have some antibiofilm activity *in vitro*,[23,24] the addition of antibiofilm excipients to create the NGAD has been demonstrated to enhance antimicrobial and antibiofilm performance *in vitro*[9,10] and *in vivo*.[25] The antibiofilm excipients added to the silver Na-CMC base dressing to create the NGAD were selected on the basis of their ability to disrupt the biofilm, by weakening its structure and providing a surface-acting, detergent-like action. This action increases the exposure of micoorganisms within

biofilm to the microbicidal action of ionic silver, while the Na-CMC can more effectively immobilise isolated microorganisms and disrupted biofilm fragments, and prevent biofilm re-formation.[9] The present clinical evaluation supports these scientific findings, and adds to the clinical evidence on the effectiveness of the dressing.[9,11,13]

In these evaluations, many clinicians had difficulty in differentiating suspected biofilm from sloughy tissue, and indeed, scientific evidence on the difference between these tissue types is lacking.[26] However, both these tissue types were reported to reduce following the NGAD evaluations. It might be expected that sloughy tissue (mainly proteinaceous, host-derived tissue) would also respond favourably to the cleansing action of a detergent-like surfactant and the physical sequestration action of Na-CMC.

It has previously been concluded that diabetic foot ulcers (DFUs) failing to reduce in size by 50% over the first 4 weeks in a defined protocol of care are unlikely to achieve healing in a reasonable timeframe.[27] That is, independent of modality used, monitoring DFU progress for 4 weeks was a strong predictor of healing rates at 12 weeks. The results of the present evaluation therefore suggest that approximately 62% (18) of the wounds, which achieved at least 50% reduction in size in the evaluation, might be expected to heal after 12 weeks. In this clinical user evaluation, as in previous evaluations and studies,[11,13] use of the NGAD for around 4–5 weeks was shown to improve the status of a majority of wounds.

No dressing can be expected to be suited to every clinical scenario, and as has been reported previously,[11,13] a small number of wounds did not progress following use of the NGAD in the present study. In the three wounds from two patients that increased in size, the clinician had recorded significant comorbidities (systemic antibiotics; peripheral vascular disease) on the clinical evaluation form. This is a reminder that unless underlying comorbidities are properly managed, topical wound-management products may only have limited effectiveness.

Limitations

First, there was no standardised protocol used in this evaluation. However, the only change in wound management practice was swapping the previous primary dressing for the NGAD. As this was the only change made, the observed changes in wound health could be fairly attributed to the dressing and its interaction with other standard protocol components, such as wound bed preparation. Second, the judgment of signs of wound infection and suspected biofilm relied on subjective clinical observations. In the absence of point-of-care diagnostic technologies, such clinical judgment is currently the best practice available.[2,3,14] Finally, these clinical evaluations were not designed to compare the NGAD against other available antiseptic dressings. Carefully designed comparative studies are required to fully elucidate the currently observed clinical effectiveness of this new dressing.

Conclusion

The NGAD is designed specifically to manage wound exudate (Na-CMC; Hydrofiber), infection (ionic silver) and biofilm (safe levels of antibiofilm excipients to aid its disruption, removal and prevent its re-formation). In the majority of wounds in these clinical evaluations, the successful management of each of these barriers to healing was accompanied by notable wound closure, and in some cases, complete healing, thus providing further evidence for the clinical effectiveness of this dressing. ■

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