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Microbial burden of repackaged *versus* original-tube clobetasol propionate 0.05% after 7 days of in-use exposure: a pilot study with paired unopened controls

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Dear Editor,

In Taiwan, dermatology and primary care clinics commonly dispense clobetasol propionate 0.05% cream either in the manufacturer's original aluminum tube or, more often, by transferring cream from larger factory containers into small plastic boxes at the clinic counter. This long-standing practice reduces drug waste and dispensing costs, but it is performed in a routine consultation environment rather than under laboratory conditions, and the destination boxes are not pre-sterilized. Patients therefore periodically express concern that repackaged creams may be more easily contaminated than original tubes. Empirical data are scarce. We undertook a small comparative pilot study with paired unopened controls (one for each packaging type) to address this concern.

Clobetasol propionate cream, a commonly dispensed super-high-potency topical corticosteroid, was tested under 10 conditions: i) an unopened-tube reference arm sampled immediately upon opening the manufacturer-sealed aluminum tube; ii) a freshly-repackaged reference arm sampled immediately after transfer of cream into a sterile 5-mL plastic container, with no further exposure; and iii) eight in-use arms generated by a 2×2×2 factorial of operator (A *vs.* B), prior hand hygiene (handwashing with soap and drying *vs.* no handwashing), and packaging type (original 1-mL aluminum tube *vs.* cream transferred into a 5-mL sterile plastic container). Each condition was tested in same-day triplicate, with three independently prepared containers handled in parallel. The eight in-use arms underwent 7 days of intermittent simulated use at ambient room temperature before sampling. Samples were collected with sterile cotton swabs from the inner surface of plastic containers and from the orifice of aluminum tubes, suspended in sterile saline, serially diluted (1:10, 1:100, and 1:1000), and inoculated onto aerobic culture plates for total colony counting. Plates were incubated aerobically at 37°C for 48 h. Because swab pick-up was not gravimetrically standardized, results are reported as colony-forming units (CFU) per swab sample at the 1:10 dilution.

Aerobic colony counts were uniformly low across all 10 conditions (Table 1). Both unopened reference arms – the unopened tube and the freshly-repackaged container – yielded zero colonies in triplicate, confirming that neither the cream itself nor the act of transfer introduced detectable contamination. Across the eight in-use arms, the highest mean count observed was 11 CFU per swab sample in a no-handwashing, repackaged-container condition; counts at the 1:100 and 1:1000 dilutions were ≤1 CFU across every arm. Although this condition showed the highest recoverable colony burden, absolute counts remained low overall, and the small number of replicates precludes inference of a packaging- or hand-hygiene effect. Representative culture plates for the four exposure combinations are shown at 1:10, 1:100, and 1:1000 dilutions: handwashing/original tube (*Supplementary Figure 1*),

handwashing/repackaged container (*Supplementary Figure 2*), no handwashing/repackaged container (*Supplementary Figure 3*), and no handwashing/original tube (*Supplementary Figure 4*).

These observations are most plausibly explained by the antimicrobial preservative system intrinsic to commercial corticosteroid creams. Because creams contain a water phase that can in principle support microbial growth, their formulations rely on robust preservative systems that must demonstrate efficacy in pharmacopoeial "challenge tests" before release.[1] Surveys of marketed and consumer-used topical preparations confirm that intact preservative systems hold aerobic counts within or below pharmacopoeial limits despite end-user surface contamination.[2] Persistent contamination of in-use multidose preparations remains a documented concern in adjacent fields, particularly ophthalmology, where dropper-tip contamination has been linked to ocular infection.[3] Our paired-control design – in which both unopened references yielded zero colonies – shows that, in this setting, neither the cream itself nor the single-step repackaging procedure introduced detectable contamination. After 7 days of in-use exposure, low-level colonies were recovered in some arms, with the highest burden observed in a no-handwashing, repackaged condition.

Several caveats apply. First, the in-use period was limited to 7 days, whereas patients in real practice often continue to apply the same container for several weeks, with repeated finger contact and exposure to bathroom humidity. Second, only one product class was examined, and only two operators participated; antibiotic, antifungal and barrier preparations may behave differently, particularly compounded formulations whose stability and microbiological quality are less well characterized.[4,5] Third, the swab pick-up volume was not gravimetrically standardized, so absolute counts should be interpreted as between-arm comparisons rather than as bioburden estimates per gram of product. Fourth, our microbiological endpoint was limited to total aerobic colony counts; no species-level identification was performed. Therefore, the study cannot determine which bacterial taxa accounted for the recovered colonies or exclude low-burden clinically relevant organisms. Fungi, anaerobes, and specific Gram-negative pathogens such as *Burkholderia cepacia* complex were also not assessed. Finally, three same-day triplicates per condition provide descriptive consistency but do not constitute formal hypothesis-testing power; we therefore interpret the results as showing comparable, rather than statistically equivalent, microbial burdens.

Within these limitations, our pilot data suggest that short-term repackaging of clobetasol propionate cream into small plastic containers did not result in substantial detectable aerobic contamination under the conditions tested. The higher colony count observed in a no-handwashing, repackaged condition supports continued attention to dispensing and hand hygiene, but the small pilot design precludes attributing the difference to packaging type or handwashing. We nevertheless endorse the continued use of basic dispensing hygiene – gloves, masks, and clean working surfaces – and recommend that

patients limit the in-use period of any repackaged container, avoid finger contact with the bulk product, and discard the container if visible changes occur. Adequately powered, multi-formulation, multi-center studies are warranted before any change to formal dispensing guidance.

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Table 1. Aerobic colony counts (mean of three same-day independent triplicates) recovered from clobetasol propionate cream after 7 days of simulated in-use exposure, compared with two unopened reference controls.

Condition	Operator	Hand hygiene	Packaging type	Mean CFU per swab
Reference 1	–	–	**Unopened tube**	**0**
Reference 2	–	–	**Freshly repackaged container, no in-use exposure**	**0**
1	A	Yes	Repackaged container	0
2	A	Yes	Original tube	1
3	A	No	Repackaged container	11
4	A	No	Original tube	1
5	B	Yes	Repackaged container	1
6	B	Yes	Original tube	0
7	B	No	Repackaged container	5
8	B	No	Original tube	0

CFU, colony-forming units. Each value is the mean of three independent containers prepared and assayed in parallel on the same day. Counts at 1:100 and 1:1000 dilutions were ≤1 CFU across every arm and are therefore not shown.

Online supplementary material:

Supplementary Figure 1. *Aerobic culture plates from clobetasol propionate 0.05% after 7 days of simulated use in the handwashing/original-tube condition. Serial dilutions: 1:10, 1:100, and 1:1000; aerobic incubation: 37°C for 48 h.*

Supplementary Figure 2. *Aerobic culture plates from clobetasol propionate 0.05% after 7 days of simulated use in the handwashing/repackaged-container condition. Serial dilutions: 1:10, 1:100, and 1:1000; aerobic incubation: 37°C for 48 h.*

Supplementary Figure 3*. Aerobic culture plates from clobetasol propionate 0.05% after 7 days of simulated use in the no-handwashing/repackaged-container condition. Serial dilutions: 1:10, 1:100, and 1:1000; aerobic incubation: 37°C for 48 h.*

Supplementary Figure 4. *Aerobic culture plates from clobetasol propionate 0.05% after 7 days of simulated use in the no-handwashing/original-tube condition. Serial dilutions: 1:10, 1:100, and 1:1000; aerobic incubation: 37°C for 48 h.*