JOHNSON & JOHNSON CONSUMER INC.

SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	An Evaluation of the Safety and Efficacy of a Hydrocolloid Bandage on Pimples
PROTOCOL NUMBER:	CCSTOH003710 Amendment 2 (v3) dated 03 Aug 2021
SITE STUDY NUMBER:	C21-D143
SPONSOR:	Johnson & Johnson Consumer Inc.
STUDY SITE:	SGS Stephens, Inc., Dallas Research Center
PRINCIPAL INVESTIGATOR:	Summer Acevedo, PhD
KEY STAFF:	*Site* Sub-Investigator: Peter D. Hino, MD, FAAD (Dermatologist) Quality Assurance Manager: Tia Walton, MLS (ASCP)cm *Sponsor* Designated Physician Representative: Valerii Korzh, MD Co-Study Director: Gabriella John, MS Co-Study Director: Gabrielle Kosmoski Study Manager: Alicia DelSasso, CCRP Department Head: Lakeisha Bell, DMH, MPH Head of Clinical Research: Andrew Myers, MD
STUDY INITIATION DATE (First Subject First Visit):	19 Jul 2021
STUDY COMPLETION DATE (Last Subject Completed):	13 Sep 2021
SITE APPROVAL:	See trial master file for final clinical study report and approvals
SPONSOR REVIEW AND APPROVAL:	See trial master file for final clinical study report and approvals

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

<table>
<tr><td>INTRODUCTION</td><td>Acne vulgaris (acne) is a common chronic skin disease involving blockage and/or inflammation of the pilosebaceous units (hair follicles and their accompanying sebaceous gland). It is a multifactorial disease which results from an interplay of the following four main factors: (1) follicular epidermal hyperproliferation with subsequent plugging of the follicle, (2) excess sebum production, (3) increased proliferation and activity of the commensal bacteria such as Propionibacterium acnes (P. acnes), and (4) inflammation.

Acne is the eighth most common skin disease with an estimated prevalence for all ages of approximately 9.4%[1]. Studies estimate that 35% to close to 100% of adolescents in various countries have experienced acne at some point[1]. Acne treatments include over the counter (OTC) topical medications, such as cleansers and gels with salicylic acid and benzoyl peroxide; prescription medications, such as topical retinoids, topical and oral antibiotics, and hormonal therapy; and procedural therapies, such as light and laser therapies[2]. These medications and therapies carry with them many side effects, including local erythema, dryness, and discoloration[3].

Hydrocolloid bandages are designed to combine the benefits of occlusion and absorbency and have been introduced in the consumer sector in various parts of the world as a non-traditional approach to treating minor wounds. Marketed hydrocolloid acne products are small circles designed to cover just one pimple. In this study we evaluated the safety and efficacy of large hydrocolloid bandages on closed and popped pimples when used overnight for 8-12 hours. In a previous repeat insult patch test study, these bandages did not increase irritation or allergic potential when worn in 24-hour increments. Furthermore, a clinical study showed that these bandages were safe and effective for use on minor wounds when worn in 48-hour increments.</td></tr>
<tr><td>OBJECTIVE</td><td>The objective of this study was to evaluate the effectiveness and tolerability of a hydrocolloid bandage on pimples when used overnight for one week. Error! No bookmark name given.</td></tr>
<tr><td>STUDY DESIGN</td><td>The study protocol referenced on page 1 of this report provides the complete study design for the study.</td></tr>
<tr><td>SUBJECT INFORMATION</td><td>The complete eligibility criteria for this study were followed as defined in the study protocol referenced on page 1 of this report.</td></tr>
<tr><td>INVESTIGATIONAL STUDY MATERIALS</td><td><table><tr><th>Identification</th><th>Product type</th></tr><tr><td>Prototype Ultrathin Hydrocolloid</td><td>Investigational Product (IP)</td></tr><tr><td>Gentle Cleanser</td><td>Auxiliary Product</td></tr></table></td></tr>
<tr><td>DOSE AND MODE OF APPLICATION</td><td>Screening/Baseline visits should have been scheduled for 3:00pm or later.

At the Screening/Baseline visit, the auxiliary product (facial cleanser) was provided to all subjects to use on their face in place of their regular facial cleanser for the duration of the study.</td></tr>
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	The trained grader identified one inflammatory lesion and one mature lesion on the face. The mature lesion was popped by the trained grader at the site. Subjects in the treatment group practiced bandage application and removal at the site. Practice was done on plastic polyethylene plates and not on the subject's face/body. Subjects were given both oral and written instructions for bandage application and removal. The subject, supervised by the study personnel designated to distribute study products, covered both the inflammatory and popped lesions with two separate IPs (bandages). If the two lesions were too close together in proximity on the face to fit two separate IPs (bandages), one bandage could have been used to cover both lesions. The treatment group washed their face twice daily using the study cleanser for all 14 days. Subjects in this group covered their closed and popped pimples with one or two bandages from day 0 to day 7. Subjects applied new bandages to the two target lesions at night after washing their face with the study cleanser; they were instructed to keep the IP(s) on for 8-18 hours overnight on day 0 and for 8-12 hours overnight on days 1-7. Subjects removed their bandages when they woke up in the morning prior to washing their face with the study cleanser. Subjects were instructed to place each used bandage in a separate container and bring it to the site at their next visit. Subjects were asked to label the bandage collection tubes with the date the bandage was removed and from which pimple the bandage covered (closed, popped, or both). Between day 7 and day 14, no bandages were worn, and subjects just washed their face twice daily with the study cleanser. The control group washed their face twice daily using the study cleanser for all 14 days. Subjects in this group did not wear bandages. Subjects in both groups were required to complete a subject diary/instruction card.
METHODOLOGY	Clinical evaluations were conducted at visit 1 (screening/baseline/day 0), visit 2 (day 1), visit 3 (day 2), visit 4 (day 4), visit 5 (day 7), and visit 6 (day 14). Subjects participated in the following procedures at the indicated time points for collection of the primary and secondary endpoints: • Clinical Grading of Wound Healing on Popped Pimple (assessed by the Trained Grader) at all visits • Clinical Grading of Acne on Closed and Popped Pimples (assessed by the Trained Grader) at all visits • Investigator's Global Assessment (IGA) of Acne Severity at visits 1 (for qualification and after pimple popped), 2, 3, 4, 5, and 6 • Cutaneous Tolerance on Full Face (as assessed by the Trained Grader) at all visits • Cutaneous Tolerance on Full Face (as assessed by the Subject) at all visits • Microbiome Swabbing* at visits 1, 2, 4, 5, and 6 • Digital Photographs * at visits 1, 2, 4, 5, and 6 (all subjects)

	• Consumer Perception Questionnaire* (subjects in the treatment group to complete at home on Days 1 through 7 and on Day 13) • Subject Video* (optional; part of the Consumer Perception Questionnaire for subjects in the treatment group to complete at home on Days 1 through 7 and on Day 13) • AE/SAE Collection *Data will be analyzed internally and reported in (a) supplemental clinical study report(s) if applicable.
MEASUREMENT AND/OR EVALUATION SCHEDULE	The following grading/assessments were conducted at the indicated time points: **Efficacy:** Clinical Grading of Wound Healing on Popped Pimple (assessed by the Trained Grader) at all visits • Edema • Crusting/scabbing • Smoothness • General wound appearance Clinical Grading of Acne on Closed and Popped Pimples on Face (assessed by the Trained Grader) at all visits • Erythema of pimples • Size in diameter • Elevation (height) • Dryness/scaling Investigator's Global Assessment (IGA) of Acne Severity at visits 1 (for qualification and after pimple popped), 2, 3, 4, 5, and 6 Cutaneous Tolerance on Full Face (assessed by the Trained Grader) at all visits • Erythema • Edema • Dryness/scaling Cutaneous Tolerance on Full Face (assessed by the Subject) at all visits • Burning/stinging • Itching • Tight/dry feeling Microbiome at visits 1, 2, 4, 5, and 6 (Day 0, Day 1, Day 4, Day 7, and Day 14) • Swabs of closed and popped pimples (2 swabs per pimple) Digital photographs at visits 1, 2, 4, 5, and 6 (all subjects) Consumer Perception Questionnaire (subjects in the treatment group to complete at home on Days 1 through 7 and on Day 13) Subject Video Diary (*optional part of the Consumer Perception Questionnaire)* (subjects in the treatment group could opt in to record a video responding to

	a prompt about their experience with the product in the morning and/or evening for the first week (Days 1 through 7 and Day 13); subjects were asked to video application and removal of the bandages. **Safety:** • Collection of adverse events, serious adverse events, and unanticipated adverse events at all visits • Had to reported regardless of causality and had to be documented as required (occurrence date, location, outcome, and assessment of causality, severity, and relatedness) • SAEs had to be reported and relevant supportive documentation had to be sent to the study manager or designee within 24 hours of learning of the event
INSTITUTIONAL REVIEW BOARD (IRB)	This study was reviewed and approved by the following IRB/IEC: - Name: Advarra Institutional Review Board (IRB) - Approval date: 02 Jul 2021 Applicable Amendments: - Approval dates: 15 Jul 2021 and 06 Aug 2021
SAFETY AND ADVERSE EVENTS	All Adverse Events (AEs/SAEs) were collected regardless of causal relationship to the subject's participation in the study. The information was collected/reported within the reporting timelines specified in the protocol.
MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE	The study monitoring was conducted as per the Sponsor's requirements. The Study Site was/is subject to review by the IRB, to quality assurance audits performed by the Sponsor, and/or to inspection by appropriate regulatory authorities. Sponsor representatives and study site personnel completed a virtual site initiation meeting on 30 Jun 2021. A virtual monitoring visit was conducted via screen share on 05 Aug 2021. After study completion, a Sponsor representative from BioResearch Quality Compliance (BRQC) visited the study site on 15-16 Sep 2021 to audit the study.
OVERALL CONCLUSIONS	Overall results from this single-center, randomized, controlled clinical trial indicate that use of Prototype Ultrathin Hydrocolloid bandage was well tolerated and effective in improving the cosmetic appearance of pimples (popped and closed) when used overnight for one week, under the conditions of this test. Treatment comparisons indicated that the popped pimple with use of the hydrocolloid bandage showed a statistically significantly greater improvement in general wound appearance on days 1 and 4 than the control. Analysis of the general wound appearance of the popped pimple showed a statistically significant improvement on days 1-14 for the active treatment (with hydrocolloid bandage) and on days 2-14 for the control (without hydrocolloid bandage) when compared with baseline. Additionally, use of the hydrocolloid bandage showed a statistically significantly greater percentage of healed popped pimples on day 4

	compared to the control, with 75% of subjects in the treatment group showing healed popped pimples in comparison to 40% of subjects in the control group showing healed popped pimples. Treatment comparisons showed the following statistically significant differences: • Use of the hydrocolloid bandage on the popped pimples showed a statistically significantly greater improvement in crusting/scabbing on day 2; smoothness and elevation on days 1-4; erythema on days 1 and 4; size in diameter on days 1-4 and 14; and dryness/scaling on days 2 and 4, when compared to the control. • Use of the hydrocolloid bandage on the closed pimple showed a statistically significantly greater improvement in size in diameter on day 4 and dryness/scaling on days 2 and 7, when compared to the control. Additionally, while not statistically significant (P = 0.05-0.056), treatment with the hydrocolloid bandage outperformed the control in erythema on day 2, smoothness on day 7, and dryness/scaling on day 14 (of the popped pimple); and in size in diameter on day 14 (of the closed pimple).
BIBLIOGRAPHIC REFERENCES	1) Heng A, Chew, FT. Systematic review of the epidemiology of acne vulgaris. Scientific Reports Nature Research. 10:5754 (2020), https://doi.org/10.1038/s41598-020-62715-3 2) Tripathi SV, Gustafson CJ, et al. (2013) Side effects of common acne treatments. Expert Opinion on Drug Safety. 12:1, 39-51, DOI:10.1517/14740338.2013.740456 3) Mayo Foundation for Medical Education and Research. Acne Treatment. Retrieved from https://www.mayoclinic.org/diseases-conditions/acne/diagnosis-treatment/drc-20368048

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