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Covered or uncovered: A randomized control trial of Tegaderm versus no Tegaderm for ocular ultrasound

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ABSTRACT

Background: Studies on ocular point-of-care ultrasound vary on whether gel should be directly applied to the eye or on top of an adhesive membrane (i.e., Tegaderm™). However, there are currently no data regarding which approach has better image quality and the impact of patient preference. In this study, we sought to address this gap by assessing the difference in image quality and patient preference between Tegaderm™ versus no Tegaderm™ for ocular ultrasound in the emergency department.

Methods: Patients were randomized to have a Tegaderm™ placed on either their right or left eye. The other eye served as a comparator with no Tegaderm™. Ultrasound was performed on the right eye followed by the left eye in all instances. After performing each ultrasound, the sonographer asked the patient to rate their maximal discomfort from the ultrasound of that eye using a Likert scale (0 = no discomfort; 10 = severe discomfort). The sonographer then asked the patient which side (Tegaderm™ vs no Tegaderm™) they preferred. Finally, images were reviewed by an experienced ultrasound fellowship-trained sonographer blinded to allocation and rated from 1 to 5. Continuous data were analyzed using descriptive statistics with mean and standard deviation. A paired samples *t*-test was performed to assess for differences between groups. Categorical data were presented as frequency and percentage.

Results: The mean image score was significantly worse with Tegaderm™ compared with no Tegaderm™ (mean difference: 0.94/5.00; 95% CI 0.79–1.08; $p < 0.001$). This was consistent in both the transverse and the sagittal plane subgroups. The percentage of acceptable images was also higher in the no Tegaderm™ group compared with the Tegaderm™ group (97.8% versus 82.8%). There was no statistically significant difference in patient discomfort with the Tegaderm™ versus no Tegaderm™ group. When asked to compare the two approaches, 54.4% of patients preferred Tegaderm™, 30.0% preferred no Tegaderm™, and 15.6% had no preference.

Conclusions: Tegaderm™ was associated with reduced image quality and no significant difference in patient discomfort when utilized for ocular ultrasound. This study suggests that ocular ultrasound may be better performed without the use of Tegaderm™. Future research should evaluate the impact of Tegaderm™ vs. no Tegaderm™ among more novice users.

1. Introduction

Ocular complaints, including vision-threatening and non-vision-threatening conditions, are a common reason for patients to present to the Emergency Department (ED). [1] One recent study found that ED visits for ocular presentations are rising, with 3.4% of ED visits being due to eye-related complaints. [2] While corneal and conjunctival pathology is more readily apparent on examination, the history and examination of the eye is more limited for posterior chamber pathology. [3] The gold standard for posterior chamber assessment is often a dilated ocular exam by a retinal specialist; however, many EDs have limited access to trained ophthalmologists or retinal specialists. [1]

In recent years, the utilization of point-of-care ultrasound (POCUS) in the ED has grown significantly, as it is free of ionizing radiation, cost-effective, and readily available in most EDs. Ocular POCUS can be used to diagnose a variety of ophthalmologic conditions, including retinal and vitreous hemorrhage, vitreous detachments, foreign bodies, neoplasm, increased intracranial pressure, lens subluxation,

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and retrobulbar hematoma [4,5]. In addition, ocular POCUS has been shown to identify retinal detachment quickly and accurately among patients presenting to the ED with visual complaints. [6]

Traditionally, ocular POCUS is performed with the patient lying supine with their eyelids closed. A copious amount of ultrasound gel is then applied to the eyelid to function as an acoustic stand-off and allow for a clear image of the eye. [4] While ultrasound gel is water soluble and hypoallergenic, the application of copious amounts of ultrasound gel on patients' eyelids can be subjectively uncomfortable for some. In order to prevent the discomfort that may be caused by this direct application of gel, some clinicians have recommended placing an adhesive membrane (Tegaderm™) film on the closed eyelid and applying the ultrasound gel directly on the Tegaderm™ film. Despite this common practice, there are no data about image quality or patient preference with this practice. In this study, we sought to address this gap by assessing the difference in image quality and patient preference between Tegaderm™ versus no Tegaderm™ for ocular ultrasound.

2. Methods

This was a prospective, randomized, crossover study comparing an adhesive cover (Tegaderm™) with no adhesive cover for ocular ultrasound. This was conducted in the Rush University Medical Center ED, a tertiary care academic institution with an annual volume of 70,000 patients per year. The institution has a 3-year Emergency Medicine residency program and a Clinical Ultrasound fellowship.

Adult patients (age ≥ 18 years) presenting with a chief complaint of visual loss or headache were eligible for enrollment. We excluded patients with evidence of ocular infection (e.g., discharge, erythema, swelling, pain with palpation), ocular pain, ocular trauma, concern for retrobulbar hemorrhage, concern for penetrating injury to the cornea, suspected acute angle closure glaucoma, and patients who did not speak English. Patients were enrolled when an ultrasound fellow was present in the ED.

Three ultrasound fellows were trained on the ocular ultrasound protocol and several proctored examinations were performed with and without Tegaderm™ to ensure quality and adherence to the protocol prior to enrolling the first patient. We utilized a Zonare ZS-3 with an L14-5 linear probe using the ocular preset.

After informed consent was obtained, patients were enrolled and randomized using a random number generator to a Tegaderm™ placed on either their right or left eye. The patient's other eye served as a comparator with no Tegaderm™. The patient was advised to close their eyes and the adhesive was applied to the allocated eye. Sterile ultrasound gel was utilized for the uncovered eye. The sonographer began with the right eye for all examinations. For the right eye, the hand was anchored on the bridge of the patient's nose, while for the left eye the hand was anchored on the patient's maxilla. The eye was imaged in both the sagittal and transverse planes for each eye and a single six-second, prospective video clip was stored per imaging plane (two total videos per eye). After obtaining the right eye images, the sonographer asked the patient to rate their maximal discomfort with the ultrasound of that eye using a Likert scale running from 0 to 10 (0 = no discomfort; 10 = severe discomfort). The sonographer then repeated the ultrasound examination on the opposite eye and again asked the patient to rate their discomfort using the same scale. Finally, the sonographer asked the patient which side (Tegaderm™ vs no Tegaderm™) that they preferred.

Images were then stored in our electronic quality assurance system (QPath E; Telexy, Inc.) without any identifiers other than eye laterality and imaging plane. An ultrasound fellowship-trained physician with >10 years of experience in ocular ultrasound reviewed all images blinded to the allocation and rated the quality for each video loop using a standardized tool (Table 1). [7]

The primary outcome was a comparison of mean image quality between Tegaderm™ versus no Tegaderm™. We performed a subgroup analysis of mean image score for the sagittal images only and mean image score of the transverse images only. Secondary outcomes included number of acceptable images (defined as an image quality score of 3–5), patient discomfort score, and patient preference.

Table 1
Image rating scale [7].

Overall Image Quality: _____ (1–5)
1 = No recognizable structures, no objective data can be gathered
2 = Minimally recognizable structures but insufficient to make a diagnosis
3 = Sufficient visualization to make a diagnosis but overall poor quality images
4 = Sufficient visualization to make a diagnosis with overall good quality images
5 = Sufficient visualization to make a diagnosis with overall excellent (textbook quality) quality images

2.1. Data analysis

Using a paired samples *t*-test, we determined a sample size of 90 patients would be required to have an 80% chance of detecting an increase in the mean image quality score from 4 in the no Tegaderm™ group to 3 in the Tegaderm™ group with an assumed 5% level of statistical significance and modest effect size of 0.3. Continuous data were analyzed using descriptive statistics with mean and standard deviation and a paired samples *t*-test completed to assess for differences between groups. Categorical data were presented as frequency and percent. Statistical analyses were completed using Statistical Package for the Social Sciences (SPSS, Inc., Armonk, NY) version 26.

3. Results

We enrolled 90 total patients with a mean age of 46 years (range: 19–85 years) and 64% being female. The most common chief complaint was headache (91%) followed by blurred vision (7%), double vision (1%), and black spots in the vision (1%). The mean image score was significantly worse with Tegaderm™ compared with no Tegaderm™ (mean difference: 0.94/5.00; 95% CI 0.79–1.08; $p < 0.001$) (Table 2). This was consistent in the transverse plane subgroup (mean difference: 0.88/5.00; 95% CI 0.69–1.06; $p < 0.001$) and the sagittal plane subgroup (mean difference: 1.00/5.00; 95% CI 0.81–1.19; $p < 0.001$). The percentage of acceptable images was also higher in the no Tegaderm™ group compared with the Tegaderm™ group (97.8% versus 82.8%).

There was no statistically significant difference in patient discomfort with the Tegaderm™ group reporting a mean discomfort score of 1.41/10 (95% CI [confidence interval] 1.07–1.75) and the no Tegaderm™ group reporting a mean discomfort score of 1.73/10 (95% CI 1.28–2.18). When asked to compare the two approaches, 54.4% preferred Tegaderm™, 30.0% preferred no Tegaderm™, and 15.6% had no preference.

4. Discussion

To the best of our knowledge, this is the first published study comparing Tegaderm™ versus no Tegaderm™ on both image quality and patient preference for ocular ultrasound. Overall, we found significantly decreased image quality when using Tegaderm™ compared with no Tegaderm™. Additionally, we identified no significant difference in patient discomfort.

We identified a significant decrease in image quality with Tegaderm™ for the transverse plane, sagittal plane, and overall image score. Moreover, Tegaderm™ was associated with a significantly higher number of images that were deemed unacceptable. Decreased image quality with the use of Tegaderm™ is likely multifactorial. The optimal placement of Tegaderm™ is operator dependent, and if not carefully applied can lead to air bubbles that entrap under the Tegaderm™ which would affect image quality. Secondly, the thin membrane itself could cause artifact during image acquisition. Given that all studies were

Table 2
Comparison of image quality scores in the Tegaderm™ versus No Tegaderm™ groups.

	Tegaderm™ (Trans)	Tegaderm™ (Sag)	Tegaderm™ Mean Score	No Tegaderm™ (Trans)	No Tegaderm™ (Sag)	No Tegaderm™ Mean Score
Mean (95% CI)	3.66 (3.50–3.84)	3.12 (2.92–3.32)	3.39 (3.22–3.56)	4.54 (4.41–4.67)	4.12 (3.95–4.29)	4.33 (4.20–4.46)
Total 5	15	7	11	56	32	44
Total 4	36	24	30	27	41	34
Total 3	33	34	33.5	7	13	10
Total 2	6	23	14.5	0	4	2
Total 1	0	2	1	0	0	0
Total Acceptable (%)*	84 (93.3%)	65 (72.2%)	74.5 (82.5%)	90 (100%)	86 (95.6%)	88 (97.8%)
Total Unacceptable (%)*	6 (6.7%)	25 (27.8%)	15.5 (17.2%)	0 (0%)	4 (4.4%)	2 (2.2%)

* Acceptable was defined as a quality score of 3–5; Unacceptable was defined as a quality score of 1–2.

done by ultrasound fellows, image quality may be even lower when performed by an average user when compared to our study.

Overall, exams with Tegaderm™ and without Tegaderm™ were generally well tolerated without a clinically or statistically significant difference in patient discomfort. Interestingly, approximately 25% more patients preferred Tegaderm™ over no Tegaderm™ and 16% of patients had no preference, though overall the mean discomfort scores for both cohorts were very low. Some patients may prefer Tegaderm™ to prevent irritation from the gel directly on the eye and when removed appropriately, it can lead to less gel left on the eye and a cleaner field. However, it is important to balance this with image quality. Therefore, one alternate approach would be to begin with Tegaderm™ among patients with a strong preference for this, with the option to remove the Tegaderm™ if the image becomes suboptimal.

Building upon our work, future research should assess whether these findings are consistent among more novice users and if certain features may help predict which patients will have better image quality with Tegaderm™. Additionally, research should determine whether different adhesive membranes or specifically designed standoff pads may be more beneficial for ocular ultrasound.

4.1. Limitations

This study was a single-center study and may not reflect other institutions. Patients were enrolled as a convenience sample when investigators were present. There were three different ultrasound fellows completing the exams with potential varying techniques in image acquisition. However, all ultrasound fellows were trained by the same expert user in technique and image acquisition. Also, all ultrasounds were performed on both eyes and in random order so that each person served as their own control. The use of ultrasound fellowship physicians may affect the generalizability of our findings as most ED providers are not ultrasound fellowship trained and may perform these exams differently or not feel as proficient in the exam. Finally, we did not assess the impact on diagnostic accuracy for ocular pathology.

5. Conclusion

Tegaderm™ was associated with reduced image quality and no difference in patient discomfort when utilized for ocular ultrasound. This study suggests that ocular ultrasound may be better performed without the use of Tegaderm™. Future research should evaluate the impact of Tegaderm™ vs. no Tegaderm™ among more novice users.

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Meetings

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Declaration of Competing Interest

We have no conflicts of interest nor financial support to disclose.

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