Calibrated Force Gauge Tested Integrity of Clear Corneal Incisions

Using the calibrated force gauge to test the integrity of clear corneal wounds in the immediate postoperative period after cataract surgery proved useful in examining the propensity for wound leaks, according to a study in the *Journal of Cataract and Refractive Surgery.* Using the calibrated force gauge delivered a controlled, consistent, and quantifiable amount of force to the ocular surface, creating a realistic model for the amount of force a patient’s eye may experience during touching, rubbing, or forced blinking.

Because wound leaks are widely believed to be a risk factor for postoperative complications following cataract surgery, a sterilizable and measurable instrument was created to analyze the vulnerability of clear corneal wounds. A Dontrix gauge, which is a precision instrument designed to measure the forces used in orthodontics, was modified (Calibrated Force Gauge; Ocular Therapeutix, Inc.) to assess wound integrity and the propensity for leakage in the immediate postoperative period. The calibrated force gauge is used to apply a gradual and quantifiable force to the ocular surface, simulating potential manipulation by the patient.

The investigators performed three separate clinical studies to examine changes in IOP and resulting leak rates during application of the calibrated force gauge. All studies were considered by the institutional review board not to be of significant risk. The first study assessed how 1 ounce of force affected changes in IOP in healthy volunteers (n = 30 patients) who were not having ocular surgery. The investigators used the results in this study to determine whether this amount of force was adequate to simulate patient manipulation by comparing IOP changes with results in the earlier literature. The second study tested the integrity and leak rates of clear corneal incisions sealed with stromal hydration alone, again using the calibrated force gauge (n = 29 patients). The final study evaluated the leak rates of clear corneal incisions closed with sutures using the calibrated force gauge (n = 29 patients).

According to the investigators, in the first study, with the application of 1 ounce of external force, the mean IOP increased from baseline (17.49-43.44 mm Hg). In the second study, using up to 1 ounce of force resulted in a leak rate of 67% for the main incision. The overall leak rate for the third study using up to 1 ounce of force was 23.8%. No adverse events or serious adverse events occurred during these studies.

Based on these results, the first study confirmed that 1 ounce of force is a realistic approximation of the amount of force a patient’s eye may experience during rubbing. After clear corneal cataract surgery, the application of 1 ounce of force to the ocular surface for approximately 2 to 3 seconds may simulate the propensity for postoperative wound leak resulting from patient manipulation, the investigators said.

"If a wound leaks under point-pressure manipulation after cataract surgery, it may be an indication that the architecture of the incision is not adequate and additional measures are necessary to prevent postoperative wound leaks and potential resulting complications," the investigators concluded. "Subsequent studies can be performed to test various patterns of incision construction, including those generated by the femtosecond laser."

This study was sponsored by Ocular Therapeutix, Inc.


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