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MODELED WIDE-AWAKE, LOCAL-ANESTHETIC, NO-TOURNIQUET SURGICAL PROCEDURES DO NOT IMPAIR DRIVING FITNESS. AN EXPERIMENTAL ON-ROAD NONINFERIORITY STUDY

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Appendix 1: Full inclusion and exclusion criteria

Inclusion Criteria:

- 35-65 years old.
- Right hand dominant.
- Possessing a valid driver's license.
- Typically drive at least two times per week.
- U.S. citizen or green card holder, and able to provide a social security number.
- Normal (or corrected to normal) hearing and vision.
- Able to drive an automatic transmission without special equipment.
- Weighing more than 100 pounds (due to the volume of lidocaine used in the study).
- Self-reported normal sensation in the hands.
- Self-reported normal function of the hands (minor arthritis controlled by oral medications was acceptable).

Exclusion Criteria:

- More than two driving violations in the past 3 years.
- Having caused an injurious accident in the past three years.
- Lingering effects of heart condition, brain damage from stroke, tumor, head injury, recent concussion, or infection.
- Epileptic seizures within 12 months, uncontrolled current respiratory disorders, motion sickness, inner ear problems, dizziness, vertigo, balance problems, uncontrolled diabetes for which insulin is required, chronic migraine or tension headaches (no more than one per month).
- Taking any substances that may interfere with driving ability (cause drowsiness or impair motor abilities).
- Pregnancy.
- Any numbness or tingling in the hands due to any medical condition or prior injury.
- Any heart rhythm disorders such as an irregular heartbeat, pacemaker or defibrillator.
- Any liver disease.
- An allergy to any local anesthetic.

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Appendix 2: Summary of events included in the driving fitness assessment



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- Event 1: Deceleration to stop at a stop sign. Acceleration and steering into a left turn from Transportation Research Plaza onto Industrial Park Drive (Blacksburg, VA). Speed limit 25 mph.
- Event 2: Deceleration to stop at stop sign. Acceleration and steering into a right turn from Berkshire Drive NW onto Gibson Drive NW (Christiansburg, VA). Speed limit 25 mph.
- Event 3: Deceleration prior to turn; acceleration and steering into a right turn from Depot St NE onto Park St (Christiansburg, VA). Speed limit changes from 35 mph to 25 mph.
- Event 4: Deceleration to stop at stop sign. Acceleration and steering into a right turn from Clearview Drive onto Wades Lane (Christiansburg, VA). Speed limit 25 mph.
- Event 5: Steering, acceleration, and deceleration to maneuver within traffic stream on North Franklin Street (Christiansburg, VA). Speed limit 35 mph.
- Event 6: Deceleration prior to turn; acceleration and steering into a left turn from Peppers Ferry Road NE onto Cinnabar Road (Christiansburg, VA). Speed limit 35 mph.
- Event 7: Steering, acceleration, and deceleration to maneuver winding segments of road and continue on Cinnabar Road (Christiansburg, VA). Speed limit 35 mph.
- Event 8: Deceleration prior to turn and, as needed, to yield to oncoming traffic (full stop was a possibility if oncoming traffic was present). Acceleration and steering into a left turn from Jennelle Road onto Yellow Sulphur Road (Christiansburg, VA). Speed limit 35 mph.

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Appendix 3: Noninferiority Limits

- Lateral acceleration: 0.05g (equivalent to taking a standard city corner at 10.6 mph *vs* 10 mph)
- Longitudinal acceleration: 0.05g (equivalent to acceleration from 0 to 60 mph in 7 seconds *vs* 8 seconds)
- Longitudinal deceleration: 0.05g (equivalent to a 50-foot change in stopping distance from 60 mph)
- Speed: 10 mph
- Steering wheel angle: 30 degrees (equivalent to turning the steering wheel from the 12 o'clock position to 1 o'clock position)
- Yaw: 10 degrees/s

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Appendix 4: Hand Use Metrics

Outcome		
	Mean (95% confidence interval)	
	Baseline	Modeled WALANT
Both hands use (percent)	72.2 (67.8 - 76.5)	62 (56.2 - 67.8)
Right hand use (percent)	11.7 (8.6 - 14.7)	10.8 (7.3 - 14.2)
Left hand use (percent)	15.6 (11.7 - 19.5)	25.6 (20.2 - 30.9)

Hand use measurements for the eight selected events during the baseline and modeled WALANT drives. 95% confidence intervals were created by bootstrapping methods.