Temple Diabetic Driving Studies

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  Assistant Professor,
  Temple University
  School of Podiatric Medicine

- October 2018
- NETSEA Conference

  “Learning is not attained by chance, it must be sought for with ardor and attended to with diligence.”
  ~Abigail Adams

- Monet’s Water Lilies
Authors/Investigators

- Todd Hasenstein, DPM
  - Chief Resident, Temple University Hospital Podiatric Surgical Residency Program

- Timothy Greene, DPM
  - Chief Resident, Temple University Hospital Podiatric Surgical Residency Program

- Kerianne E. Spiess, DPM
  - Former Resident, Temple University Hospital Podiatric Surgical Residency Program

- Andrew J. Meyr, DPM
  - Residency Director, Temple University Hospital Podiatric Surgical Residency Program
Doctor, when can I drive?

- A common question certainly, but the lack of national/state regulations and literature makes the answer difficult to determine.
Liebensteiner MC et al 2010. Driving reaction time before and after primary fusion of the lumbar spine (PubMed ID#: 20075774).

- Studied driving reaction time before and after lumbar arthrodesis with comparison to a control group and with correlation to VAS pain scores.
- Control Group: 0.49 seconds
- Experimental Group: 0.69 sec; 0.73 sec; 0.67 sec
- Moderate to high correlations between back pain and reaction times.

Concluded it is “probably” safe for patient to resume driving following hospital discharge, but driving function continued to improve over a 3 month period.
Lower Extremity Surgery and Driving

- Liebensteiner MC et al 2010. Driving reaction time before and after primary fusion of the lumbar spine (PubMed ID#: 20075774).

  - Post-operative driving reactions were statistically slower following either right or left hip replacement for most patients for **8 weeks**.
  - Some patients were slower **up to 8 months** following the procedure.
Lower Extremity Surgery and Driving

- Liebensteiner MC et al 2010. Driving reaction time before and after primary fusion of the lumbar spine (PubMed ID#: 20075774).

  - No differences observed two weeks after total knee replacement
  - Return to baseline about 4-6 weeks after arthroscopic ACL repair.
Lower Extremity Surgery and Driving

  - Return to baseline brake response time after ~9 weeks post-operatively.
  - Brake response times were significantly affected until ~6 weeks after initiation of weight bearing.
  - Delayed brake reaction times in all patients with chronic *lower extremity musculoskeletal disease* (either right or left sided) that did not improve following local anesthetic injection.
  – Evaluated 28 people undergoing HAV surgery.
  – Pre-op times were slower than a control group.
  – 21 of 28 were unable to complete assessment at two weeks secondary to pain.
  – Return to baseline in ~6 weeks.

• Myerson et al. 2011. Driving brake reaction time following right ankle arthrodesis (Pubmed ID# 22097166).
  • Slower than control group, but not abnormally slow in relation to safety thresholds.
Diabetes and Driving

• American Diabetes Association committee 2012. Diabetes and Driving (PubMed ID#: 22187475).

• Kilpatrick ES et al 2013. Implications of the new European Union driving regulations on patients with Type I diabetes who participated in the Diabetes Control and Complications Trial (PubMed ID#: 23215789).

Diabetes and Driving


Diabetic Sensorimotor Neuropathy

- Sensory neuropathy
  - Lack of plantar pedal sensation
  - *Think that might affect the depression of automobile pedals?*

- Motor neuropathy
  - Weakness, muscle atrophy, slowing of movements, unstable gait, frequency of falls
  - *Think that might affect transitioning between the gas/brake pedals?*

- Foot wounds, Partial foot amputations, Charcot neuroarthropathy....

- Diabetic auditory and visual reaction times
**Objective**
To evaluate the effect of diabetes, diabetic sensorimotor neuropathy and diabetic foot disease on driving outcomes using a series of case-control trials

**Part I:** Determine whether diabetics with neuropathy had slower brake response times than a control group/published safety thresholds

**Part II:** Compare mean brake response times between two groups of diabetic drivers with and without neuropathy.

**Part III:** Compare mean brake response times between neuropathic diabetic drivers with and without specific diabetic foot pathology
Study Protocol-Inclusion Criteria

- Received IRB approval from home institution prior to data collection
- Must be current driver within 1 year with active license
- Undergo physician assessment using Michigan Neuropathy Screening Instrument

**Michigan Neuropathy Screening Instrument**

B. Physical Assessment (To be completed by health professional)

1. Appearance of Feet
   
   **Right**
   - Normal □ 0 Yes □ 1 No
   - If no, check all that apply:
     - Deformities
     - Dry skin, callus
     - Infection
     - Fissure
     - Other
     - Specify: __________________________

   **Left**
   - Normal □ 0 Yes □ 1 No
   - If no, check all that apply:
     - Deformities
     - Dry skin, callus
     - Infection
     - Fissure
     - Other
     - Specify: __________________________

2. Ulceration
   - Absent □ 0 Present □ 1

3. Ankle Reflexes
   - Present □ 0
   - Present/Reinforcement □ 0.5
   - Absent □ 1

4. Vibration perception at great toe
   - Present □ 0
   - Decreased □ 0.5
   - Absent □ 1

5. Monofilament
   - Normal □ 0
   - Reduced □ 0.5
   - Absent □ 1

Signature: __________________________

Total Score ____________/10 Points

MNSI © University of Michigan, 2000
• Completed a total of 10 recorded trials using computer simulator
  – Participants encouraged to “test drive” the simulator until comfortable
  – Trials observed and recorded by investigators
  – Fastest and slowest trials from each set were excluded prior to data analysis
The Temple Diabetic Driving Studies
Part I

• Control Group
  – 25 active drivers with neither diabetes nor peripheral neuropathy

• Experimental Group
  – 25 active drivers with diabetes and peripheral neuropathy

• Outcome Measures
  – Mean brake response time
  – Frequency of abnormally slow reactions (\( \geq 0.70 \) seconds)

<table>
<thead>
<tr>
<th></th>
<th>Drivers with neither diabetes nor lower extremity neuropathy (n=200 trials)</th>
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<th>Comparative statistical analysis</th>
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<tbody>
<tr>
<td>Mean ± standard deviation</td>
<td>0.55 ± 0.08</td>
<td>0.76 ± 0.18</td>
<td>( p &lt; 0.001 ) (independent student t-test)</td>
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<td>Brake response time (seconds)</td>
<td></td>
<td></td>
<td></td>
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<td>Frequency of abnormally</td>
<td>7/200 (3.5%)</td>
<td>115/200 (57.5%)</td>
<td>( p &lt; 0.001 ) (Fisher’s exact test)</td>
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<td>delayed reactions</td>
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The Temple Diabetic Driving Studies

Limitations:

- **Fair comparison?**
  - Not matched for age, gender or co-morbidities….

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The Temple Diabetic Driving Studies
Part II

- **Control Group**
  - 25 active drivers with diabetes but no peripheral neuropathy

- **Experimental Group**
  - 25 active drivers with diabetes and peripheral neuropathy
  - Matched for age and HbA1c but not gender

- **Outcome Measures**
  - Mean brake response time
  - Frequency of abnormally slow reactions ($\geq 0.70$ seconds)

<table>
<thead>
<tr>
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<th>Drivers with diabetes without lower extremity neuropathy (n=200 trials)</th>
<th>Drivers with diabetes with lower extremity neuropathy (n=200 trials)</th>
<th>Statistical comparison</th>
</tr>
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<tbody>
<tr>
<td>Mean ± standard deviation Age (years)</td>
<td>58.16 ± 12.62</td>
<td>56.3 ± 10.8</td>
<td>p = 0.5746 (independent t-test)</td>
</tr>
<tr>
<td>% Male</td>
<td>56.0</td>
<td>84.0</td>
<td>p = 0.026* (Fisher’s exact test)</td>
</tr>
<tr>
<td>Mean ± standard deviation HbA1c</td>
<td>7.32 ± 1.44%</td>
<td>7.80 ± 1.25%</td>
<td>p = 0.236 (independent t-test)</td>
</tr>
<tr>
<td>Mean ± standard deviation Michigan Neuropathy Screening Instrument score</td>
<td>1.06 ± 0.917</td>
<td>5.86 ± 2.15</td>
<td>p &lt; 0.001* (independent t-test)</td>
</tr>
<tr>
<td>% History of specific diabetic foot pathology</td>
<td>0.0</td>
<td>68.0</td>
<td>p = 0.004* (Fisher’s exact test)</td>
</tr>
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<td><strong>Mean ± standard deviation brake response time (seconds)</strong></td>
<td>0.67 ± 0.12</td>
<td>0.76 ± 0.18</td>
<td>p &lt; 0.001 (independent student t-test)</td>
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<tr>
<td><strong>Frequency of abnormally delayed reactions</strong></td>
<td>70/200 (35.0%)</td>
<td>115/200 (57.5%)</td>
<td>p &lt; 0.001 (Fisher’s exact test)</td>
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**The Temple Diabetic Driving Studies**

**Part III**

- **Control Group**
  - 20 active neuropathic diabetic drivers without foot pathology

- **Experimental Group**
  - 20 active neuropathic diabetic drivers with foot pathology (ulceration, amputation, Charcot)
  - Matched for age, HbA1c and gender.

- **Outcome Measures**
  - Mean brake response time
  - Frequency of abnormally slow reactions ($\geq 0.70$ seconds)

<table>
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<tr>
<th></th>
<th>Drivers with diabetes, lower extremity neuropathy, and no history of diabetic foot pathology [n = 160 trials]</th>
<th>Drivers with diabetes, lower extremity neuropathy, and history of or current diabetic foot pathology [n = 160 trials]</th>
<th>Statistical comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD Age (years)</td>
<td>58.65 ± 11.41</td>
<td>55.35 ± 9.53</td>
<td>$p = 0.3272$ (independent t-test)</td>
</tr>
<tr>
<td>% Male (count)</td>
<td>75.0% (15)</td>
<td>95.0% (19)</td>
<td>$p = 0.1818$ (Fisher’s exact test)</td>
</tr>
<tr>
<td>Mean ± SD HbA1c</td>
<td>7.70 ± 1.59%</td>
<td>7.97 ± 1.14%</td>
<td>$p = 0.5673$ (independent t-test)</td>
</tr>
<tr>
<td>Mean ± SD Michigan Neuropathy Screening Instrument</td>
<td>3.98 ± 1.27</td>
<td>6.85 ± 1.70</td>
<td>$p &lt; 0.001^*$ (independent t-test)</td>
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<tr>
<td>Mean ± standard deviation brake response time (seconds)</td>
<td>0.79 ± 0.22</td>
<td>0.71 ± 0.14</td>
<td>p &lt; 0.001 (independent student t-test)</td>
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<tr>
<td>Frequency of abnormally delayed reactions</td>
<td>93/160 (58.13%)</td>
<td>77/160 (48.13%)</td>
<td>p = 0.093 (Fisher’s exact test)</td>
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Doctor, when can I drive?

- Significantly slower mean brake response times and more frequent “abnormally delayed” brake responses in diabetic drivers with neuropathy
  - In comparison to non-diabetic drivers, the brake response difference of 0.21 seconds observed in diabetic, neuropathic drivers would correlate to a physical stopping difference of approximately 21 feet for two cars traveling at 55mph.

- “Abnormally Delayed” responses occurred significantly more frequently in the diabetic group (35%) and in the diabetic, neuropathic group (57.5%) compared to the non-diabetic group (3.5%).
Study Limitations

- Brake response time represents only a single facet of total driving function.

- Data was collected from a limited amount of participants from a single urban environment.

- Parts II/III still did not factor in further diabetic complications (retinopathy) or other comorbidities

- Brake Simulation Equipment vs. Automobile Setting

- Potential overcompensation in the neuropathic drivers with pathology
  - Increased awareness
It is likely that the combination of diabetes and neuropathy +/- specific foot pathology has the potential to negatively affect driving outcomes.

Now does this mean that this population cohort is at a greater risk for automobile accidents?

It is likely that foot pathology/pain itself and acute surgical intervention have the potential to negatively affect driving outcomes as well.

- Observed significant changes between a shoe, Aircast and walking cast in healthy volunteers.


- Slower response times and increased “thinking times” for ankle and knee braces.


- Observed significant changes between a shoe, Aircast walker and walking cast in healthy volunteers, but that did not exceed safety thresholds.
Lower Extremity Immobilization and Driving

- **Control Group**
  - 25 healthy volunteers in a sneaker

- **Experimental Group 1**
  - The same 25 healthy volunteers in a surgical shoe

- **Experimental Group 2**
  - The same 25 volunteers in a CAM walker

- **Outcome Measures**
  - Mean brake response time from 10 emergency braking trials after practice.
  - Frequency of abnormally slow reactions ($\geq 0.70$ seconds)
  - Frequency of **inaccurate brake responses** (inadvertently hitting the accelerator/brake pedal simultaneously during an emergency braking situation).
### Lower Extremity Immobilization and Driving

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# Lower Extremity Immobilization and Driving

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## Outcome Measures Results

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<td><strong>Frequency of inaccurate brake responses</strong></td>
<td>4/200 (2.0%)</td>
<td>8/200 (4.0%)</td>
<td>36/200*^ (18.0%)</td>
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Lower Extremity Immobilization

- Significantly slower mean brake response times and more frequent “abnormally delayed” brake responses while wearing both the surgical shoe and the walking boot.
  - In comparison to the control shoe, the brake response difference of 0.161 seconds observed with the walking boot would correlate to a physical stopping difference of approximately 13 feet for two cars traveling at 55mph.

- More common for a brake response to be “abnormally delayed” than “normal” in the walking boot (55.50% vs. 44.50%)

- “Inaccurate” responses occurred significantly more frequently while in the walking boot (18%) compared to control shoe gear (2%) and the surgical shoe (4%).
How do Physicians play a role in Driving?

**Pennsylvania Driving Restrictions**

- No specific laws/restrictions on driving with a cast on, wearing immobilization devices, or post-operatively following lower extremity surgery.
- “In PA, physicians must report to PennDOT individuals whom they have diagnosed as having a condition that could impair their ability to drive safely.”
- Further, physicians are immune from civil and criminal liability if they do report, but are not immune and may be held liable if they do not report.

[http://www.dot.state.pa.us/public/dvspubsforms/BDL/BDL%20Medical-Protected/BR-Ro.pdf](http://www.dot.state.pa.us/public/dvspubsforms/BDL/BDL%20Medical-Protected/BR-Ro.pdf)
# How do Physicians play a role in Driving?

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<tr>
<td>- A representative of the Connecticut DMV informed us that it was unlawful to utilize a device on either leg that impairs the ability to drive an automobile, but we were unable to correlate this with a specific statute within their vehicle code. Applicants self-report problems and must sign a medical certification statement that they do not have any health problems or conditions preventing them from driving safely. If checking yes, then it is possible they will have to undergo a formal medical evaluation. This report asks drivers if they have any history of “muscular disease” and “missing or impaired hand, arm, foot, leg, finger, toe”. It asks physicians specifically if there is “loss or impairment of leg, foot, toe, hand, finger; perceptible limp, deformities, atrophy, weakness, paralysis, clubbing, edema, hypotonia”. Insufficient mobility and strength in lower limb to operate pedals properly; asymmetric deep tendon reflexes, sensory or positional abnormalities, abnormal patellar and Babinski’s reflexes; ataxia; previous surgery; limitation of motion or tenderness”. In the Connecticut Driver’s Manual it states “even little problems like...a sore leg can affect your driving. If you are not feeling well and need to go somewhere, let someone else drive.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Physicians may submit a written, signed report to the agency about potentially unsafe drivers. Anonymous reports are not accepted and these reports are not confidential. P.A. 75-577 added a provision to the statues that says “physician’s failure to report constitutes an infraction”. We contacted the state to get clarification on this, but were unsuccessful. Physicians are immune from civil liability with respect to reporting of drivers.</td>
<td></td>
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## How do Physicians play a role in Driving?

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<th>Physician Requirements</th>
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<tbody>
<tr>
<td><strong>MAINE</strong></td>
<td><strong>Yes. “Driving may need to be temporarily prohibited due to an immobilizing cast...if it impedes safe operation of a motor vehicle” (29 Department of the Secretary of State; 250 Bureau of Motor Vehicles; Chapter 3 Physical, emotional and mental competence to operate a motor vehicle).</strong> Applicants are asked if they have any medical conditions including &quot;diabetes&quot;. If present, then it is possible the applicant will have to undergo a medical examination. The Driver Medical Evaluation form asks physicians to fill out a functional ability profile (link provided). This includes a section on diabetes.</td>
<td>Physicians are not required to report drivers with medical conditions that could affect driving ability, but may choose to do so. Anonymous reports are not accepted. Physicians are immune from civil and criminal liability with respect to reporting of drivers.</td>
</tr>
<tr>
<td></td>
<td><strong>MASSACHUSETTS</strong></td>
<td>Applicants are asked if they have any &quot;cognitive, neurologic, physical, or any other impairment that may affect your functional ability to operate a motor vehicle safely&quot; and &quot;are you currently taking any medication that may affect your ability to safely operate a motor vehicle&quot;. Applicants are not specifically asked about the presence of diabetes. If present, then it is possible they will have to undergo a formal medical examination. The Medical Evaluation form does not specifically ask about anything directly related to diabetes or lower extremity manifestations of diabetes.</td>
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### How do Physicians play a role in Driving?

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<th>Reporting Requirements</th>
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| NEW HAMPSHIRE | - No specific regulations identified with respect to a cast or immobilization device.  
  - Applicants are not asked any medically related questions on the driver’s license application. | - Physicians are not required to report drivers with medical conditions that could affect driving ability, but may choose to do so.  
  - There is no statutory immunity from civil or criminal liability with respect to reporting potentially unsafe drivers. |                                                                                   |
| VERMONT     | - A representative of the Vermont DMV informed us drivers may be cited by police for wearing a device that limits their ability to perform the required tasks of driving, but that this was at the discretion of the police officer and we were unable to correlate this with a specific statute in the Vermont Vehicle Code.  
  - Applicants are asked on the application whether they have a physical or mental condition that could affect their ability to safely operate a motor vehicle ("including diabetes, epilepsy, seizures or black outs"). If present, then it is possible they will have to undergo a medical examination.  
  - The Universal Medical Evaluation specifically asks about "arthritis/degenerative joint disease", "amputation of leg (describe cause and extent)" and/or "permanent disability/condition". | Applicants are asked on the application whether they have a physical or mental condition that could affect their ability to safely operate a motor vehicle ("including diabetes, epilepsy, seizures or black outs"). If present, then it is possible they will have to undergo a medical examination. The Universal Medical Evaluation specifically asks about "diabetes" but nothing more specific than that and nothing with respect to lower extremity manifestations of diabetes. | - Physicians are not required to report drivers with medical conditions that could affect driving ability, but may choose to do so. Anonymous reports are not accepted.  
  - Physicians are immune from civil and criminal liability with respect to reporting of drivers. |
Take Home Points

It is likely that the combination of diabetes and neuropathy +/- specific foot pathology has the potential to negatively affect driving outcomes.

It is likely that foot pathology/pain, acute surgical intervention and commonly utilized lower extremity immobilization devices have the potential to negatively affect driving outcomes as well.

This is a potentially underappreciated aspect of foot and ankle surgery and probably an area in which we should spend more time educating our patients.
• Please do not hesitate to contact me with any further questions

Laura.sansosti@gmail.com