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Diabetic Driving Studies—Part 1: Brake Response Time in Diabetic Drivers With Lower Extremity Neuropathy

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ABSTRACT

Although the effect of lower extremity pathology and surgical intervention on automobile driving function has been a topic of contemporary interest, we are unaware of any analysis of the effect of lower extremity diabetic sensorimotor neuropathy on driving performance. The objective of the present case-control investigation was to assess the mean brake response time in diabetic drivers with lower extremity neuropathy compared with that of a control group and a brake response safety threshold. The driving performances of participants were evaluated using a computerized driving simulator with specific measurement of the mean brake response time and frequency of abnormally delayed brake responses. We analyzed a control group of 25 active drivers with neither diabetes nor lower extremity neuropathy and an experimental group of 25 active drivers with type 2 diabetes and lower extremity neuropathy. The experimental group demonstrated a 37.89% slower mean brake response time (0.757 ± 0.180 versus 0.549 ± 0.076 second; $p < .001$), with abnormally delayed responses occurring at a greater frequency (57.5% versus 3.5%; $p < .001$). Independent of a comparative statistical analysis, the observed mean brake response time in the experimental group was slower than the reported safety brake response threshold of 0.70 second. The results of the present investigation provide original data with respect to abnormally delayed brake responses in diabetic patients with lower extremity neuropathy and might raise the potential for impaired driving function in this population.

The effect of lower extremity pathology and surgical intervention on automobile driving function has been a topic of contemporary interest in orthopedic studies. Several investigators have published general guidelines and produced original data on the return to safe driving after lower extremity surgery (1–9). Others have specifically studied the effect of chronic musculoskeletal lower extremity pathologic entities and the use of immobilization devices on driving outcomes (10–15).

Despite this, we are unaware of any analysis into the effect of diabetic lower extremity neuropathy and the consequences of diabetic foot disease on driving performance. The presentation of diabetic neuropathy is as a symmetric sensorimotor polyneuropathy preferentially affecting the distal lower extremities. The most apparent effects of this occur within the sensory system and contribute to the development of an insensate plantar foot, pedal ulcerations, soft tissue and bone infection, and limb amputations (16–19). However, involvement of the motor system can also cause lower extremity weakness, skeletal muscle atrophy, slowing of movement, unstable gait, and an increased frequency of falls (20–28). Additionally, and distinct from the lower extremity, auditory and visual reaction times have been demonstrated to be impaired in the presence of diabetes (29–31). It is not difficult to envision how a combination of these factors could potentially contribute to impaired automobile driving performance.

Although some investigators have studied the effect of major limb amputation on return to driving and driving function (32–34), and more general statements about the effects of diabetes on driving have been reported (35–38), these have only addressed driving after limb loss and discussed more general topics such as hypoglycemia. The objective of this case-control study was to assess the brake response times in diabetic drivers with lower extremity neuropathy. We aimed to determine whether diabetic patients with neuropathy had slower brake response times than a control group of nondiabetic drivers without neuropathy and established safety thresholds.

Patients and Methods

After approval by our institutional review board (Temple University; protocol no. 22922), the braking performances of the participants were evaluated using a computerized driving simulator (Stationary Simple Reaction Timer; Vericom

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Computers, Inc., Rogers, MN). This device has previously been used to evaluate brake response times in the setting of lower extremity impairment and measures to a precision of 0.01 second (10). The simulator consists of a laptop computer, steering wheel, accelerator, and brake pedal system (Fig). The participants were seated in a comfortable position with adjustment of the simulator construct as needed for individual preference. For the purposes of the present investigation, the participants depressed the accelerator pedal and maintained a constant speed with their right foot as a driving scene was displayed on the monitor. Next, at a random time within a 10-second window after initiation of the constant speed, red lights were activated on the monitor, which alerted the participants to release the accelerator pedal and depress the brake pedal as fast as they could with their right foot. The interval between the red light activation and initiation of the brake pedal was recorded as the brake response time.

Verbal instructions and a demonstration describing how to use the simulator were given, and the participants had the opportunity to undergo multiple practice trials before the actual brake response testing until they were comfortable with the equipment. Ten recorded trials were then performed for each subject, with elimination of the fastest and slowest trials from each set before data analysis. The primary outcome measure was considered the mean brake response time from the 8 recorded trials, and our sample size and power estimate were based on this result. The frequency count of abnormally delayed trials was considered the secondary outcome of interest.

Although a number of studies have been reported with respect to normal and abnormal brake response times (39,40), several investigators, government sources, and the driving simulator software we used have established a cutoff threshold for potentially unsafe brake response times at 0.70 second (6,10,40). In the present investigation, we considered brake reaction times <0.70 second as normal and those ≥0.70 second as abnormally delayed.

Eligible consenting participants were enrolled consecutively from an urban U.S. podiatric medical clinic (Foot and Ankle Institute, Temple University School of Podiatric Medicine, Philadelphia, PA). We enrolled a control group consisting of 25 active drivers without a history of diabetes or lower extremity neuropathy and an experimental group consisting of 25 active drivers with a history of type 2 diabetes and lower extremity neuropathy. We considered active drivers as those who identified themselves as current drivers, possessed a valid driver's license, and who had driven at least twice in the previous month. The exclusion criteria consisted of a history of any right-sided lower extremity surgery within 3 months, current requirement for any type of protective immobilization device on the right leg (i.e., surgical shoe, removable cast boot, short leg cast), and any current driving restrictions related to patient care. All drivers were tested in their own footwear that they were wearing on that day. Additional information collected on the experimental group included age, most recent hemoglobin A1c value (<6 months), any history or current evidence of lower extremity ulceration, any history of minor or major lower extremity amputation, any history of Charcot neuroarthropathy, and the side of any ulceration, amputation, or Charcot neuroarthropathy.

Neuropathy was defined using the Michigan Neuropathy Screening Instrument, a validated measure of diabetic neuropathy encompassing sensory, motor, and autonomic components (41,42). The maximum score available is 5 points for each limb and 10 points for both limbs, with a total score of ≥2.5 defining neuropathy. Participants receive 1 point on each foot if any deformities are present (e.g., Charcot neuroarthropathy, hammertoe, previous amputation, plantar callus formation, fissuring, infection) and 0 points if no deformities are present. Participants receive 1 point on each foot if any ulceration is present and 0 points if no ulceration is present. Participants receive 1 point if the Achilles tendon reflex is absent, 0.5 point if the Achilles tendon reflex is present with reinforcement (clasping the hands and fingers together with the Jendrassik maneuver), and 0 points for an intact Achilles tendon reflex without reinforcement. They receive 1 point if vibratory sensation is absent as measured with a 128-Hz tuning fork at the dorsal hallux interphalangeal joint, 0.5 point if vibratory sensation is diminished (not able to sense after 5 seconds), and 0 points if vibratory sensation is intact (subject able to sense for >5 seconds). Participants receive 1 point if protective sensation is absent as measured with a 5.07-gauge Semmes-Weinstein monofilament (defined as the inability to sense 4 sites on the plantar foot [heel, first metatarsal head, fifth metatarsal head, and plantar hallux]), 0.5 point if 1 of the 4 sites is sensed, and 0 points if ≥2 sites are sensed. The vibratory and sensory testing was adjusted if any partial foot amputation was present.

An a priori power analysis based on a previous investigation using this simulator and participants with lower extremity pathologic features (10) was calculated assuming a primary outcome measure standard deviation of 0.1 second and detectable effect size of 0.2 second to ensure a power of 0.8 and an α of 0.05 with an independent Student's t test. We chose to collect data from 50 subjects (25 in each group). The data were stored in a password-protected personal computer for subsequent statistical analysis. All statistical analyses were performed using Statistical Analysis Systems software, version 9.2 (SAS Institute, Cary, NC). Descriptive statistics were calculated and consisted of the mean, standard deviation (SD), range, and frequency count. Comparative statistical analyses performed on the primary outcome measure (mean brake response time) used the independent Student's t test. For the secondary outcome measure (frequency count of abnormally delayed reactions), we used Fisher's exact test of the null hypothesis.

Fig. Driving simulator. The primary outcome measure of the present investigation was the mean brake response time using a computerized driving simulator. The brake response time was defined as the time from red light activation on the computer monitor, maintaining a constant accelerator speed to initiation of the brake pedal.

Results

The control group consisted of 25 participants (13 males [52.0%]) with a mean ± SD age of 32.7 ± 11.7 (range 24 to 67) years and 200 brake response trials. The mean ± SD brake response time observed in this control group was 0.549 ± 0.076 (range 0.42 to 0.79) second. An abnormally delayed brake response time was observed in 7 of these 200 trials (3.5%), with 1 participant (4.0%) demonstrating >1 abnormally delayed brake response trial.

The experimental group consisted of 25 participants (21 males [84.0%]) with a mean ± SD age of 56.3 ± 10.8 (range 28 to 75) years and 200 brake response trials. The mean ± SD Michigan Neuropathy Screening Instrument score was 5.86 ± 2.15 (range 2.5 to 9). A hemoglobin A1c value was available from 23 of the 25 subjects with a mean ± SD of 7.80% ± 1.25% (range 5.5% to 10.1%). The mean ± SD brake response time observed in this experimental group was 0.757 ± 0.180 (range 0.50 to 1.68) second. An abnormally delayed brake response time was observed in 115 of these 200 trials (57.5%), with 20 participants (80.0%) demonstrating >1 abnormally delayed brake response trial.

The experimental group demonstrated a 37.89% slower mean brake response time (0.757 versus 0.549 second; $p < .001$), with abnormally delayed reactions occurring at a greater frequency (57.5% versus 3.5%; $p < .001$) compared with the control group (Table).

A secondary analysis was performed within the experimental group of patients with neuropathy and diabetes. Male participants (n = 168 trials [84.0%]) had a brake response time of 0.725 ± 0.14 (range 0.50 to 1.30) seconds, and female participants (n = 32 trials [16.0%]) had a brake response time of 0.925 ± 0.260 (range 0.66 to 1.68) seconds ($p < .001$). Participants aged <60 years (n = 136 trials [68.0%]) had a brake response time of 0.752 ± 0.144 (range 0.50 to 1.30) seconds, while participants ≥60 years of age (n = 64 trials

Table
Primary and secondary outcome measure results

Outcome	Drivers Without Diabetes or Lower Extremity Neuropathy (n = 200 Trials)	Drivers With Diabetes and Lower Extremity Neuropathy (n = 200 Trials)	Comparative Analysis (*p* Value)
Brake response time (s)	0.549 ± 0.076	0.757 ± 0.180	<.001*
Frequency of abnormally delayed reactions (≥0.70 s)	7/200 (3.5)	115/200 (57.5)	<.001†

Data presented as mean ± standard deviation or n/n (%).
* Independent Student's *t* test.
† Fisher's exact test.

[32.0%]) had a brake response time of 0.767 ± 0.240 (range 0.50 to 1.68) seconds ($p = .59$). Participants with a hemoglobin A1c value <8.0% (n = 112 trials [60.9%]) had a brake response time of 0.723 ± 0.142 (range 0.50 to 1.30) seconds, and participants with a hemoglobin A1c value ≥8.0% (n = 72 trials [39.1%]) had a brake response time of 0.750 ± 0.129 (range 0.50 to 1.68) seconds ($p = .19$). Participants with a current lower extremity ulceration (n = 72 trials [36.0%]) had a brake response time of 0.713 ± 0.137 (range 0.50 to 1.08) seconds. Participants without a current lower extremity ulceration (n = 128 trials [64.0%]) had a brake response time of 0.782 ± 0.196 (range 0.51 to 1.68) seconds ($p = .01$). Participants with a history of any minor or major lower extremity amputation (n = 112 trials [56.0%]) had a brake response time of 0.730 ± 0.142 (range 0.50 to 1.30) seconds. Participants without a history of any minor or major lower extremity amputation (n = 88 trials [44.0%]) had a brake response time of 0.792 ± 0.215 (range 0.50 to 1.68) seconds ($p = .02$). Participants with a history of Charcot neuroarthropathy (n = 16 trials [8.0%]) had a brake response time of 0.651 ± 0.082 (range 0.56 to 0.85) second, and participants without a history of Charcot neuroarthropathy (n = 184 trials [92.0%]) had a brake response time of 0.766 ± 0.183 (range 0.50 to 1.68) seconds ($p = .01$). Participants with a history of any ulceration, amputation, or Charcot neuroarthropathy (n = 136 trials [68.0%]) had a brake response time of 0.721 ± 0.139 (range 0.50 to 1.30) seconds. Participants without a history of any ulceration, amputation, or Charcot neuroarthropathy (n = 64 trials [32.0%]) had a brake response time of 0.833 ± 0.229 (range 0.51 to 1.68) seconds ($p < .001$). Participants with a history of any right-sided ulceration, amputation, or Charcot neuroarthropathy (n = 104 trials [52.0%]) had a brake response time of 0.738 ± 0.136 (range 0.50 to 1.30) seconds, and participants without a history of any right-sided ulceration, amputation, or Charcot neuroarthropathy (n = 96 trials [48.0%]) had a brake response time of 0.778 ± 0.217 (range 0.51 to 1.68) seconds ($p = .11$).

Discussion

The results of the present investigation provide evidence that diabetic drivers with lower extremity sensorimotor neuropathy demonstrate slower mean brake response times and have an increased frequency of abnormally delayed brake reactions compared with a control group of drivers without either diabetes or lower extremity neuropathy. Although the observed differences were statistically significant, we believe these findings are clinically significant even without a comparative analysis as our observed mean brake response time in those with diabetic neuropathy was slower than an established safety threshold of 0.70 second (6,10,40). Also, we observed abnormally delayed brake response times at or greater than this threshold in 57.5% of the braking trials involving patients with diabetic neuropathy. Additionally, most (80%) neuropathic diabetic drivers studied demonstrated >1 abnormally delayed braking response during data collection. On the basis of these findings, we have concluded that this population might have at least the potential for impaired driving function.

In the 2015, the U.S. National Transportation Safety Board reported a special investigation into rear-end automobile collisions (43). They found that these crashes represented approximately 28% of highway accidents, nearly one half of all 2-vehicle accidents, and resulted in 1705 fatalities in 2012. A delayed driver response time was noted as a primary cause in many of these accidents, and they advocated for forward collision warning systems that have the potential to prevent >1000 fatal crashes annually. The 37.89% slower brake response time observed in neuropathic diabetic drivers in the present investigation would physically translate to a response difference distance of approximately 17 ft for 2 vehicles traveling 55 miles an hour.

The secondary analysis within the experimental group of neuropathic diabetic drivers found some differences when considering participant variables such as gender, history of lower extremity ulceration, history of minor or major foot amputation, and history of Charcot neuroarthropathy. We should caution, however, that our findings represent a post hoc analysis and were not the primary objective of our investigation. Furthermore, the overwhelming majority of mean brake response times within the secondary analysis were still >0.70 second. Therefore, we have refrained from drawing definitive conclusions from this secondary data analysis. Instead, we believe that elucidation of specific subject variables and their effect on driving function represents an interesting avenue for future investigation. Based on the results of our initial investigation, we have already expanded data collection to additionally study neuropathic diabetic drivers versus non-neuropathic diabetic drivers and neuropathic diabetic drivers with foot pathology versus neuropathic diabetic drivers without foot pathology (parts 2 and 3 of the diabetic driving studies).

We cannot make any assertion in the present study regarding the reason or reasons neuropathic diabetic participants demonstrated slower brake response times, only that they did. It could have specifically resulted from the sensory neuropathy and an inability to feel the accelerator and brake pedals, motor neuropathy, an inability to efficiently transition between the accelerator and brake pedals, decreased visual reaction times, or any number or combination of other confounding variables.

Just as with any scientific investigation, critical readers are encouraged to review and assess the study design and specific results to reach their own independent conclusions. The preceding represents our conclusions from the data. We also realize that all investigations have limitations, and ours had several to consider. First, we believe it is important to realize that the brake response time represents only a single facet of total driving function. Just because the brake response times are slower, does not mean that neuropathic diabetic drivers are necessarily at an increased risk of motor vehicle accidents. Elderly drivers, for example, have been observed to compensate for decreased reaction times associated with age by driving at slower speeds, during safer driving conditions, and by following vehicles at greater distances (44–49). Although it is possible that neuropathic diabetic drivers enact similar or different compensatory driving behaviors, this was not studied within our investigational design.

Second, data were collected from a limited amount of participants within an urban environment; therefore, these results might not be representative of a broader population sampling. In addition, we studied participants treated at a podiatric medical clinic; thus, at least some degree of selection bias is probable. This is underscored because most of the experimental group did not just have diabetic neuropathy but also had a history of advanced diabetic foot disease complications, including ulceration, partial foot amputation, and Charcot neuroarthropathy. The control and experimental groups were also not matched for age or gender but were rather enrolled consecutively from eligible participants without preselection. This resulted in an experimental group that was older and predominantly male. Even considering the urban setting of our clinic, we were generally surprised during subject enrollment with how many patients did not consider themselves active drivers and relied on other methods of transportation. This broad observation seemed particularly applicable to female patients, who historically form approximately 55% of our practice.

However, although this second group of limitations regarding cohort heterogeneity might affect the validity of a direct statistical comparison between the control and experimental groups, it does not change the clinical significance of the absolute findings of an abnormally delayed mean brake response time and a high frequency of abnormally delayed braking reactions in relation to established safety thresholds. Additionally, we strongly believe that this heterogeneity, although certainly relevant from a statistical standpoint, represents an artificial designation when it comes to real-life driving and the clinical significance of these results. For example, separate driving tests and regulations are not in use for young versus old or male versus female drivers. To the best of our knowledge, the present study is the first investigational analysis of a cohort of urban neuropathic diabetic drivers, who might just tend to be older males.

One might additionally suppose that a spectrum of neuropathic diabetics exists with varying degrees of neuropathy and lower extremity pathologic features. We studied them as an entire group using the Michigan Neuropathy Screening Instrument for diagnosis. Again, we believe that elucidation of specific subject variables and their effect on driving function represents an interesting avenue for future investigation now that the present study has initially described the potential problem of abnormal brake responses associated with neuropathic diabetes.

Finally, our specific investigational method had inherent limitations. The participants were tested using a driving simulator consisting of stationary pedals and a laptop computer screen on a table, not a real-life driving situation. Our threshold for an abnormally delayed brake response times could also be open to debate. We used a previously published study design and safety threshold that we have confidence in but that is possibly without universal acceptance within the automobile driving safety community.

In conclusion, the results of the present investigation have provided original data with respect to abnormally delayed brake response times in diabetic patients with lower extremity neuropathy and could raise the potential that this population has impaired driving function. It is our hope that these data are not considered definitive but rather introductory in nature and potentially useful in the development of future investigations focusing on the driving characteristics of neuropathic diabetic drivers.

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