

- 1. Title:** Evaluation of the efficacy of a low powered pulsed electromagnetic field therapy patch on lower extremity diabetic neuropathic ulcers, with comparison to standard of care.

Principal Investigator: **Tracey C. Vlahovic, DPM***

Co-investigators: **James B. McGuire, DPM, PT*[#], Kathya Zinszer, DPM*, Rhonda Cornell, BS (MS III)**

2. Objectives

The objectives in this study are to evaluate the efficacy of an FDA approved (see appendix 1) low power pulsed electromagnetic field therapy (PEMF) patch on diabetic neuropathic foot ulcers (DNFU), in comparison to the standard of care. Ulcer parameters evaluated between the 2 (two) treatment groups will be wound characteristics, time to closure, and vascular dynamics.

3. Background

Of the 194 million people diagnosed with diabetes globally, 5.8-7.8 million diabetics have a foot related ailment, and only use 12-15 percent of available healthcare resources (reviewed in 1). In 1995, diabetic ulcers cost Medicare \$1.5 billion. The National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) estimates that 16 million Americans are known to have diabetes (reviewed in 5). Amongst patients with diabetes, 15 percent will develop a foot ulcer, with 12-24 percent of individuals requiring some level of amputation. It has been reported that every year 5 percent of diabetics will develop foot ulcers, and 1 percent will require amputation. The risk of lower extremity amputations is 30-40 times higher in the diabetic population (6). Diabetic foot lesions are responsible for more hospitalizations than any other complication associated with diabetes. In fact, the length of hospital stay is approximately 60 percent longer among patients with diabetic foot ulcers, when compared to patients without ulcers (7). Moreover, the leading cause of non-traumatic lower extremity amputations in the United States is diabetes.

Today, diabetes is one of the most serious health challenges facing African Americans. In fact, it is the 5th leading cause of death among African Americans. In 2002, 2.8 million African Americans were known to have diabetes. On average, African Americans are twice as likely to have diabetes, as their white counterparts of comparable age. It has been reported that African Americans are more likely to develop complications and experience greater disability from complications than white

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

Americans. Death rates for people with diabetes are 27 percent higher for African Americans, compared with whites.

Based on the 1994 U.S. hospital discharge survey, there were approximately 13,000 amputations among African American diabetic individuals. This represents 155,000 days in the hospital for diabetic related complications, leading to amputation. The hospitalization rate for amputations for African Americans was 9.3 percent per 1000 patients in 1994, compared to 5.8 percent per 1000 white diabetic patients.

Diabetic peripheral neuropathy confers the greatest risk of foot ulceration and is present in 60 percent of diabetic persons and 80 percent of diabetic persons with foot ulcers. The recurrence rate of patients with a history of successful ulcer healing is 66 percent, with the amputation rate of 12 percent. Sadly, the 5-year risk that some level of amputation required on the contra-lateral limb is 50 percent.

Nerve damage in diabetic patients affects the sensory, motor and autonomic fibers (reviewed in 9). While motor neuropathy causes muscle weakness, atrophy and paresis, loss of sensory fibers results in impaired protective sensations of pain, pressure and heat. The inability to sense pain and pressure in an insensate foot can lead to unperceived trauma, Charcot neuroarthropathy and ulceration. Furthermore, decreased motor and sensory function can cause a patient to place abnormal stresses on the lower extremity, especially the foot. The undetected stresses may lead to infection.

Unfortunately, the patient may not seek medical treatment until the wound is significantly advanced. Autonomic dysfunction, specifically, the denervation of dermal structures, leads to loss of skin integrity (10). This can, in turn, allow a gateway for bacterial invasion. The most common causal pathway to diabetic ulceration does not happen spontaneously, but can be identified as a combination of neuropathy (loss of sensation), deformity (i.e. prominent metatarsal heads) and trauma (i.e. ill fitting foot gear).

Pressure on the diabetic lower extremity can lead to micro vascular circulatory changes that can lead to changes that result in ulceration and bacterial infection (reviewed in 9, 10). C-fiber nociceptor fibers that normally cause vasodilatation in response to painful stimuli are impaired in diabetics with neuropathy. This condition further compromises the vasodilatory response that is present in environments of stress (injury or inflammation) in the diabetic neuropathic foot. This impairment may, in part, explain why some ulcers in the diabetic neuropathic foot are slow or fail to heal at all, despite successful revascularization.

Costs associated with foot ulcers that remain unhealed are substantial for both the patient and health care system (7). The estimated costs associated with diabetes in 2002 were \$132,000,000,000 in the United States alone (reviewed in 12). While direct medical expenditures totaled \$92,000,000,000 for diabetes, the remaining \$40 billion was related to lost productivity. Therefore, patients with diabetes have increased rates of lost work time, disability and premature mortality.

During a two year period of time, the medical costs for a diabetic patient, between 40-65 years of age, with an associated foot ulcer has been estimated at \$28,000 (reviewed in 2). However, this figure only reflects direct medical costs, and does not include costs associated with continued care, and related amputations, nor the patient's loss of economic productivity. Amputation costs can range from \$20,000-

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

\$60,000 per patient (9). Most significantly, these estimates neither adequately reflect nor portray the effect these ulcers have on the productive, economic and social impact on a patient's life.

Diabetic patients should be encouraged and trained to perform self-examinations (reviewed in 9). If breaks in the skin or changes in pedal function and feeling are found, the patient should be examined by a physician immediately. Patients will be instructed as to the necessity of appropriate foot gear that allows for accommodative form and function. Diabetic foot ulcer education should include refraining from smoking. This is due to the fact that smoking reduces the rate of oxygen intake and delivery to wound site, which retards wound repair. Moreover, nicotine, carbon monoxide and hydrogen cyanide have a toxic effect on platelets and inhibits normal cellular metabolism, all of which are deleterious to the wound bed (9).

Assessment of physiological impairments to adequate wound healing is essential when designing a successful treatment plan (reviewed in 9). The necessity for vascular intervention (i.e. bypass) should be properly assessed in all patients with extremity ulcers. All bed bound patients, such as those with spinal cord injuries, should have their extremities inspected daily.

When a diabetic patient with an ulcer is first evaluated in the office/hospital setting, a comprehensive medical history should be obtained (reviewed in 9). Additional information should include primary care physician, last visit, length of time ulcer has been present and related laboratory tests. These tests should include hemoglobin A1C, to determine if blood glucose levels have been maintained adequately, in the long term.

Lower extremity physical exam also is a critical element of the initial/repeat visit (reviewed in 9). Lower extremity examination should be in depth and concise. Neurological evaluation, with Semmes-Weinstein monofilament, to determine if neuropathy is present. Vascular evaluation should determine if dorsalis pedis, posterior tibial and perforating peroneal arteries are present. If the patient's vascular status is questionable, ankle-brachial index and pulse wave recordings should be performed. The lower extremity examined should be evaluated for any overt deformities secondary to bony prominences. The integument system evaluation should include areas that are not commonly visible, such as the plantar aspect of the foot and interdigital areas. Callus formation, especially with sub-epidermal hemorrhage, is a pre-ulcerative sign. Calluses need to be debrided, in order to lower the pressure in that specific region. Additionally, the patients shoe gear should also be inspected for proper fit.

Diabetic foot ulcers are chronic wounds that do not heal unless actively treated and, in the case of pressure ulcers, offloaded (reviewed in 9). As stated above, in neuropathic ulcers, it is important to not only to offload, but also rid the wound of the causative agent (i.e. callus). Due to the underlying physiologic impairment (i.e. decreased angiogenic response, neuropathy, ischemia) that results in compromised, chronic foot wounds fail to heal in an orderly manner (reviewed in 13). The fact that diabetic patients exhibit impaired wound healing, in addition to increased susceptibility to infection, any disruption in the integument is a chronic wound, with its related complications (13). Therefore, early intervention is paramount to the successful treatment of diabetic foot ulcers and averting the associated mortality and morbidities. In short, successful intervention requires a thorough understanding of diabetic foot ulcer

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

etiology, progression and rapid implementation of effective therapy and a continuance in patient education.

Wound healing is a multi-step process and in diabetic foot ulcers requires angiogenesis, extra-cellular matrix deposition and epithelialization (14). An ideally healed wound has normal anatomic structure, function and appearance, therefore, an appropriately healed wound is characterized by restoration of sustained function and anatomic continuity (15).

Management of diabetic foot ulcers is constantly evolving. The foundation of comprehensive care for diabetic foot ulcers is removal of all non-viable tissue, including bone and soft tissue. Debridement of the ulcer is the first and foremost important step in healing (reviewed in 16). The debridement should be performed until healthy bleeding tissue is obtained. More extensive ulcers should be reserved for operating room debridement.

Recently healing rates for diabetic foot ulcers have been established (reviewed in 9). These rates allow physicians and wound care specialists a template in which to gauge patient wound healing. It has been recommended that, at least once a week, wounds should be measured to evaluate progress.

Surgical debridement should be performed with the appropriate sharp instrument. This allows one to remove all devitalized portions of a wound, so that scar and infection are no longer factors. Sharp debridement removes local contaminated bacteria, stimulates healing, removes hyperkeratotic tissue and tumor, and decreases local infection (17). The wound margins should be extended 2-3 mm into healthy, bleeding, soft non-hyperkeratotic skin (9). Debridement is necessary before application of other wound-closure related products and procedures. This has been shown to improve the outcome of diabetic foot ulcers independent of topical and growth factor treatments (17).

Parenteral antibiotics should be used to treat serious infections or to achieve higher concentrations in peripheral tissues (reviewed in 9). Oral antibiotics and outpatient therapy may not be accomplished in diabetics, due to vascular dysfunction. Diabetic patients undergoing outpatient therapy should undergo several scheduled weekly assessments to determine improvement of the wound.

It has been established that repetitive stress and shoe pressure are significant components of the etiology in the pathway to ulcerations (reviewed in 9). Plantar pressures are usually highest in the forefoot. Reducing pressure applied to the ulcerative area, is essential for optimal treatment. Even light pressure applied to a wound can impede healing and increase the risk for complications. The most studied method of offloading is the total contact cast (TCC). TCC is considered the gold standard in offloading (18). A TCC is minimally padded and molded carefully to the shape of the lower extremity. The TCC allows the majority of the weight the lower extremity bears to be redistributed off the ulcer, while the patient ambulates.

Armstrong et al (2001) has reported that the proportions of healing for patients treated with TCC, removable cast walkers (RCW), and half shoes were 89.5, 69.5 and 58.3 percent, respectively (19). Additionally, significantly higher proportions of patients were healed within in the 12 week time frame, when compared to the other two groups (19). However, patients that were treated with TCC were significantly less active. While TCC method has been shown to be extremely successful in treating diabetic ulcers, not

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

all diabetic ulcers are candidates for TCC. TCC also requires professional, technical clinicians to appropriately apply (reviewed in 9). If the TCC is not applied correctly, the risk of ulcer formation or ulcer worsening increases. Another drawback of the TCC is that the necessity of frequent wound inspection for healing and infection can not be accomplished.

In light of the TCC drawbacks, new offloading techniques have been investigated. Examples of new offloading techniques are removable cast walkers and half shoes. The goal of offloading ulcers is to facilitate an environment that enhances soft-tissue viability for proper wound healing. In addition, to proper positioning techniques, padding/support surfaces to decrease pressure, friction and shear, while providing appropriate levels of moisture, temperature and anti-biosis that support tissue health and growth, should also be used.

Wound bed preparations are also used as an aid to heal diabetic ulcers. The goal of wound bed preparation is to have well vascularized granulation tissue without presence of local infection (reviewed in 9). Debridement of non-viable tissue stimulates granulation tissue, decreases bacterial load and optimizes wound bed preparation. In preparing a wound bed, the clinician must not only ensure that the wound remains moist, as this promotes granulation, but also treat the causative ulcer pathology. Keeping a wound moist facilitates rapid epidermal migration across the wound, as well as, enhances connective tissue synthesis and neovascularization.

After tissue debridement and application of wound bed preparations, the wound must be dressed (reviewed in 9). The dressing should be able to keep the wound moist, provide a barrier from environmental contamination, and pressure free, thus preventing the formation of devitalized tissue and deepening of the wound (9). Dressing selection should will be systematically evaluated, and the patient protocol be adjusted accordingly.

In the past decade, there has been a significant increase of research in the use of biologics in ulcer management and healing. Biologic treatments are expensive, and should only be considered when the above described modalities have shown to fail after more than 2 weeks of therapy (reviewed in 9). Two common treatment regimens use autografts or recombinant growth factors. Commercially available autograft products utilize fibroblasts, with or without keratinocytes, in a Vicryl mesh. These autografts can be used to cover large areas, accelerating the wound healing timeline and decreasing the propensity for wound infection. However the products can be quite costly, \$1000-3000 per application. These figures do not include lost time involved with office visits, and, if necessary, the need for operating room debridement, prior to application not to mention the loss of productivity, and economic hardship the patient experiences.

Growth factor therapy has also shown to be effective in treating certain ulcers (reviewed in 9). Growth factors topically applied to a wound bed stimulate cellular proliferation, chemotaxis, protein expression and physiologic changes in the surround tissues. The most widely used growth factor therapy is Becaplermin (9, 21). Becaplermin is a recombinant platelet derived growth factor-BB (PDGF-BB) from *S. cerevisiae* (21). PDGF-BB is the only recombinant growth factor FDA approved for the treatment of a chronic wound (9). Similar to naturally occurring PDGF-BB, becaplermin has been shown to promote chemotactic recruitment and proliferation of cells required in the wound repair process (reviewed in 21). As with autografts, cost can be an inhibitory

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

factor for patients. 10-20 weeks of therapy can cost approximately \$700-1400 for the product alone, not including office visits and associated wound care.

In addition to biologic therapy, electromagnetic therapy devices have shown the reparative phase of wound healing to occur faster both histologically and visually. This low cost device has been used in the plastic surgery community for years in order to decrease edema and increase time-to-heal post-blepharoplasty.

In short, neuropathic ulcers are common in the diabetic population. Closure of a neuropathic wound in a diabetic patient is impaired by several physiologic dysfunctions and increased bacterial susceptibility. Expenditures associated with diabetic neuropathic ulcers are substantial for both the patient and the health care system at large. The costs are not only monetary, but psycho-social. While there are a wide variety of treatments available to physicians and wound care specialists for the treatment of diabetic neuropathic ulcers, the sheer cost may be prohibitive. The utilization of a device that would 1. be non-invasive 2. reduce edema and inflammatory cells, 3. be technically easy to apply and 4. be cost effective, has the possibility to decrease the morbidities, mortalities and cost burdens associated with neuropathic ulcers.

4. Eligibility Criteria

Human subjects involvement and characteristics- 40 (forty) male and female patients (age 18-80), who have been previously diagnosed with diabetes (type I or II) and neuropathy will be admitted into the study. The subject population will be predominantly African American, with Hispanic and non-Hispanic whites making up the minority.

In all patients admitted to the study, the diagnosis of diabetes and neuropathy will have been made before enrollment and confirmed either by communicating directly with primary care providers or by reviewing medical records. Patients will have clinically significant loss of protective sensation (>25 V), as measured with a biothesiometer, at least one palpable pedal pulse, or at least one audible, biphasic (determined by Doppler) pedal pulse, and a neuropathic diabetic foot ulcer corresponding to grade 1A (superficial, not extending to tendon, capsule, or bone using the University of Texas Diabetic Foot Wound Classification System) (21). Neuropathy will be defined as the inability to sense the 10-g Semmes-Weinstein monofilament and a vibration perception threshold >25 V (22, 23). Both tests are normally performed during routine podiatric examination, and evaluation of a diabetic patient's lower extremity. Patients will be excluded from participation who have clinical signs of active infection, have severe peripheral vascular disease (diagnosed by the criteria listed above), unable to comply with non-weight bearing due to physical limitations, or have an allergy to adhesive. If patients have more than one wound, the largest wound will be used as the index ulcer for inclusion in this study.

5. Treatment Plan

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

In this proposed, prospective clinical trial, 40 (forty) diabetic neuropathic patients (male and female, 18-80 years of age), with ulcers, will be randomized into one, of two, treatment modalities. Patients will be randomized at initial screening, if all inclusion/exclusion criteria are met. The clinical study protocol, HIPPA and informed consent, as approved by the Temple University Institutional Review Board (IRB), will be reviewed in detail with patient prior to randomization. A copy of the informed consent and HIPPA form will be supplied to the patient.

INITIAL VISIT

Admitted study patients will be randomized to one of two modalities:

- 1) Standard of care treatment with sham PEMF device
- 2) Standard of care treatment with active PEMF device

At the time of randomization, vascular flow, via laser Doppler or TcPO₂, of the affected lower extremity will be evaluated. Lower extremity wounds will be debrided and scrubbed specific to each treatment group (discussed below). Following debridement, wounds will be evaluated, photographed, and measured. At all visits, measurement of wounds will consist of tracing the ulcer on an acetate ulcer measurement grid. Digital calipers will then be utilized for proper length and width ulcer measurement utilizing the acetate grid. Depth of ulcer will be measured utilizing a sterile ruler in millimeters. A digital photograph will also be taken of the ulcer, exactly 24 inches away, in order to keep proper perspective at each evaluation. Computer measurement of length and width will also be performed.

The standard of care treatment group will consist of in office sharp debridement of fibrotic and necrotic tissue from the wound bed, down to bleeding, healthy tissue. Following debridement, the wound will be cleansed with chlorhexidine surgical scrub brush for 6 minutes. The ulcer will then be covered with a layer of saline-moistened Tegapore that completely covers the ulcer and is secured by hypoallergenic tape. This primary dressing will then be covered with a layer of saline-moistened gauze, followed by a layer of dry gauze and a layer of petrolatum gauze, and wrapped with a layer of Kling. The control treatment is selected because saline-moistened gauze has been determined to be the standard of care by the American Diabetes Association (25). Patients, who require prophylactic antibiotics medication, will receive a prescription for the appropriate antibiotics. The patient will be properly instructed as to when and how to change only the secondary dressing two times a day from for the length of their study participation, all necessary supplies, for home dressing changes, will be provided, at no charge. The patients will then use the low pulsed PEMF sham device on the wound overnight. It will be secured to the foot with hypoallergenic tape and gauze. The patients will also be instructed to refrain from bearing any excess weight on the affected lower extremity, with the aid of a walker, crutches or wheel chair.

The low pulsed PEMF active device group will have wound debridement to remove all superficial fibrotic and necrotic tissue. However, care will be taken not to debride down to bleeding tissue, in order to keep wound bed capillaries intact. Following debridement, the wound will be cleansed with chlorhexidine surgical scrub brush for six

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

minutes. The patient will then have the same dressing as described above, secured by wrapping with Kling. The patient will be instructed not to remove any portion of the dressing. The patients will then apply the active device to the ulcer at nighttime and secure the device with hypoallergenic tape and gauze. The patients will also be instructed to refrain from bearing any weight on the affected lower extremity, with the aid of a walker, crutches or wheel chair. Both groups of patients will receive Alcohol swabs to use on a daily basis to wipe the surface of the device in order to prevent contamination of the ulcer.

VISITS 1-12

All treatment group patients will be followed on a specifically scheduled basis, for up to 12 weeks. Patients will return every 7 (seven) days for dressing/device removal, wound debridement, surgical scrub, wound measurement and evaluation, as described previously. If a patient exhibits worsening (defined as increase in 10% width, or depth, or length of ulcer, or signs of active infection) of previously documented ulcers, the patient will be immediately withdrawn from the study, and appropriate medical intervention initiated.

END OF STUDY VISIT (EOS)

At the end of study visit, laser Doppler, or TcPO₂, vascular evaluation will be performed. In order to decrease the likelihood of an artificial alteration in vascular status, due to bandage removal and wound debridement, the corresponding EOS vascular evaluation, of the affected lower extremity, will be performed at the beginning of the EOS visit. Following laser Doppler measurement, EOS returning patients will have dressing/device removed, wound debrided, surgically scrubbed, measured and evaluated, as described previously. Patient diaries will be collected, and reviewed with the patient. If patient's ulcer is not healed at the end of study visit, treatment options, that best suit treatment of said ulcer, will be discussed with the patient. Patients will be made aware that such treatment options will not be part of the study.

End points

Efficacy parameters will be evaluated weekly from study day 0 to study week 12, or complete wound closure. Complete wound closure will be defined as full epithelialization of the wound with the absence of drainage. If wound closure is not complete at the end of 12 weeks, the percent granulation, in comparison to initial wound evaluation, of the wound will be recorded. Wound closure (percent wound granulation) will be assessed post-debridement, provided, debridement is necessary, at every visit. Secondary end points will include improvement in vascular dynamics, ulcer undermining, maceration, exudate, eschar, and fibrin slough. These points will be evaluated by the investigator at each visit. Changes in vascular flow will be evaluated at randomization and EOS only. A semi quantitative approach will be used with maceration and exudate graded as nonexistent, mild, moderate, or intense, whereas granulation will be graded as covering 0, 0-25, 26-50, 51-75 or 76-100 percent of the ulcer wound. Eschar and fibrin slough will be graded as covering 0, \leq 50, and \geq 50 percent of the ulcer.

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

6. Risks

Although minimal, there are certain risks associated with participation in this study. Some of the possible risks associated with participation in this study are local irritation (rash), infection, worsening of the ulcer and pain. Patients will be monitored throughout their study participation. Patients will have access to one of the study participating physicians, 24 hours a day, via pager, should any questions or problems arise. The pager number will be listed on the patient diary. If enrolled participants show signs of worsening of the ulcer, infection, rash, etc., they will be immediately withdrawn from the study, and treatment initiated for specific issues.

7. Benefits

If the low pulsed PEMF device is successful, it will decrease the amount of time that it takes for the ulcer to heal, and increase blood flow to the ulcer area. This translates into improvement in the patient's quality of life, decreased time out of work, economic burden, propensity for ulcer infection, and minimized office visits.

8. Alternative Treatments

Alternative treatments range from conservative to surgical. Conservative treatments include: standard of care, as previously described, total contact casts, surgical shoe offloading, foam offloading, non-weight bearing, various silver containing products, autografts, and growth factor therapy. Surgical treatments include: excision of the ulcer, with or without osseous reconstruction to displace the focal pressure or remove the offending deformity.

9. Data Collection and Statistics

Utilizing previously reported variances for this type of study, and calculating a 10% drop out rate (3.6 patients), with a power of 80%, a total of 40 patients will be required to detect a statistical difference, $\alpha=0.05$, of a minimum of 7 days of wound closure/granulation between groups. We will evaluate the effect of continuous variables using a Kruskal-Wallis test. We will utilize an analysis of variance (ANOVA) with

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com

Tamhane's post-hoc test for multiple comparisons to evaluate all continuous variables between treatment groups. Dichotomous variables will be evaluated with a χ^2 test with odds ratio and 95% CI. To evaluate the healing characteristics of each treatment group, as a function of weeks of therapy and mean time to closure among patients healing within the 12-week study period, we will utilize a Kaplan-Meier life-table analysis (log-rank test). Estimation of the probability of closure will be performed using the Cox's multivariate analysis (Wald χ^2). Correlation between variables will be tested using both univariate and multivariate logistical regression (Pearson correlation and multiple stepwise regression analysis). For the identification of before and after treatment vascular differences, the Fisher exact test will be used for the identification of differences between individual groups, while the paired t test will be utilized for identification within a group. For all analyses, we will use α of 0.05.

10. Medical Radiation Subcommittee/Institution Biologic Committee Approval

Not applicable

11. IND/IDE Number; Investigational Drug Data Sheet

Not Applicable (see appendix 1)

877-834-9279 TOLL FREE
651-846-4319 FAX

3080 Centerville Road
St. Paul, MN 55117

exceleronmedical.com