# Microcurrent as an adjunct therapy to increase perfusion in diabetic foot ulcers

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**Objective:** To evaluate the effectiveness and efficacy of microcurrent as an adjunct therapy in increasing perfusion for diabetic foot ulcers (DFU). **Methods:** Patients with DFUs were selected by simple randomisation from the Wound Care Unit, Hospital Kuala Lumpur. Each patient was treated with anti-inflammatory frequency, followed by a vasodilation frequency using the microcurrent device (PRO-SPORT devices, Avazzia Inc. USA). **Results:** There were five patients with diabetes and a DFU recruited for this study. The effectiveness and efficacy of the microcurrent in increasing perfusion was measured by using the SPY Elite System, before and after the microcurrent therapy. Measurement showed there was a significant increase in tissue perfusion for all five patients. No adverse events were reported. **Conclusion:** The results of the microcurrent therapy study showed that there was significant increases in levels of blood flow in tissue, thus, accelerating wound healing. Fluorescence imaging proved that all five participants had increased perfusion flow. However, direct contact accessories procedures such as the Y electrode and adhesive pads gave better perfusion flow compared with non-contact accessories procedure such as Qi Pulse and Scalar Qi. This was demonstrated by the significantly higher average increase for contact accessories compared with the non-contact accessories.

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Diabetes mellitus (DM) is a major public health concern in Malaysia and has been shown to be closely related to increased premature and preventable mortality, as well as macrovascular and microvascular complications such as heart disease, stroke, end-stage renal failure, blindness and amputation. According to the National Diabetes Registry, 2009–2012, the burden of diabetes continues to increase in Malaysia (Feisul and Azmi, 2013).

The overall prevalence of DM (known and undiagnosed) among adults of 18 years and above, in a survey that involved 19,935 respondents, was 17.5% (95% confidence interval [CI]: 16.6, 18.3). There was a general increasing trend in prevalence with age, from 5.5% (95% CI: 3.9, 7.7) in the 18–19 years age group, reaching a peak of 39.1% (95% CI: 33.6, 44.9) among the 70–74 years age group.

The prevalence of individuals with known DM was at 8.3% (95% CI: 7.8, 8.8). There was also a general increasing trend with age, starting from 0.7% (95% CI: 0.3, 1.5) within the age group of 20–24 years old, reaching a peak of 27.9% (95% CI: 22.7, 33.9) at age group 70–74 years.

The prevalence of undiagnosed DM was 9.2% (95% CI: 8.5, 9.9). There was also a general increasing trend with age, starting from 5.5% (95% CI: 3.9, 7.7) at age group 18–19 years, reaching a peak of 13.6% (95% CI: 10.7, 17.1) at age group 65–69 year olds.

Currently, 3.5 million Malaysians are suffering from DM, the highest rate of incidence in Asia and one of the highest in the world. There are seven million Malaysian adults likely to have DM by 2025, a worrying trend that will see a prevalence of 31.3% for adults aged 18 years and above. The government is giving serious

attention to this increase, as it is becoming a major economic burden on the healthcare system and national economy (Ministry of Health Malaysia, 2015).

## Common complications of diabetes

Diabetic foot ulcer (DFU) infection represents a serious and often complex clinical scenario in modern day practice. DFUs represent close to 10% of all hospital admission and reaching peaks of being the cause of one in every three orthopaedic admissions in general hospitals locally.

The contributory factor of this occurrence is the fact that surge of the prevalence of DM in Malaysia with the latest number at 17.5% based on National Health and Morbidity Survey (NHMS) 2015, which was an increase of nearly 20% when compared with NHMS 2011 (Feisul and Azmi, 2013; Ministry of Health Malaysia, 2015).

Scientific studies have shown that DM is a key risk factor leading to lower limb amputation such that in 2011, the loss of a lower limb due to DM was estimated to occur every 20 seconds somewhere in the world (International Diabetes Federation, 2017). The DM epidemic remains a serious threat and burden to Malaysia and has the potential to increase the number of physically disabled persons in the country (Arifin et al, 2017).

Vascular complications remain the major cause of morbidity and mortality in the DM population (Cooper and Johnston, 2000). These complications can be divided into macrovascular and microvascular complication. Macrovascular complications manifest themselves as accelerated atherosclerosis (Feener and King, 1997), clinically resulting in premature ischaemic heart disease, increased risk of cerebrovascular disease and severe peripheral vascular disease (Clark et al, 1995). Diabetic neuropathy is the most common microvascular complication, affecting approximately 50% of patients (Bona et al, 2010). When associated with vascular impairment of the lower limbs, this generates a set of changes in the feet, characterised as diabetic foot (Monteiro-Soares et al, 2011).

Neurostimulation technology should be incorporated in treatment for better symptomatic relief and management of chronic intractable pain; adjunctive treatment in the management of post-traumatic and postsurgical pain. This therapy is suitable for DM patients with macrovascular as well as microvascular complications with an ankle brachial pressure index of 0.5 to 0.9, hence, reducing the risk of lower limb amputation. Microcurrent impulses produced not only mimics currents generated in the body at the cellular level but also communicates with the body's nervous system. When the body's endogenous bioelectric system fails and cannot contribute to wound repair processes, exogenous microcurrent stimulation delivered into the wound tissue mimics this failed natural bioelectric currents, so that the wound healing can proceed (Nair, 2018). Certain chemotaxic factors found in wound substrates contribute to tissue repair processes by attracting cells into the wound environment. Microcurrent signals facilitate galvanotaxic attraction of neutrophil, macrophage, fibroblast and epidermal cells, which are involved in wound repair, into the wound tissue and thereby accelerate healing (Kloth and McCulloch, 1996).

### Objective

The authors undertook this study to evaluate the effectiveness and efficacy of microcurrent as an adjunct therapy in increasing perfusion for DFUs.

## Methods

### Study design

This study was done by simple randomisation, which involves a particular intervention on subjects that have the same diagnosis, therefore, no control group is required. Standard wound care was performed with microcurrent treatment as an adjunctive therapy at the wound care clinic.

This study conformed to the guidelines set out in the Declaration of Helsinki for Ethical Principles for Medical Research involving Human Subjects. The study was approved by the Kuala Lumpur Hospital Review Board (local institution board). The study objectives and potential risks involved were explained to the patient in detail. Informed consent and permission to use wound photographs and case details for publication/research purposes were obtained.

### Devices used in the study

For this study, microcurrent devices were supplied by AVAZZIA Inc. which were manufactured in Dallas, Texas, US. They feature the Bio Electric Stimulation Technology (BEST$^{TM}$), which is suitable for symptomatic relief and management of chronic intractable pain; adjunctive treatment in the management of post-traumatic and postsurgical pain. We

used two different models of microcurrent devices (namely Pro-Sport™ III and Avazzia Star™) with different types of accessories in place.

## Participants

The study was carried out in an outpatient setting at the Wound Care Unit, Kuala Lumpur Hospital, Malaysia (WCUHKL). Study participants comprised of patients who came for their routine treatment visits. The first five patients who were scheduled for microcurrent treatment were recruited.

## Clinical assessment

Participants were given standard of care by the WCUHKL nurse that involves wound assessment, wound bed preparation, debridement and application of dressings, as appropriate to wound aetiology.

## Procedure

Each participant had microcurrent therapy delivered during their visits. Pretreatment perfusion photos and video were taken using SPY Elite machine (Novodaq) to assess the perfusion rate before therapy. The microcurrent therapy was administered by either holding or placing the pulsed electro-magnetic field (PEMF) accessory (using Pulse Qi or Scalar Qi), Y electrode or adhesive pads. The steps of each accessories used will be described in detail below. Different types of accessories were used in order to get maximal penetration of the wound in both depth and breadth. SPY Elite system was used to assess the efficacy of the various accessories used in terms of increase in percentage of perfusion.

**Case 1. Pro-Sport III with Y-electrode**

The anti-inflammatory (MODULATE 0.5:1) mode was selected, the [+] button was pressed until a comfortable prickling sensation was felt and the Y-electrode was used to roll around the periwound skin for about 15 minutes for stimulation of the area. Then the vasodilation (VASO) mode was selected, the [+] button was pressed until a comfortable prickling sensation was felt and the Y-electrode was used to roll around the periwound skin for 15 minutes for stimulation of the same area.

**Case 2. Avazzia Star with adhesive pads**

We placed two 2cm x 2cm adhesive pads on either side of the open wound. The anti-inflammatory (AS 148–2) mode was selected, the [+] button was pressed until a comfortable prickling sensation was felt and was left on this mode for about 15 minutes. Then the vasodilation (AS 77–8) mode was selected, the [+] button was pressed until a comfortable prickling sensation was felt and was left on this mode for about 15 minutes.

**Case 3. Pro-Sport III with adhesive pads**

We placed two 2cm x 2cm adhesive pads on either side of the open wound. The anti-inflammatory (MODULATE 0.5:1) mode was selected, the [+] button was pressed until a comfortable prickling sensation was felt and was left on this mode for about 15 minutes. Then the vasodilation (VASO) mode was selected, the [+] button pressed until a comfortable prickling sensation was felt and left on this mode for about 15 minutes.

**Case 4. Pro-Sport III with Qi Pulse**

The Qi Pulse accessory was placed as near as possible to the open wound area without touching the open wound. The anti-inflammatory (MODULATE 0.5:1) mode was selected, the [+] button was pressed to increase the intensity level until 250 (maximum) and was left on this mode for about 15 minutes. Then the vasodilation (VASO) mode was selected, the [+] button was pressed to increase the intensity level until 250 (maximum) and was left on this mode for about 15 minutes.

**Case 5. Pro-Sport III with Scalar Qi**

The Scalar Qi accessory was placed as near as possible to the open wound area without touching the open wound. The anti-inflammatory (MODULATE 0.5:1) mode was selected, the [+] button was pressed to increase the intensity level until 250 (maximum) and was left on this mode for about 15 minutes. Then the vasodilation (VASO) mode was selected, the [+] button was pressed to increase the intensity level until 250 (maximum) and was left on this mode for about 15 minutes.

## Post-treatment

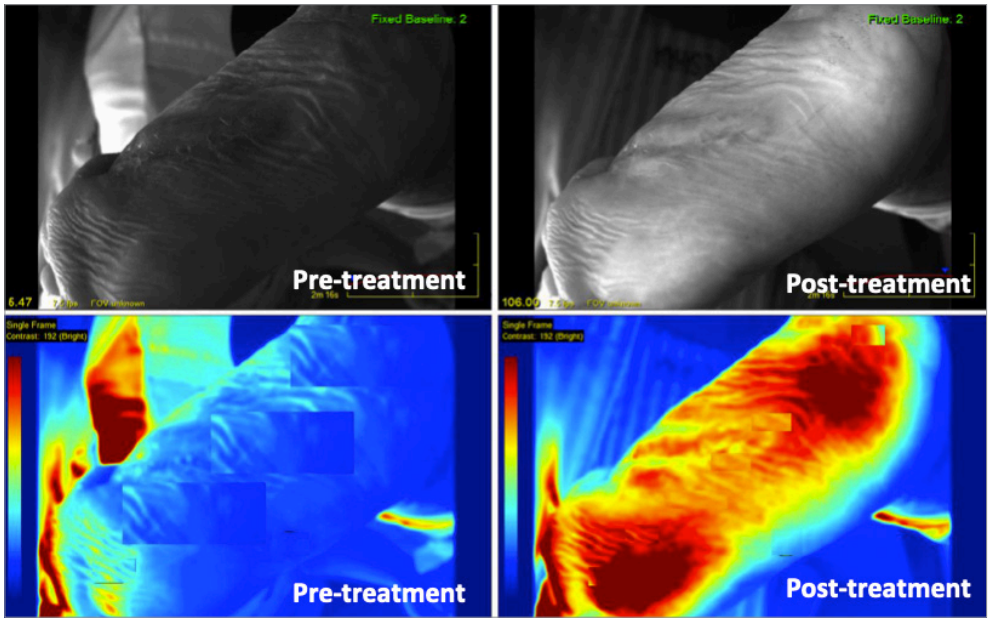
Immediately after the microcurrent therapy, post-treatment perfusion photos and video were taken using the SPY Elite device. The strength of the microcurrent device was set to maximum intensity because a stronger magnetic field was required to penetrate deeper into the cells and tissues. Patients were advised to drink at least 500ml of water after each microcurrent treatment, as it is known to eliminate waste products and toxins from the body due to lymphatic drainage.

## Potential source of bias

Selection bias will be present in this perfusion study as the participants were selected only from the pool of patients at WCUHKL and, therefore, may not represent the wider population.

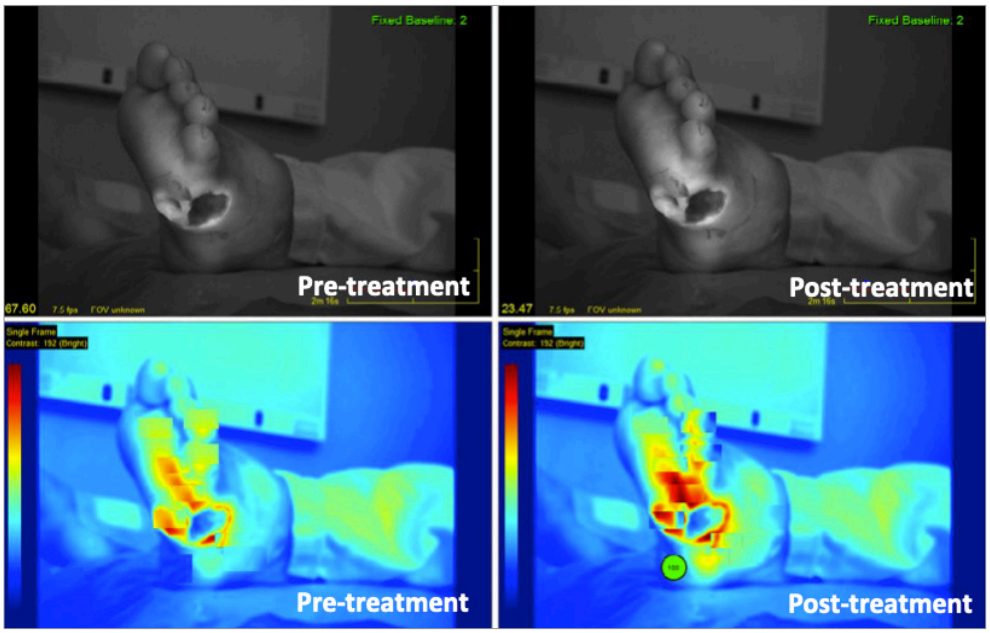
### Case 1

A 54-year-old Malay gentleman with a left diabetic foot ulcer at lateral plantar aspect of more than three years duration. There was a significant increase in perfusion rate after treatment, using the Pro-Sport III with Y-electrode. The before treatment perfusion reading was 49 and the after treatment reading was 164; a percent change of 235%.



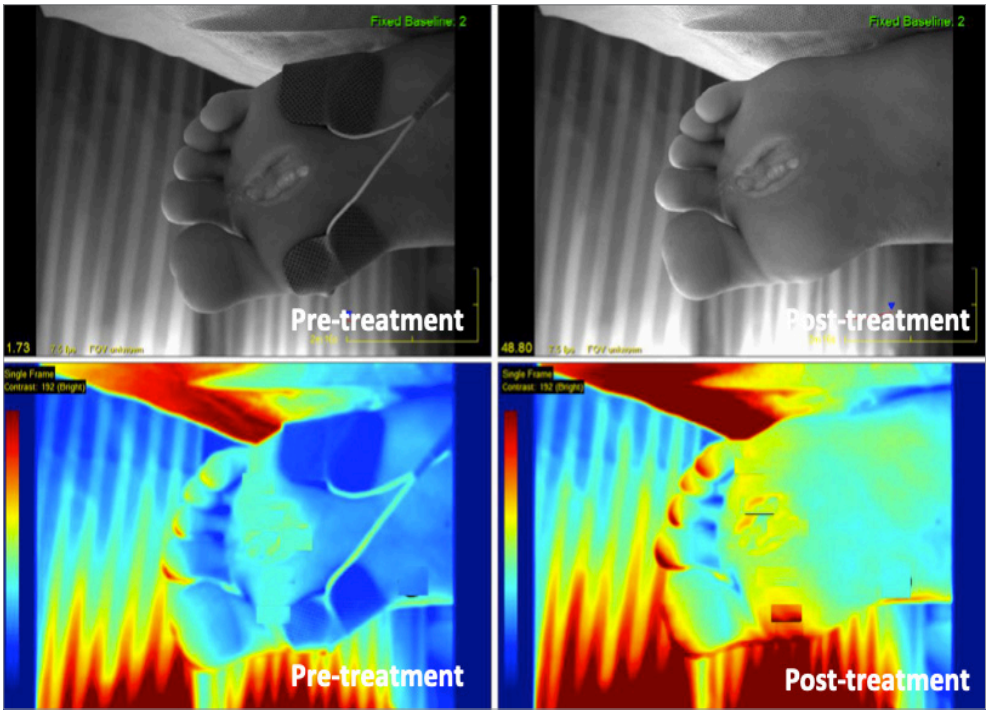

### Case 2

A 59-year-old Malay gentleman with right medial diabetic foot ulcer for two years. There was a significant increase in perfusion rate after treatment with the Avazzia Star with adhesive pads. The before treatment perfusion reading was 53 and after treatment the reading was 191; a percent change of 260%..



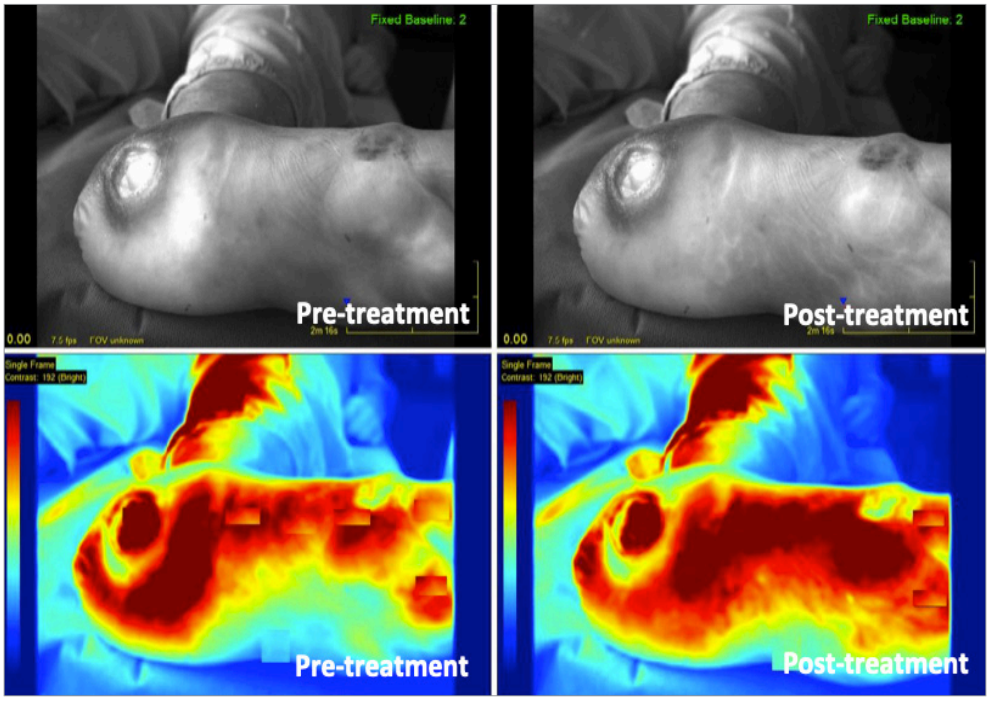
## Case 3

A 32-year-old Malay gentleman diagnoses with diabetes mellitus five years ago. There was a significant increase in perfusion rate after treatment with Pro-Sport III with adhesive pads. The before treatment perfusion reading was 53 and the after treatment reading was 191; a percent change of 260%.



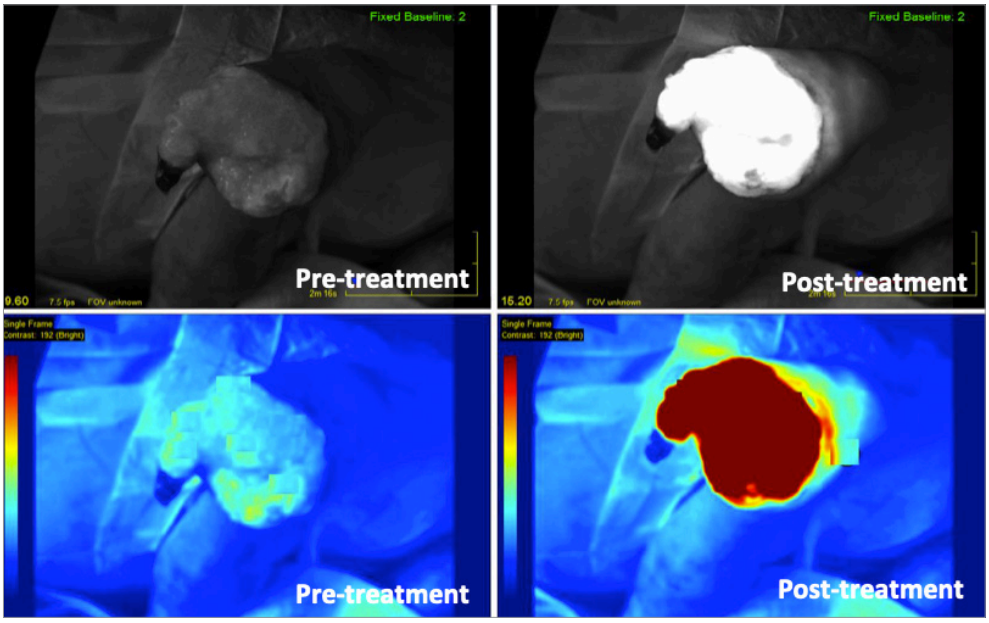

## Case 4

A 64-year-old, Indian lady, with left diabetic foot ulcer for five years duration. There was a significant increase in perfusion rate after treatment with Pro-Sport III with Qi Pulse. The before treatment perfusion reading was 81; after treatment reading was 97; a percent change of 20%.



**Case 5**

A 56-year-old, Indian gentleman, with right diabetic foot ulcer plantar aspect of five years duration. Partial foot amputation was done two weeks before perfusion study. There was a significant increase in perfusion rate after treatment with Pro-Sport III with Scalar Qi. The before treatment perfusion reading was 73 and the after treatment reading was 94; a percent change of 29%.




## Results

### Participants

The study was carried out in an outpatient setting at the WCUHKL. Study participants comprised of patients who came for their routine treatment visits. A total of five patients were recruited by simple randomisation, consisting of four males and one female. No adverse events were reported.

### Data outcome

All five participants showed an increase in perfusion flow *(Case 1–5, Figure 1)* . In conclusion, AVAZZIA BEST™ microcurrent electrical stimulation activates the pathway for angiogenesis (formation of new blood vessels), and enhances vascular network growth, which has been shown to increase blood flow rate and promote local blood circulation.

## Discussion

Chronic wounds can heal very slowly and, despite best efforts, some may never heal. The wound healing process consists of four phases: haemostasis, which takes minutes; Inflammation, which may take days; proliferation, which may take weeks; and remodelling, which may take up to years to occur.

The role of microcurrent electrical stimulation in the management of wound chronic wounds are as follows:

- Inflammatory phase: electrical stimulation increases blood flow, tissue oxygenation and stimulates fibroblasts, while reducing oedema and providing an increased antibacterial effect
- Proliferative phase: electrical stimulation increases membrane transport, collagen matrix organisation, wound contraction and stimulation of DNA and protein synthesis
- Remodelling phase: electrical stimulation increases epidermal cell proliferation and migration, as well as stimulation to fibroblasts, thus enabling wound closure.

Microcurrent stimulation accelerates wound healing by reducing inflammation and increasing perfusion. Injured cells resist the body's natural electric current, preventing the supply of blood, oxygen and other vital nutrients. The inflammatory barricade keeps free radicals from leaking into surrounding tissues and is also impenetrable to circulating antioxidants, induced microcurrent causes electrons to move across the inflammatory barricades and into pockets of inflammation, where they neutralise free radicals, and at the same time, microcurrent stimulates cellular activity and regeneration by increasing the production of adenosine triphosphate (ATP) by 500% (Cheng et al, 1982). Besides that,

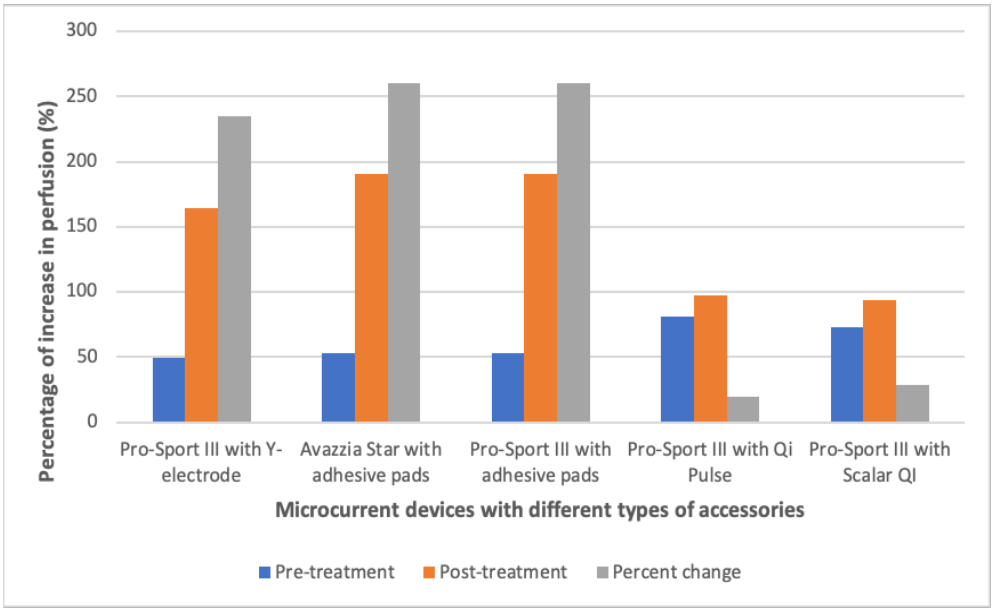



**Figure 1.** Graph on percentage of increase in perfusion versus microcurrent device with different types of accessories.

research has found that exogenous electrical stimulus can increase the growth of blood vessel networks by as much as 50% (Reilly, 2014). Exogenous electrical stimulation can change the ionic environment surrounding the endothelial cells, which form the lining of blood vessels.

SPY Elite Fluorescence Imaging proved that all five participants showed an increase in perfusion flow *(Figure 1)*. However, direct contact accessories procedure such as the Y electrode and adhesive pads gave better perfusion flow, compared with non-contact accessories procedure such as Qi Pulse and Scalar Qi. This was evidence by the average increase for contact was more significant in contrast to the non-contact.

SPY Elite Fluorescence Imaging enables surgeons to perform open procedures, such as breast and other reconstruction, gastrointestinal and cardiothoracic surgery, to visualise microvascular blood flow and perfusion in tissue intraoperatively. Intraoperative perfusion assessment allows surgeons to visualise perfusion intraoperatively and in real-time. Repeatable technique does not involve ionising radiation and uses a fluorescence imaging agent (indocyanine green) with a very short half-life, thus allowing surgeons to repeat intraoperative perfusion assessment numerous times throughout the procedure (SPY Elite Operators Manual). Clinical outcomes enhance the surgeon's ability to assess perfusion, which may improve patient outcomes. SPY Elite Fluorescence Imaging enables surgeons to visualise different levels of blood flow in tissue, illuminate perfusion zones, and therefore, improves patient outcomes (SPY Elite Fluorescence Imaging System, 2019). Hence, a perfect comparison tool to use for display and analysis of data in this study.

The efficacy of microcurrent therapy in wound healing and pain management is also proven in a 100-patient study titled '*Microcurrent as an adjunct therapy in accelerating wound healing and reducing pain in patients with chronic wounds*' which was conducted in Kuala Lumpur Hospital recently. Not only was microcurrent therapy proven to be statistically significant in terms of wound area reduction ($p<0.001$) and pain management ($p<0.001$), but patients also observed improvements in other parameters which indicated improvement in their quality of life (Nair, 2018). Moreover, research has shown that PEMF is effective in improving circulation, accelerating tissue regeneration, reducing inflammation, regulating the nervous system, relieving pain and reducing the wound healing duration (Beck-Broichsitter et al, 2014).

The potential for electrical-based treatment of wounds is far-reaching. Given the targeted, localised nature of such wound treatment, the application of non-invasive microcurrent stimulation can replace or reduce the need

***Decalration of interest***
*AVAZZIA supplied the devices and sponsored the dyes used for this study.*

of drug base treatments that affect the entire body and may carry side effects. Moreover, microcurrent therapy is able to be applied without removing the wound dressing (Nair, 2017).

## Conclusion

Microcurrent therapy was shown to have significant effect in healing wounds and reducing pain. It is thought that this is due to the increase in perfusion, whereby there was better blood flow and reduction in the inflammation. The results of the microcurrent therapy study shows that there was significant increase in levels of blood flow in tissue. Hence, microcurrent electrical stimulation activates the pathway for angiogenesis (formation of new blood vessels), and enhances vascular network growth, which has been shown to increase blood flow rate and promote local blood circulation. WAS

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