The Effectiveness of 660nm Low Level Laser Therapy for Recalcitrant Verruca Plantae
• Common
• Plane
• Filiform/Digitate

• Subungual/Periungual
• Plantar
• Mosaic
Current Verruca Treatment Modalities

- Salicylic Acid
- Cantharidin
- Canthecur-Podophyllin-Salicylic Acid
- Silver Nitrite
- Cryotherapy
- Imiquimod
- Fluorouracil
- Laser
- Surgery
Introduction

- Caused by the Human Papilloma Virus
- Plantar verrucae are a common lesion with a tendency to recur
- Asymptomatic
- Symptomatic
- Cosmetically concerning
- May have the potential to turn malignant
Introduction

- Variability in cure rates

- Successful eradication of recalcitrant verrucae, more invasive therapy may be required opposed to more conservative methods

- Recently, there has been increased support for laser therapy, specifically pulsed dye lasers and YAG lasers

- Associated consequences
Review of the Literature

- Two objectives in conducting this literature review:
  - **Objective 1:** To review the existing literature of effective treatment protocol for the use of laser therapy on plantar verrucae.
  - **Objective 2:** To determine if one specific laser type is superior.
Pulsed dye laser (PDL) therapy is based on photomechanical destruction of specific tissues with tissues being affected differently based on wavelength and fluence utilized.

- Tissue destruction occurs when light energy is transformed into thermal energy.

- 585 - 595nm PDL is used most frequently in verrucae therapy as haemoglobin has high absorption at these wavelengths.
Literature Review: Pulsed Dye Laser

- Sparreboom et. al., found an 86% success rate utilizing PDL with a fluency of 12.5 - 15.0 J/cm²
  - Remission of recalcitrant verrucae occurred after 6 treatments over 3-4 weeks
  - Participants in this study were given concomitant therapy therefore it would be beneficial to repeat this study without concomitant therapy to determine whether the success rate would be as effective
Park & Choi found a 61% clearance rate using a 585nm PDL, pulse duration 38ns and fluency 9.5 J/cm
- 2.8 treatments were provided at 2 - 3 week intervals
- No concomitant therapies were provided
- Although expensive, fewer treatments are required compared to others

El - Mohamady et. al., compared the use of YAG and PDL on multiple resistant plantar verrucae
- No significant variance between the two in success rate
- PDL was less painful but required more treatments
- YAG therapy was more painful and had more associated complications
Schellhass et al., utilized 3 different fluencies of PDL to treat resistant verruca vulgaris
  ○ 1st treatment used a low fluency of 8 J/cm to limit pain
  ○ As patients were familiarized with the treatment, fluency increased to 12 J/cm
  ○ Average of 3.7 treatments was required, maximum was 10 treatments
  ○ The treatment was associated with pain and high cost
Nd:YAG: neodymium-doped yttrium aluminium garnet

Photomechanical destruction.

Target structures absorb monochromatic coherent light of specific wavelength and fluence. Light energy gets converted to thermal energy, thus destroying the target structure.

It has been suggested hemoglobin has optimal absorption of wavelengths between 800 and 1,100nm.
Literature Review: Nd:YAG

- Han et. al., found 96% remission using 1,064nm long pulsed Nd: YAG laser
  - Pulse duration of 20msec and fluency 200J/cm²
  - Treatments every 4 weeks, maximum 4 received
  - Most common side effect was pain
CO2 laser emissions wavelength is 10,600nm, equivalent to the absorption band of water.

Majority of human tissue has a high water content which allows energy to be easily absorbed and transformed to thermal energy.

It allows precise cutting and vaporization based on set parameters.

Garden et. al., completed a study to examine the vapour of CO2 laser that could present as a health hazard:

- Power density ranged 130 - 38,200W/cm² and energy fluences 130 - 3620J/cm²
- Vapour was collected and revealed intact papillomavirus for all power and energy parameters
- Using CO2 laser suggests a viral health hazard for users.
Literature Review - CO2

- Mancuso et. al., surveyed patients who received CO2 laser at 3 months and 6 years post operatively with a success rate of 75%
  - Power setting of 10-15 W used on continuous mode
  - Lower success rate when multiple recalcitrant lesions were treated
Literature Review - LLLT

- LLLT occurs at low radiation intensities that any biological effects observed are due to effects of radiation alone and not a result of increased temperature
- Trelles & Calderhead examined verrucae treatment healing using Er:YAG laser (29J/cm\(^3\), 2.0J/pulse, 350us pulse width, 3mm collimated hand piece) followed by red light emitting diode (LED) therapy (633nm, 20 min, 126J/cm\(^3\)) to assist in wound healing
  ○ Red LED therapy provided pain free healing in difficult to treat lesions with very low recurrence rates
  ○ No control group was used
  ○ Research is needed to determine if LED therapy (633nm) is for healing or could it possibly be destroying verrucae pain free
  ○ LED is in the range of LLLT thus raising question if LED could possibly treat verrucae directly
Literature Review - LLLT

- Turner provided a baseline of LLLT setting that would be beneficial for treating verrucae with a 70% cure rate
  - 660nm with power of 15mW, energy density of 3.6 J/cm², power density of 0.12W/cm², energy per point 0.45J, pulses at 20 KHz
  - Twice weekly treatments over 6 weeks
  - No pain, unpleasant side effects or long term effects were experienced
  - Although a double blinded clinical study, it was unpublished
A Possible Solution: Our Research Proposal

The Effectiveness of 660nm Low Level Laser Therapy for Recalcitrant Verruca Plantae
Purpose of Our Study

- In reviewing the literature currently available on utilizing laser therapy as a form of verrucae treatment, it is evident there is a lack of consistency.
- A variety of wavelengths, fluences and amount of treatments required for optimal results have been proven as effective verrucae treatment.
- There are currently low level lasers of 660nm wavelengths available for a variety of treatments.
- There is a lack of evidence available in regards to low level laser therapy and its effectiveness as a verrucae treatment.
- Because of this, we plan on proving whether this could be another laser treatment option for recalcitrant verrucae.
Hypothesis

● The null hypothesis is that a 660nm laser will have no effect on the treatment of recalcitrant plantar verrucae.
● The alternative hypothesis is that a 660nm laser will be effective in the treatment of recalcitrant plantar verrucae.
Methodology

- Design
- Participants
- Interventions
- Statistical Test
- Timeline
- Outcome Measures
- Reliability & Validity
- Future Directions
Study Design

- A randomized, double blinded, placebo controlled study will be performed to determine the best protocol of energy fluence, for the treatment of recalcitrant plantar verrucae.

- The hypothesis is that a low level laser therapy of 660nm using the Omega laser for 15 minutes will be effective in treating recalcitrant plantar verrucae.

- In this study, half of the participants will receive verrucae debridement with sham laser treatment while the remaining participants will receive verrucae debridement with 660nm laser treatment.
# Study Design

Specific Laser Settings:

<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Power</th>
<th>Energy Density</th>
<th>Energy Per Point</th>
<th>Pulses</th>
<th>Time/Treatment</th>
<th># of Treatment/Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>660nm</td>
<td>15mW</td>
<td>0.12/cm²</td>
<td>0.45J</td>
<td>20KHz</td>
<td>15 minutes</td>
<td>1</td>
</tr>
</tbody>
</table>
Participants

- Males and females between 16 and 55 year olds in general good health with solitary plantar verrucae will be included for the study.
- 50 participants will receive verrucae debridement with sham laser treatment while the remaining participants will receive verrucae debridement with 660nm Omega Low-Level Laser for 15 minutes.
- Lesions must have been present for at least 6 months with a maximum presence of one year.
- Patients are required to have used some form of conservative treatment prior with no success.
- Conservative treatment must have ceased for at least a month prior to commencement of study.
Participants - Exclusion

- Any participants receiving concomitant therapy or those that did not cease conservative treatment in appropriate time will be excluded.
- Pregnant women will be excluded.
- Participants with known infection or other skin conditions (ex. psoriasis) in area or systemic infection will be excluded.
- Patients who are unable to be available for follow up visits or any treatment visits will also be excluded.
Interventions

- Patients will be allocated to one of 2 groups via computer generated software to ensure randomization.
- Each patient will receive treatments once a week for 6 weeks.
Statistical Test:

- Statistical significance of clearance rate and treatment response will be determined by ANOVA.
- A Mann-Whitney U-Test will ascertain the correlation between the fluence level and clearance rate.
- A Statistical Analysis System version 4.1.0.471 software will be required.
Timeline:

- Estimated length of time for the study will take 22 months.
- Approximately 8 months will be needed to recruit 100 participants that fit the inclusion criteria.
- Participants will attend one session of low-level laser therapy for six consecutive weeks and 3 follow-up visits at 1, 6, and 12 months post initial treatment.
- A further 2 months is needed to gather and statistically analyze the resultant data.
Outcome Measures:

- Lesions will be measured at each visit to monitor eradication by measuring the greatest length and width of the lesion.
- Lesions will be photographed using an Apple iPad, and any other clinical observations will be documented.
- Participants will be required to fill out a questionnaire before the start of the study and at the end of study, during the follow-up period.
- Questionnaire will contain a pain scale from 1-10, satisfaction level from 1-10, adverse symptoms or complications, and overall treatment outcome.
- Complete clearance of lesions means there is no recurrence, whereas partial clearance means the lesion did not completely clear or there was recurrence in the documented follow-up period.
- Evaluations will be conducted at 1, 6, and 12 months post treatment sessions by a dermatologist who had not performed the treatment.
Reliability & Validity:

- To ensure statistical validity ANOVA and Mann - Whitney u test will be utilized to determine effectiveness of laser therapy and eradicating recalcitrant plantar verrucae.
- These values will be determined by a statistician.
- The proposed study utilizes a simple method with few standardized materials making this study reliable.
- Data obtain from this study will have great validity based on the acceptable sampling method, utilizing 100 participants and the method in which data was collected.
Future Directions:

- There are few comparative studies in current literature comparing different laser therapies.
- It would be beneficial to complete more comparative studies to determine the most effective laser therapy available for the treatment of recalcitrant verrucae.
Thank You