A Trial of Low Level Laser Therapy for Reduction of Tinnitus Symptoms

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Background

A trial of laser treatment for tinnitus was conducted to determine optimal treatment duration and frequency. Over the longer term we will endeavour to predict whether maintenance treatment will be required, and to predict which patients will benefit from laser, by using a preliminary questionnaire. The trial was not double blinded, as patients were charged a nominal fee to cover expenses, and it was judged as unethical to provide sham treatment to paying patients. Trial participants were not routinely screened for somatosensory tinnitus, although some patients reported altered symptoms with varying jaw positions, or digital pressure around the temporo-mandibular joint or mastoid area. This article is written following interpretation of 32 patients' tinnitus symptoms, which have received five treatments of infrared 400 milliWatt laser to each ear. Twenty nine of thirty two patients (90.6%) have had some improvement in their tinnitus after the first 5 treatments, with duration of 10 to 40 minutes. One patient had an improvement at the fourth treatment; however after increased treatment duration, demonstrated a slight increase in tinnitus. If the fifth treatment was excluded, the improvement would have been 93.75%. Maximum improvement per session achieved was 80% reduction in symptoms. Improvement has included a decrease in perceived pitch and \ or volume, and improved acuity for conversation or listening to television. The improvement figures have been difficult to interpret, as each patient's maximum improvement occurred at different treatment duration (dosage), and an increase beyond their optimal dosage level sometimes resulted in an overall decrease in improvement, which lowered the improvement percentage. Two patients demonstrated no improvement, one of which had a 5% worsening of symptoms after the first treatment. The patient having the 5% worsening of symptoms claimed to have been confused with the visual analogue scale during the fist session, and corrected his reported position on the scale at the second and subsequent sessions. The first session score was left unchanged in the data calculations, resulting in the only recorded worsening of tinnitus for this trial.

Laser Type

Tinnihelp is a dual 400 milliWatt 808 nanometre continuous infrared lasers with collimator for beam divergence of 20 degrees, manufactured by Unilaser, Denmark. Dual 400 milliWatt 808 nanometre infrared lasers (GaAlAs) with collimator for beam divergence of 20 degrees, each laser on a headset similar to headphones. Output power claimed 2 x 400mW continuous +\- 10%. Total output 800mW.

Fig 1

Patient Selection

Patients were located via advertising in the local newspaper, and a subsequent editorial based upon an interview of one patient. Prior to treatment all patients were given an information sheet, and a consent form. The patients were aware that all treatments would use an active laser. All patients were accepted into the trial if they expressed an interest to be involved. All patients were informed that no guarantee of tinnitus reduction was made by the clinic, and signed a form confirming their understanding.

Thirty two patients (21 Male, 11 Female), 27 of which had bilateral tinnitus, were given laser to each ear. One male patient has had severe tinnitus for over 28 years, and another male patient has been symptomatic for over 25 years. Neither patient has had any success with any other form of treatment, including a number of scientific trials. Both patients had an initial improvement, with a reduction in their tinnitus levels for the first time with any treatment, during this trial.

Protocol

The protocol was determined after an internet search of previous research, and consideration of criticism of previous studies shortcomings. The trial protocol was refined on an ongoing basis as treatment knowledge was attained. Our clinic was unable to conduct a double blind research study due to lack of funding, and our limited ability to deal with large numbers of people, as we only had access to one laser unit.

Both ears were treated with the same dosage regardless of which ear was affected to avoid any possibility of vestibular disturbance due to uneven stimulation. It was decided that 5 treatments were to be given, and if no improvements were noted, laser treatment would be discontinued. Treatment time was initially 10 minutes for the first session, however this was increased to 20 minutes as minimal improvement was found at the lower level. Maximum treatment was 40 minutes, which did not further increase levels of improvement, and in some cases may have slowed or reversed improvements.

Treatment frequency was initially to be a treatment on alternate days; however this was changed to allow treatments on successive days, which tended to result in more rapid symptom change.

If patients have had tinnitus without evidence of hearing deterioration, they were advised to have blood tests for zinc levels, and discussion was had with all patients in relation to having their ESR and C-Reactive protein levels measured to determine if any infections were present. The blood tests were advised as we have had experience of patients with infection flares being directly related to tinnitus levels. The literature has reported that low zinc levels without hearing loss can be related to tinnitus. One patient enquiry resulted in us providing background information via e-mail, and the potential patient responded by self medicating with zinc supplementation (without blood test investigation), and he subsequently reported to us via phone call that his tinnitus had resolved completely. We never actually met this gentleman, and he is not included in our results.

None of the trial patients that undertook blood tests demonstrated any abnormalities. Another patient, not in this trial, has had blood tests over a 14 month period, and the raised ESR and C-Reactive protein levels have corresponded positively with tinnitus levels over this time. It was noted that the only consistent drop in the patient's blood test infection marker results over the 14 months was during the time laser treatment was provided. This patient also had a low blood zinc level; however zinc level correction did not alter the tinnitus levels.

Method

Initial Left and Right ear symptom level was noted, as well as pitch perception.

The Tinnihelp laser headsets were placed in position bilaterally on the seated patient, with the laser heads resting approximately 0.5cm into the external acoustic meatus, with a slight inclination forwards towards the nose. Not all patients' ear canal shapes allowed for orientation of the laser heads, and the insertion distance per patient varied slightly. Laser goggles or glasses were used on the patient for each treatment. (Fig 2.)

Once the treatment was completed, the patient was asked to rate their symptom levels again. Patients were to keep a note of any changes to symptom behaviour between treatments, and report such changes before the start of the next treatment. The procedure was completed again for all subsequent treatments.

Results

A visual analogue scale (vas) from 0 to 10 was used to measure change. A variation of 1 point equates to 10% difference. Participants were asked at the start and end of each treatment to report their position on the VAS, and to report any changes in pitch, volume, phase shift or hearing ability. The most obvious result to date has been the variability of symptoms in response to the laser treatment. Thirty one out of thirty two patients demonstrated a change in symptoms within the first 5 treatments, twenty nine with symptom reduction. One patient had no change after five treatments with laser, and one had a 10% change in one ear, from level one to zero tinnitus, with the more obvious tinnitus in the other ear unchanged overall, but variance of up to 10% during the trial. The patient that had a 15% worsening of tinnitus from the initial rating after 5 treatments experienced a 30% reduction in symptoms during the trial. The patient with a 5% increase in symptoms may have understated the first rating scale by 5%, and therefore it can be interpreted that no change actually occurred. Changes to symptoms within the trial have ranged from -5% to 80% improvement, with between 15 - 20% improvement average after five treatments.

The average age of patients was 56 years, with a range from 37 - 72 years.
The average duration of symptoms was 14.7 years, with a range from 0.7 - 44 years.

One patient withdrew from the trial after four treatments (not included in the 32), due to developing a fullness feel in the ears not previously present. The symptoms may or may not be related to the laser, as the local population was experiencing a viral head cold outbreak which did affect some of the other patients that completed the trial, and may account for some result variability.

Another patient had a severe tinnitus increase despite laser treatment, and was advised to try steam inhalation over two days, twice per day, and his tinnitus level dropped rapidly to minimal levels. The increase symptoms and virus did not occur during the first 5 treatments, and is not reflected in the results. Another patient attended twice and did not return, due to emotional problems unrelated to the trial, and was not included.

It is interesting to note that some patients with bilateral and equal rating per ear on the VAS had different amounts of improvement from one ear to the other, despite equal dosage. The reason for this is unknown, however it is speculated that either the cochlear on one side is more involved in symptoms and the brain is generating the sounds on the other side (similar to the phantom limb pain phenomenon), or that the perception of equal tinnitus symptoms was incorrect due to a masking effect. Some patients may have multiple causes for their tinnitus, and may require more than laser treatment to effect the maximum improvements. Recent discovery of a focally active point in the brains of tinnitus patients (Positron Emission Tomography {PET} left temporo-parietal region), suggests that at least some symptoms are centrally generated. The fact that Left sided tinnitus is more represented than Right sided tinnitus, and that the auditory centre of the brain is Left sided, is interesting and may help to explain some tinnitus resistance to treatment of the ear itself.

Physiotherapy Role

As the trial has been aimed toward the determination of the role of laser in the treatment of tinnitus, physiotherapy treatment and somato-sensory assessment was not provided to all patients, nor was a formal protocol for physiotherapy developed. When a patient described a background including

cervical trauma, an assessment was made of the cervical spine to determine whether tinnitus symptoms could be altered via mobilisation pressure applied to the joints or musculature.
Patients were also asked to clench their jaw with even pressure, and left then right sided pressure. If patients noticed a change in volume or pitch, the temporo-mandibular joint (TMJ) was suspected of being involved or contributory to the tinnitus. Palpation pressure applied around the TMJ and or mastoid was applied, and if symptoms changed, the area was confirmed as a contributing factor in the tinnitus.
If the cervical spine, TMJ, or mastoid area musculature was suspected, deep tissue massage was provided for the musculature, and cervical facet joint mobilisation of the Maitland type was given to the cervical spine.
If no change in tinnitus was effected with the abovementioned procedure, and cervical trauma could have been a factor, cervical intermittent traction was provided in a supine position at 14 kilograms for 80 seconds, then 12 kilograms for 20 seconds alternating for 10 minutes. Treatment continuation depended upon whether symptoms were alleviated.
No conclusions can be drawn in relation to the physiotherapy input provided in this trial, as the physiotherapy assessment was mainly provided to gain further insight into the tinnitus causation, and possible ways to treat the problem. Of those patients that demonstrated musculoskeletal related tinnitus, only a few had changes with physiotherapy techniques, and none had lasting tinnitus alteration.
Some patients had tinnitus symptom alteration with light digital pressure on the scalp posterior, superior, and anterior to the ear. Interestingly, tinnitus pitch could be raised on one side and decreased on the opposite side on the same patient. The significance of the above finding is not yet understood, and requires more study. Local anaesthetic applied to the scalp in patients with a presentation as described may be a way to further define the varying types of tinnitus cause.
Future trials could test physiotherapy techniques for tinnitus more formally, plus electrotherapeutic techniques such as pulsed magnetic field therapy, trigger point dry needling techniques for musculoskeletal problems, and inhaled 5% lignocaine solution for temporarily reducing severe tinnitus exacerbations.

Discussion
As the results are so variable between and within treatments, prediction of response is not yet possible. We will attempt to refine the questionnaire to become more discriminatory in order to predict who will benefit from the laser treatment.

The majority of our patients have been told by the medical profession that there is no effective treatment for tinnitus, and that they must learn to ignore or tune out the annoying noise. During our trial we ask the patients to report their symptoms on a visual analogue scale at the start and completion of each session, and to log any changes of symptom behaviour between sessions. It is possible that the increased attention to symptoms, rather than attempting to ignore them, could give a feeling of perceived tinnitus increase, rather than a physiological increase. The perception of increased symptoms may interfere with the measurement scale results, returning a decrease in actual improvement.

It has also been found that patients have difficulty defining their subjective position on the zero to ten rating scale, which could introduce potential errors into the results. Patients also have difficulty separating their tinnitus tone from the tinnitus volume, and this can affect results as a tone decrease may not be accompanied by a volume drop, which could leave the rated level the same despite improvement. Tinnitus levels that were previously constant and equal bilaterally and then changed with treatment to be uneven were reported as difficult for the patient to rate on the visual analogue scale.

A number of patients have reported no or minimal change between or after treatment, yet report that conversation was easier to comprehend when people are out of view (eg behind), and \ or the

television volume can be decreased significantly. For interpretation in this trial, we would regard these changes as improvement.

The over 90% patient rate of improvement must be interpreted cautiously at this stage, as it needs to be determined whether the improvements will be lasting, or reduce without further treatment. A maintenance dose may be required for ongoing tinnitus control, although the dosage at this stage has not been determined. Further investigation will be needed to fine tune the ongoing management protocols, as this becomes necessary.

The above quoted figures are for the first 5 treatments, and may not reflect ongoing tinnitus behaviour.

The full trial ran from 28 June 2004 to the 10 September 2004. Some patients have continued treatment, or added in physiotherapy techniques such as cervical traction. A number of patients with low level improvement proceeded to try pulsed electromagnetic field treatment, which preliminary research indicates may be of assistance in centrally generated (brain generated) tinnitus. The extended treatments are not included in this paper.

Some previous trials of laser treatment for tinnitus have not been found to be significantly beneficial. It is difficult to make comparisons between previous results as pulsed or combination pulsed and continuous laser was used, wavelengths were different or multiple wavelengths were used for each treatment, laser power varies widely between trials, dosage calculation method was either not stated or varied widely, area of application varied (mastoideus and \ or acoustic meatus), and treatment duration was usually much less than in this trial.

It is expected that the results gained in this trial would have demonstrated greater average improvement if the patient's maximum gain within the trial was logged rather than the results at the end of the five treatments, as some patients had reached greater than optimal dosage by the fifth treatment, and maximum gain was reduced.

Conclusion

The results of this non double blinded trial indicate that Low Level Laser Therapy using 808 nanometre dual 400 milliWatt infrared laser beamed into the acoustic meatus bilaterally for a duration of between 20 to 40 minutes each ear can alter a patients perception of their tinnitus volume or tone by up to 80%, and on average 20%, and alter continuous tinnitus symptoms to variable. Some patients also reported an increased hearing acuity, being able to lower the television volume by 10 decibels, or 4 levels lower on the volume scale for their televisions. Non face to face conversations were also reported as improved, which means the previous reliance on lip reading or postural signal interpretation was reduced.

Patients reported the perceived increase in hearing acuity to be the most significant improvement, even when the pitch or volume levels were minimally changed following treatment.

Further trials to verify the above results are needed, as well as to identify whether follow up maintenance laser therapy would be required, and what level of treatment and dosage would be ideal. Larger trials could ascertain which therapy would be appropriate for different types of tinnitus, and lead to the development of a screening test to be completed prior to treatment.

After interpretation of this trials result, future trials would have the following protocol.
Initial treatment would be 20 minutes, with the longest treatment being 30 minutes. As symptom change occurred both within the treatment and between treatments, the requirement to have treatments on successive days could be softened. The delay between treatments before optimal

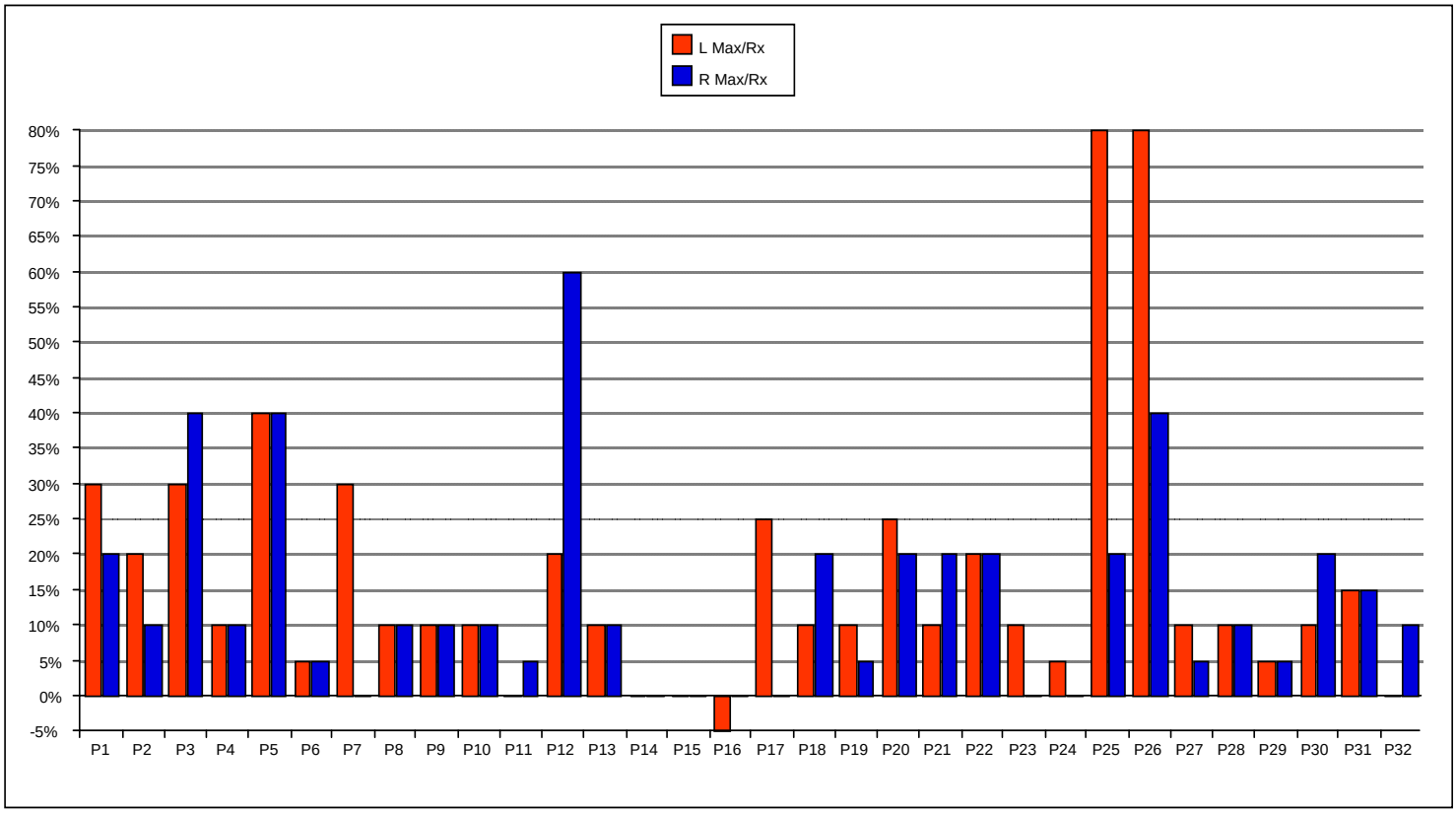
treatment results are compromised is unknown. Both ears would be treated simultaneously to avoid vestibular problems.

Once an improvement in symptoms was reported, the dosage level that achieved the improvement would be maintained until no further change was demonstrated. The original protocol allowed for a gradual increase in dosage until improvement was slowed or improvement began to reverse, which allowed the therapist to determine the optimal dosage level safely. If available, future trials should include an initial hearing acuity test, and a retest at the end of treatment to determine the accuracy of the patient's subjective assessment of improved hearing acuity. As all the patients in the current trial volunteered for treatment of their tinnitus based upon their symptom perception, and the trial relied upon their subjective assessment of symptom change, the visual analogue scale measurement plus additional recorded observations was deemed sufficient to determine whether the laser treatment produced change perceived as significant by the patient.

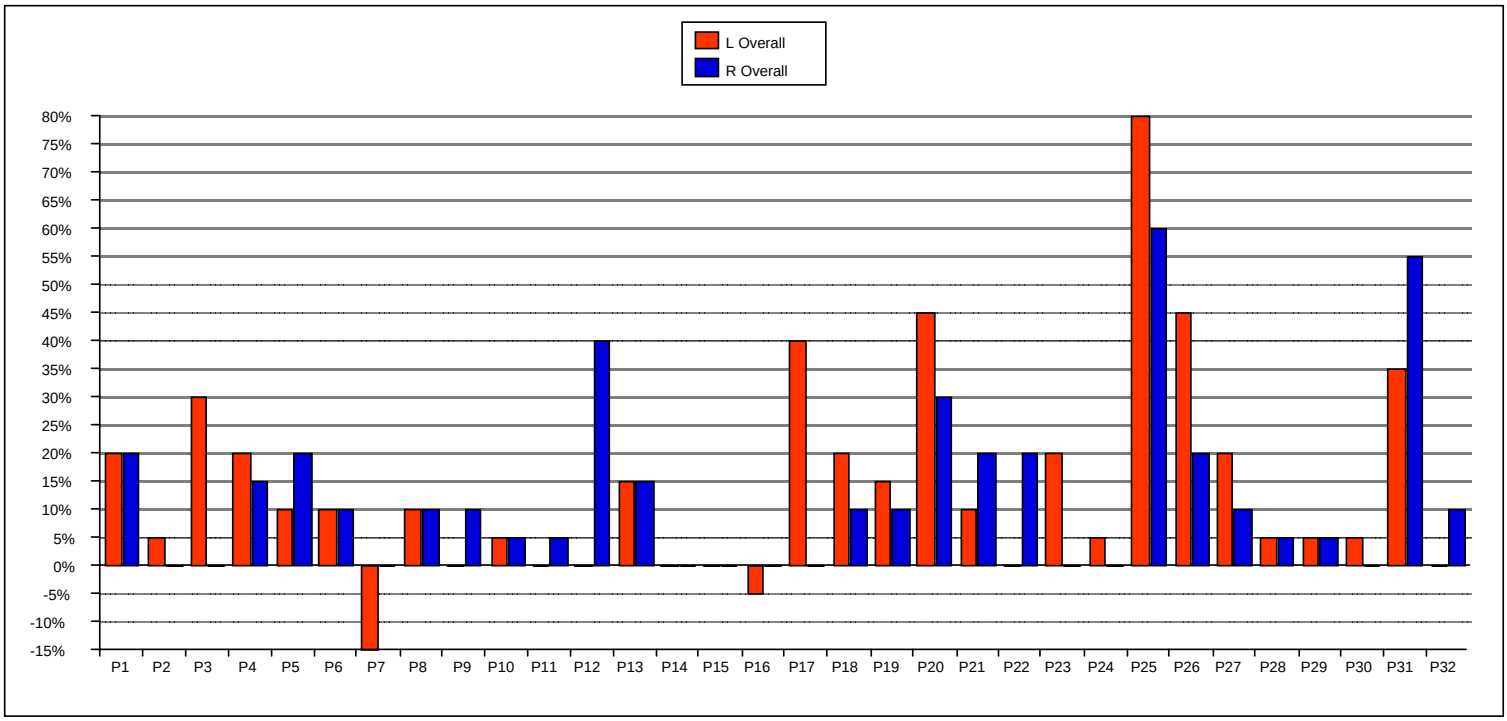
Figures
1. Tinnihelp laser unit
2. Patient receiving treatment

Attachments
1. Data
2. Graph - Maximum positive change during treatment
3. Graph - Improvement after 5 treatments
4. Graph - Age / Tinnitus duration

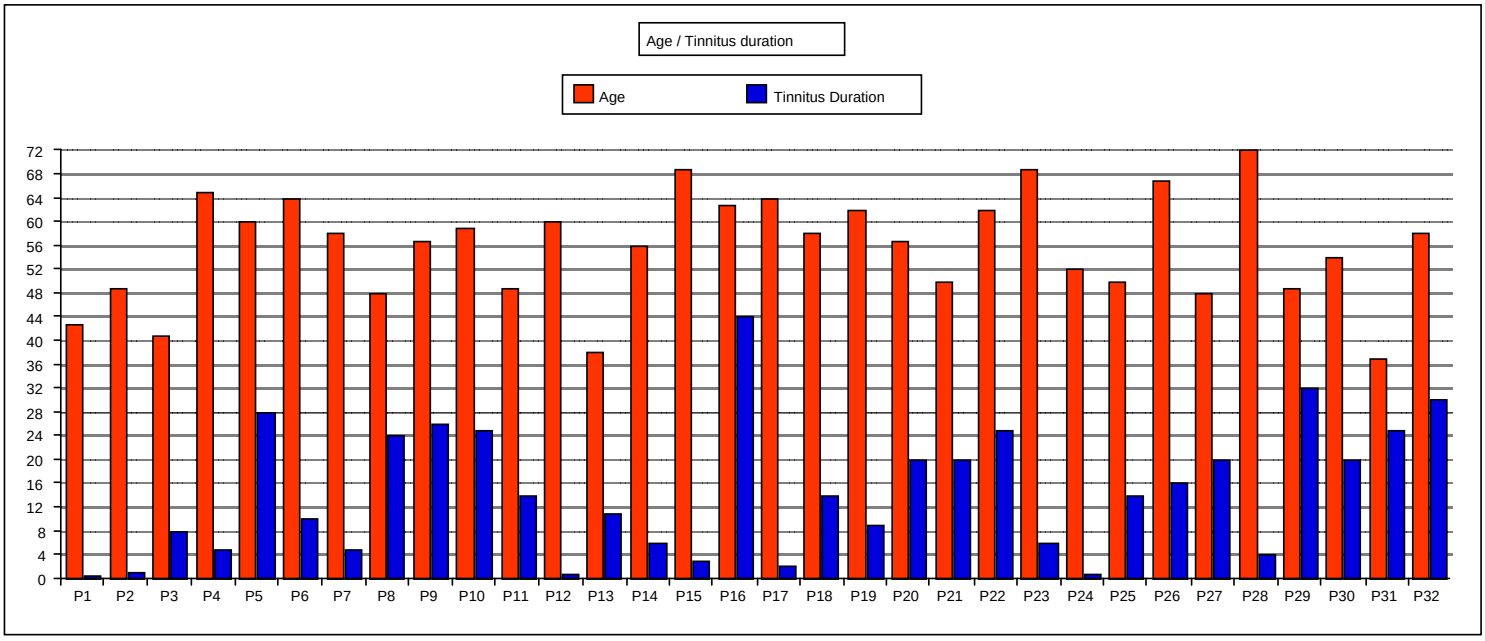
Graph - Maximum positive change during treatment



Overall



Age



Declaration

This trial was unfunded, with no financial contribution by outside agencies. The Laser unit was supplied on loan by Polylasers - Mr. William Verran who is the Australian Distributor of the Tinnihelp Lasers, manufactured by Unilaser, Denmark.

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