



## Evidence based review: Bioptron light therapy

Reviewers	Amanda Bowens: principal reviewer, literature searching
Date review completed	November 2006

### *Important Note:*

The purpose of this evidence based review is to summarise information on the effectiveness and safety of Bioptron light therapy and provide best practice advice. It is not intended to replace clinical judgement or to be used as a clinical protocol. A reasonable attempt has been made to find and appraise papers relevant to the focus of this review; however, it does not claim to be exhaustive.

The review was developed by staff of ACC's Evidence Based Healthcare Advisory Group. However, the content does not necessarily present the official view of ACC or represent ACC policy. The review is based upon information supplied up to the end of November 2006.

### Executive summary

#### **Background**

In response to a number of funding requests the Evidence Based Healthcare Advisory Group was asked to assess the effectiveness of Bioptron, a form of therapy using low energy polarised light devices, in reducing inflammation and promoting healing of soft tissue injuries.

#### **Search strategy**

A range of medical, nursing, allied health and other databases was systematically searched to find English language studies published since 2000. The manufacturer was also contacted to provide any additional studies.

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### **Selection criteria**

- ***Study type:*** secondary studies (e.g. systematic reviews) or quantitative primary studies (e.g. randomised controlled trials) with at least five Bioptron-treated subjects.
- ***Outcomes:*** measures of wound healing, inflammation, pain, function or quality of life.
- ***Study participants: human clinical subjects*** with injuries or other conditions affecting the skin or soft tissues, e.g. burns, wounds, ulcers or sports injuries.

### **Methodology**

Studies were evaluated and graded according to methodological quality using the Scottish Intercollegiate Guidelines Network (SIGN) grading system.

### **Main results**

Ten studies met the selection criteria and were included in the review. They dealt with the following conditions: burns, carpal tunnel syndrome, lateral epicondylitis (2), post-surgical healing (3), venous ulcers and pressure ulcers (2). The studies tended to be of low methodological quality. They included four case series, three controlled studies without randomisation and three randomised controlled trials.

### **Reviewer's conclusions**

On the whole, the evidence for the effectiveness of Bioptron light therapy is weak. It is slightly stronger in the case of venous ulcers and skin graft donor site wounds. The included studies reported no adverse effects and did not discuss cost effectiveness.

Purchasing decisions should take account of the weakness of the evidence for Bioptron light therapy. There may be circumstances where Bioptron light therapy can be purchased on a case by case basis as an adjunctive treatment.

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## **1. Background**

Over the past few years ACC has received a number of requests to fund Bioptron light therapy for a range of disorders including soft tissue and eye injuries. The Evidence Based Healthcare Advisory Group has therefore been asked to review the effectiveness of this treatment.

ACC has been asked to approve the purchase of Bioptron light therapy equipment for claimants to use at home. ACC may also be approached to fund providers who offer this type of treatment.

## **2. Objectives**

This review aims to determine the effectiveness and safety of Bioptron light therapy in the treatment of injuries, for example in:

- Reducing inflammation.
- Promoting tissue healing.

## **3. Health technology**

Bioptron therapy uses a non-invasive optical device to project a beam of light on to the skin. This light has four characteristics, the combination of which is unique to Bioptron:

1. Polarisation – the light waves move in parallel planes, producing a narrow, concentrated beam, unlike ordinary light, where waves oscillate in all directions.
2. Polychromy – it contains a broad spectrum of wavelengths or colours, including visible light & part of the infrared range, enabling it to stimulate a range of light receptors on the skin (cf. lasers, which are monochromatic, i.e. they contain only one wavelength).
3. Incoherency – the light waves are out of phase or unsynchronised, unlike laser light, which is coherent.
4. It has low energy density, unlike laser light, which may have high or low energy.

The manufacturers claim that these characteristics enable Bioptron light to penetrate the skin and underlying tissues in order to stimulate various biological processes. They assert that Bioptron light improves microcirculation, stimulates regeneration and repair, promotes wound healing and relieves pain, with no adverse effects.

Bioptron light therapy devices are manufactured in Switzerland by Bioptron AG<sup>a</sup>, part of the Zepter Group (an international enterprise that produces and sells a wide range of

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<sup>a</sup> See <http://www.bioptron.com/>

health and luxury products, mainly through direct sales). Three Bioptron devices are available, two designed specifically or mainly for health professionals (Bioptron 2 and Bioptron Pro) and one for home use (Bioptron Compact III). See Table 1 for details:

<b>Table 1: Bioptron devices available in New Zealand</b>		
<b>Product name</b>	<b>Product details</b>	<b>Prices (NZ\$)<sup>b</sup></b>
Bioptron Compact III	Mainly for home use <ul style="list-style-type: none"><li>• Tripod stand</li><li>• Colour therapy set</li></ul>	\$859 \$165 \$625
Bioptron Pro	Mainly for professionals but may be used at home	\$2,590 (with stand)
Bioptron 2	For professional use only <ul style="list-style-type: none"><li>• Tripod stand</li><li>• Mobile stand</li></ul>	\$4,990 \$760 \$3,490

Bioptron light therapy is used by a range of complementary and mainstream health practitioners. Complementary therapists charge around \$25 - \$40 for a half hour session. Bioptron devices are also used by some beauty therapists and animal health practitioners.

## **4. Methodology**

### **4.1 Selection criteria**

The review included Bioptron light therapy research on human clinical subjects published in English from January 2000 to November 2006 that met the following criteria:

**Study type:** secondary studies, e.g. meta-analyses, or quantitative primary studies, e.g. randomised controlled trials (RCTs) or case series, with at least five Bioptron-treated subjects. Qualitative studies, single case reports and abstracts were excluded.

**Study participants:** patients with injuries or other conditions affecting the skin or soft tissues, e.g. burns, wounds, ulcers or sports injuries. In vitro studies, animal studies and experiments on healthy volunteers were excluded.

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<sup>b</sup> According to <http://www.bellatron.com/pricelist.php>, visited 29 November 2006.

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**Interventions:** Bioptron light therapy.

**Outcomes:** measures of wound healing, inflammation, pain, function or quality of life. The presence of any adverse effects arising from the therapy was also of interest.

### **4.2 Search strategy**

In order to identify relevant research, the following databases were searched up to the end of November 2006:

- Allied & Complementary Medicine (AMED)
- American College of Physicians (ACP) Journal Club
- Cochrane Central Register of Controlled Trials (CCTR)
- Cochrane Database of Systematic Reviews (CDSR)
- Cumulative Index to Nursing & Allied Health Literature (CINAHL)
- Database of Abstracts of Reviews of Effects (DARE)
- Embase
- Journals @ Ovid
- Medline and Medline In-Process
- Psycinfo
- Science Direct
- Scopus
- Trip Database Plus at <http://www.tripdatabase.com/>

Search strategies included the subject heading “phototherapy” and the free text terms “Bioptron”, “polarised light therapy” and “polarized light therapy”. Also, the scientific references list<sup>c</sup> at the manufacturer’s website was checked and the manufacturer was contacted and asked to provide any additional studies.

### **4.3 Review methodology**

Studies that met the inclusion criteria were critically appraised and graded 1++ (strongest) to 3 (weakest) according to their methodological quality and therefore the level of evidence they represent. Grading was carried out according to a system developed by the

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<sup>c</sup> See <http://www.bioptron.com/index.php?&m=411>

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Scottish Intercollegiate Guidelines Network (SIGN)<sup>d</sup>. See Appendix 1 for a description of the SIGN grading system.

Grades or levels of evidence were assigned according to the methodological quality of the studies. Factors taken into account included sample size, whether blinding and randomisation were carried out, period of follow-up, drop-out rates, generalisability and sources of potential bias. Evidence tables summarising the levels of evidence, outcomes and other characteristics of included studies are presented in Appendix 2.

### **5. Description of studies**

Ten studies met our selection criteria and were included in the review. They are briefly summarised in Table 2 below. For a detailed analysis of the included studies please see the commentary in Section 6 and the evidence tables in Appendix 2.

<b>Table 2: research studies on Bioptron light therapy</b>		
<b>Patient group</b>	<b>Author(s) &amp; date</b>	<b>Study design</b>
Burns (deep dermal)	Monstrey et al. 2002a <sup>1</sup>	Case series (n=22)
Carpal tunnel syndrome	Stasinopoulos et al. 2005 <sup>2</sup>	Case series (n=25)
Lateral epicondylitis	Stasinopoulos 2005 <sup>3</sup>	Case series (n=25)
Lateral epicondylitis	Stasinopoulos & Stasinopoulos 2006 <sup>4</sup>	Controlled trial (n=75)
Post-surgical healing (cosmetic procedures)	Colic et al. 2004 <sup>5</sup>	Controlled trial (n=462)
Post-surgical healing (skin graft donor site wounds)	Monstrey et al. 2002b <sup>6</sup>	RCT (n=20)
Post-surgical (major abdominal surgery)	Simic et al. 2001 <sup>7</sup>	RCT (n=52)
Ulcers (pressure)	Iordanou et al. 2002 <sup>8</sup>	Controlled trial (n=55)
Ulcers (venous)	Medenica & Lens 2003 <sup>9</sup>	Case series (n=25)
Ulcers (venous)	Jankovic et al. 2005 <sup>10</sup>	RCT (n=45)

<sup>d</sup> See <http://www.sign.ac.uk/>

## 6. Results

### 6.1 Clinical effectiveness (please see Appendix 2 for evidence tables)

***Burns (one study identified, see evidence table 1):*** the case series by Monstrey et al.<sup>1</sup> investigated whether daily Biopton therapy accelerated wound closure in 22 patients with deep second degree burns. The study concluded that Biopton significantly shortened healing time, reduced scarring and optimised long-term aesthetic and functional results. However, the participants appeared to vary widely with respect to age and severity of injury, and outcome assessment was based on expert opinion rather than clearly defined, objective criteria. An expert panel was asked to: (i) estimate healing time and scarring rates (estimates were then compared with the actual results); and (ii) compare the long-term outcomes with the results they would have expected following surgery or standard conservative treatment. Validity could have been improved by the inclusion of a control (e.g. a historical control group). This study was graded “3” and was judged to be a relatively low quality case series. Biopton AG funded the study.

***Carpal tunnel syndrome (one study identified, see evidence table 2):*** the preliminary study by Stasinopoulos et al.<sup>2</sup> examined the effects of a four week course of Biopton therapy on self-reported nocturnal pain and paraesthesia in 25 patients with carpal tunnel syndrome. At the end of the course, 23 (92%) patients felt that pain had decreased and 21 (84%) reported reduced paraesthesia. Improvements were maintained at six month follow-up, with all patients reporting decreased pain and all but two commenting that paraesthesia was reduced to some extent. The study was graded “3” and, despite somewhat simplistic outcome assessment and statistical analysis, it was judged to be a moderate quality case series.

***Lateral epicondylitis (two studies identified, see evidence table 3):*** the case series by Stasinopoulos<sup>3</sup> assessed the effects of four weeks of Biopton therapy on pain, function and grip strength in 25 patients with acute lateral epicondylitis. At the end of week four, improvements were seen in all three outcome measures. The improvements were statistically significant when compared with baseline measures. As the study was intended as a pilot and there was no long term follow-up, it was not possible to establish whether these improvements were maintained after treatment ceased. The study was graded “3” and was felt to be a moderate quality case series.

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The controlled trial by Stasinopoulos and Stasinopoulos<sup>4</sup> compared the effects of Bioptron therapy, supervised exercise and Cyriax physiotherapy<sup>e</sup> on 75 patients with lateral epicondylitis. Treatment lasted for four weeks and patients were followed up for six months. At all follow-up points, patients who had received the supervised exercise programme reported significantly greater reductions in pain and improvements in function than patients in the other two treatment groups. Treatment effects were marginally greater in the Cyriax physiotherapy group than in the Bioptron group. The study was graded “2+” and was judged to be a moderate quality controlled study.

***Post-surgical wound healing (three studies identified, see evidence table 4):*** Colic et al.<sup>5</sup> reported a study in which 462 patients, who had undergone various facial cosmetic procedures, had one side of their face treated with Bioptron therapy in the week following surgery. The other side was not treated and served as a control. Assessors then compared the treated and untreated sides and evaluated the difference between them as “significant”, “moderate” or “no difference”, according to the extent to which post-operative swelling, bruising etc. was reduced. The majority of patients exhibited significantly or moderately faster healing on the Bioptron-treated side of the face. Treatment effects appeared to be greatest in patients who had undergone eyelid surgery. However, the criteria by which differences were evaluated were not adequately described and the study was graded “2-” – a low quality controlled study.

The RCT by Monstrey et al.<sup>6</sup> compared the wound healing process with and without Bioptron therapy in 20 pairs of identical wounds. The participants were 20 burn patients undergoing skin grafts and the study looked at their skin graft donor sites rather than their burns. Each participant had two identical donor site wounds and therefore acted as their own control. In addition to standard care, one wound was randomised to Bioptron, and the other to air exposure without light therapy, for 12 consecutive days. All wounds were photographed and evaluated on a 5 point scale on days 1 to 12 and at 1, 3, 6 and 12 months by two independent, blinded assessors. The assessors were plastic surgeons familiar with burn wounds. Following 4-6 days of treatment, the treated wounds began to display significantly better outcomes for the following wound healing parameters: degree of epithelialisation; quality of granulation tissue; degree of inflammation; subjective feeling of the patient; and formation of early scar tissue. Long term follow up found no significant differences in scar tissue quality between the Bioptron-treated and untreated wounds, but there was a trend towards better cosmetic results in the treated group. This RCT was

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<sup>e</sup> A form of physiotherapy involving manipulation and deep massage.

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graded “1+” as it provides moderate quality evidence that Bioptron may accelerate healing of skin graft donor site wounds in the short term.

The RCT by Simic et al.<sup>7</sup> added Bioptron therapy to the standard care regime of 26 out of 52 patients with carcinoma of the cardia (part of the stomach) who had undergone total gastrectomy leaving left thoracophrenolaparotomy wounds with a mean length of 42cm on the chest and abdomen. When wound healing parameters were assessed on a four point scale on the 12th postoperative day, outcomes were significantly better in the Bioptron group. However, the report lacked detail and issues such as method of randomisation, identity and blinding of assessors, clinical comparability between treatment and control groups and the nature of the standard care regime were not addressed. The study was therefore graded “1-”.

***Ulcers (three studies identified, see evidence table 5):*** the controlled study by Iordanou et al.<sup>8</sup> examined the effect of Bioptron therapy on 55 in-patients with pressure ulcers. Each patient had two pressure ulcers, the larger of which received standard care plus ten Bioptron treatments while the smaller had standard care only. Statistically significant differences between treated and untreated ulcers were observed at both assessment points (the ends of weeks one and two), with indicators of healing observed to a greater degree in the treated ulcers. At the end of week one, ulcers in the treated group had shrunk in size by a mean 10.56% versus 0.95% in the control group. At this point 23 treated ulcers were judged to be healed and those 23 patients were excluded from further treatment or analysis. However, the authors did not carry out an intention-to-treat analysis and failed to report the outcomes at week one for the remaining 32 patients separately. Thus mean outcomes for the whole group (n=55) at baseline and week one were invalidly compared against mean outcomes for the subset of patients who completed the second week of treatment (n=32). For our purposes, the week one assessment was therefore considered to be the endpoint of the study. It was judged to be a low quality controlled trial as there were questions concerning the validity of the control and the outcome assessment (see evidence table). The study was therefore graded “2-”.

In the case series by Medenica and Lens<sup>9</sup>, 25 inpatients with one or more venous leg ulcers received four weeks of Bioptron treatment. Treatment regimes were standardised and ulcer size was measured by independent observers. At the end of the study, all but one of the 73 treated ulcers had decreased in size. The mean post treatment decrease in surface area was a statistically significant 57%. This was judged to be a moderate quality case

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series and was graded “3”. The study was supported by Bioptron AG, which supplied the light therapy equipment used.

The RCT by Jankovic et al.<sup>10</sup> compared the effects of seven weeks of Bioptron therapy, electroionising radiation treatment and standard care on 45 elderly inpatients with venous ulcers. The authors devised a numerical scoring system to evaluate the various parameters of ulcer healing (e.g. changes in ulcer size, pain, itching, the condition of the skin in the vicinity of the ulcer). Ulcers healed faster in the two therapy groups than in the control group who received standard care only. While the Bioptron group demonstrated slightly better overall results according to the symptom scoring system, reductions in the surface area, depth and volume of ulcers were greater in the group who received electroionising radiation, and epithelialisation was faster in this group also. The study was graded “1+/-”, as it was considered to be of moderate-to-low quality.

### **6.2 Safety, adverse effects and cost effectiveness**

No adverse effects were reported in any of the ten studies included in the review. The manufacturers point out that, as Bioptron light’s electromagnetic spectrum starts above the ultraviolet range, it does not redden or tan the skin and poses no risk to the eyes<sup>11</sup>. They also claim that, as of 1997, Bioptron devices “have never been reported to cause any side effect whatsoever”. They do however warn that “hypertherapy may be possible in certain cases”, and stress that recommended treatment durations should not be exceeded.

None of the included studies reported on cost effectiveness.

## **7. Discussion**

### **7.1 Methodological quality of included studies**

The included studies tended to be of low methodological quality. The majority were case series or controlled studies without randomisation. Only three of the ten included studies were RCTs and only one of these was judged to be of moderate quality.

### **7.2 Effectiveness, cost effectiveness and safety of Bioptron light therapy**

None of the included studies reported any adverse effects or any information on cost effectiveness. The review’s findings on clinical effectiveness are summarised as follows:

**Burns:** there is weak evidence from a single case series that Bioptron therapy is effective in the conservative treatment of deep second degree burns.

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**Carpal tunnel syndrome:** there is weak evidence from a single case series that Biopton therapy is effective in the treatment of carpal tunnel syndrome.

**Lateral epicondylitis:** there is weak evidence from one case series that Biopton therapy is an effective short term (four weeks) treatment for lateral epicondylitis. However, a more rigorous controlled study found that a supervised exercise programme was more effective than Biopton in both the short and longer term (six months).

**Post surgical skin and tissue healing:** there is weak evidence from a single low quality controlled study that Biopton therapy speeds healing following cosmetic facial procedures, and weak evidence from a low quality RCT that Biopton speeds healing of large wounds following major abdominal surgery. There is stronger evidence from a moderate quality RCT that Biopton improves healing of skin graft donor site wounds.

**Ulcers:** there is weak evidence from a single low quality controlled study that Biopton therapy is an effective treatment for pressure ulcers. There is slightly stronger evidence from one case series and one moderate to low quality RCT that Biopton therapy is an effective treatment for venous ulcers.

### **7.3 Limitations of the review**

Biopton appears to be most widely used in Eastern European and Balkan countries and there is therefore a small body of research published in Serbian, Ukrainian, German and Russian. The review excluded studies that were published prior to 2000 or in languages other than English. As a result, some potentially relevant studies may have been missed.

## **8. Conclusions**

### **8.1 Implications for practice**

On the whole, the included research studies tended to be of low quality and did not provide strong evidence with which to assess the clinical effectiveness of Biopton light therapy for the conditions covered in the review. The evidence of effectiveness was slightly stronger in the case of skin graft donor site wounds and venous ulcers.

None of the included studies discussed cost effectiveness or reported any adverse effects. Biopton light therapy is a non-invasive treatment that appears to be safe so long as devices are used according to the manufacturer's instructions.

## **8.2 Implications for research**

Good quality studies, preferably well designed RCTs, are required in order to be able to assess the effectiveness of Bioptron light therapy more thoroughly.

Where possible, outcome measures should be objectively validated rather than based on expert opinion. In cases where subjects “act as their own controls” (e.g. where one site, such as an ulcer, is treated with Bioptron while a similar site receives a different treatment or no treatment), the experimental and control sites should be clinically comparable at the outset of the study.

## **8.3 Implications for policy and purchasing decisions**

Purchasing decisions need to take the weak evidence for the effectiveness of Bioptron light therapy into account. If other treatment options with low risks and a stronger evidence base are available, they should be purchased before Bioptron in most circumstances. Decisions to fund Bioptron as an adjunctive treatment may be taken on a case by case basis.

In cases where ACC is asked to purchase Bioptron devices for claimants’ own use, it may be advisable to fund a trial course of Bioptron treatments from a provider first. The decision to purchase a device could then be made on the basis of any clinical benefits the claimant derived from the trial. However, it is important to consider whether the claimant has a condition for which self-administered home treatment is advisable. Post-surgical wound healing and ulcers, for which there is weak evidence that Bioptron is effective, are more appropriately treated in the in-patient setting.

## **9. Acknowledgements**

The author would like to thank Dr John de Geus, cosmetic and reconstructive plastic surgeon, for providing expert peer review of the draft report, and also Christine Powell and Helen Brodie of ACC Information Services, for promptly and efficiently obtaining copies of the included studies.

## **10. Conflicts of interest**

None declared.

## Appendix 1: Scottish Intercollegiate Guidelines Network (SIGN) Revised Grading System<sup>f</sup>

### *Levels of evidence*

- 1++** High quality meta analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
- 1+** Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
- 1 -** Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
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- 2++** High quality systematic reviews of case-control or cohort studies  
High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
- 2+** Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
- 2 -** Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
- 
- 3** Non-analytic studies, e.g. case reports, case series
- 
- 4** Expert opinion

<sup>f</sup> From <http://www.sign.ac.uk/guidelines/fulltext/50/section6.html>. In this review studies were awarded a “2” grading if:

- (i) they were controlled but not randomised; or
- (ii) an attempt at randomisation was made but the method used was judged inadequate to ensure true randomisation. Such studies are sometimes referred to as quasi- or pseudo-randomised trials.

**Appendix 2: Evidence Tables**

*Evidence table 1: burns*

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
<p>Monstrey et al. 2002a<sup>1</sup></p>	<ul style="list-style-type: none"> <li>▪ Case series</li> <li>▪ Carried out at a university hospital plastic surgery department, Gent, Belgium</li> </ul>	<ul style="list-style-type: none"> <li>▪ 22 patients with deep dermal 2<sup>nd</sup> degree burns with limited potential for spontaneous healing</li> <li>▪ 12 male, 10 female; mean age 38.6 years (range = 1-88); mean total body surface area burned = 14.4% (range = 2%-36%)</li> <li>▪ Mean hospital stay = 18.1 days (range = 1-53 days)</li> <li>▪ The majority of evaluating surgeons would have recommended surgery; however surgery was not possible for various reasons (e.g. patient's own wishes)</li> <li>▪ Study was approved by hospital ethics committee</li> </ul>	<ul style="list-style-type: none"> <li>▪ Conservative treatment with Bioptron light therapy (6 minutes per day at a distance of 10cm from skin) until complete wound closure</li> <li>▪ Light wavelength 400-2000nm; power density 40mW/cm<sup>2</sup>; light energy 2.4J/cm<sup>2</sup></li> <li>▪ After each Bioptron treatment, burns were dressed with Vaseline gauze in combination with silver sulphadiazine</li> <li>▪ Patients also underwent the standard care protocol of customised pressure garments, where necessary in combination with silicone inlays</li> </ul>	<p>Photographs of subjects' burns were taken at various stages of the treatment process &amp; evaluated by a blinded panel of 4 experienced burns surgeons who compared the outcomes against their own expectations of healing, scarring etc. at each stage:</p> <ul style="list-style-type: none"> <li>▪ Mean time to wound closure (22 days, range = 2.1–5.5 weeks) was significantly shorter than the panel estimate (mean 41 days)</li> <li>▪ Actual incidence of hypertrophic scarring (1/22 patients, 4.5%) was significantly lower than the panel estimate (mean 15.8/22 patients, 72%)</li> <li>▪ At long-term follow-up (mean 10.2 months, range = 7-25 months) the panel rated clinical results “at least comparable” with surgery in 73.8% of cases (65.3% of cases for whom they would have recommended surgery); 97.6% were rated at least comparable with the expected results of a standard conservative treatment</li> <li>▪ The panel commented that the results on hand burns were particularly good</li> </ul>	<ul style="list-style-type: none"> <li>▪ Study funded by Bioptron</li> <li>▪ Subjects varied widely with regard to age, severity of injury &amp; length of hospitalisation</li> <li>▪ Outcome assessment was based on expert opinion rather than clearly defined, objective criteria</li> <li>▪ Low quality case series</li> <li>▪ Evidence level 3</li> </ul>

**Evidence table 2: carpal tunnel syndrome**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Stasinopoulos et al. 2005 <sup>2</sup>	<ul style="list-style-type: none"> <li>Prospective case series</li> <li>Carried out at rheumatology /rehabilitation centre, Athens, Greece</li> </ul>	<ul style="list-style-type: none"> <li>25 patients (22 female) with unilateral idiopathic carpal tunnel syndrome diagnosed using standard criteria</li> <li>Symptoms included mild – moderate nocturnal pain &amp; paraesthesia of &gt; 3 months’ duration</li> <li>Participants’ mean age = 47.4 years (range = 34 – 58); mean duration of symptoms = 5.2 months (range = 3 – 11 months)</li> </ul>	<ul style="list-style-type: none"> <li>6 minute Biopton light therapy session 3 times per week for 4 weeks</li> <li>Biopton 2 device fixed 5-10cm above wrist; light wavelength 480-3400nm; power density 40mW/cm<sup>2</sup>; light energy 2.4J/cm<sup>2</sup></li> <li>No other treatment was given &amp; patients were asked to refrain from taking analgesics during the course of the study</li> </ul>	<p>Participants’ verbal self-report of changes in nocturnal pain &amp; paraesthesia on a 5-point categorical scale (worse, no change, slightly better, much better, symptom resolved); outcomes were assessed post-treatment at end of week 4:</p> <ul style="list-style-type: none"> <li>Changes in nocturnal pain: 2 patients (8%) reported no change; 6 (24%) had slightly less pain; 12 (48%) had much less pain; and 5 (20%) were pain-free</li> <li>Changes in paraesthesia: 4 patients (16%) reported no change; 5 (20%) were slightly better; 13 (52%) were much better; and 3 (12%) were without paraesthesia</li> </ul> <p>And at 6 month follow-up:</p> <ul style="list-style-type: none"> <li>Changes in nocturnal pain: 3 patients (12%) had slightly less pain; 13 (52%) had much less pain; and 9 (36%) were pain-free</li> <li>Changes in paraesthesia: 2 patients (8%) reported no change; 2 (8%) were slightly better; 14 (56%) were much better; and 7 (28%) were without paraesthesia</li> </ul>	<ul style="list-style-type: none"> <li>All 25 participants completed the study &amp; were included in 6 month follow-up</li> <li>Participants given option of quitting Biopton &amp; opting for clinic’s standard therapy; however, none chose to do so</li> <li>Compliance with “no analgesia” rule was not examined</li> <li>Outcomes recorded by blinded assessor who had not been involved in therapy</li> <li>Outcomes measures were subjective &amp; statistics were descriptive rather than analytical</li> <li>Symptoms were not assessed at baseline</li> <li>Moderate quality case series</li> <li>Evidence level 3</li> </ul>

**Evidence table 3: lateral epicondylitis, study (i)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Stasinopoulos 2005 <sup>3</sup>	<ul style="list-style-type: none"> <li>▪ Case series</li> <li>▪ Carried out at rheumatology &amp; rehabilitation centre, Athens, Greece</li> </ul>	<ul style="list-style-type: none"> <li>▪ 25 patients with clinically diagnosed acute (symptom duration &lt; 6 weeks) unilateral epicondylitis</li> <li>▪ 19 women, 6 men; mean age 43 years (range = 30–50); mean symptom duration 16 days (range = 1–42)</li> <li>▪ All had pain at the most common site among epicondylitis patients</li> <li>▪ Condition acquired through manual work or housework</li> <li>▪ Patients were self referred or else referred by their physician or physiotherapist</li> <li>▪ Those who had previously received other treatment regimes were excluded</li> </ul>	<ul style="list-style-type: none"> <li>▪ Biopton light 3 times per week for 4 weeks</li> <li>▪ At each session, 2 positions on the lateral epicondyle were treated for 6 minutes each</li> <li>▪ Biopton 2 device fixed 5-10cm from skin; light wavelength 480 - 3400nm; power density 40mW/cm<sup>2</sup>; light energy 2.4J/cm<sup>2</sup></li> <li>▪ Patients received no other treatments during the course of the study &amp; were asked to refrain from taking anti-inflammatory medication</li> </ul>	<p>At baseline &amp; end of week 4:</p> <ul style="list-style-type: none"> <li>▪ Pain &amp; function assessed on visual analog scales (VASs)</li> <li>▪ pain-free grip strength measured with JAMAR hand dynamometer</li> </ul> <p>Results at end of week four:</p> <ul style="list-style-type: none"> <li>▪ Statistically significant reductions in pain, improvements in function and increases in grip strength were reported (compared to baseline measures)</li> </ul>	<ul style="list-style-type: none"> <li>▪ All patients completed the study</li> <li>▪ Outcomes were recorded by a blinded assessor who had not been involved in therapy</li> <li>▪ Assessment methods had been previously validated in lateral epicondylitis patients</li> <li>▪ Compliance with “no anti inflammatory medication” rule was not examined</li> <li>▪ There was no long term follow-up</li> <li>▪ Moderate quality case series</li> <li>▪ Evidence level 3</li> </ul>

**Evidence table 3: lateral epicondylitis, study (ii)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
<p>Stasinopoulos &amp; Stasinopoulos 2006<sup>4</sup></p>	<ul style="list-style-type: none"> <li>▪ Controlled trial</li> <li>▪ Carried out at rheumatology &amp; rehabilitation centre, Athens, Greece</li> </ul>	<ul style="list-style-type: none"> <li>▪ 75 patients (29 female) aged 30-60 (mean 40) years with lateral epicondylitis of at least one month's duration (mean duration 5 months)</li> <li>▪ Patients were self referred or referred by a physician or physio-therapist</li> <li>▪ Patients who had received other treatments during the preceding 4 weeks were excluded</li> </ul>	<p>Patients were assigned to 3 groups by sequential allocation:</p> <ul style="list-style-type: none"> <li>▪ Group A (n=25) had Cyriax physiotherapy consisting of deep massage &amp; manipulation of the forearm, individualised according to level of discomfort experienced during treatment</li> <li>▪ Group B (n=25) had a supervised programme of wrist &amp; forearm exercises, individualised according to level of discomfort experienced during treatment</li> <li>▪ Group C (n=25) had standard Biopton light therapy to 3 areas on the elbow/forearm for 6 minutes each (Biopton 2 device fixed 5-10cm from skin; light wavelength 480 - 3400nm; power density 40mW/cm<sup>2</sup>; light energy 2.4J/cm<sup>2</sup>)</li> </ul> <p>All patients received 3 sessions of treatment per week for 4 weeks &amp; were asked to refrain from taking analgesics during the study</p>	<p>At baseline and ends of week 4, week 8, week 16 and week 28 (6 month follow-up):</p> <ul style="list-style-type: none"> <li>▪ Pain &amp; function were assessed on visual analog scales (VASs)</li> <li>▪ pain-free grip strength was measured using a JAMAR hand dynamometer</li> </ul> <p>At all follow-up time points, Group B (the supervised exercise programme group) reported significantly greater reductions in pain &amp; improvements in function than either of the other two Groups; Group A (Cyriax physiotherapy) reported marginally larger treatment effects than Group C (Biopton therapy)</p>	<ul style="list-style-type: none"> <li>▪ No randomisation</li> <li>▪ Power calculations were carried out to determine an appropriate sample size</li> <li>▪ Groups were comparable at baseline with respect to demographics, symptom duration &amp; symptom severity</li> <li>▪ Treatment regimes in Groups A &amp; B were not standardised</li> <li>▪ Attempts were made to monitor compliance with the “no analgesic medication” rule using a treatment diary</li> <li>▪ Outcomes were recorded by a blinded assessor</li> <li>▪ Assessment methods had been previously validated in lateral epicondylitis patients</li> <li>▪ Moderate quality controlled study</li> <li>▪ Evidence level 2+</li> </ul>

**Evidence table 4: post-surgical wound healing, study (i)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Colic et al. 2004 <sup>5</sup>	<ul style="list-style-type: none"> <li>▪ Controlled trial</li> <li>▪ Subjects acted as their own controls</li> <li>▪ Carried out at a cosmetic surgery centre, Belgrade, Serbia</li> </ul>	<ul style="list-style-type: none"> <li>▪ 462 patients who had undergone facial cosmetic surgery at the centre over a 2 and a half year period from September 2001</li> <li>▪ Procedures included face lifts (n=45), bilateral blepharoplasties<sup>g</sup> (n=67) &amp; other ancillary facial procedures, e.g. brow lifts, lip augmentation (n=350)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Each patient received Biopton therapy to one side of the face only; the other side served as the control</li> <li>▪ Patients received 3 x 10 min sessions during the first 24 hrs after surgery, then one 10 min session per day for the next 6 days</li> <li>▪ Biopton 2 (40mW/cm<sup>2</sup>, 2.4J/cm<sup>2</sup> per minute) device held 15cm from the surface of the skin</li> </ul>	<ul style="list-style-type: none"> <li>▪ Each patient was photographed before surgery and on post-operative days 1, 3 and 7; the authors then assessed the differences between the Biopton- and non-Biopton-treated sides of each face as 'significant', 'moderate' or 'no difference' according to the degree of swelling, bruising, haematoma and signs of healing (e.g. epithelialisation) present and the length of the recovery period</li> <li>▪ Face lift group: 26 (57.8%) significant, 8 (17.8%) moderate, 11 (24.4%) no difference</li> <li>▪ Blepharoplasty group: 48 (71.6%) significant, 13 (19.4%) moderate, 6 (8.9%) no difference</li> <li>▪ Facial ancillary group: 164 (46.9%) significant, 59 (16.9%) moderate, 127 (36.3%) no difference</li> </ul>	<ul style="list-style-type: none"> <li>▪ Unclear whether assessments were made after examining the patients or just their photographs</li> <li>▪ Independence/blinding not mentioned; assessors appear to have been the operating surgeons</li> <li>▪ The criteria by which differences were assessed as 'significant' etc. were not adequately described – <i>assessors' subjective judgements?</i></li> <li>▪ Low quality controlled study</li> <li>▪ Evidence level 2-</li> </ul>

<sup>g</sup> Cosmetic procedures carried out to improve the appearance of the upper and lower eyelids.

**Evidence table 4: post-surgical wound healing, study (ii)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Monstrey et al. 2002b <sup>6</sup>	<ul style="list-style-type: none"> <li>▪ RCT (single blind)</li> <li>▪ Subjects acted as their own controls; wounds, rather than subjects, were randomised to treatment or control</li> <li>▪ Carried out at a university hospital plastic surgery department, Gent, Belgium</li> </ul>	<ul style="list-style-type: none"> <li>▪ 20 burn patients with matched pairs of split thickness skin graft donor wounds of identical surface area &amp; thickness</li> <li>▪ Grafts were taken by the same surgeon from identical areas of each patient's body (usually the left &amp; right anterior thigh)</li> </ul>	<p>Daily for 12 consecutive days, starting on first post-op day:</p> <ul style="list-style-type: none"> <li>▪ Treatment: in each patient, one donor site was treated with a 6 minute Bioptron light therapy session</li> <li>▪ Bioptron lamp fixed 10cm from skin surface</li> <li>▪ Light wavelength 400-2000nm; power density 40 mW/cm<sup>2</sup>; energy density (dose per patient per session) 14.4J/cm<sup>2</sup></li> <li>▪ Control: the paired donor site was exposed to the air for 6 minutes without light therapy</li> </ul> <p>Apart from exposure to treatment or control, all other aspects of the wound care protocol (e.g. dressings) were identical for all wounds</p>	<p>7 parameters of wound healing were evaluated on a standardised 5 point scale by 2 independent, blinded assessors: degree of epithelialisation, quality of granulation tissue, degree of inflammation, degree of infection, blister formation, formation of early scar tissue &amp; the subjective feeling of the patient</p> <p>Outcomes were assessed daily on days 1-12 with long term follow-up after 1, 3 &amp; 6 months and at 1 year:</p> <ul style="list-style-type: none"> <li>▪ After 4-6 days, significantly better wound healing scores were recorded for degree of epithelialisation, quality of granulation tissue, degree of inflammation, early scar tissue formation &amp; subjective feeling of patient in the treatment group</li> <li>▪ No infection or blister formation was reported in either group</li> <li>▪ No significant differences between groups were observed at longer term follow-ups</li> </ul>	<ul style="list-style-type: none"> <li>▪ The authors carried out power analysis to check that sample size was sufficient for adequate pair-wise analysis</li> <li>▪ Inter-rater agreement was found to be acceptable</li> <li>▪ Neither authors nor department had any financial interest in the Bioptron company</li> <li>▪ The pairs of assessors used varied during the study period</li> <li>▪ The 5 point outcome scale used was not described in detail</li> <li>▪ The method of randomising wounds to treatment or control was not described</li> <li>▪ Moderate quality RCT</li> <li>▪ Evidence level 1+</li> </ul>

**Evidence table 4: post-surgical wound healing, study (iii)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Simic et al. 2001 <sup>7</sup>	<ul style="list-style-type: none"> <li>▪ RCT</li> <li>▪ Carried out at a university gastric surgery facility, Belgrade, Serbia</li> </ul>	<ul style="list-style-type: none"> <li>▪ 52 cardiac carcinoma<sup>h</sup> patients with left thoracophrenolaparotomy wound (mean wound length 42±3.5cm)</li> <li>▪ Subjects had undergone total gastrectomy &amp; distal oesophagectomy with systematic D2 lymphadenectomy &amp; Roux-en-Y reconstruction</li> <li>▪ All patients were chronically ill and the majority were elderly</li> </ul>	<ul style="list-style-type: none"> <li>▪ Treatment (n=26): “standard” care regime plus 5 minute Bioptron light therapy session daily for 10 days starting on 2<sup>nd</sup> post-op day</li> <li>▪ Treatment delivered by Bioptron 2 device 15 cm from skin surface</li> <li>▪ Control (n=26): “standard” care only</li> </ul>	<p>Wounds assessed on 12th postoperative day according to 4 point wound healing scale: excellent (healed without seroma or inflammation); satisfactory (slight inflammation and/or seroma); unsatisfactory (seroma &amp; inflammation present, suture removal delayed); bad (large scale infection):</p> <ul style="list-style-type: none"> <li>▪ Treatment: 21 (80.77%) subjects rated excellent, 5 (19.23%) rated satisfactory</li> <li>▪ Control: 14 (53.85%) rated excellent, 7 (26.92%) rated satisfactory, 4 (15.38%) rated unsatisfactory and 1 (3.85%) rated bad</li> </ul> <p>Differences between groups were found to be statistically significant</p>	<ul style="list-style-type: none"> <li>▪ Randomisation method not reported</li> <li>▪ “Standard” care not described</li> <li>▪ Little discussion of group characteristics or baseline comparability</li> <li>▪ Assessors do not appear to have been blinded</li> <li>▪ No long term follow up</li> <li>▪ Some aspects of study design difficult to assess (due to poor translation?)</li> <li>▪ Low quality RCT</li> <li>▪ Evidence level 1-</li> </ul>

<sup>h</sup> Carcinoma of the *cardia*, the part of the stomach immediately adjacent to and surrounding the cardiac opening of the oesophagus.

**Evidence table 5: ulcers, study (i)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & evidence level
Iordanou et al. 2002 <sup>8</sup>	<ul style="list-style-type: none"> <li>Controlled trial</li> <li>Carried out over a 2 year period at 4 hospitals in Athens, Greece</li> </ul>	<ul style="list-style-type: none"> <li>55 in-patients, each with 2 pressure ulcers of 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> grades<sup>i</sup> on legs, trochanters<sup>j</sup>, sacrum, buttocks or shoulders</li> <li>Subjects aged 37-85 (mean 67) years; 45 (81.8%) bed bound &amp; with very limited mobility, 16 (29%) with hip fracture</li> <li>Exclusion criteria included presence of skin necrosis, previous or planned surgical excision of ulcer, and patients in palliative care</li> </ul>	<ul style="list-style-type: none"> <li>Treatment: 5 min light therapy session daily for 2 weeks excl. weekends (10 sessions in total) using 20W Bioptron lamp</li> <li>Energy density (dose per patient per session) 20 J/cm<sup>2</sup></li> <li>Control: “typical therapy of each hospital”</li> </ul> <p>The larger of each subject’s 2 ulcers was treated while the smaller served as the control</p> <p>Patient care in all 4 hospitals was described as being “very similar”: turning of patients, dressing &amp; cleansing of ulcers etc. were carried out in accordance with common hospital guidelines</p>	<p>Ulcers assessed at admission &amp; ends of weeks 1 &amp; 2 for following indicators of ulcer healing: presence of epithelial tissue, positive changes in ulcer colour, absence of exudates &amp; decrease in surface area. Statistically significant differences were observed at end of week 1 (n=55):</p> <ul style="list-style-type: none"> <li>More positive colour change seen in treated ulcers</li> <li>More treated ulcers classed as having “no or minimal exudate” (35 or 63.6%, versus 13 or 23.6% of control ulcers)</li> <li>Greater decreases in surface area noted in treated ulcers (from 2.84 to 2.54cm<sup>2</sup> [10.56% decrease] versus from 2.10 to 2.08cm<sup>2</sup> in controls [0.95% decrease])</li> </ul> <p>23 treated ulcers were judged “healed” at end of week 1 and those 23 patients were excluded from further treatment. The following statistically significant differences were observed at end of week 2 (n=32):</p> <ul style="list-style-type: none"> <li>More positive colour change in treated ulcers</li> <li>More treated ulcers classed as “no or minimal exudate” (21 or 65.6%, versus 11 or 34.4% of control ulcers)</li> <li>Greater surface area reduction in treated ulcers (mean final area of 2.26cm<sup>2</sup> versus 2.04cm<sup>2</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>Closeness of match between treated &amp; control ulcers (size, site, severity, grade etc.) not described</li> <li>Unclear whether assessors were (1) the same throughout, or (2) blind to treatment protocol</li> <li>No intention-to-treat analysis; 23 “healed” patients (42%) were excluded at the end of week 1, making some of the week 2 v. baseline statistical comparisons invalid</li> <li>Short duration</li> <li>Low quality controlled study</li> <li>Evidence level 2-</li> </ul>

<sup>i</sup> At an earlier stage, and therefore more responsive to treatment, than more advanced 4<sup>th</sup> and 5<sup>th</sup> grade pressure ulcers.

<sup>j</sup> Situated at the top of the thigh.

**Evidence table 5: ulcers, study (ii)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & level of evidence
Medenica & Lens 2003 <sup>9</sup>	<ul style="list-style-type: none"> <li>▪ Prospective case series</li> <li>▪ Carried out at a university dermatovenereology facility, Belgrade, Serbia</li> </ul>	<ul style="list-style-type: none"> <li>▪ 25 patients aged &gt;40 with one or more venous leg ulcers of surface area &gt;1cm<sup>2</sup>; 21 (84%) men, 4 (16%) women; mean age 61.9, range 46-84 years</li> <li>▪ Patients with arterial disease of the legs, uncontrolled diabetes, diabetic neuropathy, cellulitis, vasculitis, collagen vascular disease or carcinoma were excluded</li> <li>▪ Subjects had between 1 and 6 ulcers each; total number of ulcers in sample = 73</li> <li>▪ Mean initial wound size = 26.45cm<sup>2</sup> (range 1.45 - 94.66cm<sup>2</sup>, SD = 24.6)</li> <li>▪ Subjects were hospitalised &amp; care was standardised throughout the study period</li> <li>▪ All patients completed the study</li> </ul>	<ul style="list-style-type: none"> <li>▪ 8 minute Biopton light therapy session once a day for 4 weeks (28 sessions in total)</li> <li>▪ Treatment delivered by Biopton 2 device fixed 10cm from skin surface</li> <li>▪ Light wavelength 480-3400nm; power density 40 mW/cm<sup>2</sup>; energy density (dose per patient per session) 19.2J/cm<sup>2</sup></li> <li>▪ Additional care was standardised and involved daily saline rinsing &amp; simple dressings</li> </ul>	<p>Wound size was measured by 2 independent observers at baseline &amp; ends of weeks 1-4:</p> <ul style="list-style-type: none"> <li>▪ 99% of ulcers (all but 1) were reduced in size after 4 weeks</li> <li>▪ Mean post-treatment wound size = 12.79 cm<sup>2</sup> (range = 0 – 84.5 cm<sup>2</sup>, SD = 18.2)</li> <li>▪ Post-treatment decrease in wound surface area was statistically significant (mean 57.15%, SD 31.87%)</li> <li>▪ 22 ulcers (30%) healed completely</li> </ul> <p>Histological evaluation by an independent pathologist was carried out on 11 patients with larger and/or more severe ulcers at baseline &amp; end of week 3):</p> <ul style="list-style-type: none"> <li>▪ Baseline biopsy showed complete epidermal/dermal necrosis &amp; poor granulation</li> <li>▪ Significant improvements (e.g. re-epithelialisation) were noted at end of week 3</li> </ul>	<ul style="list-style-type: none"> <li>▪ Efforts were made to reduce bias by hospitalising patients and standardising treatment regimes</li> <li>▪ Objective outcome measure (wound size) used</li> <li>▪ Little information given on subjects' baseline comparability (e.g. stage of disease progression), or on how well they represented the population as a whole</li> <li>▪ Study supported by Biopton</li> <li>▪ Moderate quality case series</li> <li>▪ Evidence level 3</li> </ul>

**Evidence table 5: ulcers, study (iii)**

Ref.	Study type & setting	Participants	Intervention(s)	Outcome measures & results	Comments & evidence level
Jankovic et al. 2005 <sup>10</sup>	<ul style="list-style-type: none"> <li>▪ Randomised controlled trial</li> <li>▪ Carried out at a physical therapy centre for patients with peripheral circulation disorders, Niš, Serbia</li> </ul>	<ul style="list-style-type: none"> <li>▪ 45 elderly inpatients with venous ulcers</li> <li>▪ 17 men, 28 women,</li> <li>▪ Mean age = 69.84 years; mean ulcer duration = 14.53 years</li> </ul>	<p>Patients were randomised into 3 groups as follows:</p> <ul style="list-style-type: none"> <li>▪ Group ER (n=15) had electroionising treatment, 1 x 10 min session daily for 7 weeks</li> <li>▪ Group PL (n=15) had Bioptron light therapy, 1 x 10 min session daily for 7 weeks (Bioptron 2 device)</li> <li>▪ Group C (n=15), the control group, received standard care only – no physical therapy</li> </ul> <p>The standard hospital care regime received by all patients included daily washing &amp; bandaging, and topical steroids &amp; antibiotics as required</p>	<p>Parameters of ulcer healing were assessed at baseline and after 1, 3, 5 and 7 weeks of treatment. Parameters were divided into 3 groups: ulcer characteristics (e.g. surface area, depth, volume, epithelialisation, exudation); ulcer vicinity (e.g. swelling, maceration); and associated symptoms (e.g. pain, itching). Each parameter was scored on a numerical scale and totals were calculated for each parameter group and overall. At the end of the treatment period, statistically significant results were as follows:</p> <ul style="list-style-type: none"> <li>▪ Ulcers healed faster in the treated groups than in the control group</li> <li>▪ Of the treated groups, Group PL demonstrated slightly better overall results when scores for all parameters of ulcer healing were totalled</li> <li>▪ However, reductions in surface area, depth and volume of ulcers were greater in Group ER, and epithelialisation was faster in Group ER</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mean ulcer duration was longer in the control group: 17 years v. 12.4 and 14.2 years in ER &amp; PL groups respectively</li> <li>▪ No mention of whether outcome assessors were blinded/independent</li> <li>▪ Outcome scoring lacked transparency (no absolute scores were reported, just %age decreases); reporting made it difficult to assess which active treatment was associated with the most clinically significant outcomes</li> <li>▪ Moderate/low quality RCT</li> <li>▪ Evidence level 1+/-</li> </ul>

**Appendix 3**

*Units & abbreviations*

J	Energy in Joules
mW	Power in milliwatts
nm	Wavelength in nanometres
W	Power in Watts

## **References**

1. Monstrey S, Hoeksema H, Saelens H, Depuydt K, Hamdi M, Van Landuyt K, et al. A conservative approach for deep dermal burn wounds using polarised-light therapy. *British Journal of Plastic Surgery* 2002;55:420-426.
2. Stasinopoulos D, Stasinopoulos I, Johnson MI. Treatment of carpal tunnel syndrome with polarized polychromatic noncoherent light (Biopton light): A preliminary, prospective, open clinical trial. *Photomedicine and Laser Surgery* 2005;23(2):225-228.
3. Stasinopoulos D. The use of polarized polychromatic non-coherent light as therapy for acute tennis elbow/lateral epicondylalgia: A pilot study. *Photomedicine and Laser Surgery* 2005;23(1):66-69.
4. Stasinopoulos D, Stasinopoulos I. Comparison of effects of Cyriax physiotherapy, a supervised exercise programme and polarized polychromatic non-coherent light (Biopton light) for the treatment of lateral epicondylitis. *Clinical Rehabilitation* 2006;20(1):12-23.
5. Colic M, Vidojkovic N, Jovanovic M, Lazovic G. The use of polarized light in aesthetic surgery. *Aesthetic Plastic Surgery* 2004;28(5):324-27.
6. Monstrey S, Hoeksema H, Depuydt K, Van Maele G, Van Landuyt K, Blondeel P. The effect of polarized light on wound healing. *European Journal of Plastic Surgery* 2002;24(8):377-382.
7. BIOPTRON Light Therapy and Thoracophrenolaparotomy wound healing in patients operated due to cardiac carcinoma. *4th International Gastric Cancer Congress*; 2001 April 30 - May 2, 2001; New York.
8. Iordanou P, Baltopoulos G, Giannakopoulou M, Bellou P, Ktenas E. Effect of polarized light in the healing process of pressure ulcers. *International Journal of Nursing Practice* 2002;8(1):49-55.
9. Medenica L, Lens M. The use of polarised polychromatic non-coherent light alone as a therapy for venous leg ulceration. *Journal of Wound Care* 2003;12(1):37-40.
10. Jankovic A, Stanojevic M, Binic I. Physical therapy of venous ulcers: effects of electroionotherapy and polarized light. *Acta Facultatis Medicae Naissensis* 2005;22(1):29-35.
11. Biopton AG. *Biopton light therapy*. 2nd ed. Monchaltorf, Switzerland: Biopton AG, 1997.