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Editorial

Integrative Medicine and Helmet Constructions—A Feature Article about Milestones and Perspectives

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Abstract: Helmet designs have not only been used successfully in integrative medicine for decades in acupuncture research, but they are also increasingly being used in the field of transcranial photobiomodulation (TPBM), primarily in so-called mental diseases. The author of this article has been dealing with developed helmet constructions for neuromonitoring for over 25 years and not only gives an overview of the development of these methods, but also shows new methods and perspectives. The future of this branch of research certainly lies in the development of so-called sensor-controlled therapy helmets for TPBM.

Keywords: helmet constructions; helmet; acupuncture research; alopecia; transcranial photobiomodulation (TPBM); traditional Chinese medicine; integrative medicine; complementary medicine

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1. Introduction

Helmet constructions play an important role both in acupuncture research and in transcranial photobiomodulation (TPBM) therapy. One can differentiate, on the one hand, between helmets used for diagnostic purposes, which ideally contain numerous non-invasive sensors, and, on the other hand, helmets that primarily have a therapeutic function, for example, in the context of photobiomodulation (PBM) [1].

This article will deal with both variants, since the development and research of both methods reflects, among other areas of research, some of the author's research priorities over the past few decades and represents significant contributions to further research into evidence-based complementary medicine over the past 25 years. The reporting is supplemented by current studies that focus primarily on the latter areas, namely TPBM.

2. Materials and Methods

2.1. Search Strategy

For this article, the databases of PubMed, Google Scholar, and China National Knowledge Infrastructure (CNKI) were searched up to July 2022 (photobiomodulation helmet). The strategy and keywords have been adjusted according to the respective database.

2.2. Database Search

The search query in the databases resulted in a number of articles to be analyzed in more detail by the author (see Figure 1).

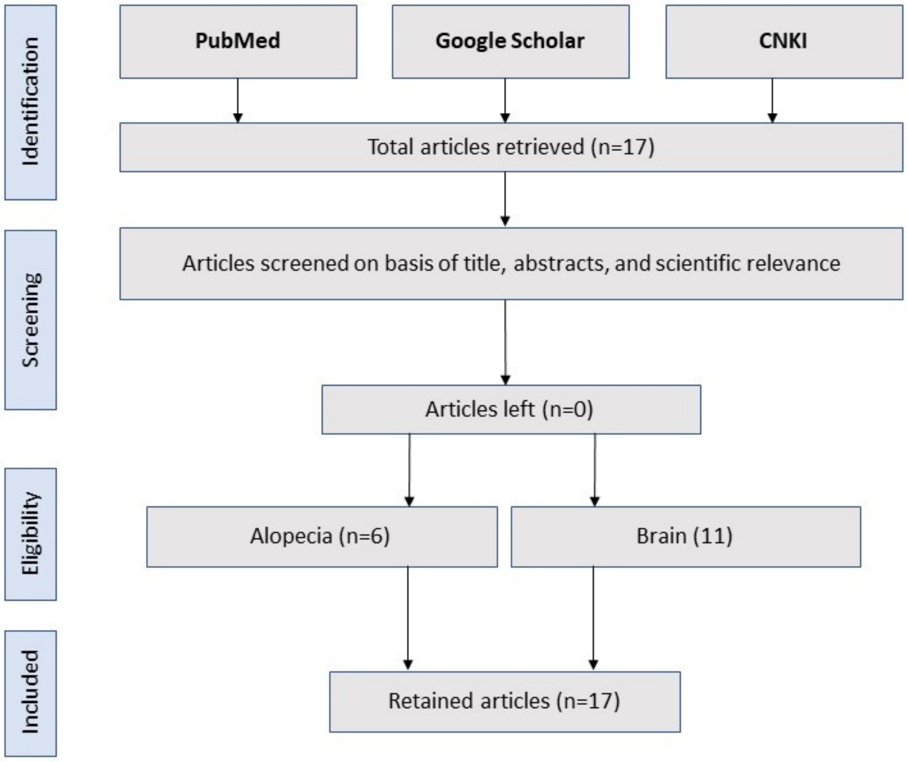

Figure 1. Selection of articles for this overview.

3. Results and Discussion

3.1. The Multifunctional Helmet as a Multimodal Sensor System in Acupuncture Research

Exactly a quarter of a century ago, in 1997, our research team at the Medical Faculty of the University of Graz showed how acupuncture can work without the manual help of an acupuncturist, and we introduced the term "computer-controlled acupuncture" [2–4]. However, we did not imply that the computer would replace the acupuncturist; rather, we wanted to emphasize the scientific quantification of the measurable effects of acupuncture. For this purpose, a helmet construction was developed at that time that contained numerous sensors (Figure 2) and with which it was possible to prove, for the first time worldwide, that acupuncture in the brain can develop general changes in blood circulation, as well as very specific effects (Figure 3) [5]. The helmet attracted disproportionately large attention from both the scientific community and the media. Television teams from all over the world from Europe, America and Asia reported on this success and were guests in our laboratory (Figure 4). In the Austrian media, where, at that time, acupuncture did not necessarily—let's say it carefully—have a high status as an evidence-based method, the research results were reported as a top story in the main news program at prime time.

A quarter of a century later, this vision of "computer or robot-controlled acupuncture" is now reality [6]; research publications in scientific journals such as *Medicines* [7] impressively show the current status in this field. Further modernizations of acupuncture, such as the automatic detection of dynamic pulse reactions for robot-controlled ear or body acupuncture, are in advanced development phases.

Figure 2. Multiparametric helmet construction in acupuncture research from 1997 (© Gerhard Litscher).

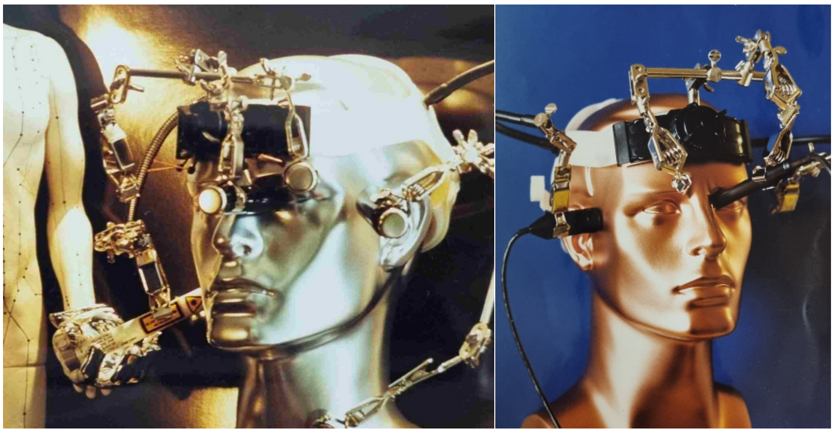

Figure 3. Simultaneous ultrasonic blood flow measurements in different cerebral arteries using a helmet construction developed in Graz in 2001 (© Gerhard Litscher).

Figure 4. Graz acupuncture research laboratory in 1997 (**left**) and in 2022 (**right**) (© Gerhard Litscher). The different helmet constructions developed can be seen in the background.

3.2. Scientific Investigations with PBM Stimulation Helmets

With regard to developed helmet constructions, low-level laser therapy (LLLT), which partly emerged from laser acupuncture, was initially used to promote hair growth [8]. A double-blind, randomized, controlled study was conducted already in 2013 to assess the safety and possible physiological effects of LLLT in men with androgenic alopecia. A total of forty-four men aged 18–48 were recruited. A scalp site in the transition zone was selected for evaluation. The hair was cut to 3 mm height and the appropriate area was tattooed and photographed. The active group received treatment with a total of 21 5 mW lasers (655 ± 5 nm) and 30 LEDs (655 ± 20 nm) implemented in a bicycle-helmet-like device. The placebo group received white light. The patients were treated at home every day over a period of 16 weeks (60 treatments, 67.3 J/cm^2 irradiance, 25 min treatment). Forty-one patients completed the study (22 active, 19 placebo). No adverse events or side effects were reported. Scalp LLLT at 655 nm significantly improved hair count in men with androgenetic alopecia [8].

In another study a year later, the same research group, this time in 47 women aged 18–60, also with androgenic alopecia, was able to show that LLLT with 655 nm also significantly reduced the hair count in women at a rate similar to that in men of the same parameters improved [9].

Further studies on alopecia followed. Devices for home use with, according to the authors, optimal penetration energy have been developed [9]. In conclusion, these novel helmet-type devices appear to be an effective treatment option in both male and female patients with minimal side effects. However, the limitations of these studies are their small sample size and the lack of long-term follow-up data [10].

Finally, a meta-analysis was used in 2021 [11] to summarize the effectiveness of PBM treatment in androgenetic alopecia. A sub-analysis was performed to determine whether the type of device used or whether the use of lasers versus light emitting diodes (LEDs) significantly affected the results. A subgroup analysis comparing comb-style devices to helmet/hat-style devices revealed no significant difference. A second subgroup analysis suggested that the laser treatment was significantly more effective than a combination laser/LED treatment, although the combination treatment was still significantly better than the control treatment. The results of the meta-analysis suggest that PBM could be used to effectively treat androgenetic alopecia [11]. Limitations include unit cost and lack of standardized protocols [12].

Hair loss is one of the most common complaints in dermatology [13]. It causes considerable psychosocial stress and reduced quality of life in affected patients. Low-level laser therapy of the scalp at 655 nm significantly improved hair count. What is currently missing are studies that determine the long-term effects of LLLT on hair growth and hair maintenance and the laser modality is to be further optimized [13].

One of the first relevant TPBM studies on the human brain, which was carried out with a helmet construction, is described by Hamblin [14] in a first review in 2016. He reported about different diseases of the brain, which can be divided into three large groups: traumatic events (stroke, traumatic brain injury and global ischemia), degenerative diseases (dementia, Alzheimer's and Parkinson's disease) and psychiatric diseases (depression, anxiety, post-traumatic disorders). There is evidence that all these seemingly different states can be positively influenced by the application of light. There is even a possibility that PBM could be used for cognitive enhancement in normal healthy people. In this TPBM application, near-infrared (NIR) light is often applied to the forehead due to better penetration (no hair, longer wavelength). Some researchers have used lasers, but the advent of inexpensive light-emitting diode (LED) arrays has also enabled the development of light-emitting helmets, or "brain caps". Already at that time, Hamblin described possible mechanisms of action of PBM on the brain and summarized some important preclinical studies and clinical studies that were carried out for various brain diseases [14].

In 2017, Alzheimer's disease (AD) became the focus of research [15]. A double-blind, placebo-controlled, pilot study evaluating the effect of 28 consecutive, six-minute transcranial sessions of NIR diode stimulation using 1060–1080 nm light emission was reported. The patients were diagnosed with dementia, which was carried out in an outpatient clinic for behavioral medicine. The results showed changes in different functions (clock drawing, instantaneous recall, practice memory, visual attention and task switching) and a trend towards improved brain electrical function [15].

PBM thus describes the use of, for example, red or NIR light to stimulate or regenerate tissue. It has been discovered that NIR (800–900nm) and red (600 nm) light-emitting diodes (LED) wavelengths are able to penetrate the scalp and skull and have the potential to ameliorate the subnormal cellular activity of damaged brain tissue. Various experimental and clinical studies have been conducted to test LED therapy in traumatic brain injuries with promising results. In a double-blind, randomized, controlled study of patients with diffuse axonal injury due to severe traumatic brain injury in an acute stage, subjects were randomized in a 1:1 ratio into two helmet groups with active and inactive stimulation, respectively. The protocol included 18 sessions of transcranial LED stimulation (627 nm, 70 mW/cm^2, 10 J/cm^2) at four points in the frontal and parietal regions for 30 s each, totaling 120 s, three times per week for 6 weeks, duration 30 min. The first results of transcranial LED therapy showed that cognitive function was improved and there were beneficial hemodynamic changes in the cerebral circulation [16].

In 2019, our research group carried out investigations with newly developed TPBM stimulation helmets for the first time [17]. A new device for PBM of the brain with LED has been scientifically presented for the first time. Preliminary results of regional cerebral oxygen saturation and thermography were shown before, during and after stimulation. The method now offers a new possibility to quantify the biological effects of a possible innovative therapy method [17].

Investigating the effect of PBM on human brain activity is more difficult than in animal experiments [18]. Not only is human perception far more complex, but the human skull is designed in such a way that light cannot penetrate deep into the brain tissue. In more recent research, we now examined the effects of helmet designs in which PBM devices are implemented [17,18]. A PBM helmet studied contains 256 60 mW, 810 nm LEDs with a total output power of approximately 15 W (see Figure 5). Using the differential signals from 730 and 805 nm radiation measured at two different locations, we recorded regional cerebral oxygen saturation under three conditions: 20 min at rest, 15 min of light stimulation, and an additional 20 min at rest. We found that blood oxygenation increased during PBM and decreased after PBM, but to levels above baseline. While we are confident that PBM modulates blood oxygenation, we recognize that many questions remain. Ideally, PBM could also be used in the future to treat certain mental illnesses or alleviate their symptoms, but the power density, the exposure time, the frequency of the light and most of the other technical parameters are currently not standardized in any way [17,18]. Before the helmet can be used clinically, further basic studies on the subject must be carried out [17,18].

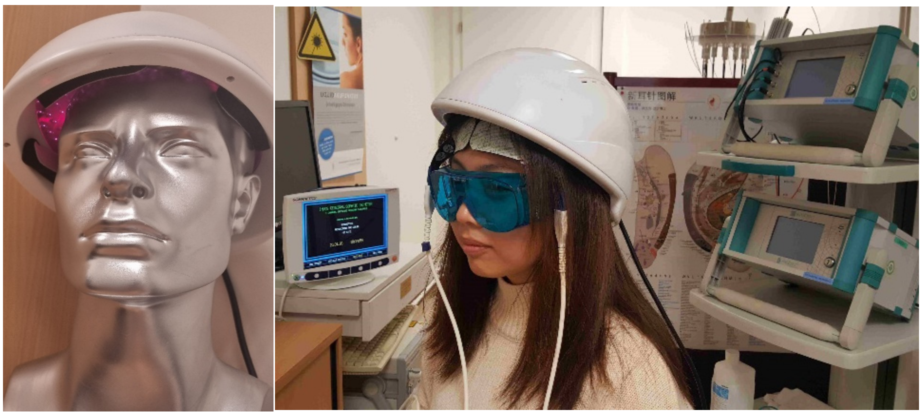

Figure 5. Transcranial photostimulation using helmet construction at the TCM Research Center of the Medical University of Graz 2020–2022 (© Gerhard Litscher).

Researchers at the Center for Addiction and Mental Health in Toronto, Canada, studied the effects of light stimulation by another wearable PBM device [19]. This device included both a nasal applicator and a headset with four 810 nm LED modules. Twenty healthy subjects between the ages of 61 and 74 received either sham stimulation or a 20-minute exposure to pulsed 40 Hz light. After a one-week adaptation period, the subjects all received the opposite treatment. Brain activity was monitored using an electroencephalogram (EEG) [18,19].

The people who received light therapy showed an increase in the power of alpha, beta and gamma waves and a decrease in the low-frequency delta and theta waves. This is particularly interesting as Alzheimer's disease is characterized by brainwave synchrony and PBM may be able to modify these frequencies. The research is still in its early stages, but nonetheless, this is in some respects the first double-blind study demonstrating the modulations of cortical oscillation by TPBM. Although the exact mechanism is still largely unknown, the modified brain waves showed significant differences to the placebo stimulation [18,19].

In 2019, a case report of improvement in cognitive impairment, olfactory dysfunction and quality of life measurements in a patient with cognitive deficits after multimodal photobiomodulation therapy was presented [20]. The patient received TPBM + PBM therapy twice daily at home using three different portable light emitting diode (LED) devices. A prototype transcranial light helmet and body pad were used in the first week, which included a mixture of red (635 nm) and NIR LEDs (810 nm) in continuous mode. The body pad was placed at various points on the lower back and the helmet was worn while seated. After the first week of treatment, an intranasal LED device, 10 Hz pulse wave mode NIR (810 nm), was inserted into the left nostril twice daily. All three devices were used simultaneously for an irradiation time of 25 min per session. Cognitive improvement was accompanied by improvement in olfactory dysfunction. The quality of life was also improved and the stress for the caregivers was reduced. No side effects were found [20].

Parkinson's disease is a well-known neurological disorder with distinct motor signs and non-motor symptoms. In 2019, six patients with Parkinson's disease who used TPBM helmets (LEDs 670, 810 and 850 nm) or were stimulated intranasally (660 nm) were reported. Progress was assessed by those treated themselves, their spouses or their treating physicians. Of these subjects, 55% showed an overall improvement, while 43% showed no change and only 2% worsened [21].

Also in 2019, a review article on TPBM in Alzheimer's dementia was published [22]. PBM may have antiviral and anti-inflammatory effects in neurodegenerative diseases and has been shown to improve memory and cognition. The authors envisage that next-generation studies may include whole-body stimulation [22].

More recently (2021), TPBM has been shown to be beneficial in animal models of Parkinson's disease as it improves movement behavior and is neuroprotective. Early observations in people with Parkinson's disease have also been positive, with improvements seen most consistently in the non-motor symptoms of the disease [23]. Although the exact mechanisms behind these improvements are not clear, two procedures have been proposed: direct stimulation, in which light reaches and acts directly on neurons, and remote stimulation, in which light affects cells and/or molecules that provide systemic protection and thereby acts indirectly on disturbed neurons. Given that, in relation to Parkinson's disease, the main zone of pathology is deep in the brain and light from an extracranial or external PBM device would not or only with difficulty reach these vulnerable regions, direct neuronal stimulation via intracranial delivery of light can be performed with an implanted device located near the vulnerable regions. For indirect systemic stimulation, PBM could be applied either to the head using a transcranial helmet or via a more remote body part (e.g., abdomen, leg). However, currently, the evidence for both the direct and indirect neuroprotective effects of PBM in Parkinson's disease is discussed, and it is also stated that at present both types of treatment modalities, when combined with intracranial and extracranial devices, represent the best possible therapeutic option of the PBM [23].

In 2021, another pilot study on NIR 1068 nm TPBM therapy was presented [24]. The effects on motor function, memory and processing speed in healthy subjects over 45 years of age were assessed. PBM therapy was performed at home using a transcranial phototherapy device, a helmet containing 14 air-cooled light emitting diode panel arrays with a peak wavelength of 1068 nm and full width at half maximum bandwidth of 60 nm. The average total optical power was 3.8 W. The device was used twice daily for 6 min on age-matched, middle-aged subjects with normal mental function. A significant improvement in motor skills, memory and processing speed was observed in healthy subjects with PBM-T compared to the placebo group. No side effects have been reported. PBM therapy could be a promising new approach to improve memory in middle-aged individuals [24].

4. Perspectives

The perspectives of this article are of course already obvious. It is the development of sensor-controlled therapeutic helmets that contain both general components—namely, neuromonitoring multi-parametric data acquisition to control the therapeutic function of the applied stimulation. Not an easy project, but the author is convinced that the necessary technologies have long been available and only a few steps are required to implement them (Figure 6).

Exactly 25 years ago, when the author published the first studies on it, computer-controlled and robot-controlled acupuncture [3–7] was given little chance of being realized. Now this is already a reality and is constantly being further developed in the field of laser acupuncture with always innovative approaches [25].

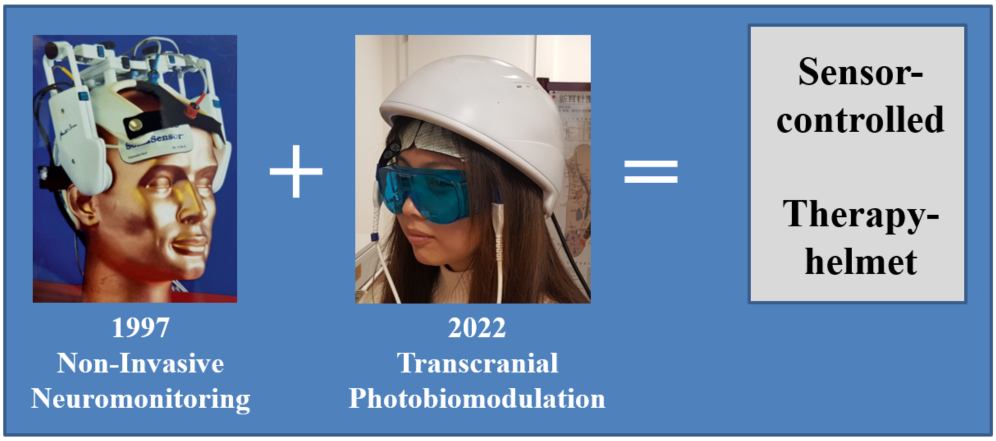

Figure 6. Helmet constructions—perspectives [18,26] (© Gerhard Litscher).

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Conflicts of Interest: The author declares no conflict of interest.

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