



1. Anhang

1.1 Anhang 1: Social Media Analyse – Workshop

Social Media for EMF workshop 11.10.17

A workshop was held at the offices of **Forschungsstiftung Strom und Mobilkommunikation** on the topic of using social media to gather product reviews on a range of devices from a wide audience. We covered fundamentals of social media, set up a social media "sandbox" using Slack to share links and practice basic ways of communicating in a messaging interface, looked at the prominent channels where reviews are exchanged, covered search methods and monitoring tools, discussed the skills and work involved in a project to collect and process data on a wider scale.



The workshop was facilitated by:

Oleg Lavrovsky, Datalets.ch ~ [@oleg](https://twitter.com/oleg) ~ oleg@datalets.ch ~ 0763060739

Notes – Social Media Workshop 11.10.17

Oleg Lavrovsky, Datalets

Introduction

Social media are (at least a very important part of*) the **next web**

- Information **easily** published, **quickly** and **widely** distributed, in standard **formats** to a large variety of **devices**.
- A definition that is constantly **broadening** through Internet of Things, Smart Devices, Social Apps, and so on..
- An extremely important vehicle to understanding the **digital society**.

Social media, often confusingly referred to as big data, is incredibly useful - but also presents a variety of problems to people who wish to mine its riches:

- **Biased**
 - representing population slices
- **Misleading**
 - often the needle you find is something else than you think
- **Hollow**
 - there is no deep center, except perhaps in the networks own analytics
- **Noisy**
 - it can be extremely difficult, or extremely easy, to find a good signal

What (usually*) does not work?

- Asking specific questions and expecting **universal answers**
- Expecting **quick, cheap, good** results (see below)
- Assuming you will "**know something**" about sources

If you want to make use of public social media data (in my opinion), take two:

- Quick + Cheap = **The "Firehose"**
 - <https://brightplanet.com/2013/06/twitter-firehose-vs-twitter-api-whats-the-difference-and-why-should-you-care/>
- Quick + Good = **Data brokers**
 - https://en.wikipedia.org/wiki/Information_broker
- Cheap + Good = **Open data**
 - <https://okfn.org/>

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Understanding social media

What are online social networks? They are diverse places facilitating communications within and between groups of people, including:

- Our neighbourhood
 - Rules of engagement underpinning modern life are also the basis for online culture.
- Email
 - Arguably the world's largest and most pervasive social network.
- Web
 - PageRank as a social network of web page creators, bloggers, etc.
- [Slack](#)
 - A private social network for teams, which we learned to use @ replies.
- [WhatsApp](#)
 - The largest social network by number of profiles, that we are all familiar with.
- [Twitter](#)
 - We learned how to filter tweets and use [advanced search](#). Ask Jürg for more insights.
- [Facebook](#)
 - The proverbial elephant in the room, we learned how pages and [ad campaigns](#) work.
- [Instagram](#)
 - Ask Krysztina for some insights into today's most rapidly growing social network.
- [LinkedIn, Xing](#)
 - Ask Georg, Jürg about their experience with these social networks for business.
- [Dropbox](#)
 - Yes, this and anything else that lets us share online, is also a type of social network..
- Academic networks are of particular interest to people at ETH, e.g.:
 - [ResearchGate](#)
 - [Academia.edu](#)
 - [Frontiers](#)
- Blogs, forums & commenting widgets are also social networks:
 - [Disqus](#) is used on many product sites, and the group's own web site
 - [RSS](#) - we talked in detail about how this enables data mining the Web

Monitoring social media

Monitoring tools help us keep track of what's happening in online social networks. We looked at and tested the following:

- [Google.com/Alerts](#)
- [TweetDeck.com](#)
- [Hootsuite.com](#)
- [Feedly.com](#)

Data aggregation is about collecting raw / unfiltered / large-scale data from social networks. For this it is necessary to know about:

- Programming interfaces (APIs)
 - [developers.facebook.com](#)
 - [developer.twitter.com](#)
 - [developer.feedly.com](#)
 - ...
- Cloud computing infrastructure
 - [aws.amazon.com](#)
 - [scrapinghub.com](#)
 - ...
- Data brokers
 - [datasift.com](#)
 - ...

A variety of tools are used to dig into the data of social networks.

- [Data Science](#) is about ...
 - Analytics
 - Visualisation
 - Classification
 - Statistics
- ..and much more. See [toolbox.schoolofdata.ch](#) for the pipeline we use in **School of Data** workshops, and some tools recommended for people with a little experience in Web development.

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Casting the net

If you want to have a look at how data is collected and analysed, here are some starting points:

- Python
 - [Mining-the-Social-Web-2nd-Edition](#)
 - [an-introduction-to-text-analysis-with-python](#)
 - [www.diveintopython3.net](#)
- R
 - [twitter-sentiment-analysis-with-r](#)
- BI
 - Many "batteries included" toolboxes from the Business Intelligence (BI) domain, such as from [Microsoft](#) or [Tableau](#) can be used to effectively analyse social media data without programming.

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Further development

As we discussed in the workshop, next steps could include:

1. Creating a **Data Inventory** listing all the sources (the big social media platforms mentioned above, as well as any major channels where consumer responses can be extracted). Every source can be quantified and prioritised according to various criteria.
2. Researching, following and listing "**Magnets**", prominent profiles on social media on key topics, well represented organisations, blog aggregators and so on, which should be especially closely monitored and possibly collaborated with.
3. **Collecting and analysing** data from a selection of the sources identified, building up necessary infrastructure, establishing some preliminary patterns that help to visualise the **information landscape**.
4. Working with **partners** to broaden the scope and reach of the analysis, through more data or deeper analysis. Working with an engineering partner like [Datalets.ch](#) you could create **Dashboards** to pull information into one place from automated processes, **Crawlers/ agents** which retrieve data from diverse, hard-to-reach places, and even **Widgets/ bots** that can extend and crowdsource your data gathering efforts.



Reading list

[Bedeutende Daten](#)

[Mining the Social Web](#)

[Data Science from Scratch](#)

1.2 Anhang 2: Social Media Analyse – Portale

1. Ärztebewertungsportale

- [jameda.com](#)
- [die-artztempfehlung.com](#)
- [docbewertung.com](#)
- [estheticon.de](#)

keine Treffer, Ärzte lassen nur positive Bewertungen stehen

Bewertung vom 22.02.2016
1,0 **Es sind alle sehr freundlich und kompetent:**
Frau Dr. Schröder werde ich gern weiter empfehlen. Ich komme gern wieder." [Mehr »](#)

Bewertung vom 12.02.2016, Alter: über 30
Warum ist diese Bewertung aktuell nicht online?
Dr. Schröder hat uns die Bewertung gemeldet, da sie sie für rechtswidrig hält. Aus diesem Grund wird die Bewertung derzeit von uns überprüft. Zummindest bis zum Abschluss der Prüfung ist die Bewertung offline.
[Mehr zum jameda Prüfprozess »](#)

Bewertung vom 01.02.2016
1,0 **Professional, einfühlsam, zugewandt, sympathisch:**
Meine "Probleme" jeder Art werden hier immer professionell und einfühlsam behandelt. Ich fühle mich hier sehr gut aufgehoben." [Mehr »](#)

Bewertung vom 29.01.2016, Alter: über 60
1,0 **Kompetenz gepaart mit Freundlichkeit:**
Ich bin seit vielen Jahren sehr zufriedene Patientin bei Frau Dr. Schröder (wie mehrere meiner Freunden). Seit länger Zeit nutze ich nicht nur die klassische Hautarztpraxis, in der Frau Dr. ... [Mehr »](#)

Bewertung vom 28.01.2016
1,0 **Sehr nette Mitarbeiter im Kosmetikinstitut sehr angenehme Atmosphäre in dem Kosmetikinstitut tolle Beratung und Erläuterung bzgl. diverser Behandlungen:**
Ich komme seit April 2017 zum Micro Needling in das Institut "schöne Haut" und ich

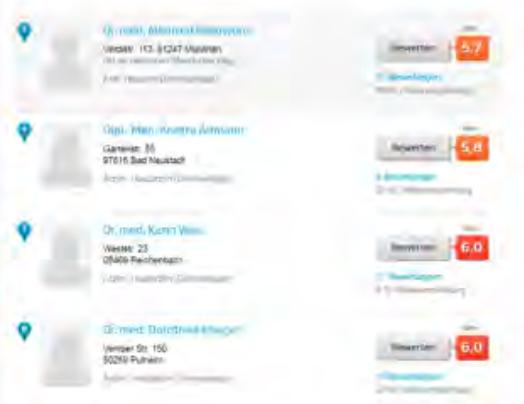
bis auf jameda.de, dort darf man auch kritisch bewerten:

Fachgebiet

Hautärzte (Dermatologen) X

Bewertungen

Positiv bewertet (3.280)
 Kritisch bewertet (347)
 Nicht bewertet (1.426)



ansonsten

immer alles super...

2. Beauty-Foren

[erfahrungen.com](#)

Das einzige Beauty-Thema, das nicht Produkte wie Cremes etc. bewertete, war die IPL-Haarentfernung. Wenige Beiträge, 4-5 Jahre alt, alle positiv. Z. B.

Erfahrungen mit IPL Haarentfernung (3)

	Amely 1 Bewertung		Donnerstag, 19. Juni 2014
Hallo zusammen,			
Ich habe im Juli 2013 mit einer IPL-Haarentfernung an den Unterschenkel begonnen. Seitdem habe ich schon die fünfte Sitzung hinter mich gebracht. Im August mache ich meine sechste und letzte Sitzung an den Unterschenkeln. Die Sitzungen müssen in einem zeitlichen Abstand von acht bis zwölf Wochen erfolgen. Pro Sitzung zahle 160,-Euro. Mehr anzeigen			
	Leistungssamme 56 Bewertungen		Donnerstag, 31. Januar 2013
Meine Frau hatte an einer nicht besonders vorteilhaften Stelle einen unschönen Haarschuss. Sie hat ihr Leben lang diese Stelle akribisch rasiert, so dass das Problem überhaupt nicht sichtbar war. Mich hat es öfter nicht gestört, aber meine Frau hat darunter immer gelitten. Deswegen habe ich ihr letztes Jahr zum Geburtstag eine dauerhafte Haarentfernung geschenkt.... Mehr anzeigen			
	Faztoothan 41 Bewertungen		Donnerstag, 31. Januar 2013
Ich hatte Haare auf dem Rücken, die mich sehr gestört haben. Es waren nicht Viele. Und meine Freundin hat nie etwas gesagt. Aber mich stören diese Haare schon seit vielen Jahren. Deswegen habe ich letztes Jahr eine IPL machen lassen und bin sehr zufrieden mit dem Ergebnis. Die Haare sind endgültig weg und ich muss mich nicht mehr über diese unschöne Stelle ärgern.... Mehr anzeigen			

IPL Haarentfernung im Test - Note: Sehr gut

[mein-erfahrungsbericht.de](#)

kein Treffer für das Thema, behandelt nur operative Eingriffe

[combeauty.com](#)

kein Treffer für das Thema, behandelt nur Drogerieprodukte

test.de:

kein Treffer, es wurden nur Drogerieprodukte sowie Botox getestet

kennstdueinen.de

kein Treffer für das Thema; Dienstleister können sich eintragen, Kund*innen können Bewertungen schreiben, diese sind **immer positiv**

gefundene Anti-Aging- bzw. Beauty-Themen: IPL Haarentfernung, Laser-Faltenbehandlung, Laser-Fettabsaugung, Hautbild-Verbesserung mit Laser, Tattoo-Entfernung, Cellulitis-Behandlung

treatwell.de

Dienstleister aufgelistet, oft viele Bewertungen, alle positiv! Preise bzw. aktuelle Sonderangebote ersichtlich; von den Dienstleistern „gepflegtes“ Portal.

The screenshot shows a search results page for 'Thermage' in Berlin on the treatwell.de website. The results are categorized under 'Beauty Moments' and 'Thermage'. There are two main service providers listed:

- CICOLA - EXPERTS FOR LASHES**: Offers eyelash extensions and treatments. One service is listed: 'Wimpernverlängerung' (17 reviews, 10.0 rating). A large red arrow points from the left towards this entry.
- Studio Kleebaum**: Offers various aesthetic services including Thermage. One service is listed: 'Thermage (Laser-Augen-Faltenbehandlung)' (1 review, 10.0 rating).

On the left sidebar, there are filters for 'Anti-Aging / Hautverjüngung' and 'Thermage'.

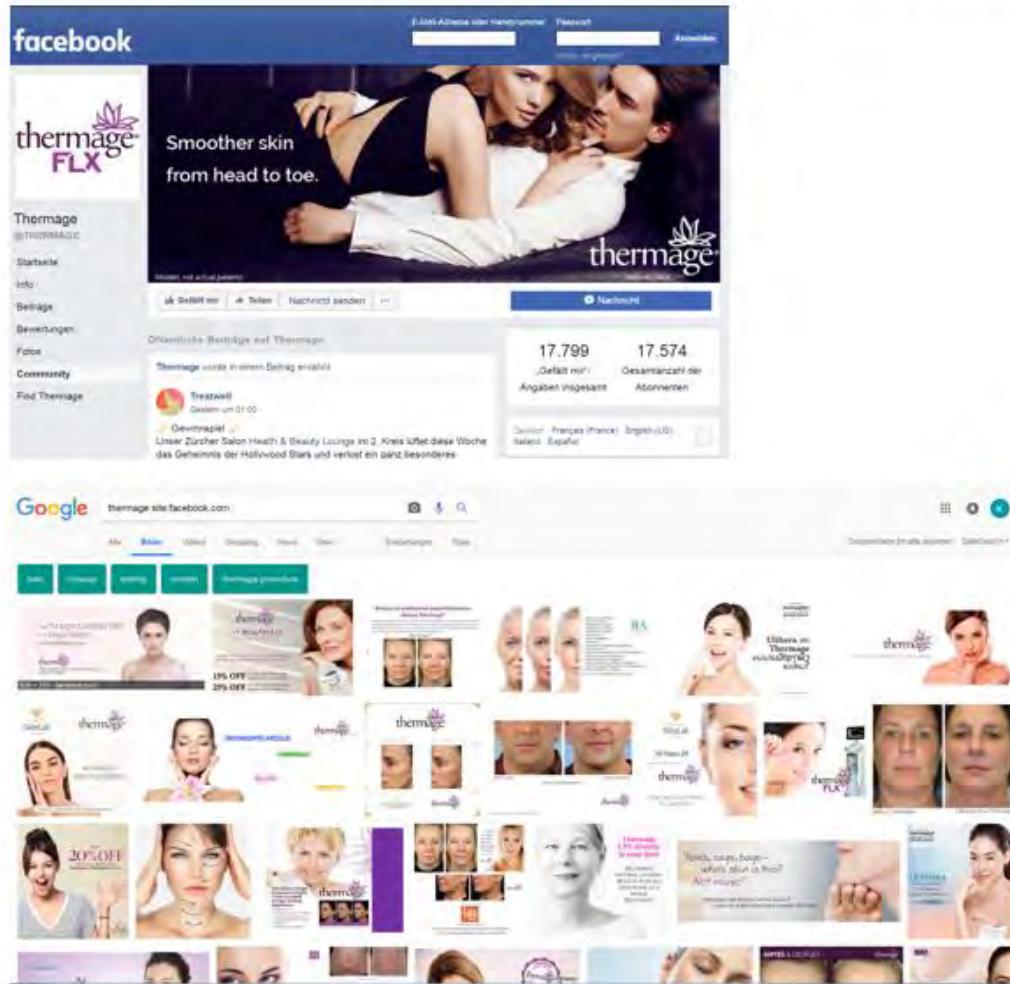
youtube (Beispiel: Thermage): alles Promo

The screenshot shows a YouTube search results page for 'thermage'. The search bar at the top has 'thermage' typed in. Below the search bar, it says 'Ergebnisse für thermage'. There are four video thumbnails displayed:

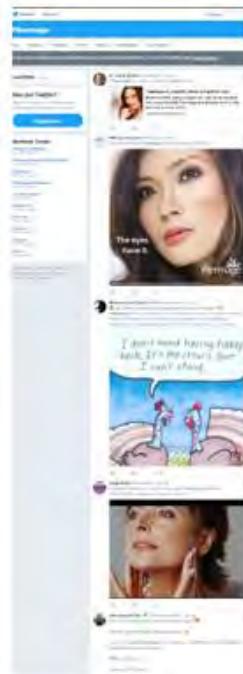
- Thermage im Selbstversuch: Kann Thermage die Zeit zurück drehen? Falten reduzieren und straffen?** (by Dr. med. Michael C. Eichner) - 1,000,000 views
- THERMAGE-LIVEBEHANDLUNG | Hautstraffung ohne OP | Aktenarbeiten | DERMA LOFT Gladbeck** (by DERMA LOFT Gladbeck) - 1,450,000 views
- Thermage-SAM Pro7 - Ein Model berichtet über ihre Erfahrungen mit Thermage** (by Michael C. Eichner M.D. and Yvonne) - 4,029 views
- New Thermage CPT Procedure Video! · Dr. Bill Johnson** (by ThermageCPT) - 1,040,000 views and 1,000 likes

facebook (Beispiel: Thermage)

Entweder Ärzte , die (potentielle) Kundinnen beraten, oder Werbung für Kosmetikinstitute



twitter (Beispiel: Thermage): dito



1.3 Anhang 3: Social Media Analyse – Treffer

Hochfrequenz Diathermie - Thermage

Bei den Thermage®-Behandlungen geht es um gebündelte Hochfrequenzenergie, die den körpereigenen Erneuerungsprozess in der Haut anstößt.

Erfahrungsbericht trueffi am 04.10.2011 auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/206081-refacing-thermage-faltenbehandlung-risiken-negative-erfahrungen.html#post13433726>

„Hallo,
... Ich bin 45 und wollte gerne nur etwas frischer aussehen.

*Ein befreundeter Arzt empfahl mir eine ganz schonende Behandlung, welche sich ReFacing bzw. Thermage nennt. Dieses Refacing Gerät ist, wie ich jetzt erfahren habe, die "kleine Schwester" der Thermage... Es ist eine DEUTSCHE FIRMA und ... die Behandlung ist viel erschwinglicher und wird ... als völlig ungefährlich angepriesen. ... Ich unterzog mich im Dez. 2010 und Jan. 2011 insgesamt 5 Behandlungen am Augen- und Halsbereich. ...
... bei einem meiner Frisörbesuche fiel mit auf, daß mein Hals viel runzeliger aussieht... und kürzlich sagte mein Mann auch zu mir, dass ich sehr schlecht aussehe, ob ich krank wäre...? Auch bemerkte ich selbst, daß mein Augenbereich seit einiger Zeit so eingefallen wirkt...*

...
Mein Gesicht wird immer schmäler, das Fett schmilzt regelrecht. Stellenweise hängt die Haut bereits und neue Falten sind entstanden. Die Knochen sind im Wangenbereich stark hervorgetreten und das Kinn ganz spitz geworden. Auch hat sich die Hautstruktur irgendwie verändert, sie fühlt sich weicher an und ist empfindlicher geworden.

Ich habe auch festgestellt, daß ich regelrechte Schübe bekomme (Dellen), wenn ich in der Hitze oder Sonne bin. Wir haben unseren Strandurlaub im Sept. daher frühzeitig abgebrochen.

Tinchen1 am 10.06.2008 auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/59597-thermage-behandlung-bzw-thermalifting-ohne-skalpell-11.html>

...ich habe die Thermage Behandlung auch gemacht... Meine Wangen sehen seitdem ungleichmäßig aus, bin auch hagerer geworden. ... Mal abgesehen davon, dass die Behandlung auch schweineweih getan hat, ist es rausgeworfenes Geld und noch viel schlimmer.....

altpuzzle am 14.04.2008 auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/59597-thermage-behandlung-bzw-thermalifting-ohne-skalpell-10.html#post3887659>

Hallo,
im Dez. 06 haben wir leider die Thermage an unseren Gesichtern machen lassen. Bei einem schmalen Gesicht trat relativ prompt der Fettverlust ein (tiefe Falten auf der zuvor glatten Stirn und um die Mundwinkel herum, Schläfen und Backen weg. Mein volles Gesicht verlor auch Fett, was aber leider nichts bringt. Deutliche Falten und Einfallstellen, die auch noch im Apr. 08 mehr oder weniger schnell fortschreiten. Die Oberlider sind um mehrere mm abgesackt, was einen etwas bescheuerten Ausdruck erzeugt. Die Backen befinden sich in einem Auflösungsprozeß. Völlig weiches Gewebe. Unter den Augen ist mehr "weiß" zu sehen und man empfindet die nicht mehr richtig anliegenden Unterlider als ausgesprochen unangenehm. Meine rel. vollen Lippen werden immer schmäler und die Mundwinkel zeigen nach unten. Auch im Inneren waren die (10-Meter) Radiowellen z. T. durchschlagend: Schlaflosigkeit, hoher Blutdruck, Irritation vieler Organe. Die Kiefergelenke von uns beiden wurden z. T. beeindruckend geschädigt. 3 x täglich weiche Kost dank Thermalifting ist schon lästig.

Erfahrungsberichte auf <https://www.biowellmed.de/patientenbericht-500.html>

(anonym) am 22.04.2017
Hallo,

auch ich habe sehr schlechte Erfahrungen mit meiner Thermagebehandlung gemacht.

Auch bei mir schmolz das Hautvolumen wie Fett in der Sonne.

Aber was für mich noch schlimmer zu ertragen ist, ist die Tatsache, dass ich nach der Thermagebehandlung nachweislich keine Pigmente mehr im Gesicht habe. Absolut grauenhaft, jeden Tag darauf angesprochen zu werden. Ich verfluche den Tag der angeblich so harmlosen Behandlung.

(anonym) am 24.04.2016

Ich habe vor vier Jahren eine Thermagebehandlung machen lassen. Damals hatte ich ein rosiges Gesicht mit viel Volumen. Eigentlich wollte ich nur meine leichten Nasolabialfalten behandeln lassen.

Dann entschloß ich mich zu einer folgenschweren Thermagebehandlung. Angeblich mit dem neusten Gerät.

Nach der einstündigen Behandlungsdauer hatte ich starke Verbrennungsschmerzen und mußte einen Hautarzt aufsuchen, der sich mit Entsetzen meine Haut anschaute und mir dann eine Salbe gegen die Schmerzen im Gesicht verschrieb. Heute, drei Jahre danach leide ich unter starken Volumenverlust im ganzen Gesicht. Ich werde mind. 10 Jahre älter geschätzt, als vor der Thermagebehandlung. Darüber hinaus sieht meine Gesichtshaut immer aschfahl und leichenblass aus.

Beitrag der Firma Thermage Deutschland (ungekürzt), Beitrag vom 06.01.2016:

Guten Tag liebe Leser,

im Namen von Thermage Deutschland liegen uns Ihre Meinungen und Erfahrungen sehr am Herzen. Sollten Sie nach einer Behandlung unerwartete Begleiterscheinungen oder Schädigungen beobachten, bitten wir Sie, unverzüglich sich mit Ihrem behandelnden Arzt in Verbindung zu setzen.

Generell gilt:

Original Thermage-Behandlungen werden nur von zertifizierten Anwendern in ärztlichen Praxen durchgeführt. Stellen Sie in jedem Fall sicher, dass Ihr Arzt ein original Thermage-System sowie ein offizielles Schulungszertifikat besitzt (Zertifizierte Ärzte und Informationen über Thermage finden Sie auf der Produktwebseite www.thermage.de).

Das Thermage-System befindet sich mittlerweile in der dritten Generation, wurde in zahlreichen klinischen Studien auf Sicherheit und Effizienz getestet und ist durch die FDA (Food and Drug Administration) zertifiziert.

Die Qualität der Behandlung, sowie die Sicherheit der Patienten, stehen für uns an erster Stelle. Deshalb arbeiten wir eng mit unseren zertifizierten Ärzten zusammen. Prüfen Sie bei einem Thermage-Angebot bitte immer im Vorfeld, ob der behandelnde Arzt oder die Arztpraxis in unserem Arzt-Finder www.thermage.de/arzt_finden hinterlegt ist. Nur so können wir unserem hohen Qualitäts- und Sicherheitsanspruch gerecht werden.

Vielen Dank und mit freundlichen Grüßen

Patrick Majerle

Produktmanagement Thermage

(anonym) am 24.10.2015

Vor ca. 8 Jahren habe ich mich einer Thermage-Behandlung in Nürnberg unterzogen. Trotz Betäubungscreme war die Behandlung um die Augen sehr schmerhaft. Die Haut sah nach einigen Wochen etwas frischer aus, aber der angestrebte Straffungseffekt um Wangen und Kinn blieb bei mir aus. Jetzt muss ich seit 2 Jahren eingefallene Augenringe und Wangen durch Hyaluron auffüllen lassen. Das Unterhautfettgewebe hat sich langsam aber sicher abgebaut.

(anonym) am 14.07.2010

...Die Thermage kann regelrechte Alterungsschübe auslösen, wie in unserem Fall. Wenn die Lymphkanäle unter den Augen durch falsche Thermage-Behandlung verbrannt (exakter verkocht) wurden, ändert sich allein schon dadurch das Leben einschneidend. Da insgesamt Unterhautfettgewebe am ganzen Körper eingebüßt wurde (und wird), ist die Rekonstruktion leider nicht einfach. Ein Arzt gab Hya im z. B. kritischen Stirnbereich (mangels Ankergewebes) nur eine Haltbarkeit von 3 Tagen und lehnte ab, ein anderer nannte höchstens 4 - 6 Wochen, was bei ihm stimmte.

Unser PC ist zum Glück ein wirklicher Könner und trainiert auch Kollegen. Bei mir brauchte er allein für die verkochten Backen 10 ml und beim Auffrischen nach über 1 Jahr immer noch ca. 8 ml Hya.

(anonym) am 30.06.2010

Ich habe die Thermage vor circa 16 Monaten machen lassen- leider...die Folgen sind furchtbar: eingezogene Wangen wegen Fettverlust, herunterhängende Hautlappen seitlich neben dem Kinn. Ich bin in einem Jahr mindesten um fünf Jahre gealtert! Es ist wie ein Albtraum der immer schlimmer wird - von Woche zu Woche. Der Prozess ist offenbar nicht aufzuhalten.

Der behandelnde Arzt beantwortete meine Frage, wie ernst die Warnungen zu nehmen seien, die ich im Internet gelesen hatte ,damit, dass dies Veröffentlichungen von Konkurrenzinstituten seien, die Patienten für einen Lift gewinnen wollten . Und ich war so naiv das zu glauben!

(anonym) am 28.03.2008

Ich habe leider sehr schlechte Erfahrungen mit der Thermage gemacht. Jetzt weiß man kaum, wie man mein dünn gewordenes Gesicht (Fett ist weg geschmolzen, tiefe Falten und Dellen sind entstanden) wieder hin bekommen soll.

Info von KM: Auf diesem Portal wurde das Thema Thermage eher zufällig behandelt. Andere relevante Themen sind auf der Seite nicht vorhanden (s. Screenshot).

The screenshot shows a web page from the biowellmed website. At the top, there's a navigation bar with links to various news sites like My Maps, WEB.DE, FFM, Der Tagesspiegel, ZEIT ONLINE, Le Monde, Amazon, and Regenbogen metro. Below the navigation is the biowellmed logo and the tagline 'Ihr Portal für Gesundheit'. A sidebar on the left lists various medical topics such as Startseite, Aktuelles Thema, Aus dem Leben, Fälle aus der Praxis, Krankheiten und Behandlung (Allergie, Augenkrankheiten, Blutkrankheiten, Bösartige Lymphomkrankungen, Darmkrankheiten, Drogenkrankheiten, Erkrankungen der Bauchspeicheldrüsen, Erkrankungen im Zahnbereich, Essstörungen, Experten berichten, Frauenkrankheiten, Galle und Gallenwege, Hals- Nasen- Ohrenkrankheiten, Harn- und Geschlechtsorgane, Hautkrankheiten). The main content area is titled 'Experten berichten' and contains a sub-section 'Erfahrungsberichte zum Thema Experten berichten'. It includes a text block about external experts and a bulleted list of treatments: Arthroskopische Kniegelenksoperation, Krampfadernbehandlung mit Laser/EVLTTM, Neuraltherapie, and Thermolifting mit Thermage.

Forum <http://www.patient-zu-patient.de>

Zum Thema Thermage haben drei User, die bei Brigitte/Bfriends Ihre negativen Erfahrungen bereits geschildert haben, Beiträge mit demselben Inhalt geschrieben

User anneamsel am 14. August 2012 auf <http://beauty.gofeminin.de/forum/thermage-fd150547#af-post-150547-6650>

Thermage Erfahrung

Die Thermage ist eine der größten Betrügereien, die es in der Schönheitsindustrie gibt. Alle Ärzte, die sich die teuren Geräte angeschafft haben, müssen sie auch anwenden und preisen demzufolge das Verfahren in den Himmel. Ich habe es machen lassen, nachdem ich mich von mehreren namhaften Ärzten habe beraten lassen. Ich bin über 50 Jahre alt und wollte meinen herabsinkenden Hals auffrischen. Fakt ist: Es tut entsetzlich weh! Kein Arzt war hier ehrlich. Es sind schon Wochen vergangen und es ist immer noch schmerhaft - wie nach einem starken Sonnenbrand. Ein gutes Ergebnis ist nicht ersichtlich. Im Gegenteil, die Haut am Hals ist total zerknittert und sieht schrecklich aus. Der Arzt sagt jetzt, es dauert bis zu einem Jahr bis die Haut glatt ist! Und plötzlich spricht er auch darüber, dass es nicht bei jedem klappt und man müsse ja auch noch Botox spritzen und mit einem Laser arbeiten! Ich bin extrem verärgert, nicht nur wegen des herausgeschmissenen Geldes, sondern wegen der Lügerei, der Schmerzen und einem Hals, der schlimmer aussieht als vorher.

nur als Info von KM/Vergleich: Real Self

Beiträge auf <https://www.realself.com/Thermage/reviews?rating=not-worth-it>

The screenshot shows the realself.com website with the following details:

- Header:** realself. (with a logo), Search reviews, photos and more, and a user icon.
- Main Navigation:** TREATMENTS, VIDEO, FIND A DOCTOR, ASK A DOCTOR, STAR.
- Section Title:** Thermage
- Sub-navigation:** Reviews, Cost, Photos, Providers, Q&A, Guides, Videos, Forum.
- Breadcrumbs:** Treatments > Thermage
- Rating:** 48% (WORTH IT) based on 29 Ratings.
- Description:** Thermage uses radiofrequency energy to smooth and tighten skin. The applicator targets energy to stimulate collagen production beneath the skin's surface. There is no downtime, but it can take months and multiple treatments to see results. [LEARN MORE](#).
- Call-to-action:** Choosing a doctor? [FIND DOCTORS NEARBY](#), AVERAGE PRICE: 2,432 CHF, START YOUR REVIEW.
- Section:** Community Reviews & Photos (with a red arrow pointing to it).
- Filter Options:** Narrow 398 reviews by: Not Worth It, All - Popular, All - Age.
- Sort Options:** Sort by: Best match, Recent, Nearby, Comments.
- Text:** *Treatment results may vary.

Hochfrequenz Diathermie - Elos

ELOS-Technologie (Elos = elektro-optische Synergie). Das Gerät nutzt einen kombinierten Impuls aus Lichtblitz, Radiofrequenz und Kühlung dazu, kleine Unregelmäßigkeiten an der oberen Hautschicht abzutragen und die Bildung von körpereigenem Kollagen anzuregen.

Erfahrungsbericht User maximilian_bf vom 01.12.11 auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/59597-thermage-behandlung-bzw-thermalifting-ohne-skalpell-14.html>

„Ich habe 2006 eine ELOS-Behandlung 2x im Gesicht durchführen lassen, eigentlich nur, um einige Äderchen veröden zu lassen.“

Das Ergebnis war, dass meine Haut ausgehend von einem sehr jugendlichen und extrem glatten Zustand immer mehr verknitterte, punktuell vernarbte und zunehmend unnatürlich aussah.

Mit der Zeit höhnten sich v.a. die Augenpartien zunehmend aus, wohl durch den von Dir beschriebenen Fettabbau. Bis heute wirken die Backen abgeflacht und abgesunken, die Nase dürrer, die Mundpartie abgesunken und die Augen kleiner (wie auch immer das möglich ist).

Vor 3 Monaten ... haben verschiedene Hautärzte mir eine Mikrodermabrasion empfohlen, um die durch ELOS entstandenen Verhorungen vorsichtig abzutragen. ... Ergebnis: viel hat sich nicht getan...

Obiger User hat diesen Beitrag auch auf <http://www.patient-zu-patient.de/phpBB3/viewtopic.php?f=8&t=190&p=27259&hilit=ELOS#p27259> veröffentlicht

Cold Atmospheric Plasma - Plasma Pen

Johann am 23.10.2017 auf

<https://www.estheticon.de/diskussion/tranensacke-entfernen/erfahrungen-mit-plasma-pen-fur-unterlidkorrektur-i188222>

Ich suche eine Methode für eine etwas schwierigere Unterlid –Behandlung im Raum Osnabrück/Münster. Schwellungen und Malar-Bags. Hat jemand Erfahrungen mit dem Plasma-Pen?

Antwort Prof. Dr. med. Ernst Magnus Noah, Facharzt für Plastische und Ästhetische Chirurgie am 24.10.2017 ebenda

Hallo,

Im Internet gibt es nun Plasma PEN ab 10€ zu kaufen, dies führt dazu bzw. wird dazu führen, dass auch Laien das Gerät anwenden. Die frei erhältlichen Geräte haben kein CE und sind in den falschen Händen als gefährlich einzustufen.

Die Geräte machen eine thermische Schädigung. Egal ob da etwas von 4 Dimension und Molekülnebel fabuliert wird. Wir haben das Top Gerät von einem hoch erfahrenen Kollegen demonstriert bekommen.

Ergebnis : je dicker die Haut, desto besser das Ergebnis , sehr gut bei Lippenfalten bei tatsächlich stärker Hautverdickung. Vorsicht beim Unterlid. Hier haben wir Pigment Ablagerungen, die wir nun behandeln.

Unser Test bei 4 Personen mit Lippe und Unterlid hat mir die Power der Geräte gezeigt. Bei der richtigen Indikation und bei einer gewissen Widerstandsfähigkeit der Hautpartien, ist es eine Behandlungsoption. Aber es ist eine Art Verbrennung! Das muss dem Behandler bewusst sein. Dieser MUSS zum einen Arzt sein und zum anderen Erfahrungen in der Behandlung von thermischen Verletzungen haben. Wenden sie sich an Plastische Chirurgen und Dermatologen. Lassen Sie die Haut gut untersuchen. Bei Malarbags muss komplexer behandelt werden, bei Tränensäcken hat es keinen Sinn mit Plasma zu arbeiten.

Wir sind auf der Suche nach den besten Gerät und testen nächste Woche weiter.

Also: interessante Technik, optimales Gerät noch nicht gefunden, Respekt vor der Power!

Mit freundlichen Grüßen

Prof. E.M. Noah

PS. Die Abheilung ist nicht unkompliziert. Sie werden einen Schorf haben und sind ca 10- 14 Tage nicht voll gesellschaftsfähig!

Elein im Februar 2017 auf <https://www.combeauty.com/lidstraffung-ohne-op-mit-plasma-was-ist-davon-zu-halten.html>

Lidstraffung ohne OP mit Plasma - was ist davon zu halten?

Antwort pauline6424 ebenda

.... ich finde nicht das man da einen großen unterschied sieht....

...wenn die schwelling weg ist, sieht man fältiger wie vorher aus

...ich würde das nie wieder machen lassen.

User mica321 am 15.12.2017 auf

<http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/523399-erfahrungen-und-warnung-vor-plasmage-plasma-pen-behandlung-augenlider-etc.html>

ich habe vor knapp 5 Wochen eine Plasmage Behandlung (Plasma Pen) an den Augenlidern (oben u. unten), zusätzlich an Ober-und Unterlippe und den Nasolabialfalten durchführen lassen.

...Ich gehe seit 5 Wochen nicht mehr aus dem Haus. ...Ich fühle mich total entstellt und könnte beim Blick in den Spiegel nur heulen.... kann nur dringend von dieser Behandlung abraten.

Antwort Atos am 27.12.2017 ebenda

...Ich selbst habe eine Plasma Pen Behandlung an den Oberlidern vor 6 Monaten durchführen lassen, welche zu Verbrennungsschäden und damit verbundener Narbenbildung (Ersatzgewebe) geführt hat. Damit einhergehend neben teils heftigen Spannungen in den Lidern auch Reduktion des stützenden Gewebes und vermehrte Faltenbildung...

Julia_dus am 09.09.2017 auf

<http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/517231-narben-nach-plasma-pen-behandlung.html>

... Ich habe mir vor knapp 4 Wochen die Oberlider wie auch die Zornesfalte, Stirnfalten und die Nasolabialfalten mit dem Plasma Pen behandeln lassen. Nun, Falten wie auch Schlupflider sind genauso vorhanden wie vorher und ich um knapp 450€ ärmer.

...Zornesfalte wie auch Nasolabialfalten sind noch stark rot und haben die Struktur von Narbengeweben angenommen. Ohne Camouflage-Makeup kann ich gar nicht rausgehen... ich bin total entstellt.

Antwort mis_cid am 19.10.2017 ebenda

... Ich habe mir auch vor 7 Wochen die Augenlider mit dem Plasma Pen behandeln lassen... Das Ergebnis ist bei mir auch = 0 und ich bereue diese Behandlung. Ich habe 350 € für die Behandlung bezahlt die eigentlich noch eine Nachbehandlung beinhaltet. Da ich mit dieser Tortur mit null Ergebnis ehrlich gesagt nicht nochmal antun möchte, überlege ich es lassen.

Ich glaube, deine Kosmetikerin als auch Meine haben mit einer zu hohen Frequenz gearbeitet und die Haut zu stark verbrannt.

Antwort Jay7 am 19.10.2017

Hallo, habe ebenso Augenlider behandeln lassen. Bis heute 5 Monate nach d Behandlung sind weiterhin kleine Löcher / Punkte eher Verbrennungsnarben zu sehen und die Haut ist fältiger als zuvor. Es ist mit der Zeit weniger geworden. Denke aber dieses Ergebnis bleibt.

Die 2te Behandlung nehme ich nicht wahr. Das nächste Mal gibt es einen OP-Eingriff.

Antwort lateb am 21.02.2018

Ich habe die Behandlung vor 4 Wochen machen lassen (Oberlider und Zornesfalte). Die Augen sehen jetzt wie vorher aus - nichts geändert, aber dafür wenn man ganz genau hinschaut, da sind die kleinen Punkten (wie Verbrennungen) sichtbar.

Meine Zornesfalte sieht katastrophal aus! Sie ist gerötet und sieht so aus wie da sich eine Narbengeweben gebildet hat.

Antwort ski_haase am 15.02.2018

ich hatte ebenso eine Plasmabehandlung am 11.11.2017 und wie Greek13 hatte ich auch die Nasolabialfalte. ...ich kann Euch nur raten die Finger davon zu lassen. Ich sah aus wie ein Indianer und hatte auch so dicke Krusten etc. Heute nach über 3 Monaten habe ich immer noch Punkt-Narben... Ich denke die Kosmetikerin hat den Pen zu lange und zu tief bei mir draufgehalten, die Schmerzen dabei waren extrem und die Schmerzen am nächsten Tag unerträglich!!!

Auch in diesem Thread: mehrere gelöschte Beiträge:

■ 02.02.2018, 13:35

Redaktion_Akte

Dieser Beitrag wurde von [mkr](#) gelöscht.

Grund

AGB-Verstoß

■ 02.02.2018, 13:36

Redaktion_Akte

Dieser Beitrag wurde von [R-rosa](#) gelöscht.

Grund

AGB Verstoß

In einem anderen (nicht kritischen) Thread – als Beispiel dafür, dass die Foren von Profis überwacht werden:

User Molu1958, Anzahl Beiträge: 3 (alle untereinander) auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/488816-plasma-pen-ersetzt-lidstraffung-4.html>

Beitrag1 Molu1958 am 21.02.2017

AW: Plasma Pen ersetzt Lidstraffung ?

Hallo Mal in die Gruppe und zum Thema SCHLUPFLIDER und Plasmapenbehandlungen. Ich biete diese Behandlung nun schon eine Weile an. Es gibt diesen Plasmapen ja erst seit etwas über 1 Jahr.

Ich selbst habe meine SCHLUPFLIDER schon zum 2.Mal von einer Kollegin bearbeiten lassen und bin mehr als zufrieden....

Beitrag 2 Molu1958:

Selbstbehandlungen kann ich nicht empfehlen. Das Behandlungsfeld muss nach einem fachmännischen Raster bearbeitet werden um die Haut an den richtigen Stellen zu reduzieren. Schnell ist z. B. eine Falte tiefer als vorher, weil der Plasmapen an der falschen Stelle angesetzt wurde. ☺

Beitrag 3 Molu1958 (gelöscht):

...

(Geändert von BRIGITTE Community-Team (23.02.2017 um 10:53 Uhr) Grund: Unerlaubte Werbung)

Noch ein Beispiel für Werbung

The screenshot shows a forum post with two main parts. The first part is a deleted post by 'BeautybyPatI' from April 6, 2017, at 11:37. It contains a message about a deleted post from 'Rotfuchs'. The second part is a reply from 'Krolock' on April 7, 2017, at 20:58, regarding a plasma pen treatment. Krolock asks if a plasma pen replaces lidstraffung and provides a response comparing it to Purebeau treatments.

06.04.2017, 11:37
BeautybyPatI
Dieser Beitrag wurde von [Rotfuchs](#) gelöscht.
Grund
Werbung lt. AGB nicht gestattet

07.04.2017, 20:58
Krolock
Registriert seit: 27.08.2013
Beiträge: 215
AW: Plasma Pen ersetzt Lidstraffung ?
Hallo BeautybypatI,
als Expertin wirst du uns sicher erklären können was der Unterschied zwischen dem Purebeau und den anderen auf dem Markt befindlichen Geräten ist, von billiger China-Ware einmal abgesehen.
Jetzt schon danke für die Unterweisung.
Gruß
Krolock

[Zitieren](#)

Beispiel für Gerätebezeichnung im selben Thread:

User elein 04.03.2017

... Mit welchem Plasma Pen (Marke) wurdet Ihr behandelt? Es gibt ja verschiedene Geräte, die sich eventuell auch in der Qualität unterscheiden können und somit auch unterschiedliche Ergebnisse bringen können.

Antwort

babeloo am 05.03.2017

*Soweit ich weiß gibt es 3 oder 4 verschiedene Geräte. Ich würde mit dem **PlaCo Gerät** behandelt, meine Freundin mit einem sehr teuren (Marke muss ich noch einmal erfragen) . Die Ergebnisse sind absolut identisch. Bei Beiden ist nicht so ganz viel passiert. Warte auf die 2.te Behandlung.*

Antwort Irie-bella am 08.03.2017:

*ich habe es jetzt machen lassen vor 5 Tagen. Bei mir wurde der **Accor Plasma Pen** benutzt. Ich denke schon, daß eine 2. Behandlung nötig sein wird.*

Antwort Lilithdaenmon am 13.03.2017

*erste Behandlung mit dem **Accor Plasma Pen** ist jetzt 2,5 Wochen her und der Effekt ist gleich Null In 4 Wochen soll die 2. Behandlung gemacht werden - sehr optimistisch bin ich nicht mehr.*

Antwort Cinderella3468 am 20.03.2017

*Ich bin Heilpraktikerin und Kosmetikerin und arbeite auch mit dem **Purebeau Plasmapen**. Falls ihr Fragen dazu habt, beantworte ich sie gerne.*

Krolock am 22.03.2017

Auch ich habe Interesse an dieser Form der Lidstraffung.

Ich habe recherchiert und nichts darüber gefunden, welches Gerät denn zu empfehlen ist, welches ist stärker usw.

Erfahrungsbericht mit Bildern im Beauty-Blog AVAGANZA Fashion und Lifestyle

<http://avaganza.com/allgemein/augenlidstraffung-mittels-plexr-was-ihr-darueber-im-internet-nicht-lest/>

Stand am 1. März 2018

Die Bloggerin antwortet auf die Nachfrage, wie es ihr heute geht:

Liebe Michaela,

aufgrund sämtlicher Bemühungen haben sich die Narben sehr verbessert, sind aber bleibend vorhanden :-(. Nachdem die Klinik zu keiner außergerichtlichen Lösung bereit war und ist, geht diese leidige Geschichte jetzt zu Gericht. Nachdem bei meiner Aufklärung grobe Fehler passiert sind, wird das wohl strafrechtlich relevant sein. Aber das müssen jetzt Gerichte klären. Ich werde in diese Klinik keinen Fuß mehr setzen ...

Liebe Grüße

Verena

Elektrostimulation - TENS

Quelle: https://www.medicinenet.com/transcutaneous_electrical_nerve_stimulation/patient-comments-3961.htm

Question: Did you experience any side effects from transcutaneous electrical nerve stimulation?

Comment from: Linda 68, 65-74 Female (Patient) Published: March 21

I used a transcutaneous electrical nerve stimulation (TENS) machine and it shorted out, raining a blister on my upper hip, right below my waist. It's been almost three months and the tissue is still blackish brown. It seems to be keeping me from taking a normal step in walking and I cannot walk more than 20 or 30 feet before giving out. Before this, I was walking 3 miles daily.

Comment from: JACKIE, 45-54 Female (Patient) Published: May 06

Yes, I have noticed my anxiety is acting up with the use of the TENS (transcutaneous electrical nerve stimulation) machine. I don't have pain but I suffer from leg spasms.

Comment from: Robert roberts, 75 or over Male (Patient) Published: March 22

After a fall a few months ago I went to a physiotherapist for help with hip pain. She fastened the TENS (transcutaneous electrical nerve stimulation) unit and said I could change the setting. I did. I possibly set it too high. I had no experience with this technology. Now I have what seems to be sciatica or a pinched nerve. I can't prove but I relate it to the use of TENS. Keep the settings low to avoid nerve damage is my advice if I ever use TENS again.

Comment from: RAOatesy, 25-34 Female (Patient) Published: August 18

Even on the lowest setting, TENS (transcutaneous electrical nerve stimulation) quickly made the rheumatoid arthritis affected joints in my feet hurt worse.

Comment from: Prof Sanchez, 55-64 Male (Caregiver) Published: January 02

Every time they use transcutaneous electrical nerve stimulation on my neck I leave confused, disoriented and my memory is slow. My mother's physical therapist used TENS on my mother and I watched, learned and was oriented on where never to put the patches and electrodes. One of the areas is on the neck. Stimulation should not be applied to the neck. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck could also have adverse effects on the heart

rhythm or blood flow. This disorientation you are feeling may be due to the reduced blood flow to your brain. I would consult the physician, and the person who is giving you these therapies. It should be a trained medical professional. TENS placed in the wrong locations can do more harm than good. If placed correctly, it works wonders. Take care and hope this info helps.

Comment from: duffy, 55-64 (Patient) Published: March 23

Transcutaneous electrical nerve stimulation works great for my pain from a stroke and lead poisoning side effect of severe joint arthritis. But it seems to activate making my Tourette syndrome episodes.

Comment from: eyb, 55-64 Female (Patient) Published: February 08

I have had no side effects from transcutaneous electrical nerve stimulation (TENS) for me yet! I had left knee swelling and pain for the past two years and over the past three months it had grown to the point of my having to take Aleve twice a day, rub with Bengay and wear a brace. I have no recollection of injury but have iced it forever. I am a walker, not a runner and I try to stick to grass and dirt, not asphalt or cement. My coworker suggested I try a TENS unit. One 15 minute session at level 9 on the knead mode zapped the pain. I couldn't believe it, wasn't sure it would last. The next day, no swelling, no sharp pains, but I wore the brace to work just in case the treatment failed. A week and the pain has not returned. Three fifteen minute sessions I have had.

Comment from: joseph, 55-64 Male (Patient) Published: November 11

I have started feeling tinnitus after taking transcutaneous electrical nerve stimulation (TENS) for a week on my neck for cervical spondylosis.

Comment from: Jane, 55-64 Female (Patient) Published: September 21

I used a TENS (transcutaneous electrical nerve stimulation) unit on my shoulders and upper back. After a few days of intermittent use, my anxiety has gone through the roof. It may not be related, just wondered if anyone else had such an experience.

Comment from: jmaisoui813, 55-64 Female (Patient) Published: May 19

Every time they use transcutaneous electrical nerve stimulation on my neck I leave confused, disoriented and my memory is slow.

1.4 Anhang 4: Social Media Analyse – Kontrolle (Laser)

Foren mit Berichten über Nebenwirkungen

[forum.haarpunkt.com](#)

tattooentfernung negative Erfahrungen 4, Verbrennung, Narbenbildung

[gutefrage.net](#)

tattooentfernung negative Erfahrungen 4, Narbenbildung, Tattoo weiterhin sichtbar

[bfriends.brigitte.de](#)

tattooentfernung negative Erfahrungen 6, Narbenbildung, Tattoo weiterhin sichtbar

[blog-de.remove-tattoo-skinial.com](#)

tattooentfernung negative Erfahrungen 2

Foren ohne Treffer zu Nebenwirkungen

patient-zu-patient.de

beauty.gofeminin.de

biowellmed.de

estheticon.de

combeauty.com

test.de

mein-erfahrungsbericht.de

kennstdueinen.de

treatwell.de

doc-tattooentfernung.com

Zitate

1. Fraxel-Laser

Erfahrungsbericht Zelli123 vom 16.06.2009 auf <http://bfriends.brigitte.de/foren/schoenheitsbehandlungen/112774-hilfe-rote-flecken-nach-fraxel-behandlung-im-gesicht.html#post5939505>

Hallo zusammen,

ich habe mich jetzt durch diverse Foren gewühlt, aber irgendwie keine Antwort auf meine Frage bekommen.

Ich habe - meiner Meinung nach durch die Hormonspirale - einige größere Pigmentflecke im Gesicht bekommen, die mich extrem gestört haben. Ich habe zwar Sommersprossen, aber die sind absolut okay, und gehören zu mir. Mein Hautarzt sagte, kein Problem, das fraxeln wir weg. Kosten 107,- Euro pro Behandlung. Man würde so 2-3 brauchen, je nach dem, wie die Haut darauf reagiert.

Am Behandlungstag wurde mir dann Betäubungscreme ins Gesicht geschmiert, die ca. 2 Stunden drauf blieb. Dann wurde genau festgelegt, wo gefraxelt wird, und ich dachte okay, wenn wir schon mal dabei sind: Stirn, Oberlippe, der Fleck am Nasenflügel, ein Fleck linke Wange, zwei Flecken rechte Wange, soll sich ja lohnen.

Das Fraxeln selber war ein echter Alptraum. Die Schmerzen waren kaum auszuhalten. Ich hab dann irgendwann wohl die Luft angehalten, bis mein Arzt meine ich sollte doch weiteratmen. Mir liefen die Tränen in Strömen. Ich hab gedacht, das brennt mir das Gesicht weg.

Nach der Behandlung war mein Gesicht feuerrot. Eine Stunde lang hat das so gebrannt, daß ich im Auto nur vor der kalten Lüftung sitzen konnte.

Abends konnte man dann zwar schon sehen, daß die Pigmentflecke auf die Behandlung reagiert haben. Die dicken Flecke konnte man einfach wegreiben mit dem Finger. Ich habe mich dann mit einer vom Arzt mitgegebenen Creme eingecremt.

Am nächsten Morgen sah ich aus, als wenn ich unter einen Bus gekommen wäre. Dicke rote Flatschen überhall mit leicher Verkrustung. Beim Arzt wurde das ganze fotografiert. Die Rötung wäre aber absolut normal.

Es hat über zwei Wochen gedauert, bis mein Gesicht sich soweit erholt hatte, daß ich mich wieder schminken konnte, und ich habe normalerweise gutes Heilfleisch!!

Jetzt zu meinem Problem: Ich habe bis heute rote Flecken an den Stellen, an denen gefraxelt wurde. Auf meiner Oberlippe liegt immer ein leichter Schatten, so als ob ich einen Oberlippbart hätte. Zwei dicke rote Flecken auf den Wangen, auf der Nase. Horror, ich bin total unglücklich.

Die Frage ist jetzt: Ist das normal?????? Geht das wieder weg? Mein Arzt hat sich da auf kein Gespräch eingelassen. Ja, ja ist normal. Das ganze ist jetzt etwas über 2 Monate her.... Ich bin total frustriert, denn ich sehe schlimmer aus als vorher. Ich hab shcon eine Creme gekauft, die so ähnlich wie Narbencreme wirken soll. Bis jetzt noch keine Erfolge!

Hat irgendjemand eine Idee? Ich hab einfach Angst, daß das jetzt so bleibt,. Ohne Puper geh ich nicht mehr aus dem Haus. Meine Haut sieht einfach total fleckig aus, und das war vorher nicht so.

Lieben Dank im Voraus und viele Grüße

Zeli123

Antwort von Gina38 ebenda

Hallo,

Deine Erfahrung deckt sich mit der, die in amerikanischen Foren beschrieben wurde.

Bitte google die Worte Worte "was it worth it" in Kombination mit "fraxel". Du kommst dann zu einem Forum in den USA indem viele Frauen von Ihrer Erfahrung mit Fraxel Lasern berichten.

Ca. 50 % der Frauen berichten nach dem Fraxel Laser über negative Hautveränderung z.B. Fettverlust im Gesicht, plötzliche Alterungsschübe der Haut, Pigmentverschiebungen, Pigment-artig trockene Haut, und ähnlich unschöne Erscheinungen. Die anderen ca. 50 % äußern sich positiv.

Hoffentlich geht gehörst auch Du bald zu den zweitgenannten 50%. Ich drücke Dir ganz fest die Dauermen :-)

Liebe Grüße,

Gina38

Antwort von mariska ebenda

Ich warn jetzt hier nochmal alle eindringlich davor, sich mit diesen durch die oberste Hautschicht dringenden Lasern behandeln zu lassen. Die sollen zu einer Neubildung von Collagenfasern in der Tiefe der Haut führen. Es besteht aber immer das Risiko von Pigmentverschiebungen, rascher Hautalterung und Fettverlust. Ich habe das selbst erlebt: Fettverlust und Pigmentverschiebungen sind bei mir die Folge. Es ist ein Drama... Wenn das Kind sozusagen schon in den Brunnen gefallen, würde ich empfehlen nach so einer Behandlung konsequent einen extrem hohen Lichtschutz anzuwenden, damit nicht noch mehr Pigmentflecken entstehen.

Tattoo-Entfernung

Frage

von Kathleen384 auf <https://www.gutefrage.net/frage/bei-tattooentfernung-mit-dem-laser-verbrannt-am-04.05.2017>

Bei Tattooentfernung mit dem Laser verbrannt?

Hallo Zusammen, am Montag hatte ich meine 3. Lasersitzung. Diese war auch schmerzhafter gegenüber den anderen Beiden. Am nächsten Morgen, als ich den Verband abnahm, sah ich eine große Brandblase (ca. 1 cm Durchmesser) und mehrere kleinere. Die große Blase ist nach kurzer Zeit geplatzt und es kam eine Neue kleinere an der selben Stelle. Hatte das jemand schon mal? Kann man gegen die Klinik vorgehen? Was würdet ihr machen?

Antwort

von Doctare „Business“ ebenda

Hallo Kathleen384, bist Du bei allen 3 Behandlungswiederholungen in der gleichen Klinik gewesen und bist Du mit dem selben Lasersystem behandelt worden? Eine Blasenbildung nach der Laserbehandlung ist nicht unüblich. Wenn es sich um ein professionelles Lasersystem gehandelt hat mit dem Du behandelt wurdest, dann kann man "Verbrennungsblasen" fast ausschliessen. Die Blasen, die sich am gelaserten Hautareal entwickeln, sind meist Folge von massiver Pigmentzertrümmerung. Gute Nano- oder Pikosekundenlaser arbeiten mit ihren milliarden- oder billionen Sekunden kurzen Laserimpulsen im Bereich der kalten Ablation bzw. Absorption. Trotzdem handelt es sich um viel Energie, die da auf Deinen Körper einwirkt. Dein davon angeregtes Immunsystem versucht nun nach der Laserbehandlung die ganzen Fremdstoffe (Pigmenttrümmer), die da ja eigentlich nicht hingehören, aus Deinem Körper so schnell wie möglich auszuschwemmen. Sprich, Dein Lymphsystem spült neben den eigentlich für den Abtransport tätigen Fresszellen (Makrophagen) die Pigmente aus der Haut/ aus dem Körper aus. Es bilden sich Blasen mit Lymphflüssigkeit, die aussehen wie Brandblasen. Sind sie aber nicht unbedingt. Tipp: Pflege die Blasen. Bitte nicht selber aufstechen. Wenn sie von alleine platzen - nun denn. Verwende Cremes zur Heilungsunterstützung (z.B. Bepanthen, Laser Aftercare und Co) und schütze die Hautstelle vor Reibung und weiterem Schaden. Bitte nur mit klarem Wasser reinigen und trocken tupfen - nicht rubbeln mit dem Handtuch. Es muss sich erst eine neue und stabile Hautschicht darunter bilden. Die Blasen, die entstanden sind, schützen die Haustelle eigentlich vor Infektionen und ähnlichem. Ist diese Hautschicht verletzt, musst Du das in der Nachsorge und Pflege für Deinen Körper übernehmen. Leider kennen wir Deine gelaserte Haustelle nicht. Sprich daher am besten mal mit Deinem Lasertherapeuten. Wir spekulieren aber mal, dass es sich eben nicht um Brandblasen handelt. Die können vor allen Dingen entstehen, wenn Billiglaser im Spiel sind, die mit ihren schlechten Laserimpulszeiten zu lange mit zu viel Energie auf die Haut einwirken. Wenn Du Fragen hast, dann melde Dich gerne mit einer PN bei uns. Viele Grüße.

Userin valent auf <http://forum.haarpunkt.com/dauerhafte-haarentfernung-laser-shr-ipl-geraeten/6008-schlechte-erfahrung-inos-geraeten-haarentfernung.html>

Bei mir hat das INOS Gerät auch nicht funktioniert, ich habe schwarze Haare. Ich wurde stark verbrannt mit Narbenbildung.

1.5 Anhang 5: Informationsblatt, Fragebogen, Aufruf



FSM – Forschungsstiftung
Strom und Mobilkommunikation
FSM – Swiss Research Foundation for
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Kosmetik, Wellness und die Gesundheit – EMF-Quellen ausserhalb der Medizin.

Systematische Erfassung und Charakterisierung von hoch- und niederfrequenten Quellen einschl. Ultraschall im gewerblichen Bereich und in der Anwendung für zuhause

Kontext

Zunehmend werden EMF-Quellen und Ultraschall emittierende Geräte zu kosmetischen Zwecken oder im Sport- und Wellness-Bereich eingesetzt. Auch für private Nutzungen werden solche Anwendungen üblich. Es ist nicht immer klar, ob und für welche Nutzergruppen gesundheitliche Gefährdungen – if any – mit diesen Geräten verbunden sind. Das Bundesamt für Strahlenschutz hat dieses Projekt finanziert, um genau das herauszufinden.

Interessierende Anwendungen

Provisorische Liste von ausgewählten Anwendungen / verwendeten Therapiebegriffen im Zusammenhang mit den interessierenden Produkten (alphabetische Liste):

Cold Atmospheric Plasma (CAP) / kaltes Atmosphären-druck Plasma	Microcurrent electrical neuromuscular stimulation (MENS) / Mikro(strom)elektrotherapie
Diathermy / Diathermie	Plasma Skin Regeneration (PSR) / Plasma Hautverjüngung
Electric Muscle Stimulation (EMS) / Elektrische Muskelstimulation (auch: neuromuscular electrical stimulation NEMS / neuromuskuläre Elektrostimulation, Elektromyostimulation)	Pulsed Signal Therapy / gepulste Signaltherapie
Galvanic Treatment / Galvanische Behandlung (auch: Cosmetic Electrotherapy / kosmetische Elektrotherapie)	Sonography / Sonografie (siehe Ultrasound Therapy)
High Frequency Therapy / Hochfrequenztherapie	Transcranial Direct Current Stimulation (TDCS) / Transkranielle Gleichstrom Nevenstimulation
Infrasound Therapy / Infraschall-Therapie	Transcranial Magnetic Stimulatin (TMS) / Transkranielle Magnetfeldstimulation
Ionstream Therapy / Ionenstrom-Therapie	Transcranial Alternate Current Stimulation (tACS) / Transkranielle Wechselstrom Nevenstimulation
(pulsed) Ultrasound Therapy / Gepulste Ultraschall-Therapie (auch: Sonography / Sonographie)	Transcutaneous Electric Nerve Stimulation (TENS) / Transkutane elektrische Nervenstimulation
Magnetic Field Stimulation / Magnetfeldstimulation (auch: (pulsed) magnetic field therapy / gepulste) Magnet-feldtherapie)	Neuromuscular electrical stimulation NEMS / Elektromyostimulation (siehe: EMS)

Abgrenzung

Ausgeschlossen sind rein medizinische EMF-Anwendungen die ärztliches Fachwissen erfordern. Sodann sind auch diagnostische Medizingeräte ausgeschlossen, die Elektroden und Antennen nutzen, um bioelektrische Signale – insbesondere das EEG, das EKG – aufzuzeichnen.

Unser konkretes Anliegen

Abschätzung / Erfassung von Nebenwirkungen obiger Anwendungen. In wenigen Minuten kann dazu der beigelegte Fragebogen ausgefüllt werden. Wir danken Ihnen ganz herzlich für Ihre Mitwirkung!



FSM – Forschungsstiftung
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Kurzfragebogen Kosmetik- und Wellnessprodukte

Ihre Organisation

Name:

Kontaktadresse:

Kontaktperson (falls wir Sie/Ihre Organisation nochmals kontaktieren möchten):

Name:

Email:

Telefon:

Informationen zu Vorfällen und Nebenwirkungen

Haben Sie Kenntnis / Meldungen von Vorfällen mit Produkten, welche elektromagnetische Felder oder Schall für Kosmetik-, Sport/Gesundheits- und Wellnesszwecke einsetzen?

- Ja
 Nein

Anmerkung:

Falls ja

Könnten Sie in wenigen Stichworten Art und Umfang Ihrer Kenntnisse (Daten/Meldungen) angeben?

Dürften wir Ihre Daten / Informationen für die vorliegende Studie nutzen (Vertraulichkeit zugesichert)?

- Ja
 Nein

Anmerkung:

Ist es grundsätzlich denkbar, einen Aufruf auf Ihrer Website / Printmedium / etc. zu schalten, um bei ihren Mitgliedern bzw. Ihren Leserinnen und Lesern oder weiteren Ansprechpersonen aktiv nach Vorfällen zu fragen?

- Ja
 Nein

Anmerkung:

Anderes

Haben Sie noch Bemerkungen / Anmerkungen?

Mit der Bitte um Rücksendung bis 23.02.2018.

Elektronische Rücksendeadresse: info@emf.ethz.ch, postalisch: FSM – Forschungsstiftung Strom und Mobilkommunikation, c/o ETH Zürich, Gloriastr. 35, CH-8092 Zürich.

c/o ETH Zürich, IEF ETZ K89, Gloriastrasse 35, CH - 8092 Zürich

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Nebenwirkungen von Kosmetik- und Wellnessgeräten?

Haben Sie mit Kosmetik- und Wellnessgeräten, die elektrische Ströme, magnetische Felder oder Ultraschall verwenden (z.B. zur Muskelstimulation, Entspannung, kosmetischen Therapie, etc.) schon negative Erfahrungen gemacht (Hautirritationen, Unwohlsein, Schmerzen, Verletzungen)? Für ein Forschungsprojekt möchten wir abklären ob es solche Fälle gibt.

Bitte schreiben Sie uns. Die Informationen werden streng vertraulich gehandhabt. Vielen Dank!

Email: info@emf.ethz.ch, postalisch: FSM – Forschungsstiftung Strom und Mobilkommunikation, c/o ETH Zürich, Gloriastr. 35, CH-8092 Zürich, Schweiz.

1.6 Anhang 6: Literatur

1.6.1 Zitierte Literatur

1.6.2 Ausgewählte Literatur: Abstracts und Kommentare

EMF Generell

Investigation of assumptions underlying current safety guidelines on EM-induced nerve stimulation

E. Neufeld et al 2016 Phys. Med. Biol. 61 4466

The EM simulation results are in agreement with previous publications. The results show that field inhomogeneity affects stimulation thresholds; therefore, local field strength-based limits might be insufficient and coupled EM-NEURON simulations are necessary. Realistic anatomical models are required to determine the inhomogeneous fields. Temperature has only a minor impact on the stimulation threshold, but strongly affects neuronal dynamics.

Numerische Studie zur Untersuchung der Validität der den Grenzwerten zugrundeliegenden Annahmen. Als wichtige Voraussetzungen werden realistische anatomische Modelle identifiziert. Im Weiteren wird die Gültigkeit von Grenzwerten basierend auf lokalen Feldwerten in Frage gestellt. Vorgeschlagen werden erweiterte Modelle, die numerische Simulationen von Nervenstimulation zulassen.

Elektrische Stimulation

General

The safety of electrical stimulation in patients with pacemakers and implantable cardioverter defibrillators: A systematic review

J. Badger, P. Taylor, I. Swain

Journal of Rehabilitation and Assistive Technologies Engineering, Volume 4: 1–9, 2017

Introduction: A number of patients are excluded from electrical stimulation treatment because there is concern that electrical stimulation could cause electromagnetic interference with pacemakers and implanted cardioverter defibrillators. The decision to use electrical stimulation in these patients needs to be supported by an assessment of benefit and harm.

Methods: We conducted a systematic review of the risk of electromagnetic interference between electrical stimulation and pacemakers or implanted cardioverter defibrillators. We included the electronic databases MEDLINE and EMBASE in the time period between 1966 and 26 August 2016.

Results: 18 papers fulfilled the inclusion criteria (eight safety studies and ten case studies). Although we were unable to accurately estimate the risk of electromagnetic interference, the studies revealed that patients having electrical stimulation of the lower limb are less susceptible to electromagnetic interference.

Conclusions: The results suggest that electrical stimulation could be used safely to help drop foot in

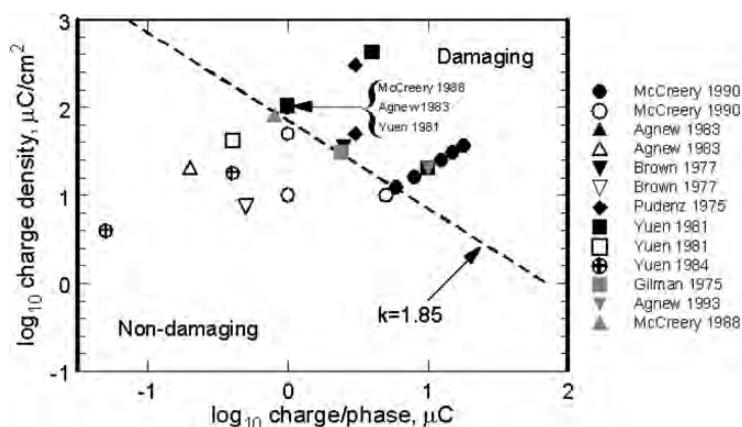
patients with pacemakers or implanted cardioverter defibrillators. However, in order to obtain an accurate estimate of the risk of electromagnetic interference, a large, long-term, and intervention-specific safety study is required. Until such a study is undertaken, electrical stimulation should be used with caution in patients with pacemakers and implanted cardioverter defibrillators.

Bewertung von elektrischer Stimulation im Zusammenhang mit Patienten mit Implantaten. Forderung nach einer gross angelegten, interventionsspezifischen Langzeitstudie. Warnung bezüglich Anwendung von elektrischer Stimulation in Patienten mit Herzschrittmachern und implantierten Defibrillatoren.

Topical Review: Tissue damage thresholds during therapeutic electrical stimulation

S. F. Cogan, K. A. Ludwig, C. G. Welle, P. Takmakov
J. Neural Eng. 13 (2016)

Objective. Recent initiatives in bioelectronic modulation of the nervous system by the NIH (SPARC), DARPA (ElectRx, SUBNETS) and the GlaxoSmithKline Bioelectronic Medicines effort are ushering in a new era of therapeutic electrical stimulation. These novel therapies are prompting a re-evaluation of established electrical thresholds for stimulation-induced tissue damage. **Approach.** In this review, we explore what is known and unknown in published literature regarding tissue damage from electrical stimulation. **Main results.** For macroelectrodes, the potential for tissue damage is often assessed by comparing the intensity of stimulation, characterized by the charge density and charge per phase of a stimulus pulse, with a damage threshold identified through histological evidence from *in vivo* experiments as described by the Shannon equation. While the Shannon equation has proved useful in assessing the likely occurrence of tissue damage, the analysis is limited by the experimental parameters of the original studies. Tissue damage is influenced by factors not explicitly incorporated into the Shannon equation, including pulse frequency, duty cycle, current density, and electrode size. Microelectrodes in particular do not follow the charge per phase and charge density codependence reflected in the Shannon equation. The relevance of these factors to tissue damage is framed in the context of available reports from modeling and *in vivo* studies. **Significance.** It is apparent that emerging applications, especially with microelectrodes, will require clinical charge densities that exceed traditional damage thresholds. Experimental data show that stimulation at higher charge densities can be achieved without causing tissue damage, suggesting that safety parameters for microelectrodes might be distinct from those defined for macroelectrodes. However, these increased charge densities may need to be justified by bench, non-clinical or clinical testing to provide evidence of device safety.



Figur 1: Damaging and non-damaging levels of electrical stimulation of non-human brain with planar macroelectrodes using $k = 1.85$ in the Shannon equation to delineate the boundary between damaging and non-damaging stimulation. Black and gray solid symbols = tissue damage; open symbols = no damage. Studies referenced (Gilman et al 1975, Pudenz et al 1975, Brown et al 1977, Yuen et al 1981, 1984, Agnew et al 1983, McCreery et al 1988, 1990).

Faradaic versus capacitive charge injection

In a single study, McCreery et al (1988) showed that under equivalent stimulation conditions, Ta/Ta2O5 electrodes operating by capacitive charge-injection were as equally damaging to tissue as platinum electrodes, which inject charge at least partially by faradaic mechanisms. This study supports the assertion that neural hyperactivity rather than the generation of noxious products at an electrode is the first tissue damage mechanism encountered as simulation intensity is increased. Repeating this study with indwelling as well as surface electrodes and including contemporary capacitive and faradaic electrodes such as fractal-TiN and sputtered iridium oxide (Weiland et al 2002, Cogan et al 2009) would usefully confirm the earlier findings. It would also be informative to investigate whether charge density regimes can be identified in which there are differences in the extent and type of stimulation-induced tissue damage between capacitor and faradaic electrodes.

Framework zur Bestimmung der Grenze zwischen Stromstärken die das Gewebe schädigen und denjenigen die das Gewebe nicht schädigen. Es werden verschiedene dafür wesentliche Faktoren beschrieben. Die Bestimmungsformel bezieht sich auf sogenannte Makroelektroden. Erste weiterführende Experimente mit Mikroelektroden weisen darauf hin, dass das die hier diskutierten Sicherheitsparameter nicht auf Mikroelektroden übertragbar sind.

Public Regulatory Databases as a Source of Insight for Neuromodulation Devices Stimulation Parameters

D. Kumsa, G. K. Steinke, G. F. Molnar, E. M. Hudak, F. W. Montague, S. C. Kelley, D. F. Untereker, A. Shi, B. P. Hahn, C. Condit, H. Lee, D. Bardot, J. A. Centeno, V. Krauthamer, P. A. Takmakov
Neuromodulation 2018; 21: 117–125

Objective: The Shannon model is often used to define an expected boundary between non-damaging and damaging modes of electrical neurostimulation. Numerous preclinical studies have been performed by manufacturers of neuromodulation devices using different animal models and a broad range of stimulation parameters while developing devices for clinical use. These studies are mostly absent from peer-reviewed literature, which may lead to this information being overlooked by the scientific community. We aimed to locate summaries of these studies accessible via public regulatory databases and to add them to a body of knowledge available to a broad scientific community.

Methods: We employed web search terms describing device type, intended use, neural target, therapeutic application, company name, and submission number to identify summaries for premarket approval (PMA) devices and 510(k) devices. We filtered these records to a subset of entries that have sufficient technical information relevant to safety of neurostimulation.

Results: We identified 13 product codes for 8 types of neuromodulation devices. These led us to devices that have 22 PMAs and 154 510(k)s and six transcripts of public panel meetings. We found one PMA for a brain, peripheral nerve, and spinal cord stimulator and five 510(k) spinal cord stimulators with enough information to plot in Shannon coordinates of charge and charge density per phase.

Conclusions: Analysis of relevant entries from public regulatory databases reveals use of pig, sheep, monkey, dog, and goat animal models with deep brain, peripheral nerve, muscle and spinal cord electrode placement with a variety of stimulation durations (hours to years); frequencies (10–10,000 Hz) and magnitudes (Shannon k from below zero to 4.47). Data from located entries indicate that a feline cortical model that employs acute stimulation might have limitations for assessing tissue damage in diverse anatomical locations, particularly for peripheral nerve and spinal cord simulation.

Table 1. A List of Key Word Statements Used in the Search.

Key word statements	
DBS preclinical	Epilepsy PMA
PMA animal studies	Sacral nerve stimulation PMA
PMA <i>PMA number</i>	Thoracic nerve stimulation PMA
PMA brain implant	Cervical nerve stimulation PMA
<i>Company name</i> spinal cord stimulation PMA	Lumbar nerve stimulation PMA
<i>Company name</i> cochlear stimulation PMA	Coccygeal nerve stimulation
<i>Company name</i> deep brain stimulation PMA	Vagus nerve stimulation PMA
Chronic pain PMA	Sciatic nerve stimulation PMA
Parkinsonian tremor PMA	Functional electrical stimulation PMA
Bladder control PMA	

The key words statements that were used to search on the FDA.gov website. The variables in *italics* were replaced with the reference words.

Table 2. A List of the Product Codes for Approved Neuromodulation Devices.

Product code	Description
MCM	Implant, cochlear
PGQ	Hybrid cochlear implant
MHY	Stimulator, electrical, implanted, for Parkinsonian tremor
PFN	Implanted brain stimulator for epilepsy
GZB	Stimulator, spinal-cord, implanted (pain relief)
GZF	Stimulator, peripheral nerve, implanted (pain relief)
LHG	Electrode, spinal epidural
LGW	Stimulator, spinal-cord, totally implanted for pain relief
LYJ	Stimulator, autonomic nerve, implanted for epilepsy
EZW	Stimulator, electrical, implantable, for incontinence
PIM	Neuromodulator for obesity
MNQ	Stimulator, hypoglossal nerve, implanted, apnea
GZC	Stimulator, neuromuscular, implanted

Each device gets assigned a product code and (13 relevant product codes have been identified).

Table 3. Stimulation Parameters for PMA Neuromodulation Devices Extracted From Information on Preclinical Animal Studies Found in Public Regulatory Databases.

Device	Anatomy	Animal	f, Hz	Stim, days	P.W., ms	A, cm ²	Q, µC	D, µC·cm ⁻²
*Activa	Brain	8 pigs	185	0.3	0.913–2.0	0.06	9.5–42	159–700
		2 pigs	130	0.3	0.913–2.1	0.06	9.5–42	159–700
		8 pigs	185	60–210	0.415	0.06	N/A	N/A
Neuropace RNS	Brain	5 sheep	N/A	33–200	N/A	0.08	N/A	N/A
Interstim	PNS	3 pigs	N/A	N/A	N/A	0.12	N/A	N/A
Neuro Cybernetic	PNS	6 monkeys	143	3	N/A	N/A	N/A	N/A
	PNS	3 sheep	N/A	90	N/A	N/A	N/A	N/A
*Maestro	PNS	> 12 pigs	5,000	7–84	0.1	0.14	0.72	5.3
Inspire UAS	PNS	8 dogs	N/A	54–84	N/A	N/A	N/A	N/A
NeuroControl Freehand	Muscle	5 dogs	12–16	450–1530	N/A	N/A	N/A	N/A
*Senza	SCS	12 goats	10,000	10	0.02–0.05	0.127	0.004–0.06	0.031–0.47

*These summaries of safety and effectiveness data (SSEDs) had enough information to calculate charge (*Q*, µC) and charge density (*D*, µC/cm²) per phase.

f, stimulation frequency (Hz); Stim, length of stimulation; P.W., pulse width (milliseconds); A, electrode area; PNS, peripheral nerve stimulation; SCS, spinal cord stimulation; N/A, data not available.

Activa (acute): damage detected in 2 out of 9 pigs (simulation vs control); Activa (chronic): damage detected in 4 out of 14 pigs; Interstim: histology showed no "significant adverse effects" for both control and stimulation; Neuro Cybernetic (monkey): no electrical or mechanical damage observed, but compression damage to large axons noted; Neuro Cybernetic (sheep): no nerve fiber damage for both stimulated and control; Maestro: nerve degeneration is observed which is attributed to mechanical stress; Senza: no signs of damage from neurostimulation. The Neuropace RNS, Inspire UAS and Neurocontrol Freehand SSEDs did not provide a clear statement on damage from neurostimulation.

Table 4. Stimulation Parameters for Spinal Cord Stimulators Extracted From 510(k) Summaries Found in Public Regulatory Databases.

Device	510(k)	Control	f, Hz	P.W., ms	A, cm ²	Q _{max} @500 Ω, µC	D _{max} @500 Ω, µC·cm ⁻²
Xtrek (Medtronic)	K883780	Voltage	5–1400	0.05–1	0.1225	14.2	118.3
Matrix (Medtronic)	K934065	Voltage	5–240	0.05–0.5	0.1225	10.8	90
Renew (ANS)	K000852	Current	10–1500	0.05–0.5	0.13*	7.6	58.5
Freedom (2014, Stimwave)	K141399	Current	2–1500	0.05–0.5	0.1272	7.2	56.6
Freedom (2015, Stimwave)	K150517	Current	5–1500	0.05–0.5	0.1272	6.4	50.3

510(k), 510(k) submission number, f, stimulation frequency (Hz); Control, current or voltage control; P.W., pulse width (millisecond); A, electrode area; Q_{max}@500 Ω, µC; and D_{max}@500 Ω, µC·cm⁻², maximum charge per phase and charge density per phase calculated from device stimulation parameters listed in summaries (assuming 500 Ohm load for voltage controlled stimulation).

Zusammenfassung der bisherigen Studien zur Sicherheit von elektrischer Stimulation in Tiermodellen für verschiedenen Anordnungen der Elektroden, Zeitdauer und Signalparameter. Zum Teil vollständige Angaben zu Stromdichten, totale Ladungsmengen und Frequenzbereichen der Anwendungen.

The regulation of cognitive enhancement devices: extending the medical model

H. Maslen, T. Douglas, R. Cohen Kadosh, N. Levy, J. Savulescu

Journal of Law and the Biosciences, 68–93; doi:10.1093/jlb/lst003

This article presents a model for regulating cognitive enhancement devices (CEDs). Recently, it has become very easy for individuals to purchase devices which directly modulate brain function. For example, transcranial direct current stimulators are increasingly being produced and marketed online as devices for cognitive enhancement. Despite posing risks in a similar way to medical devices, devices that do not make any therapeutic claims do not have to meet anything more than basic product safety standards. We present the case for extending existing medical device legislation to cover CEDs. Medical devices and CEDs operate by the same or similar mechanisms and pose the same or similar risks. This fact coupled with the arbitrariness of the line between treatment and enhancement count in favour of regulating these devices in the same way. In arguing for this regulatory model, the paper highlights potential challenges to its implementation, and suggests solutions.

SUMMARY OF OUR PRESCRIPTIVE MODEL FOR THE REGULATION OF CEDS

Based on the above discussion, we recommend the following for the regulation of CEDs:

- CEDs should be regulated within the MDD: the justifications for this are that CEDs have similar mechanisms and risk-profiles to some medical devices and are often essentially the same device; parsimony in legislation is desirable; and the inclusion of some cosmetic implantable and invasive devices sets a precedent for broadening the remit of the directive in this way.
- A ‘positive list’ of ‘cognition improving or facilitating devices’ should be drawn up: although this means that the legislation has to react to the emergence of hitherto unregulated devices as they come on to the market, the extension of the directive to all cognition improving or facilitating devices would generate huge difficulties for regulators in keeping the purview of the directive appropriately narrow.
- The devices that should be included on the initial positive list are: transcranial electrical stimulation (e.g., tDCS, transcranial random noise stimulation, transcranial alternating current stimulation); transcranial magnetic stimulation; neurofeedback equipment.
- For CEDs presenting a moderate risk profile, benefits should be identified and weighed against risks in a similar (but not identical) way to the assessment made for medical devices: unlike cosmetic enhancement, improvements elicited by CEDs are more easily quantifiable, and in many cases it may be possible to assess these improvements using standard tests. Assessing the benefits of CEDs in this way gives an estimation comparable to the assessment of the effectiveness of medical devices. However, given that people will value these benefits to different degrees, and given the absence of the particular vulnerabilities that attend the medical context, the risk benefit assessment should err on the side of allowing consumers to decide whether the risks are worth taking. In practical terms, this will mean that the regulatory assessment will not require the objective benefits to clearly outweigh the risks.
- Prohibit CEDs with high risk profiles: where a device poses significant risks (such as likely seizures) that substantially outweigh its benefits a device should be prohibited from sale on the market.
- Exempt CEDs with low risk profiles from continued regulatory oversight: where CEDs are deemed to be low-risk and are unlikely to generate large indirect costs to the healthcare system, there would be a case for exempting them from continued regulatory evaluation, regardless of whether objective benefits have been demonstrated. This promotes consumer choice. Neurofeedback devices would be an example of a low-risk CED unlikely to require ongoing evaluation.
- Require manufacturers to provide consumers with comprehensive, evidence based information about mechanisms, safe use, risks and benefits: by making this a stringent requirement for CEDs within the MDD, consumers will be better equipped to make informed decisions about the risks they are willing to take.
- Limit the low-risk exemption to protect vulnerable parties: there ought to be an exception to our low-risk exemption proposal when devices are intended for use on/by vulnerable third parties such as children. For such devices, evidence of objective benefit (effectiveness) should be required and weighed against the risks, as for medical devices.

- *Create supplementary criminal sanctions to protect non-competent third parties: due to the possibility that individuals lacking adequate training could use CEDs that are intended for adults on children or vulnerable adults, we propose that such use should attract criminal sanctions in the same way as supplying children with alcohol attracts criminal sanctions.*

Es wird ein Modell für die Regulierung von 'Cognitive Enhancement Devices' vorgeschlagen. Damit soll die Lücke zwischen der reinen Produktsicherheit und den vermuteten Wirkungen der CED's geschlossen werden. Es wird eine 'positive list' von Geräten vorgeschlagen, die eine Auswirkung auf die Kognition haben.

Electrically and hybrid-induced muscle activations: effects of muscle size and fiber type

K. Stratton, P. D. Faghri

Eur J Transl Myol 26 (3): 249-254

ES and voluntary activations appear to generate two different modes of muscle recruitment. ES may provoke muscle strength by activating more fatiguing fast acting fibers, but voluntary activation elicits more muscle coordination. Therefore, during the hybrid activation, less electrical activity may be detected due to recruitment of more fatigue-resistant deeper muscle fibers, not reachable by surface EMG.

Elektrische Stimulation und freiwillige Aktivierung haben verschiedene Auswirkungen auf die Muskeln. Dabei wurde festgestellt, dass durch die verschiedenen Arten der Stimulation verschiedenen Arten von Muskelfasern aktiviert werden.

NMES

Time Course of Central and Peripheral Alterations after Isometric Neuromuscular Electrical Stimulation-Induced Muscle Damage

A. Fouré, et al.

PLOS ONE, 1 September 2014, Volume 9, Issue 9

Interestingly, the chronological events differ from what has been reported so far for voluntary exercise-induced muscle damage.

A 5 cm x 10 cm electrode was positioned on the proximal part of the thigh (i.e., placed ca. 5 cm below the inguinal ligament) and two 5 cm x 5 cm electrodes were located on the vastus lateralis [VL] and vastus medialis [VM] muscle bellies [29].

Biphasic symmetric rectangular pulses were delivered at a frequency of 100 Hz using a portable battery-powered stimulator (Compex Performance, Djo Global, France). Pulse duration was 400 ms (40 contractions, duty cycle = 12.5% with 5 s on and 35 s off throughout the NMES exercise) and stimulation intensity was gradually increased in order to reach the maximal level of evoked force according to the pain threshold (i.e., level of maximal tolerance) of each subject similarly to previous studies [9,10,30].

Resultate zeigen eine andere Chronologie der Vorgänge im Muskel als vorherige Studien zum Thema Muskelschädigungen durch EMS und freiwilliges Training.

EMS

Less indication of muscle damage in the second than initial electrical muscle stimulation bout consisting of isometric contractions of the knee extensors

A. Aldayel, et al.

Eur J Appl Physiol (2010) 108:709–717

In conclusion, EMS induces symptoms of muscle damage, but a protective adaptation is conferred after the initial EMS bout, resulting in less indication of muscle damage following the second EMS bout.

Abnahme der Muskelschäden und eine protektive Adaption der Muskeln mit der Anzahl Behandlungszyklen durch EMS.

Comparison between voluntary and stimulated contractions of the quadriceps femoris for growth hormone response and muscle damage

M. Jubeau, et al.

J Appl Physiol 104: 75–81, 2008.

This study aimed to compare voluntary and stimulated exercise for changes in muscle strength, growth hormone (GH), blood lactate, and markers of muscle damage. ...

It was concluded that a single bout of electrical stimulation exercise resulted in greater GH response and muscle damage than voluntary exercise.

Abnahme der Muskelschäden und eine protektive Adaption der Muskeln mit der Anzahl Behandlungszyklen durch EMS.

Whole-body electromyostimulation and protein supplementation favorably affect sarcopenic obesity in community-dwelling older men at risk: the randomized controlled FranSO study

W. Kemmler et al.

Clinical Interventions in Aging 2017;12:1503–1513

WB-EMS&P is a safe and efficient method for tackling sarcopenia and SO in older men. However, the suboptimum effect on functional parameters should be addressed by increased voluntary activation during WB-EMS application.

Abnahme der Muskelschäden und eine protektive Adaption der Muskeln mit der Anzahl Behandlungszyklen durch EMS.

Muscle damage induced by electrical stimulation

K. Nosaka

Eur J Appl Physiol (2011) 111:2427–2437

The magnitude of muscle damage induced by ES is significantly reduced when the second ES bout is performed 2–4 weeks later. It is possible to attenuate the magnitude of muscle damage by “pre-conditioning” muscles, so that muscle damage should not limit the use of ES in training and rehabilitation.

Wie in der vorherigen Studie: Abnahme der Muskelschäden und eine protektive Adaption der Muskeln mit der Anzahl Behandlungszyklen durch EMS. Präkonditionierung der Muskeln reduziert die durch EMS induzierten Schäden.

Effects of Loaded Squat Exercise with and without Application of Superimposed EMS on Physical Performance

N. Wirtz

Journal of Sports Science and Medicine (2016) 15, 26-33

The aim of the present study was to investigate the effects of a multiple set squat exercise training intervention with superimposed electromyostimulation (EMS) on strength and power, sprint and jump performance. Twenty athletes from different disciplines participated and were divided into two groups: strength training (S) or strength training with superimposed EMS (S+E). Both groups completed the same training program twice a week over a six-week period consisting of four sets of the 10 repetition maximum of back squats.

Additionally, the S+E group had EMS superimposed to the squat exercise with simultaneous stimulation of leg and trunk muscles. EMS intensity was adjusted to 70% of individual pain threshold to ensure dynamic movement. Strength and power of different muscle groups, sprint, and vertical jump performance were assessed one week before (pre), one week after (post) and three weeks (re) following the training period. Both groups showed improvements in leg press strength and power, countermovement and squat jump performance and pendulum sprint ($p < 0.05$), with no changes for linear sprint. Differences between groups were only evident at the leg curl machine with greater improvements for the S+E group ($p < 0.05$). Common squat exercise training and squat exercise with superimposed EMS improves maximum strength and power, as well as jumping abilities in athletes from different disciplines. The greater improvements in strength performance of leg curl muscles caused by superimposed EMS with improvements in strength of antagonistic hamstrings in the S+E group are suggesting the potential of EMS to unloaded (antagonistic) muscle groups.

Studie mit verschiedenen Sportlern mit Training und gleichzeitiger EMS. EMS Intensität wurde auf 70% des individuellen Schmerzempfindens eingestellt. Die gleichzeitige Anwendung von EMS beim Training erhöht Stärke und Leistungsfähigkeit der Muskeln.

Transcutaneous Electric Nerve Stimulation (TENS)

ACPWH guidance on the safe use of Transcutaneous Electrical Nerve Stimulation (TENS) for musculoskeletal pain during pregnancy

Y. Coldron, et al.

ACPWH 2007

TENS has been used by pregnant women for many years without any reported side effects for either the mother or baby. In fact, it has been suggested that TENS enhances placental blood flow (Enzelsberger et al. 1991). More recently there has been debate about the theoretical risk to the foetus by the electrical field produced by a TENS unit. In order to clarify current thinking in this area the ACPWH brought together a panel of experts who reviewed the literature surrounding this area and together with clinical experience developed these statements.

Specific potential areas of concern are the induction of uterine contractions, the effects on the foetal heart conduction and the possibility of teratogenic effects induced in the foetus.

Bericht eines Expert Panels zum Thema Anwendung von TENS während der Schwangerschaft.

Transcutaneous Electrical Nerve Stimulation (TENS) for fibromyalgia in adults

M. I. Johnson

Cochrane Database of Systematic Reviews 2016, Issue 4. Art. No.: CD012172

TENS is used extensively to manage painful conditions because it has few contra-indications or reported side effects and has no potential for overdose (Johnson 2014). A Cochrane review by Johnson 2015a concluded that there was tentative evidence that TENS reduces pain intensity when administered as a standalone treatment for acute pain in adults and a non-Cochrane meta-analyses found superiority of TENS over placebo for reducing postoperative analgesic consumption.

Cochrane Review zur Wirksamkeit von TENS bei chronischen Muskelschmerzen (Fibromyalgie)

Transcutaneous electrical nerve stimulation for relieving acute pain in the prehospital setting: a systematic review and meta-analysis of randomized-controlled trials

Paul M. Simpson et al.

European Journal of Emergency Medicine 2014, 21:10–17

No safety risks were identified. When administered by medics in the prehospital setting to patients with acute pain, TENS appears to be an effective and safe nonpharmacological analgesic modality that should be considered by emergency medical services organizations in which pharmacological pain management is restricted or unavailable.

Review zur Sicherheit der klinischen Anwendung von TENS zur Schmerzbehandlung. Die Behandlungen wurden durch geschultes Personal durchgeführt.

Using TENS for pain control: the state of the evidence

C. GT. Vance et al.

Pain Management (2014) 4(3), 197–209

No side effects reported.

Keine Nebeneffekte durch Anwendung von TENS für Schmerzbehandlung.

TENS Protocol

Dr. Deirdre M. Walsh

CONTRAINDICATIONS

It is essential to screen potential TENS users for any relevant contraindications prior to the initial application. There are only a few contraindications to TENS and common sense prevails with the majority of them. (i) Lack of normal skin sensation. A simple sharp/blunt test will determine if cutaneous innervation is intact. The danger of placing electrodes over skin which has a deficient sensation is that greater stimulus intensities will have to be employed which may cause skin irritation and even a burn. It is important to remember that treatment will be ineffective if the appropriate afferent nerves are not stimulated. If sensation is absent in a specific area, the electrodes may be placed proximal in an area which has intact sensation. (ii) Patients who are incompetent or who do not comprehend the therapist's instructions should not be treated. If a patient is required to operate a TENS unit themselves, it is desirable that they are responsible individuals. (iii) Electrodes should never be placed over the eyes or on the anterior aspect of the neck over the carotid sinuses. Stimulation in latter area may cause a drop in blood pressure. The carotid sinuses are located at the origin of the internal carotid arteries; they

contain baroreceptors which detect changes in blood pressure. (iv) Many texts include pregnancy as a contraindication to TENS but this requires clarification. This generally refers to placement of electrodes over the pregnant uterus, however some sources recommend not using TENS for any painful area during pregnancy despite the fact that no adverse reaction to TENS during pregnancy appears to have been reported to date. However, it is prudent not to place TENS electrodes over the trunk or pelvis during the first trimester. TENS electrodes should not be placed over the pregnant uterus except if TENS is used for labour pain. (v) TENS has been shown to interfere with certain types of cardiac pacemakers. Therefore if TENS is indicated for this type of patient, the clinician is advised to consult with the patient's cardiologist before embarking on a TENS trial. It would be advisable to perform an initial trial with concomitant ECG/ Holter monitoring when a patient with a pacemaker is considered for TENS treatment. (vi) If the patient has an allergic reaction to the electrode gel or tape, this can usually be ascertained in the first treatment. If this occurs, the clinician should change to another type of electrode/tape. (vii) Patients who have epilepsy should be treated at the discretion of their clinician. (viii) Patients should be advised not to wear TENS while driving or operating machinery.

Angaben zu Kontraindikationen, die vor einer Behandlung mit TENS überprüft werden sollten.

Safety of Noninvasive Electrical Stimulation of Acupuncture Points During a Routine Neonatal Heel Stick

C. C. Yates et al.

MEDICAL ACUPUNCTURE Volume 25, Number 4, 2013

NESAP is safe for infants with low settings on a TENS unit.

Studie zur Safety von TENS zur Schmerzbehandlung von Kleinkindern.

Peripheral Nerve Stimulation

Peripheral nerve stimulation by electric currents: exposure to time varying magnetic fields

J. P. Reilly

Med. & Biol. Eng. & Comput., 1989, 27, 101-110

The review evaluates thresholds of peripheral nerve stimulation by complex current waveforms. A neuromagnetic model employing Frankenhaeuser-Huxley membrane nonlinearities is used to derive excitation thresholds for monophasic and biphasic pulse sequences, as well as sinusoidal stimuli. The model, along with principles of magnetic field induction, is used to derive criteria of acceptability for exposure to time-varying magnetic fields. Applications to pulsed gradient fields from magnetic resonance imaging devices are discussed.

Review von 1998 zu 'thresholds' von peripherer Nervenstimulation bei komplexen Signalformen.
Auf der Basis eines Modells werden Kriterien für die Exposition gegenüber induzierten Strömen durch magnetische Felder. Dies wird für monophasische, biphasische und sinusförmige Stimuli bestimmt. Grundlage für viele Bewertungen.

Vagus Nerve Stimulation

Vagus nerve stimulation: effectiveness and tolerability in 64 paediatric patients with refractory epilepsies

R. O. Cersósimo, et al.

Epileptic Disord 2011; 13 (4): 382-8

Sixty-four patients (34 male and 30 female) implanted with VNS for refractory epilepsy were analysed.

The NeuroCybernetic Prosthesis (NCP) system (Cyberonics, Webster, TX, USA) was employed and the following stimulation parameters were used: output current of 1 to 2.5mA, signal frequency of 30Hz, signal pulse width of 500µs, and signal “on” and “off” times of 30 seconds and 5 minutes, respectively.

Conclusion:

VNS is an effective and well-tolerated treatment for paediatric patients with refractory epilepsies, improving quality of life and neuropsychological performance.

Studie zeigt positive Wirkung auf Lebensqualität und neuropsychologische Leistung von VNS bei therapiereistenten Epilepsiepatienten.

Transcutaneous vagus nerve stimulation (tVNS) enhances divergent thinking

L. S. Colzato, et al.

Neuropsychologia 111 (2018) 72–76

Creativity is one of the most important cognitive skills in our complex and fast-changing world. Previous correlative evidence showed that gamma-aminobutyric acid (GABA) is involved in divergent but not convergent thinking. In the current study, a placebo/sham-controlled, randomized between-group design was used to test a causal relation between vagus nerve and creativity. We employed transcutaneous vagus nerve stimulation (tVNS), a novel non-invasive brain stimulation technique to stimulate afferent fibers of the vagus nerve and speculated to increase GABA levels, in 80 healthy young volunteers. Creative performance was assessed in terms of divergent thinking (Alternate Uses Task) and convergent thinking tasks (Remote Associates Test, Creative Problem Solving Task, Idea Selection Task). Results demonstrate active tVNS, compared to sham stimulation, enhanced divergent thinking. Bayesian analysis reported the data to be inconclusive regarding a possible effect of tVNS on convergent thinking. Therefore, our findings corroborate the idea that the vagus nerve is causally involved in creative performance. Even though we did not directly measure GABA levels, our results suggest that GABA (likely to be increased in active tVNS condition) supports the ability to select among competing options in high selection demand (divergent thinking) but not in low selection demand (convergent thinking).

Studie in 80 gesunden jungen Freiwilligen zu Auswirkungen von VNS auf verschiedene kognitive Endpunkte.

The Transcutaneous Vagus Nerve Stimulation Output of the NuCalm Device of Solace Lifesciences Is Found to Be a Multifractal and Therefore It Is Indicated in the Treatment of Heart Rate Variability in the Dysfunction of Autonomic Nervous System in Anxiety, Depression and Stress

S. Conte, et al.

Journal of Behavioral and Brain Science, 2017, 7, 532-543

We have investigated the Nu Calm Transcutaneous Vagus Nerve Stimulation device of the NuCalm Solace Lifesciences founding that it gives a multifractal output. A diminishing fractal/multifractal HRV is consistently reported in literature as related to a serious Autonomic Nervous System (ANS) dysfunction that of course we observe in several psychological and psychiatric disorders. Therefore, we suggest the investigators to apply such a device in subjects affected from anxiety, depression and stress using the method of inducing tVNS stimulation.

Studie mit einem spezifischen Gerät

Vagus Nerve Stimulation

Robert H. Howland

Curr Behav Neurosci Rep. 2014 June ; 1(2): 64–73

The effectiveness of various forms of non-invasive transcutaneous VNS for epilepsy, depression, primary headaches, and other conditions has not been investigated beyond small pilot studies. The relationship between depression, inflammation, metabolic syndrome, and heart disease might be mediated by the vagus nerve. VNS deserves further study for its potentially favorable effects on cardiovascular, cerebrovascular, metabolic, and other physiological biomarkers associated with depression morbidity and mortality.

Forderung nach weiterreichenden Studien zur Wirksamkeit. Bislang nur kleinere Pilotstudien.

Transcutaneous vagus nerve stimulation: retrospective assessment of cardiac safety in a pilot study

P. M. Kreuzer et al.

frontiers in PSYCHIATRY, August2012|Volume3|Article70

Results: Two adverse cardiac events (one classified as a severe adverse event) were registered but considered very unlikely to have been caused by the tVNS device. Retrospective analyses of electrocardiographic parameters revealed a trend toward shortening of the QRS complex after tVNS.

Conclusion: To our knowledge this is one of the first studies investigating feasibility and safety of tVNS in a clinical sample. In those subjects with no known pre-existing cardiac pathology, preliminary data do not indicate arrhythmic effects of tVNS.

Pilotstudie zur sicheren Anwendung von VNS zur Behandlung von Tinnitus

Nichtinvasive Vagusnervstimulation (nVNS) bei Kopfschmerzen – ein Update

Neuromedizin 3. Jahrgang 2016 | Juni 2016

Bericht vom Kopfschmerzsymposium im Rahmen der 5. Dreiländertagung Kopfschmerz (DMKG u.a.), 21.–23.4.2016 in Tutzing am Starnberger See. Gemäss diesen Resultaten ist die Anwendung von VNS zur Behandlung von Kopfschmerzen erfolgsversprechend.

Electrical Vagus Nerve Stimulation for the Treatment of Chronic Heart Failure

H. N. Sabbah

Cleve Clin J Med. 2011 August ; 78(0 1)

This review examines results of experimental animal studies that provide support for the possible use

of electrical Vagus nerve stimulation (VNS) as a long-term therapy for the treatment of chronic HF. The review will also address the effects of VNS on potential modifiers of the HF state including pro-inflammatory cytokines, nitric oxide elaboration, and myocardial expression of gap junction proteins. Finally, we will briefly review the safety, feasibility and efficacy trends of VNS in patients with advanced HF.

Review zu experimentellen Studien mit Labortieren zur Behandlung von chronischen Herzfehlern durch VNS.

MENS

Microcurrent Electrical Neuromuscular Stimulation Facilitates Regeneration of Injured Skeletal Muscle in Mice

H. Fujiya

Journal of Sports Science and Medicine (2015) 14, 297-303

MENS facilitated the recovery of the muscle dry weight and protein content relative to body weight, and the mean cross-sectional areas of muscle fibers in CTX-induced injured TA muscle. The number of Pax7-positive muscle satellite cells was increased by MENS during the regenerating period. Decrease in the percentages of fibers with central nuclei after CTX-injection was facilitated by MENS. MENS may facilitate the regeneration of injured skeletal muscles by activating the regenerative potential of skeletal muscles.

Studie zur Wirksamkeit von MENS in Mäusen. MENS Stimulationsparameter: 10 µA, 0.3 Hz, 250 msec, 60 min pro Tag, 3 Tage pro Woche während 3 Wochen jeweils anästhetisiert.

Transcranial (Electric) Stimulation allgemein

Low intensity transcranial electric stimulation: Safety, ethical, legal regulatory and application guidelines

A. Antal, et al.

Clinical Neurophysiology 128 (2017) 1774–1809

Low intensity transcranial electrical stimulation (TES) in humans, encompassing transcranial direct current (tDCS), transcutaneous spinal Direct Current Stimulation (tsDCS), transcranial alternating current (tACS), and transcranial random noise (tRNS) stimulation or their combinations, appears to be safe. No serious adverse events (SAEs) have been reported so far in over 18,000 sessions administered to healthy subjects, neurological and psychiatric patients, as summarized here. Moderate adverse events (AEs), as defined by the necessity to intervene, are rare, and include skin burns with tDCS due to suboptimal electrode-skin contact. Very rarely mania or hypomania was induced in patients with depression (11 documented cases), yet a causal relationship is difficult to prove because of the low incidence rate and limited numbers of subjects in controlled trials. Mild AEs (MAEs) include headache and fatigue following stimulation as well as prickling and burning sensations occurring during tDCS at peak-to-baseline intensities of 1–2 mA and during tACS at higher peak-to-peak intensities above 2 mA.

The prevalence of published AEs is different in studies specifically assessing AEs vs. those not assessing them, being higher in the former. AEs are frequently reported by individuals receiving placebo stimulation.

The profile of AEs in terms of frequency, magnitude and type is comparable in healthy and clinical populations, and this is also the case for more vulnerable populations, such as children, elderly persons, or pregnant women. Combined interventions (e.g., co-application of drugs, electrophysiological measurements, neuroimaging) were not associated with further safety issues.

Safety is established for low-intensity ‘conventional’ TES defined as <4 mA, up to 60 min duration per day. Animal studies and modeling evidence indicate that brain injury could occur at predicted current densities in the brain of 6.3–13 A/m² that are over an order of magnitude above those produced by tDCS in humans. Using AC stimulation fewer AEs were reported compared to DC. In specific paradigms with amplitudes of up to 10 mA, frequencies in the kHz range appear to be safe.

In this paper we provide structured interviews and recommend their use in future controlled studies, in particular when trying to extend the parameters applied. We also discuss recent regulatory issues, reporting practices and ethical issues. These recommendations achieved consensus in a meeting, which took place in Göttingen, Germany, on September 6–7, 2016 and were refined thereafter by email correspondence.

Typical signal parameters for tDCS, tACS:

tDCS:

induced electric field strengths in tissue:

0.2–0.5V/m @ 1mA for typical montages

0.5V/m @ 0.4S/m would lead to a power deposition of 0.1mW/kg (metabolic heat production in the brain 11W/kg)

tACS:

treatment protocols:

1mA @ 5kHz for 10min

1.5mA @ 40, 60 and 80Hz for 45+/-10min

1.5mA 20min/day for 5 consecutive days

Empfehlungen und Angaben zur sicheren Anwendung für die verschiedenen Technologien tDCS, tACS, TES, rTMS basierend auf einem Konsens einer Gruppe von Experten. Unterlagen zur systematischen Erfassung der Anwendung der verschiedenen Technologien in Studien.

The electric field in the cortex during transcranial current stimulation

P. Cavaleiro Miranda, et al.

NeuroImage 70 (2013) 48–58

The electric field in the cortex during transcranial current stimulation was calculated based on a realistic head model derived from structural MR images. The aim of this study was to investigate the effect of tissue heterogeneity and of the complex cortical geometry on the electric field distribution. To this end, the surfaces separating the different tissues were represented as accurately as possible, particularly the cortical surfaces. Our main finding was that the complex cortical geometry combined with the high conductivity of the CSF which covers the cortex and fills its sulci gives rise to a very distinctive electric field distribution in the cortex, with a strong normal component confined to the bottom of sulci under or near the electrodes and a weaker tangential component that covers large areas of the gyri that lie near each electrode in the direction of the other electrode. These general features are shaped by the details of the sulcal and gyral geometry under and between the electrodes. Smaller electrodes resulted in a significant improvement in the focality of the tangential component but not of the normal component, when focality is defined in terms of percentages of the maximum values in the cortex. Experimental validation of these predictions could provide a better understanding of the mechanisms underlying the acute effects of tCS.

Numerische Bestimmung der induzierten elektrischen Feldverteilungen durch tCS. Bedürfnis/Notwendigkeit nach experimenteller Validierung.

Endogenous Electric Fields May Guide Neocortical Network Activity

Flavio Fröhlich and David A. McCormick

Neuron 67, 129–143, July 15, 2010

Modulation of network activity by positive and negative feedback fields based on the network activity in real-time provide direct evidence for a feedback loop between neuronal activity and endogenous electric fields (EF). This significant susceptibility of active networks to EFs that only cause small changes in membrane potential in individual neurons suggests that endogenous EFs could guide neocortical network activity.

Hinweise auf eine Wirkung von elektrischen Feldern auf das Membranpotential von Neuronen und dadurch auf die neuronale Netzwerkaktivität.

Hirnmanipulation per Hightech

Walter Paulus

Gehirn&Geist 6/2015, Spektrum der Wissenschaft

Kongressbericht zu transkranieller Magnet- und Gleichstromstimulation.

Non-invasive electrical and magnetic stimulation of the brain, spinal cord, roots and peripheral nerves: Basic principles and procedures for routine clinical and research application. An up-dated report from an I.F.C.N. Committee (Review)

P.M. Rossini, et al.

Clinical Neurophysiology 126 (2015) 1071–1107

These guidelines provide an up-date of previous IFCN report on “Non-invasive electrical and magnetic stimulation of the brain, spinal cord and roots: basic principles and procedures for routine clinical application” (Rossini et al., 1994). A new Committee, composed of international experts, some of whom were in the panel of the 1994 “Report”, was selected to produce a current state-of-the-art review of noninvasive stimulation both for clinical application and research in neuroscience.

Guidelines für die routinemässige klinische Anwendung nicht-invasiver elektrischer und magnetischer Stimulation des Hirns, Wirbelsäule und Nervenwurzeln. State-of-the-art Review eines Gremiums internationaler Experten.

Transcranial Current Brain Stimulation (tCS): Models and Technologies

G. Ruffini, et al.

IEEE TRANSACTIONS ON NEURAL SYSTEMS AND REHABILITATION ENGINEERING, VOL. 21, NO. 3, MAY 2013

... family of related noninvasive techniques including direct current (tDCS), alternating current (tACS), and random noise current stimulation (tRNS). These techniques are based on the delivery of weak currents through the scalp (with electrode current intensity to area ratios of about 0.3-5 A/m²) at low frequencies (typically 1kHz) resulting in weak electric fields in the brain (with amplitudes of about 0.2-2 V/m).

Übersicht über Modelle und Technologien im Bereich der tDCS, tACS und der Rauschstrom-stimulation.

tDCS

Determinants of the electric field during transcranial direct current stimulation

Alexander Opitz, Walter Paulus, Susanne Will, Andre Antunes, Axel Thielscher

NeuroImage 109 (2015) 140–150

Transcranial direct current stimulation (tDCS) causes a complex spatial distribution of the electric current flow in the head which hampers the accurate localization of the stimulated brain areas. In this study we show how various anatomical features systematically shape the electric field distribution in the brain during tDCS. We constructed anatomically realistic finite element (FEM) models of two individual heads including conductivity anisotropy and different skull layers. We simulated a widely employed electrode montage to induce motor cortex plasticity and moved the stimulating electrode over the motor cortex in small steps to examine the resulting changes of the electric field distribution in the underlying cortex. We examined the effect of skull thickness and composition on the passing currents showing that thinner skull regions lead to higher electric field strengths. This effect is counteracted by a larger proportion of higher conducting spongy bone in thicker regions leading to a more homogenous current over the skull. Using a multiple regression model we could identify key factors that determine the field distribution to a significant extent, namely the thicknesses of the cerebrospinal fluid and the skull, the gyral depth and the distance to the anode and cathode. These factors account for up to 50% of the spatial variation of the electric field strength. Further, we demonstrate that individual anatomical factors can lead to stimulation “hotspots” which are partly resistant to electrode positioning. Our results give valuable novel insights in the biophysical foundation of tDCS and highlight the importance to account for individual anatomical factors when choosing an electrode montage.

Adjusting the electrode position is the main measure taken in practical tDCS experiments for targeting a certain brain structure. Our results obtained in two head models indicate that the effectiveness of this approach can be strongly influenced by anatomical factors and that it can be very difficult to steer a significant amount of current to the selected target region. As anatomy exhibits interindividual variability, this further means that the same montage can stimulate very different brain regions across different subjects. Thus, variability in anatomy very likely contributes strongly to the interindividual variability in the physiological and behavioral tDCS effects.

While we investigated the effects of individual anatomy on the electric field for transcranial direct current stimulation, the general pattern of our findings most likely also applies for other forms of transcranial electrical stimulation, like transcranial alternating current stimulation (tACS) or transcranial random noise stimulation (tRNS). In this study we focused on the electric field strength and its dependence on anatomical and electrode factors.

Studie zu den induzierten elektrischen Feldern in verschiedenen Anatomien und deren Einfluss auf die Feldverteilung. Die Variabilität der anatomischen Bedingungen erschwert die gezielte Stimulation bestimmter Bereiche des Hirns. Es zeigt sich, dass 50% der räumlichen Variation der Feldverteilung durch die Faktoren Dimension der Schicht der Hirnflüssigkeit, Tiefe der Gyri und deren Distanz zur Anode und Kathode bestimmt sind. Es wird vermutet, dass dadurch auch lokale Stimulationsmaxima entstehen können.

Es werden keine möglichen negativen Effekte erwähnt.

Spatial and polarity precision of concentric high definition transcranial direct current stimulation (HD-tDCS)

Alam et al.

2016 Phys. Med. Biol. 61 4506

Simulation study (FEM, anatomical models)

Simulationsstudie mit anatomischen Modellen zu tDCS.

Enhancing Working Memory Training with Transcranial Direct Current Stimulation

J. Au, et al.

Journal of Cognitive Neuroscience 28:9, pp. 1419–1432

Results showed that tDCS enhanced training performance, which was strikingly preserved several months after training completion. Furthermore, we observed stronger effects when tDCS was spaced over a weekend break relative to consecutive daily training, and we also demonstrated selective transfer in the right prefrontal group to nontrained tasks of visual and spatial WM. These findings shed light on how tDCS may be leveraged as a tool to enhance performance on WM-intensive learning tasks.

Experimentelle Studie zu Auswirkungen von tDCS auf die Gedächtnisleistung.

Safety of Transcranial Direct Current Stimulation: Evidence Based Update 2016

M. Bikson, et al.

Brain Stimulation 9 (2016) 641–661

This review updates and consolidates evidence on the safety of transcranial Direct Current Stimulation (tDCS). Safety is here operationally defined by, and limited to, the absence of evidence for a Serious Adverse Effect, the criteria for which are rigorously defined. This review adopts an evidence-based approach, based on an aggregation of experience from human trials, taking care not to confuse speculation on potential hazards or lack of data to refute such speculation with evidence for risk. Safety data from animal tests for tissue damage are reviewed with systematic consideration of translation to humans. Arbitrary safety considerations are avoided. Computational models are used to relate dose to brain exposure in humans and animals. We review relevant dose-response curves and dose metrics (e.g. current, duration, current density, charge, charge density) for meaningful safety standards. Special consideration is given to theoretically vulnerable populations including children and the elderly, subjects with mood disorders, epilepsy, stroke, implants, and home users. Evidence from relevant animal models indicates that brain injury by Direct Current Stimulation (DCS) occurs at predicted brain current densities (6.3–13 A/m²) that are over an order of magnitude above those produced by conventional tDCS. To date, the use of conventional tDCS protocols in human trials (<40 min, <4 milliamperes, <7.2 Coulombs) has not produced any reports of a Serious Adverse Effect or irreversible injury across over 33,200 sessions and 1000 subjects with repeated sessions. This includes a wide variety of subjects, including persons from potentially vulnerable populations.

Review als Update zur evidenzbasierten Bewertung der Sicherheit der Anwendung von tDCS an verschiedenen Personengruppen.

Effects of tDCS on motor learning and memory formation: A consensus and critical position paper

E. R. Buch, et al.

Clinical Neurophysiology 128 (2017) 589–603

- We review investigations of whether tDCS can facilitate motor skill learning and adaptation.
- We identify several caveats in the existing literature and propose solutions for addressing these.
- Open Science efforts will improve standardization, reproducibility and quality of future research.

Review zu Untersuchungen der Anwendung von tDCS. Identifizierung von Widersprüchen und Vorschläge zur Verbesserung der Standardisierung, Reproduzierbarkeit und Qualität der Forschung in diesem Bereich.

Ethics of the Electrified Mind: Defining Issues and Perspectives on the Principled Use of Brain Stimulation in Medical Research and Clinical Care

L. Y. Cabrera et al.

Brain Topogr (2014) 27:33–45

... and it would be worthwhile for the community of practitioners and investigators working with these technologies to consider whether guidelines for public use—based on data and expert experience—would be appropriate. Thus, in addition to developing and refining best practices of medical research and clinical care, ethical leadership with respect to the use of minimally invasive brain stimulation may also eventually call for proactive steps to be taken in both public education and public policy.

Aufforderung zur Übernahme der Verantwortung zur Verwendung minimal-invasiver Hirnstimulation und zu proaktiven Schritten bezüglich Information der Öffentlichkeit und der Politik.

Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework

Veljko Dubljević

Neuroethics (2015) 8:115–126

There is mounting evidence that non-invasive brain stimulation devices - transcranial direct current stimulation (tDCS) and transcranial magnetic stimulation (TMS) could be used for cognitive enhancement. However, the regulatory environment surrounding such uses of stimulation devices is less clear than for stimulant drugs—a fact that has already been commercially exploited by several companies. In this paper, the mechanism of action, uses and adverse effects of noninvasive neurostimulation devices are reviewed, along with social and ethical challenges pertaining to their use as cognitive enhancements. Two regulatory approaches that could be used to facilitate responsible use of these devices as products and services are outlined. Apart from establishing the urgently needed comprehensive regulatory framework, they might provide a starting point for establishing long term physiological and social effects of enhancement uses of tDCS and TMS. The analysis of currently available data suggests that more reliable information on the neurophysiological mechanisms of action of tDCS and TMS is necessary. Even though the physiological profile of non-invasive neurostimulation devices seems to be safe in strictly controlled laboratory settings (i.e., with sufficiently trained users), if inadequately regulated, they can incur social and health risks.

Review zu nicht-invasiven Stimulationsgeräten für tDCS und TMS. Es wird dringend ein entsprechender regulativer Rahmen gefordert. Die Analyse der momentan verfügbaren Daten ergibt die Notwendigkeit nach mehr verlässlichen Daten zur Wirkungsweise von tDCS und TMS. Bei der Verwendung dieser Technologien im Labor von entsprechend geschulten Personen scheinen diese Technologien sicher zu sein.

The challenge of crafting policy for do-it-yourself brain stimulation

N. S. Fitz, P. B. Reiner
J Med Ethics 2015; 41:410–412

Transcranial direct current stimulation (tDCS), a simple means of brain stimulation, possesses a trifecta of appealing features: it is relatively safe, relatively inexpensive and relatively effective. It is also relatively easy to obtain a device and the do-it-yourself (DIY) community has become galvanised by reports that tDCS can be used as an all-purpose cognitive enhancer. We provide practical recommendations designed to guide balanced discourse, propagate norms of safe use and stimulate dialogue between the DIY community and regulatory authorities. We call on all stakeholders—regulators, scientists and the DIY community—to share in crafting policy proposals that ensure public safety while supporting DIY innovation.

Diskussion der relevanten Aspekte für einen regulatorischen Rahmen für die Do-it-yourself Anwendung von tDCS.

Early adopters of the magical thinking cap: a study on do-it-yourself (DIY) transcranial direct current stimulation (tDCS) user community

A. Jwa
Journal of Law and the Biosciences, 292–335, 2015

Among currently available technologies, transcranial direct current stimulation (tDCS) is one of the most promising neuroenhancements because it is relatively effective, safe, and affordable. Recently, lay people have begun to build—or purchase—the tDCS device to use it at home for treatment or as a cognitive enhancer. The tDCS device is currently not covered by the existing regulatory framework, but there are still significant potential risks of misusing this device, and its long-term effects on the brain have not been fully explored. Thus, researchers have argued the need for regulations or official guidelines for the personal use of tDCS. However, until now, no systematic research on the do-it-yourself (DIY) tDCS user community has been done. The present study explores the basic demographic characteristics of DIY tDCS users as well as why and how they are using this device through a questionnaire survey, in-depth interviews, and a content analysis of web postings on the use of tDCS. This preliminary but valuable picture of the DIY tDCS user community will shed light on future studies and policy analysis to craft sound regulations and official guidelines for the use of tDCS.

Side effects of tDCS

A total of 56 out of 121 responding users (46%) reported that they have experienced side effects while using tDCS. These respondents have experienced headache, discomforting changes such as pain, tingling, itching or burning under the electrodes, fatigue, nervousness, visual perceptual changes, acute mood changes, difficulties in concentrating, nausea, and sleeping disturbance (Appendix L). However, the degree of side effects was not severe—the average severity of most types of side effects were rated at about one, on the scale of one (not severe at all) to five (extremely severe), except discomforting changes, such as pain, tingling, itching or burning under the electrodes, where the average severity was about 2.3 (Appendix M). Power users and the physician reported that the side effects of tDCS are almost negligible, and this result corresponds to previous empirical results showing that there are no severe short-term adverse or side effects.

Interessante Studie zur Demographie der 'Early adopters Do-it-yourself' Anwender von tDCS. Mittels Fragebogen wurden die Gründe und die Art der Verwendung abgefragt. Im Rahmen einer Internetsuche wurden auch nach Sicherheitshinweisen gesucht. 46% der Studienteilnehmer stellten Nebeneffekte fest. Der Schweregrad wurde aber durchwegs als gering eingestuft.

Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS)

J.-P. Lefaucheur

Clinical Neurophysiology 128 (2017) 56–92

A group of European experts was commissioned by the European Chapter of the International Federation of Clinical Neurophysiology to gather knowledge about the state of the art of the therapeutic use of transcranial direct current stimulation (tDCS) from studies published up until September 2016, regarding pain, Parkinson's disease, other movement disorders, motor stroke, poststroke aphasia, multiple sclerosis, epilepsy, consciousness disorders, Alzheimer's disease, tinnitus, depression, schizophrenia, and craving/addiction. ...

... In addition, the easy management and low cost of tDCS devices allow at home use by the patient, but this might raise ethical and legal concerns with regard to potential misuse or overuse. We must be careful to avoid inappropriate applications of this technique by ensuring rigorous training of the professionals and education of the patients.

Expertenreview und evidenzbasierte Guidelines zur Verwendung von tDCS. Umfassende Übersicht der Studien bis 2016.

Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation

M. A. Nitsche and W. Paulus

Journal of Physiology (2000), 527.3, pp. 633—639

In the different experiments, the current flowed continuously for 4 s and for 1—5 min with an intensity of 0.2–1.0 mA. Excitation could be achieved selectively by anodal stimulation, and inhibition by cathodal stimulation. By varying the current intensity and duration, the strength and duration of the after-effects could be controlled.

Studie ergibt Unterschiede bei verschiedener Polarität des Stroms bei tDCS Stimulation.

Modelling the electric field and the current density generated by cerebellar transcranial DC stimulation in humans

M. Parazzini, et al.

Clinical Neurophysiology 125 (2014) 577–584

Results: The stronger E and J occurred mainly in the cerebellar cortex, with some spread (up to 4%) toward the occipital cortex. Also, changes by ± 1 cm in the position of the active electrode resulted in a small effect (up to 4%) in the E and J spatial distribution in the cerebellum. Finally, the E and J spreads to the brainstem and the heart were negligible, thus further supporting the safety of this technique.

Conclusions: Despite inter-individual differences, our modeling study confirms that the cerebellum is

the structure mainly involved by cerebellar tDCS.

Significance: Modeling approach reveals that during cerebellar tDCS the current spread to other structures outside the cerebellum is unlike to produce functional effects.

Numerisch Studie zur Verwendung von tDCS mit einer für das Cerebellum spezifische Anordnung der Elektroden. Elektrische Felder im Cerebellum erreichen Werte um 1V/m und die Stromdichte Werte bis zu 50mA/m².

The Mental Cost of Cognitive Enhancement

T. Iuculano and R. Cohen Kadosh

The Journal of Neuroscience, March 6, 2013 • 33(10):4482– 4486

Noninvasive brain stimulation provides a potential tool for affecting brain functions in the typical and atypical brain and offers in several cases an alternative to pharmaceutical intervention. Some studies have suggested that transcranial electrical stimulation (TES), a form of noninvasive brain stimulation, can also be used to enhance cognitive performance. Critically, research so far has primarily focused on optimizing protocols for effective stimulation, or assessing potential physical side effects of TES while neglecting the possibility of cognitive side effects. We assessed this possibility by targeting the high-level cognitive abilities of learning and automaticity in the mathematical domain. Notably, learning and automaticity represent critical abilities for potential cognitive enhancement in typical and atypical populations. Over 6 d, healthy human adults underwent cognitive training on a new numerical notation while receiving TES to the posterior parietal cortex or the dorsolateral prefrontal cortex. Stimulation to the posterior parietal cortex facilitated numerical learning, whereas automaticity for the learned material was impaired. In contrast, stimulation to the dorsolateral prefrontal cortex impaired the learning process, whereas automaticity for the learned material was enhanced. The observed double dissociation indicates that cognitive enhancement through TES can occur at the expense of other cognitive functions. These findings have important implications for the future use of enhancement technologies for neurointervention and performance improvement in healthy populations.

In conclusion, the current results clearly demonstrate that enhancement of a specific cognitive ability can happen at the expense of another ability. This mental cost might be the result of a shift of metabolic consumption and neurochemical modulation caused by TES (Fritsch et al., 2010), which changes the respective involvement of different brain areas.

Studie zeigt 'cognitive enhancement' kann auf Kosten anderer kognitiver Funktionen erreicht werden.

The neuroethics of non-invasive brain stimulation

R. Cohen Kadosh

Current Biology Vol 22 No 4, 2012

Transcranial direct current stimulation (TDCS) is a brain stimulation tool that is portable, painless, inexpensive, apparently safe, and with potential long-term efficacy. Recent results obtained from TDCS experiments offer exciting possibilities for the enhancement and treatment of normal or impaired abilities, respectively. We discuss new neuroethical problems that have emerged from the usage of TDCS, and also focus on one of the most likely future applications of TDCS: enhancing learning and cognition in children with typical and atypical development.

Diskussion von neuroethischen Aspekten im Zusammenhang der Verwendung von tDCS.

Transcranial direct current stimulation (tDCS) in a realistic head model

R. J. Sadleir, et al.

NeuroImage 51 (2010) 1310–1318

Distributions of current produced by transcranial direct current stimulation (tDCS) in humans were predicted by a finite-element model representing several individual and collective refinements over prior efforts. A model of the entire human head and brain was made using a finely meshed (1.1×1.1×1.4 mm³ voxel) tissue dataset derived from the MRI data set of a normal human brain. The conductivities of ten tissues were simulated (bone, scalp, blood, CSF, muscle, white matter, gray matter, sclera, fat, and cartilage). We then modeled the effect of placing a “stimulating” electrode with a saline-like conductivity over F3, and a similar “reference” electrode over a right supraorbital (RS) location, as well as the complements of these locations, to compare expectations derived from the simulation with experimental data also using these locations in terms of the presence or absence of subjective and objective effects. The sensitivity of the results to changes in conductivity values were examined by varying white matter conductivity over a factor of ten. Our simulations established that high current densities were found directly under the stimulating and reference electrodes, but values of the same order of magnitude occurred in other structures, and many areas of the brain that might be behaviorally active were also subjected to what may be substantial amounts of current. The modeling also suggests that more targeted stimulations might be achieved by different electrode topologies.

Transcranial Direct Current Stimulation (tDCS) involves the application of relatively weak direct current to the brain through the scalp with the aim of modulating underlying cerebral function. Current is typically introduced through a relatively large (ca. 35 cm²) sponge electrode over the region to be stimulated, using a constant current stimulator (e.g., Wagner et al., 2007b). A reference sponge electrode of similar size is placed elsewhere to complete the circuit.

Numerische Studie zur Stromdichteverteilung in einem realistischen Kopfmodell basierend auf MRI Schnitten. Entsprechend den Resultaten können in bestimmten Bereichen Stromdichten gleicher Größenordnung wie direkt unter den Elektroden auftreten.

Who Uses Direct-to-Consumer Brain Stimulation Products, and Why? A Study of Home Users of tDCS Devices

A. Wexler

Journal of Cognitive Enhancement (2018) 2:114–134

Most who use tDCS for treatment find the technology to be effective, whereas most who use it for non-treatment purposes (i.e., only enhancement and/or restoration) find it to be ineffective. Approximately 40% of those who purchase tDCS devices either quit using the device (mostly due to lack of efficacy) or have never used the device (mostly due to lack of guidance). Participants depart from established scientific protocol particularly with regard to frequency of stimulation, with 8.4% reporting self-administering 100+ sessions of tDCS. With regard to side effects, a small subset of users ($n = 10$) reported serious skin burns. This study provides an empirical foundation on which to base policy recommendations and offers a fact-based perspective on a bioethical debate that has too-often been one step removed from reality.

Aktuelle Studie zur Verwendung von tDCS und deren Einschätzungen bezüglich Wirksamkeit und Nebeneffekten.

tACS

Induction of self awareness in dreams through frontal low current stimulation of gamma activity

U. Voss et al.

nature neuroscience, VOLUME 17 | NUMBER 6 | JUNE 2014

Recent findings link fronto-temporal gamma electroencephalographic (EEG) activity to conscious awareness in dreams, but a causal relationship has not yet been established. We found that current stimulation in the lower gamma band during REM sleep influences ongoing brain activity and induces self-reflective awareness in dreams. Other stimulation frequencies were not effective, suggesting that higher order consciousness is indeed related to synchronous oscillations around 25 and 40 Hz.

Studie zum Einfluss von tACS Anwendung während REM Schlaf. Resultate weisen auf eine Frequenzselektivität hin.

Transkranielle Wechselstromstimulation Entrainment und Funktionssteuerung neuronaler Netzwerke

J. Vosskuhl

Nervenarzt 2015, 86:1516–1522

Wichtig für eine erfolgreiche Anwendung der tACS ist die hypothesengeleitete und auf die jeweilige Symptomatik hin angepasste Einstellung der Frequenz, Intensität und Dauer der Stimulation sowie die Position der Stimulationselektroden. Von großer Bedeutung für einen möglichen Therapieerfolg ist das Fortbestehen eines tACS Effektes über die Stimulationsdauer hinaus. Ein Mechanismus, der solche dauerhaften Effekte erklären kann und der sich therapeutisch nutzen lässt, ist neuronale Plastizität. Ein besseres Verständnis von tACS-Nacheffekten stellt daher einen aktuellen Forschungsschwerpunkt dar.

Die Parameter der Stimulation müssen hypothesengeleitet und speziell für jede Fragestellung bzw. Anwendung angepasst werden. Die Position der Elektroden sowie Frequenz, Intensität und Dauer der Stimulation beeinflussen die Wirkung.

Artikel stellt die Methode der tACS sowie einige experimentelle Ergebnisse vor und zeigt mögliche therapeutische Anwendungsfelder.

Tumor Treating Fields

The Evolving Role of Tumor Treating Fields in Managing Glioblastoma Guide for Oncologists

S. H. Burri et al.

Am J Clin Oncol 2017

TTFields therapy involves a medical device and transducer arrays to provide targeted delivery of low intensity, intermediate frequency, alternating electric fields to produce antimitotic effects selective for rapidly dividing tumor cells with limited toxicity. In the phase 3 EF-14 trial, TTFields plus temozolomide provided significantly longer progression-free survival and overall survival (OS) compared with temozolomide alone in patients with newly diagnosed GBM after initial chemoradiotherapy. The addition of TTFields to standard therapy improved median OS from 15.6 to 20.5 months ($P = 0.04$). In the phase 3 EF-11 trial, for recurrent GBM, TTFields provided comparable efficacy as investigator's choice

systemic therapy, with improved patient-reported quality of life and a lower incidence of serious adverse events. Primary toxicity associated with TTFIELDS is skin irritation generally managed with array relocation and topical treatments including antibiotics and steroids. TTFIELDS therapy has demonstrated proven efficacy in management of GBM, including improvement in OS for patients with newly diagnosed GBM, and is under current investigation in other brain and extracranial tumors.

Studie zu 'Tumor Treating Fields' bei Glioblastomen. TTF ist eine medizinische Anwendung von schwachen elektrischen Feldern im Kopf, die in der Zellteilungsphase die Vermehrung von Tumorzellen reduzieren soll. Resultate deuten auf eine Wirkung hin.

Tumor treating fields: a novel and effective therapy for glioblastoma: mechanism, efficacy, safety and future perspectives

P. Zhu, J.-J. Zhu

Clinical Oncology 2017;6(4):41

Results: Pre-clinical studies showed that TTF could inhibit tumor growth in vitro and in vivo by disrupting mitosis, inducing cell cycle arrest and apoptosis. Two randomized phase III trials evaluated the efficacy and safety of TTF in GBM patients. It was revealed that the combination of TTF and standard chemotherapy (temozolamide) prolonged the progression-free survival (PFS) and overall survival (OS) without systemic safety issues in newly diagnosed GBM (EF-14 trial). For recurrent GBM, the efficacy of TTF monotherapy was shown to be equivalent in PFS and OS without systemic adverse events when compared to the control group that received best physicians-chosen chemotherapies (EF-11 trial).

Studie bestätigt positive Resultate bei Glioblastomen.

Electroconvulsive (and Magnetic) Seizure Therapy

How Electroconvulsive Therapy Works?: Understanding the Neurobiological Mechanisms

Amit Singh, Sujita Kumar Kar

Clinical Psychopharmacology and Neuroscience 2017;15(3):210-221

Electroconvulsive therapy (ECT) is a time tested treatment modality for the management of various psychiatric disorders. There have been a lot of modifications in the techniques of delivering ECT over decades. Despite lots of criticisms encountered, ECT has still been used commonly in clinical practice due to its safety and efficacy. Research evidences found multiple neuro-biological mechanisms for the therapeutic effect of ECT. ECT brings about various neuro-physiological as well as neuro-chemical changes in the macro- and micro-environment of the brain. Diverse changes involving expression of genes, functional connectivity, neurochemicals, permeability of blood-brain-barrier, alteration in immune system has been suggested to be responsible for the therapeutic effects of ECT. This article reviews different neurobiological mechanisms responsible for the therapeutic efficacy of ECT.

Review der verschiedenen neurobiologischen Mechanismen, die für die therapeutische Wirksamkeit von ECT verantwortlich sein sollen.

Computational models of Bitemporal, Bifrontal and Right Unilateral ECT predict differential stimulation of brain regions associated with efficacy and cognitive side effects

S. Bai, V. Ga' Ivez, S. Dokos, D. Martin, M. Bikson, C. Loo

European Psychiatry 41 (2017) 21–29

Background: Extensive clinical research has shown that the efficacy and cognitive outcomes of electroconvulsive therapy (ECT) are determined, in part, by the type of electrode placement used. Bitemporal ECT (BT, stimulating electrodes placed bilaterally in the frontotemporal region) is the form of ECT with relatively potent clinical and cognitive side effects. However, the reasons for this are poorly understood.

Objective: This study used computational modelling to examine regional differences in brain excitation between BT, Bifrontal (BF) and Right Unilateral (RUL) ECT, currently the most clinically-used ECT placements. Specifically, by comparing similarities and differences in current distribution patterns between BT ECT and the other two placements, the study aimed to create an explanatory model of critical brain sites that mediate antidepressant efficacy and sites associated with cognitive, particularly memory, adverse effects.

Methods: High resolution finite element human head models were generated from MRI scans of three subjects. The models were used to compare differences in activation between the three ECT placements, using subtraction maps.

Results and conclusion: In this exploratory study on three realistic head models, Bitemporal ECT resulted in greater direct stimulation of deep midline structures and also left temporal and inferior frontal regions. Interpreted in light of existing knowledge on depressive pathophysiology and cognitive neuroanatomy, it is suggested that the former sites are related to efficacy and the latter to cognitive deficits. We hereby propose an approach using binarised subtraction models that can be used to optimise, and even individualise, ECT therapies.

Given the dual functional role of the left medial temporal structures in verbal learning and recall, and especially the role of the hippocampus in memory retrieval processes, greater stimulation of this region with BT relative to BF and RUL ECT, as shown with our computational modelling, is therefore consistent with this profile of increased cognitive side effects. Furthermore, regions of the frontal cortex are also identified to underlie memory retrieval processes, specifically the inferior and middle frontal gyri [47,48], which are considered part of a common retrieval network [45]. Greater relative stimulation of left frontal regions with BT ECT as shown with our modelling, particularly Brodmann areas 44, 45, and 47 (i.e., corresponding to the left inferior frontal lobe), is additionally broadly consistent. For reorientation and retrograde memory side effects specifically, this could be the case as assessment typically involves verbal recall of a mixture of both episodic (e.g., place you are in, last birthday) and semantic information (e.g., date of birth, family member/friends details). As there is evidence that long term episodic memories become “semanticised” over time [49], greater relative left inferior frontal cortex stimulation may also therefore be relevant.

Overall, this study suggests that when compared to RUL or BF ECT, BT electrode placement leads to a particular pattern of brain excitation that might be related to its characteristic efficacy profile and greater cognitive side effects.

Numerische Modellierungsstudie zum Einfluss der Platzierung der Elektroden und möglichen Nebeneffekten durch Stimulation bestimmter Hirnareale.

Cerebellar volume change in response to electroconvulsive therapy in patients with major depression

M. S. Depping, H. M. Nolte, D. Hirjak, E. Palm, S. Hofer, B. Stieltjes, K. Maier-Hein, F. Sambataro, R. C. Wolf, P. A. Thomann

Progress in Neuro-Psychopharmacology & Biological Psychiatry 73 (2017) 31–35

Electroconvulsive therapy (ECT) is remarkably effective in severe major depressive disorder (MDD). Growing evidence has accumulated for brain structural and functional changes in response to ECT, primarily within corticolimbic regions that have been considered in current neurobiological models of

MDD. Despite increasing evidence for important cerebellar contributions to affective, cognitive and attentional processes, investigations on cerebellar effects of ECT in depression are yet lacking. In this study, using cerebellum-optimized voxel-based analysis methods, we investigated cerebellar volume in 12 MDD patients who received right-sided unilateral ECT. 16 healthy controls (HC) were included. Structural MRI data was acquired before and after ECT and controls were scanned once. Baseline structural differences in MDD compared to HC were located within the “cognitive cerebellum” and remained unchanged with intervention. ECT led to gray matter volume increase of left cerebellar area VIIa crus I, a region ascribed to the “affective/limbic cerebellum”. The effects of ECT on cerebellar structure correlated with overall symptom relief. These findings provide preliminary evidence that structural change of the cerebellum in response to ECT may be related to the treatment's antidepressant effects.

Studie zeigt strukturelle und funktionelle Veränderungen im Hirn bei Anwendung von ECT.

Comparison of electric field strength and spatial distribution of electroconvulsive therapy and magnetic seizure therapy in a realistic human head model

W.H. Lee, S.H. Lisanby, A.F. Laine, A.V. Peterchev

European Psychiatry 36 (2016) 55–64

Background: This study examines the strength and spatial distribution of the electric field induced in the brain by electroconvulsive therapy (ECT) and magnetic seizure therapy (MST).

Methods: The electric field induced by standard (bilateral, right unilateral, and bifrontal) and experimental (focal electrically administered seizure therapy and frontomedial) ECT electrode configurations as well as a circular MST coil configuration was simulated in an anatomically realistic finite element model of the human head. Maps of the electric field strength relative to an estimated neural activation threshold were used to evaluate the stimulation strength and focality in specific brain regions of interest for these ECT and MST paradigms and various stimulus current amplitudes.

Results: The standard ECT configurations and current amplitude of 800–900 mA produced the strongest overall stimulation with median of 1.8–2.9 times neural activation threshold and more than 94% of the brain volume stimulated at suprathreshold level. All standard ECT electrode placements exposed the hippocampi to suprathreshold electric field, although there were differences across modalities with bilateral and right unilateral producing respectively the strongest and weakest hippocampal stimulation. MST stimulation is up to 9 times weaker compared to conventional ECT, resulting in direct activation of only 21% of the brain. Reducing the stimulus current amplitude can make ECT as focal as MST.

Conclusions: The relative differences in electric field strength may be a contributing factor for the cognitive sparing observed with right unilateral compared to bilateral ECT, and MST compared to right unilateral ECT. These simulations could help understand the mechanisms of seizure therapies and develop interventions with superior risk/benefit ratio.

Numerische Studie zum Vergleich der im Gewebe induzierten elektrischen Feldstärken bei ECT und MST.

Electroconvulsive therapy increases temporal gray matter volume and cortical thickness

A. Sartorius et al.

European Neuropsychopharmacology(2016) 26, 506–517

We corroborate earlier findings of hippocampal and amygdala GM volume increase following an acute ECT series in patients with MDE. Temporal GM volume increase was significant on a whole brain level and further corroborated by a cortical thickness analysis. Our data widely exclude white matter loss as

an indirect cause of GM growth. Our data add further evidence to the hypothesis that ECT enables plasticity falsifying older ideas of ECT induced “brain damaging”.

Studie zu möglichen Schädigungen des Hirngewebes. Resultate scheinen bisherige Hypothesen bezüglich Schädigung der weissen Hirnmasse zu widerlegen.

Neuromodulation in response to electroconvulsive therapy in schizophrenia and major depression

P. A. Thomann et al.

Brain Stimulation 10 (2017) 637-644

Background: Electroconvulsive therapy (ECT) is one of the most effective treatments in severe and treatment-resistant major depressive disorder (MDD). ECT has been also shown to be effective in schizophrenia (SZ), particularly when rapid symptom reduction is needed or in cases of resistance to drug-treatment. However, its precise mechanisms of action remain largely unknown.

Objective/Hypothesis: This study examined whether ECT exerts disorder-specific or unspecific modulation of brain structure and function in SZ and MDD.

Methods: We investigated neuromodulatory effects of right-sided unilateral ECT in pharmacoresistant patients with SZ or MDD. Magnetic resonance imaging was conducted before and after ECT to investigate treatment-related effects on brain structure and function. Imaging data were analyzed by means of Voxel Based Morphometry and Resting State Functional Connectivity (RSFC) methods.

Results: Right unilateral ECT induced transdiagnostic regional increases of limbic gray matter and modulations of neural coupling at rest. Structural effects were accompanied by a decrease in RSFC within temporoparietal, prefrontal and cortical midline structures, and an increase in hypothalamic RSFC. The extent of structural and functional change was partially inversely associated with the baseline measures.

Conclusion: The present findings provide first evidence for transdiagnostic changes of brain structure together with modulation of brain function after ECT. The data indicate diagnosis-unspecific mechanisms of action with respect to regional gray matter volume and resting-state functional connectivity.

Studie zu Wirkungsmechanismen von ECT bei behandlungsresistenten Depressionen und Schizophrenie.

Magnetic Stimulation

TMS, rTMS

Staff exposure to pulsed magnetic fields during depression treatment with transcranial magnetic stimulation

O. J. Møllerløkken et al.

International Journal of Occupational Safety and Ergonomics, 23:1, 139-142

Introduction. Transcranial magnetic stimulation or repetitive transcranial magnetic stimulation (TMS/rTMS) are currently used in research and treatments of diseases of the central nervous system, such as recurring depression. Strong electric pulses are used to produce strong pulsed magnetic fields that are directed to the patient's cerebral cortex where the fields induce electric pulses. The pulses may be causing unnecessary exposure of the staff. Method. The MagVenture TMS/rTMS system was investigated, without patient presence, through measurements of magnetic field pulses at

varying distances from the emitting coil and different power settings (94–127 A/s). Results. Fourteen measurements were done which displayed exposures exceeding the given guidelines up until a distance of 40 cm from the transmitting coil. Discussion. The study shows that the exposure of staff in this type of treatment may exceed the given guidelines for occupational exposure, thus confirming previous findings. This necessitates good routines in information and treatment procedures to avoid this exposure.

Studie mit einem kommerziell erhältlichen Gerät. Die Anwendung verletzt die geltenden Grenzwerte für die berufliche Exposition für Fachangestellte.

Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial

J. P. O'Reardon

Biol Psychiatry 2007;62:1208–1216

Safety Outcomes

Spontaneous Adverse Events. There was a higher incidence of scalp discomfort and pain with active than sham TMS (Table 3). These events were generally reported as mild or moderate in severity and diminished rapidly in incidence after the first treatment week. Scalp discomfort had the potential to compromise the study blind, and a separate analysis was conducted to examine the relationship between clinical outcome and the experience of cutaneous discomfort. The findings were negative regarding an association between any of these adverse event terms and the primary outcome measure (data not shown).

Serious Adverse Events

There were no deaths in this study, and no seizures were reported. During the acute treatment phase, 16 serious adverse events were reported, 9 in the active TMS group and 7 in the sham TMS group. Events reflecting disease-related exacerbation were the most common serious adverse events. These included suicidality (1.9% with sham vs. 0.6% with active TMS), exacerbation of depression (1.9% with sham vs. .6% with active), and a single suspected suicide gesture (in the sham group). Overall risk of exacerbation of suicidality was evaluated by determining the proportion of patients in either group who increased in score on the suicide item of the HAMD (item 3) from a value of 0 or 1 at baseline to a value of 3 or 4 at any time point during the acute treatment phase. Cumulatively, 10 events meeting this criterion were observed in the sham TMS group compared with 1 event in the active TMS group.

Audiometry

All subjects used earplugs during the treatment sessions. No differences in air-conduction thresholds were detected between or within treatment groups across the acute treatment phase of the study (data not shown, to be presented in a subsequent report).

Table 3. Adverse Events Occurring in the Active Treatment Group at a Rate of 5% or More and at Least Twice the Rate for Sham (with ME-Coded Preferred Terms Shown)

Body System Preferred term	Active TMS (n = 165) n (%)	Sham TMS (n = 158) n (%)
Eye disorders		
Eye pain	10 (6.1)	3 (1.9)
Gastrointestinal Disorders		
Toothache	12 (7.3)	1 (.6)
General Disorders and Site Administration Conditions		
Application site discomfort	18 (10.9)	2 (1.3)
Application site pain	59 (35.8)	6 (3.8)
Facial pain	11 (6.7)	5 (3.2)
Musculoskeletal and connective tissue disorders		
Muscle twitching	34 (20.6)	5 (3.2)
Skin and subcutaneous tissue disorders		
Pain of skin	14 (8.5)	1 (.6)

MedDRA, Medical Dictionary for Regulatory Activities.

Randomisierte Multi-Center Studie zu Wirksamkeit und Nebenwirkungen von TMS.

Transkranielle Magnet- und Gleichstromstimulation

W. Paulus

Deutsches Ärzteblatt, Jg. 106, Heft 9, 27. Februar 2009

Insgesamt handelt es sich bei den transkraniellen Stimulationsverfahren um nebenwirkungsarme Therapieverfahren. Bei der rTMS liegt das Hauptrisiko in sehr selten aufgetretenen epileptischen Anfällen, bei der tDCS sind einige wenige lokale reversible Exantheme durch unzureichende Elektrodenkontakte bekannt geworden.

Hinweise auf die in seltenen Fällen auftretenden epileptischen Anfälle, die durch TMS ausgelöst werden können und zu akut auftretendem Hauausschlag durch unzureichenden Elektrodenkontakt.

The Clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder

T. Perera

Brain Stimulation 9 (2016) 336–346

Conclusions: Daily left prefrontal TMS has substantial evidence of efficacy and safety for treating the acute phase of depression in patients who are treatment resistant or intolerant. Following the clinical recommendations in this document should result in continued safe and effective use of this exciting new treatment modality.

Konsensreview und Behandlungsempfehlungen der Gesellschaft für TMS für die Anwendung bei schweren Depressionen.

How much detail is needed in modeling a transcranial magnetic stimulation figure-8 coil: Measurements and brain simulations

P. I. Petrov et al.

PLoS ONE 12(6): e0178952

Substantial differences in the induced currents are observed, both theoretically and empirically, between highly idealized coils and coils with correctly modeled spiral winding turns. Thickness of the coil winding turns affect minimally the induced electric field, and it does not influence the predicted activation.

Numerische Studie zu den minimalen Anforderungen an die Modellierung der Spulengeometrie zur genügend exakten Simulation der Feldverteilungen.

Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research

S. Rossi e al.

The Safety of TMS Consensus Group

Clinical Neurophysiology 120 (2009) 2008–2039

The occurrence of seizures (i.e., the most serious TMS-related acute adverse effect) has been extremely rare, with most of the few new cases receiving rTMS exceeding previous guidelines, often in patients under treatment with drugs which potentially lower the seizure threshold.

Diskussion von Sicherheits- und ethischen Aspekten und Anwendungsempfehlungen für TMS in der klinischen Praxis und Forschung. Verfasst von der 'Safety of TMS Consensus Group'.

Das TMS-Buch Handbuch der transkraniellen Magnetstimulation

H. Siebner, U. Ziemann (Hrsg.)

Buch zum Thema TMS. Im Kapitel 4 gibt es eine ausführliche Darstellung der Sicherheitsaspekte und Anwendungsrichtlinien.

Risk and safety of repetitive transcranial magnetic stimulation: report and suggested guidelines from the International Workshop on the Safety of Repetitive Transcranial Magnetic Stimulation, June 5–7, 1996

E. M. Wassermann

Electroencephalography and clinical Neurophysiology 108 (1998) 1–16

6. Adverse effects of rTMS

- 6.1. Accidental seizures and their sequelae
- 6.2. Neuropsychological and motor effects
- 6.3. Effects on mood
- 6.4. Effects on hormones
- 6.5. Immunological effects
- 6.6. Effects on hearing
- 6.7. Local pain and headache
- 6.8. Scalp burns from electrodes
- 6.9. Histotoxicity
- 6.10. Effects of magnetic fields
- 6.11. Kindling

Ältere Studie zum Thema Sicherheit der repetitiven Anwendung von transkranialer magnetischer Stimulation.

Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research

S. Rossi, et al.

Clinical Neurophysiology 120 (2009) 2008–2039

7.4. Contraindications and precautions

The bulk of TMS studies over the last decade following the 1998 published guidelines suggest that the following considerations can be made, for which full consensus was reached:

1. *The only absolute contraindication to TMS/rTMS is the presence of metallic hardware in close contact to the discharging coil (such as cochlear implants, or an Internal Pulse Generator or medication pumps). In such instances there is a risk of inducing malfunctioning of such implanted devices.*
2. *Conditions of increased or uncertain risk of inducing epileptic seizure are:*
 - a. *Related to the protocol of stimulation:*
 - i. Any “novel paradigm” (i.e., that is not a classical method of high-/low-frequency rTMS, performed with a flat Figure 8 coil and biphasic pulse waveform). Pre-conditioning (i.e.,

- priming), TMS applied on more than a single scalp region, and prolonged PAS protocols are included in this category.*
- ii. Conventional high-frequency rTMS protocol with parameters of stimulation (intensity, frequency, train length or intertrain duration) exceeding the known safety limits reported in the Tables 4–6 of Section 7.2.*
- b. Related to the disease or patient's condition:*
- i. Personal history of epilepsy (untreated patients with one or a few past episodes), or treated patients.*
 - ii. Vascular, traumatic, tumoral, infectious, or metabolic lesion of the brain, even without history of seizure, and without anticonvulsant medication*
 - iii. Administration of drugs that potentially lower seizure threshold (see Section 5.3 for a full list), without concomitant administration of anticonvulsant drugs which potentially protect against seizures occurrence*
 - iv. Sleep deprivation, alcoholism*
- 3. Conditions of increased or uncertain risk of other events are:*
- c. Related to patient's condition:*
- i. Implanted brain electrodes (cortical or deep-brain electrodes)*
 - ii. (see Section 3.4)*
 - iii. Pregnancy*
 - iv. Severe or recent heart disease*
- 4. No risk: none of the previous conditions and single- or pairedpulse TMS or conventional low- or high-frequency rTMS protocol with parameters of stimulation (intensity, frequency, train length or intertrain duration) within the “safety limits” reported in the Tables 4–6 of Section 7.2.*

Empfehlungen und Angaben zur sicheren Anwendung für rTMS. Zudem Angaben zu Kontraindikationen und Vorsichtsmassnahmen.

PEMFT

Therapeutic Effects of Whole-Body Devices Applying Pulsed Electromagnetic Fields (PEMF): A Systematic Literature Review

K. Hug and M. Röösli

Bioelectromagnetics 33:95-105 (2012)

... applied magnetic flux densities ranged from 3.4 to 200 mT. In some trials sporadic positive effects on health were observed. However, independent confirmation of such singular findings was lacking. We conclude that the scientific evidence for therapeutic effects of whole-body PEMF devices is insufficient. Acute adverse effects have not been reported. However, adverse effects occurring after long-term application have not been studied so far. In summary, the therapeutic use of low-frequency whole-body PEMF devices cannot be recommended without more scientific evidence from high-quality, double-blind trials.

Systematische Literaturstudie zum Thema Gepulste magnetische Stimulation. Diese Studie lieferte die Grundlage zu den Empfehlungen des schweizerischen Bundesamtes für Gesundheit.

Expanding Use of Pulsed Electromagnetic Field Therapies

M. S. Markov

Electromagnetic Biology and Medicine 26:3, 257-274

no relevance, no negative side effects reported...

Human Exposure from Pulsed Magnetic Field Therapy Mats: A Numerical Case Study With Three Commercial Products

V. De Santis et al.

Bioelectromagnetics 36:149-161 (2015)

As expected, a strong influence of exposure on the PMFT design, anatomy, lying position and body orientation was found. The maximum exposure of one PMFT exceeds 3.1 times the basic restrictions of ICNIRP 1998 for the central nervous system tissues and 1.36 times the limit of ICNIRP 2010 for the peripheral tissues. Body loops can significantly increase the electric fields close to the skin, e.g., when the hand and thigh are in contact during mat use. In conclusion, PMFT products are not intrinsically compliant with ICNIRP 1998 and ICNIRP 2010 basic restrictions and therefore require special considerations.

Numerische Studie verschiedener Spulengeometrien wie sie in den Magnetfeldmatten verwendet werden. Dabei wurden für den Fall maximaler Exposition durch die gegebenen Produkte eine deutliche Überschreitung der 'basic restrictions' für beide das ZNS und das PNS errechnet.

Therapeutic Use of Pulsed Magnetic Field Exposure: A Review

N. M. Shupak et al.

Radio Science Bulletin, No. 307, December 2003

Table 1: Overview on Studies, field strengths and effects of PEMF

Review zu den bisherigen Studien zu Effekten von gepulsten Magnetfeldern.

Mechanisms and therapeutic effectiveness of pulsed electromagnetic field therapy in oncology

M. Vadalà et al.

Cancer Medicine 2016; 5(11):3128–3139

At present, only limited application of PEMF in cancer has been documented in humans. In this article, we review the experimental and clinical evidence of PEMF therapy discussing future perspectives in its use in oncology.

Review zu Studien mit Anwendungen von PEMF in der Onkologie

PST

Pulsed Signal Therapy®: An overview

R. MARKOLL

APLAR Journal of Rheumatology 2003; 6: 89–100

Pulsed Signal Therapy® (PST®) is a unique form of therapy that entails directing a specific physiological signal carried on a series of magnetic field pulses to the treatment site. These uniquely specific energy parameters are transmitted through the injured tissue to target the affected area via direct induction. The corrective PST® signal, carried on the magnetic wave-pulse, induces a tiny electrical signal that mimics the physiological signaling normally occurring in healthy living organisms.

Übersicht zu der spezifischen Form von Magnetstimulation bei der versucht wird physiologische Signale zu immittieren.

High Frequency Stimulation

HF-DT

Diathermy

P. Sekaran and R. Carachi

in R. Carachi, S. Agarwala, T. J. Bradnock (Eds), Basic Techniques in Pediatric Surgery, Springer-Verlag Berlin Heidelberg 2013

Diathermy (dia [through] + therme [heat]) is a tool used by surgeons to effect coagulation and cutting of tissues. The passage of high-frequency alternating current through the body causes a localised heating effect, with temperatures in some circumstances reaching 1000°C. The safety of diathermy relies on the fact that neuromuscular tissue (such as cardiac tissue) is only stimulated by low-frequency alternating current. At frequencies above 50 kHz, the muscle contractions observed at lower frequencies disappear. Surgical diathermy employs current frequencies between 400 kHz and 10 MHz, allowing greater amounts of current to be used safely.

There are two types of diathermy used in surgical practice, monopolar and bipolar.

Diathermie wird in der medizinischen Anwendung zum Schneiden von Gewebe und zur Antikogulation verwendet. Dabei wird normalerweise ein hochfrequenter Strom (>50kHz) verwendet. Bei diesen Frequenzen lösen diese Ströme keine Muskelkontraktionen oder Nervenstimulationen aus.

Short-wave diathermy: current clinical and safety practices

N. Shields et al.

Physiotherapy Research International, 7(4) 191–202, 2002

Given the availability of SWD equipment and its apparent efficacy in certain conditions, future research should aim to establish this by means of controlled clinical trials. The findings on safety practices underline the urgent need for comprehensive guidelines to ensure the safety of operators, patients and the general public during SWD application.

Forderung nach kontrollierten klinischen Studien zur Wirksamkeit und Sicherheit von Kurzwellendiathermie.

Plasma

CAP

Potential cellular targets and antibacterial efficacy of atmospheric pressure non-thermal plasma

Y. Alkawareek et al.

International Journal of Antimicrobial Agents 43 (2014) 154– 160

Plasma-mediated damaging effects were observed, to varying degrees, on all of the investigated cellular components including DNA, a model protein enzyme, and lipid membrane integrity and permeability. The antibacterial efficacy of APNTP appears to involve a multiple-target mechanism, which potentially reduces the likelihood of emergence of microbial resistance towards this promising antimicrobial approach. However, cellular membrane damage and resulting permeability perturbation was found to be the most likely rate-determining step in this mechanism.

Plasma source

The in-house-built kHz-driven plasma source used in this study (shown in Fig. 1) has been described previously [11]. The plasma jet consists of a dielectric quartz tube with inner and outer diameters of 4 mm and 6 mm, respectively. Two copper electrodes (2 mm wide) encircle the tube with inter-electrode distance of 25 mm. For this study, the output of a high-voltage pulse source (Hiden PHK-2k; Hiden Laboratory Inc., Hyogo, Japan), operating at a repetition frequency of 20 kHz and voltage amplitude of 6 kV, was applied to the downstream electrode, which is 10 mm from the end of the plasma tube, i.e. 20 mm from the sample to be treated. The upstream electrode was grounded. The plasma jet was operated with a gas mixture of 0.5% oxygen and 99.5% helium at a total flowrate of 2 standard litres per min. Under these conditions, an intense core plasma was formed between the two electrodes, and a luminous plume, with a rotational gas temperature of ca. 39°C [11], extended out of the tube end reaching the treated sample.

Publikation beschreibt Kaltplasmatherapie als erfolgreiche antimikrobielle Behandlung. Unerwünschte Nebenwirkungen sind keine erwähnt.

Use of cold atmospheric plasma in the treatment of cancer

Parker Babington, Kenan Rajjoub, Jerome Canady, Alan Siu, Michael Keidar, and Jonathan H. Sherman

Citation: Biointerphases 10, 029403 (2015);

Cold atmospheric plasma (CAP) is an emerging modality for the treatment of solid tumors. In-vitro experiments have demonstrated that with increasing doses of plasma, tumor cells assays display decreased cell viability. CAP is theorized to induce tumor cells into apoptosis via multiple pathways including reactive oxygen and nitrogen species as well as cell cycle disruption. Studies have shown CAP treatment can decrease mouse model glioblastoma multiforme tumor volume by 56%, increase life span by 60%, and maintain up to 85% viability of normal cells. Emerging evidence suggests that CAP is a viable in-vivo treatment for a number of tumors, including glioblastoma, as it appears to selectively induce tumor cell death while noncancerous cells remain viable. Plasma can be created by heating a gas or placing it under a strong electromagnetic field. It consists of a partially ionized gas with charged ions, electrons, and a collection of several other uncharged particles. The overall charge of plasma is close to zero, with plasma being described as an electrically neutral medium of unbound negative and positive particles. In a magnetic field the particles are free to move, which generates electrical currents. Plasma does not have a shape or volume unless contained, since it is electrically conductive. However, it will form structures such as a beam when placed in a magnetic field. There are two types of plasma, thermal and nonthermal, which are based on the temperature of the elec-

trons compared to the other particles. In thermal plasma, the electrons and heavy particles are in thermal equilibrium, while in nonthermal plasma the ions and neutral particles are approximately at room temperature while the electrons reside at a much higher temperature. Traditional thermal plasma temperatures exceed 3000 °C at the target, making it ideal for metallurgy but unusable for human tissue treatment. Nonthermal plasma is also called cold plasma, and at the point of application, cold plasma has a temperature of less than 40 °C, making it an ideal treatment for living tissue.

Keine unerwünschten Nebeneffekte erwähnt.

High Throughput Image Cytometry Micronucleus Assay to Investigate the Presence or Absence of Mutagenic Effects of Cold Physical Plasma

S. Bekeschus et al.

Environmental and Molecular Mutagenesis 59:268-277 (2018)

Several millions of cells were automatically analyzed by a MN quantification strategy outlined in detail in this work. Our data demonstrates the absence of newly formed MN in any feed gas condition using the atmospheric pressure plasma jet kINPen.

Keine erbgutschädigenden Effekte durch Kaltplasmatherapie festgestellt.

Low Temperature Plasma: A Novel Focal Therapy for Localized Prostate Cancer?

A. Hirst et al.

BioMed Research International, Volume 2014

The rapidly evolving plasma technology has the potential to deliver a wide range of promising medical applications via the delivery of plasma-induced reactive oxygen and nitrogen species. Studies assessing the effect of low temperature plasma on cell lines and xenografts have demonstrated DNA damage leading to apoptosis and reduction in cell viability. However, there have been no studies on prostate cancer, which is an obvious candidate for this novel therapy. We present here the potential of low temperature plasma as a focal therapy for prostate cancer.

Anwendung von Kaltplasmatherapie auf Prostatakrebs.

Cold Atmospheric Plasma: methods of production and application in dentistry and oncology: Review

Clotilde Hoffmann, Carlos Berganza and John Zhang, Medical Gas Research 2013, 3:21

Cold Atmospheric Plasma is an ionized gas that has recently been extensively studied by researchers as a possible therapy in dentistry and oncology. Several different gases can be used to produce Cold Atmospheric Plasma such as Helium, Argon, Nitrogen, Heliox, and air. There are many methods of production by which cold atmospheric plasma is created. Each unique method can be used in different biomedical areas. In dentistry, researchers have mostly investigated the antimicrobial effects produced by plasma as a means to remove dental biofilms and eradicate oral pathogens. It has been shown that reactive oxidative species, charged particles, and UV photons play the main role. Cold Atmospheric Plasma has also found a minor, but important role in tooth whitening and composite restoration. Furthermore, it has been demonstrated that Cold Atmospheric Plasma induces apoptosis, necrosis, cell detachment, and senescence by disrupting the S phase of cell replication in tumor cells. This unique finding opens up its potential therapy in oncology.

Anwendungen von Kaltplasmatherapie auf Zahnmedizin und Onkologie.

The repetitive use of non-thermal dielectric barrier discharge plasma boosts cutaneous microcirculatory effects

T. Kisch, S. Schleusser, A. Helmke, K. L. Mauss, E. T. Wenzel, B. Hasemann, P. Mallaender, R. Kraemer

Microvascular Research 106 (2016) 8–13

Results: Tissue oxygen saturation and postcapillary venous filling pressure significantly increased after the first application and returned to baseline values within 10 min after treatment. After the second and third applications, both parameters increased significantly vs. baseline until the end of the 40-minute measuring period. Cutaneous blood flow was significantly enhanced for 1 min after the first application, with no significant differences found during the remainder of the observation period. The second application improved and prolonged the effect significantly until 7 min and the third application until 13 min. Conclusion: These data indicate that the repetitive use of non-thermal atmospheric plasma boosts and prolongs cutaneous microcirculation and might therefore be a potential tool to promote wound healing.

Kommentar: Kaltplasmatherapie als mögliche Anwendung für Verbesserung der Wundheilung.

Biophysical effects of cold atmospheric plasma on glial tumor cells, Dissertation der Fakultät für Physik der Ludwig-Maximilians-Universität München, Vorgelegt von Julia Köritzer, München, 2013

Keine Hinweise auf einen negativen Nebeneffekt. Wobei hier der Fokus auf Tumorbehandlung liegt.

Risk assessment of the application of tissue-tolerable plasma on human skin

J. Lademann et al.

Clinical Plasma Medicine 1 (2013), 5–10

The results of the risk assessment of the tissue-tolerable plasma (TTP) jet kINPen med and first results of pilot clinical studies are presented. Producing an atmospheric pressure plasma, this plasmajet entails no risk for humans in terms of temperature increase, UV radiation or free radical formation by the plasma. The antiseptic efficacy in vitro on porcine skin and in vivo on human skin was compared to that of octenidine. TTP could significantly reduce the bacterial load in comparison to untreated skin. However, the slightly reduced antiseptic properties of TTP are attributed to the current parameter set-up and technical limitations.

Kein Risiko für Menschen in Form von Temperaturerhöhung, UV Strahlung und der Bildung freier Radikale durch das Plasma.

Human health risk evaluation of a microwave-driven atmospheric plasma jet as medical device

A. Lehmann, F. Pietag, Th. Arnold

Clinical Plasma Medicine 7–8 (2017) 16–23

In summary, the results of the experiments indicate a high potential of the plasma jet to be used as a medical device exhibiting low gas temperatures up to 34 °C. The calculated leakage currents are mostly below the 10 µA threshold. The limiting UV exposure duration for the APJ with a calculated

maximum effective irradiance of 2.6 µW/cm² is around 19 min, based on the exposure limits of the international commission on non-ionizing radiation protection guidelines (ICNIRP) [2]. A significant ozone concentration was observed mainly in the axial effluent gas flow. Ozone concentration strongly decreases with increasing distance from the plasma source exit nozzle.

Kein Risiko für Menschen in Form von Temperaturerhöhung, UV Strahlung und der Bildung freier Radikale durch das Plasma.

Introduction to DIN-specification 91315 based on the characterization of the plasma jet kINPen MED

M. S. Mann et al.
Clinical Plasma Medicine 4 (2016), 35–45

We demonstrate that both test methods described in the DIN Specification 91315 are easily to adapt and that the plasma device kINPen MED is safe and effective with regard to its physical and biological requirements.

Hinweis und Tests der in der DIN Specification 91315 beschriebenen Verfahren und deren Anwendung auf den kINPen MED.

Plasmamedizin

H.-R. Metelmann
Springer 2016

... dass die derzeitigen Erkenntnisse berechtigten Anlass geben zu der grundsätzlichen Aussage: Die medizinische Anwendung kalter Atmosphärendruckplasmen ist sicher!

Umfassendes Buch zum Thema Plasmamedizin. Mögliche Nebenwirkungen bei speziellen Therapieformen aber nicht im Bereich Kosmetik und Wellness.

Risk assessment of a cold argon plasma jet in respect to its mutagenicity

K. Wende et al.
Mutation Research 798–799 (2016), 48–54

However, only little data regarding the mutagenic potential of this new treatment option is available. Accordingly, we investigated the mutagenic potential of an argon plasma jet (kINPen) using different testing systems in accordance with ISO norms and multiple cell lines: a HPRT1 mutation assay, a micronucleus formation assay, and a colony formation assay. Moderate plasma treatment up to 180s did not increase genotoxicity in any assay or cell type investigated. We conclude that treatment with the argon plasma jet kINPen did not display a mutagenic potential under the test conditions applied and may from this perspective be regarded as safe for the use in biomedical applications.

Keine erbgutschädigenden Effekte durch Kaltplasmatherapie festgestellt.

PSR

Evaluation of Plasma Skin Regeneration Technology in Low-Energy Full-Facial Rejuvenation

M. A. Bogle, K. A. Arndt, J. S. Dover

ARCH DERMATOL/VOL 143, FEB 2007

Plasma skin regeneration using the multiple low-energy treatment technique allows significant successful treatment of photodamaged facial skin with minimal downtime. Results are comparable to a single high-energy treatment, but with less healing time.

Erfolgreiche Behandlung mit 'low-energy' Kaltplasmatherapie von geschädigter Haut.

Atmospheric pressure plasma in dermatology: Ulcus treatment and much more

S. Emmert, F. Brehmer, H. Hänßle, A. Helmke, N. Mertens, R. Ahmed, D. Simon, D. Wandke, W. Maus-Friedrichs, G. Däschlein, M. P. Schön, W. Viöl

Clinical PlasmaMedicine1(2013)24–29

We as well as others did not notice any side effects of plasma treatment so far. In summary, cold atmospheric pressure plasma constitutes a new and innovative treatment option especially for superinfected skin diseases. These promising relatively new clinical applications warrant further carefully conducted translational research to delineate the modes of actions of plasma as well as potential longterm side effects. This should lead to norms for the technical devices to allow a standardized treatment of given diseases in the mid-term.

Keine unerwünschten Nebeneffekte gefunden.

Plasmamedizin in der Dermatologie

S. Karrer · S. Arndt

Hautarzt 2015 · 66:819–828

Seither wird versucht die Wirkungsweise von Plasma genauer zu verstehen, um Niedertemperaturplasmen ohne Risiko in den unterschiedlichsten medizinischen Bereichen, sei es zur Antiseptik oder zur Behandlung von bakteriellen, viralen oder mykotischen Infektionen, zur Zerstörung von Biofilmen, zur Wundbehandlung und Geweberegeneration sowie zur Tumorthерапie, anwenden zu können [24, 42]. Die Behandlung mit Plasma erfolgt dabei kontakt- und schmerzfrei, rein physikalisch, ohne einen Angriffspunkt für allergische Reaktionen zu bieten [22, 25]. Die keimtötende Wirkung von kaltem atmosphärischem Plasma gegen ein breites Spektrum von Mikroorganismen wurde in zahlreichen Studien bereits bestätigt, ohne dass es bisher Hinweise auf eine Resistenzbildung der Bakterien gibt

Keine Resistenzbildung von Keimen auf Kaltplasmatherapie festgestellt.

Schall Stimulation

Ultraschall

Hazards, risks and safety of diagnostic ultrasound

Francis A. Duck

Medical Engineering & Physics 30 (2008) 1338–1348

The safety of exposure to diagnostic ultrasound is evaluated using a structured approach to risk assessment, based on the acoustic output of present ultrasound scanners. Thermal hazard is described, the magnitude and probability of temperature rise is reviewed, and the severity of harm from any outcome is reviewed. Similar assessments are made separately for acoustic cavitation and gas-body effects, which have previously been considered together. Finally, radiation pressure is considered in a similar manner. In each case, means to minimize the risk are suggested where appropriate. The highest risks are associated with the use of gas-bubble contrast agents. It is concluded that there is a medium risk associated with trans-cranial Doppler use, and that this use of ultrasound deserves more detailed safety review. The risks associated with the current practice of obstetric ultrasound are low. Whilst the severity of radiation pressure as a hazard is low, it is always present. Little is known about any associated cell responses and so the associated risk cannot be evaluated.

Hazard	Physical phenomenon	Comments
Tissue heating	Visco-elastic absorption processes	
Acoustic cavitation	Gas bubble in a liquid experiences the variations in pressure of an acoustic wave	
Gas-body effects	Presence of gas inclusions within a medium	
Radiation pressure	During the passage of ultrasound through a material, that material experiences local stress arising from energy density gradients. At a fundamental level, this originates from the inherent non-linearity of acoustic propagation.	With the current level of understanding, however, it would be wrong to argue other than for caution, and for considerable effort to explore more deeply the ways in which mechanical forces might alter developmental pathways

Hazard	Circumstances	Probability of harm	Severity of harm	Risk
Heating	Embryo and fetus	Very low	High	Low
	Trans-cranial	Medium	Medium	Medium
	Cardiovascular	Very low	Low	Very low
Acoustic cavitation	In tissue	Extremely low	High	None
	With contrast	High	High	High
Gas-body effects	Lung	Possible	Low	Low
	Intestine	Possible	Low	Low
Radiation pressure	General	High	Unknown but possibly low	Unknown

Table 1: A summary of the main hazards, probability of occurrence, severity of outcome and overall risk (Ultrasound exposure is assumed to be at the levels at which current ultrasound scanners operate.)

Identifikation der möglichen Nebeneffekte und Evaluation der daraus resultierenden Risiken von medizinischem Ultraschall. Die Stärke der Exposition ist durch die momentan eingesetzten Ultraschallgeräte gegeben.

Functional Assessment and Quality of Life in Essential Tremor with Bilateral or Unilateral DBS and Focused Ultrasound Thalamotomy

D. S. Huss et al.

Movement Disorders, Vol. 30, No. 14, 2015

TABLE 3. Adverse events: Transient and 12 months

Klinischer Versuch mit Tremor Patienten. Systematische Aufstellung der möglichen Nebenwirkungen von transkraziellem Ultraschall.

Influence of subcutaneous fat in surface heating of ultrasonic diagnostic transducers

L. I. Petrella et al.

Ultrasonics 54 (2014) 1476–1479

The transducers of diagnostic ultrasonic equipment generate undesired local heating at the applied part of the transducer surface. The assessment of this heating is fundamental in warranting patient safety. On the standard IEC 60601-2-37, methods have been established for the reliable measurement of heating, where three tissue models based on tissue-mimicking materials are recommended: soft tissue mimic only, bone mimic close to the surface of soft tissue, and skin mimic at the surface of soft tissue. In the present work, we compared the last-mentioned tissue model with a new one using a layer of porcine subcutaneous fat inserted between the soft tissue and skin-mimicking materials. We verify significant statistical differences between models, with the average temperature rise measured for the tests without subcutaneous fat at $6.7^{\circ}\text{C} \pm 1.7^{\circ}\text{C}$ and for the ones with subcutaneous fat at $8.9^{\circ}\text{C} \pm 1.8^{\circ}\text{C}$ ($k = 2$; $p = 0.95$). For each model, the procedure was performed 10 times in repeatability conditions of measurement. It has been suggested that the influence of subcutaneous fat for external transducers heating evaluation should be considered, as the presence of many millimeters of subcutaneous fat is a common condition in patients. Otherwise, the transducer surface heating and, therefore, the risk to the patient may be underestimated.

Erwärmung an der Oberfläche des Transducers ist abhängig von der Schichtdicke des subkutanen Fetts. (Ähnliche Unsicherheitsaspekte wie bei EMF Dosimetrie)

Ultrasonic Stimulation of Mouse Skin Reverses the Healing Delays in Diabetes and Aging by Activation of Rac1

J. A. Roper et al.

Journal of Investigative Dermatology (2015) 135, 2842–2851

We discover that mechanical stimulation of the skin with ultrasound can overturn healing defects by activating a calcium/CamKinasell/Tiam1/Rac1 pathway that substitutes for fibronectin-dependent signaling and promotes fibroblast migration.

Methods

To examine the effect of mechanical stimuli on dermal wound closure, we compared the effect of a 20-minute daily ultrasound treatment, proven to be efficacious for fracture repair (30mWcm^{-2} , 1.5 MHz wave frequency, 1 kHz pulse frequency), with a sham treatment where the device was applied, but not activated.

An issue that has hindered the clinical use of ultrasound is that different studies have used a range of ultrasound parameters with a range of success. Efficacy in fracture repair has been demonstrated using ultrasound intensities ranging from 2 to 500mWcm^{-2} (Claes and Willie, 2007; Angle et al., 2011),

although intensities above 100mWcm⁻² have been reported to result in lower maximum torque in the repaired bone than intensities of 30–50mWcm⁻² (Claes and Willie, 2007). Previous studies into effects on skin healing have been even more diverse, with most studies examining low frequency ultrasound as a form of physiotherapy massage.

One study using high-frequency (3 MHz) ultrasound actually found that treatment retarded healing of ischemic skin flap wounds in rats (Altomare et al., 2009) but this study applied ultrasound at 500mWcm⁻². At below 50mWcm⁻², the thermal effects of ultrasound are negligible (0.01 °C; Duarte, 1983), but at 500mWcm⁻² it would be sufficient to affect temperature-sensitive enzymes such as matrix metalloproteinases and collagenase (Claes and Willie, 2007). It is logical that an ischemic wound would be more susceptible to such damage, because of the reduced ability to dissipate heat.

Studie zur Anwendungen von Ultraschall für die Überwindung von Heilungsdefiziten von Wunden in Mäusen.

Survey on limiting exposure to ultrasound

Tim Toivo, Pasi Orreveteläinen, Sami Kännälä, Tommi Toivonen

STUK-TR 26 / JUNE 2017, RADIATION AND NUCLEAR SAFETY AUTHORITY, FINLAND

Umfassender Bericht der finnischen Strahlenschutzbehörde zur Verwendung von Ultraschall mit speziellem Fokus auf den Einsatz für Wellness und Kosmetik. In den Anhängen sind Empfehlungen zur Regulierung der Exposition gegenüber Ultraschall sowie Listen von Kontraindikationen in der Kosmetik, für Anwendungen der Kavitationstechnik in der Kosmetik und der Medizin.

Infraschallbelastungen

Leitfaden „Nichtionisierende Strahlung“, Infraschall, FS-05-136-AKNIR (Borgmann 2005, Fachverband für Strahlenschutz e.V.)

Da die Wirkung von tieffrequenten Schall sehr stark von der Frequenz abhängt, wurden für die Erfassung und Beurteilung Bewertungskurven ähnlich wie im Audio-Bereich eingeführt. Die Norm für Schallpegelmesser DIN EN 60651 [5] sieht neben der unbewerteten Schalldruckerfassung „linear“ (lin bzw. flat) zwei unterschiedliche Frequenzbewertungen vor, die auch für den Infraschallbereich definiert sind. Die Frequenzbewertung A führt eine ohrgemäße Bewertung der Schallsignale bei niedrigen und mittleren Pegeln im normalen Hörbereich durch, und ist für die Erfassung und Bewertung von tieffrequentem Lärm ungeeignet [1]. Die Frequenzbewertung C entspricht der Lautheitsbewertung des Ohres bei hohen Pegeln (> 80 dB) und kann bedingt auch für Infraschall eingesetzt werden. In der Norm ISO 7196 [15] ist die Bewertungskurve G für den Infraschall definiert, die eine Frequenzgewichtung mit Schwerpunkt bei 16 Hz vornimmt (s. Abb. 7). Erfahrungen mit dieser Bewertungskurve liegen bisher nicht vor. Als Grenz- bzw. Anhaltswert für Infraschallbelastungen am Arbeitsplatz werden 85 dB(G) vorgeschlagen. Im Nachbarschaftsbereich liegen diese Pegel im Bereich von 45 bis 55 dB(G) [21] in den Wohnräumen, bei 50 bis 65 dB(G) im Außenbereich (Terrasse oder Balkon).

Abb. 7: Frequenzbewertungskurven im tieffrequenten Bereich nach ISO 7196 [15] und DIN EN 60651 [5]

Verschiedene Autoren und Standards geben in sogenannten Noise-Rating-Verfahren Grenzwerte für bandbegrenzte Geräuschanteile an. Die Grenzwerte orientieren sich an der Hörschwelle im zugehörigen Frequenzbereich und sind als Oktav- oder Terzpegel [6] üblich.

1.7 Anhang 7: Abkürzungsverzeichnis

1.7.1 Allgemeine Abkürzungen

ACS: transkranielle Wechselstromstimulation
AP: Arbeitspaket
API: Application Programming Interface
BAG: Bundesamt für Gesundheit
BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte
BfS: Bundesamt für Strahlenschutz
CAP: Cold Atmospheric Plasma
CE: Conformité Européenne
CED: Cognitive Enhancement Devices
CENELEC: Europäisches Komitee für elektrotechnische Normung
DAkkS: Deutsche Akkreditierungsstelle
DCS: transkranielle Gleichstromstimulation
DEB: Dielektrisch Behinderten Entladung
DEGEUK: Deutsche Gesellschaft für EU Konformität
DGKN: Deutsche Gesellschaft für Klinische Neurophysiologie
DIN: Deutsches Institut für Normung
EEG: Elektroenzephalogramm
EC, EG, EU: Europäische Kommission, Gemeinschaft, Union
EKG: Elektrokardiogramm
EMC: Elektromagnetische Verträglichkeit
EMF: Elektromagnetische Felder
EMS: Elektrische Muskelstimulation
EN: Europäische Norm
ES: Elektrische Stimulation
FDA: Food and Drug Administration
FSM: Forschungsstiftung Strom und Mobilkommunikation
GT: Galvanic Treatment
HF: Hochfrequenz
HF-DT: Hochfrequenz Diathermie
HFT: Hochfrequenztherapie
HIFU: Hochintensiver Fokussierter Ultraschall
ICNIRP: International Commission on Non-Ionizing Radiation Protection
IEEE: Institute of Electrical and Electronics Engineers
ISM: Industrial, Scientific and Medical Band
ISO: International Organization for Standardization
MDD: Medical Device Directive
MDR: Medical Device Regulation
MENS: Microcurrent Electrical Neuromuscular Stimulation
MI: Mechanischer Index
MS: Magnetfeldstimulation
NA: Nicht Anwendbar
NMES: Neuromuskuläre Elektrostimulation
IEC: International Electrotechnical Commission
PEMF, PEMFT, PMFT: Pulsed Magnetic Field Therapy
PNS: Periphere Nervenstimulation
PSR: Plasma Skin Regeneration
PST: Pulsed Signal Therapy
r: repeated
RAPEX: Rapid Alert System for Dangerous Non-Food Products
RCT: Randomized Controlled Trail
RF: Hochfrequenz
RFA: Hochfrequenzablation

RNS: Reaktive Stickstoffspezies
ROS: Reaktive Sauerstoffspezies
SAR: Spezifische Absorptionsrate
SG: Sonographie
IT: Infraschall-Therapie
SHEER
SP: Schalldruck
SSK: Strahlenschutzkommission
t: Transkutan
TB: TheraBionic Therapy
TES, TENS: Transkutane Elektrische (Nerven-)Stimulation
TI: Zeitindex
TMS: transkranielle Magnetfeldstimulation
TTF: Tumor Treating Fields
UDI: Unique Device Identity
U-DT: Ultraschall-Diathermie
UK: Ultraschall-Kavitation
UT: Ultraschall-Therapie
UV: Ultraviolett
VDE: Verband der Elektrotechnik, Elektronik und Informationstechnik
VNS: Vagusnervstimulation

1.7.2 Technische Größen

A, mA, μ A: Stromstärke – Ampère, Milliampère, Mikroampère
 A/m^2 : Stromdichte – Ampère pro Quadratmeter
dB: Pegel – Dezibel
Hz, kHz, MHz, GHz: Herz: Frequenz – Hertz, Kilohertz, Megahertz, Gigahertz
ms, μ s: Zeit – Millisekunde, Mikrosekunde
T, mT, μ T: Magnetische Flussdichte – Tesla, Millitesla, Mikrotesla
V, kV, mV: Elektrische Spannung – Volt, Kilovolt, Millivolt
V/m, V/cm: Elektrische Feldstärke – Volt pro Meter, Volt pro Zentimeter
W, mW: Leistung – Watt, Milliwatt
W/kg: absorbierte Leistung – Watt pro Kilogramm
W/ m^2 , W/ cm^2 , kW/ cm^2 : Leistungsdichte – Watt pro Quadratmeter, Kilowatt pro Quadratzentimeter