18 Absolute and Relative Contraindications

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18.1 Introduction

Functional electrical stimulation (FES) via skin-attached electrodes relies on relatively simple technical tools, which, only in combination with comprehensive understanding of clinical and physiological operation principles, become an important and powerful therapy option for a wide range of applications.

As the human organism is an electrolytic medium and electrical stimulation relies on impulse fields, that are induced via electrical current flow through electrode-skin-contacts, it is essential to comply with basic technical provisions and limitations for avoiding irreversible electrochemical processes and potential biological tissue damage. In addition, a number of health-related risk conditions need to be co-considered for a decision, if a planned intervention can be administered, requires adaptations, or even needs to be suspended due to intolerable risks [1]. After a thorough initial evaluation regular update assessments are recommended along longer application periods, as on one hand relevant border conditions can change over time, on the other hand in rare cases also negative reactions to the stimulation could appear and need to be detected as early as possible upon occurrence of first adverse signs.

General recommendations for identifying and handling contraindications are difficult, due to an enormous diversity in available devices and electrodes. Even though manufacturers usually provide lists of counterindications and their handling, that had been verified for certification, compliance with those can only cover part of factual risks. Also, electrical parameters and application protocols play an important role in specific risk assessments.

E.g., afferent nerve stimulation with intensity near the sensory threshold can be applied safely, if a passive metal implant is situated close to the surface electrodes. Neuromuscular or direct muscular stimulation with the same electrode configuration can be associated with a considerable risk for implant corrosion and tissue damage. Other concerns, like presence of active implants, intolerance against electrode materials, etc. would equally be relevant for all three modalities. Reality is more diverse than any accurately assembled list. It remains in the responsibility of physicians and therapists to identify additional individual risk factors, rate them, give personalized recommendations and carefully supervise the course of application.

Also, there is to be distinguished between primary assessments ahead a first application and later check-ups, in case of later observed salience. It is necessary to address unexpected observations in follow-up consultations, but also advice patients to stop application, in case of introspection of unusual symptoms or new health conditions, and ask back for qualified opinion and advice.

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As a general rule it is strongly recommended for the work with patients with manifest physical or mental health conditions – critical examples are increased thrombosis- or bleeding risk or epilepsy, or pregnancy – to contact involved clinical specialist and discuss if and how safe application is possible and under what precautions (Table 18.1). Possibilities to apply FES in patients with different forms and development stages of epilepsy require in any case consultations with the caring clinical specialists and strictly controlled conditions for the application with individually necessary safety measures. Generally, compliance with any recommendations by the manufacturer has to be taken seriously, which are obligatory parts of medical product documentation and are validated in specific risk assessment procedures in the product certification. Also, those can be relevant already with begin of an intended treatment or relevant later in case of changes in boarder conditions.

18.2 Skin Reaction

Manufacturers are obliged to guarantee that only validated biomaterials are used for contact surfaces and as contact media (e.g., electrode gel). Usually applied impulse currents are charge-balanced without direct current (DC) components. In addition, material and surface-specific charge injection limits per pulse phase must not be exceeded under any operational conditions. Under these precautions, stimulation can usually be applied safely to the intact skin surface. Still, in a minority of patients a slow conditioning phase can get necessary, where the skin can adapt to contact with electrode material, gel and current flow without pronounced irritation, in very rare cases also allergic reactions can occur. Therefore, it is essential to keep an eye on the skin condition after removal of electrodes, in particular at the beginning of a treatment series, but also regularly in long-term applications. Redness that declines within roughly 30 min and appears less pronouncedly with repeated application can be seen as uncritical and suggests stimulation-induced increased skin perfusion. If stronger and persisting alterations are noticed, the intervention needs to be stopped for medical investigation. It is important to explain these necessities to patients in preparation of home-based application and remind them from time to time on a regular basis.

Open wounds are taboo for applying FES for both initiating a session and continuing with series of session. Otherwise, there is a pronounced risk for compromising wound healing or infecting the wound via electrode placement. There are FES systems specifically dedicated to foster wound healing, but these rely on special stimulation systems and application procedures. For other therapeutic applications, it is strongly recommended to await wound healing before initiation or proceeding with application sessions. Should a wound have been caused by the FES, e.g., through locally excessive current density, it is mandatory to identify the exact history and develop provisions for reliably avoiding risks of reoccurrence [2].

18.3 Passive Implants

Special attention is required regarding passive metal implants. As FES is an important and versatile tool for movement rehabilitation, often after surgical osteosynthesis or joint replacement, there is increased probability for presence of metal components in or near the therapeutic target area. But metal parts can also be remains from older surgery, forgotten or at least with reduced awareness of type and location by the patient. Such passive metal implants can cause serious problems as they have far better electrical conductivity in comparison to surrounding tissue externally applied electrical current concentrates to pathways with lowest electrical resistance. Embedded metal components develop anodic and cathodic surface areas when current flows through and, like in electrodes in general, electrochemical processes can develop on these active interface surfaces with adjacent electrolytic conductors, like biological tissue. This can result in metal corrosion, electrochemical tissue damage, and migration of corrosion products (foreign body particles) into the biological tissue.

Unfortunately, these facts are often underestimated by manufacturers, statements seeing this interaction as more or less problem-free need to be critically scrutinized for individual application scenarios. The acute impact of short duration neural stimuli maybe so small that it becomes obvious only after longer repeated application, but immediate high risk can be associated with

Table 18.1 Checklist for handling relevant contraindications for application of FES

verification before and during treatment period		action
manifest underlying physical or mental disease	✓	consult attending physician
pregnancy	✓	consult attending physician
contra-indication according to manufacturer documents	✓	absolute compliance – in doubt contact manufacturer
acute signs of skin disease or allergy visible	✓	no treatment before verification of reason and risk
wounds or scars in electrode application area	✓	no treatment before verification of reason and risk
metal implants in or near the anatomical treatment area	✓	verification of exact type and position evaluation of treatment options without electrical field induction in the implant exception: sensory nerve stimulation, not exceeding threshold intensity, generally uncritical
presence of active implants (even in distant anatomical regions)	✓	verification of exact type and position strict compliance with manufacturer's warnings, ev. consultation of manufacturer, by no means: unauthorized testing

application with long-duration impulses for direct activation of denervated muscles. Relatively uncritical is application of short duration pulses with threshold intensity for afferent nerve stimulation, as the current intensity is low enough to just reach neural skin sensors, and deeper lying metal components are not exposed to critical electrical field strength—but in any case, the specific configuration needs to be rated.

Therefore, in patients with obvious recent traumatic injuries, but also in persons where indicators for older injuries are suspected, it is of utmost importance to ask for type and anatomical position of implants and preferably for provision confirming medical documents. As soon as implants are verified special care must be taken to keep them securely outside applied electrical field ranges. Usually this can be accomplished by creative placement of electrode configurations, if this turns out to be impossible there is no other choice than omitting FES treatment in the respective body area till the implant gets surgically removed.

Similar considerations are necessary for tattoos in the treatment area, as tattoo colors often

rely on metal particles for colourfastness, or metal piercings. In both cases electrochemical interaction with biological tissue can occur as soon as stimulation current is applied, which can result in metal corrosion and tissue damage. Therefore, electrode configurations need to reliably spare those danger zones. Of course, also temporary removal of piercings solves the problem.

18.4 Active Implants

A very complex situation occurs, if active implants like cardiac pacer, cardioverter, implants for pain treatment or neuromodulation, or drug administration pumps are present. As such implants usually are encapsulated in a metal shell there are similar risks for electro corrosion and tissue damage like described above for passive metal implants. In addition, risks for electrical malfunction and damage in the electronic circuitry need to be taken into account. Test with frequently implanted actual cardiac pacer models has given evidence that risks for harming the electronics have become very low, as manufacturers have implemented effective protection circuits against potentially dangerous excessive voltage at output terminals of the implant. Consequently, it has become more likely that the electrical field induction, associated with the stimulation, causes malfunction by false interpretation of stimulation artifacts as a valid bio-signal, most commonly an ECG. Modern pacers have sophisticated algorithms implanted to minimize such risks. So usually signals with high amplitude than expected are disregarded, which could, e.g., emerge from stimulation via surface electrodes that are placed close to implanted recording electrodes. The popular assumption, to expect less risk of pacemaker malfunction if just pacer and treatment site are far enough apart, does not hold, in contrary, the resulting small size artifacts are more likely misinterpreted as bio-signal.

Literature on this important topic is in principle available, but published results can hardly be generalized beyond the described specific test setup. Reasons are diversity of pacers, operation modes, and frequent model updates on one hand and patient-related factors like physiognomy, implant position, and indication related setup on the other hand. Studies are only valid for exact conditions; transfer of conclusions is only possible with great caution [3, 4].

In particular critical are cardioverter implants, implanted defibrillators with automated arrhythmia detection. If the monitored ECG gets contaminated by stimulation artifacts it can come to unnecessary delivery of an electrical shock, which is not only highly irritating and painful for the patient, but also substantially reduces implant lifetime due to drain of a considerable amount of energy from the battery. Usually implant manufacturers refuse clearance for use of electrotherapy, generally or at least with limitation to switched off state. It remains more or less impossible to find generally valid criteria for predicting safe operation conditions with all diversity of individual anatomy and locations of implant components. Therefore, utmost care and careful monitoring are required if there are reasons for applying FES despite the increased risk situation. In any case this should not be undertaken without consultation of the manufacturer for acquiring at least a conditional clearance [5, 6].

Meticulous initial assessments and regular re-evaluation are mandatory conditions for ensuring best possible patient safety.

18.5 Conclusion

In an overall view, the vast majority of FES applications can be regarded as safe and effective. Nevertheless, it is necessary to keep critical awareness for potential risk factors to be assessed before intervention and monitored along application series. If specific precautions are to be met also measures for ensuring patient compliance are essential. Most crucial conditions for self-responsible home-based application are informed patients and a sustainable confidence base, and a low-threshold option for consulting the therapist in case of worrisome observations.

References

1. ELECTROPHYSICAL AGENTS - contraindications and precautions: an evidence-based approach to clinical decision making in physical therapy. Physiother Can. 2010;62(5):1–80. https://doi.org/10.3138/ptc.62.5. Epub 2011 Jan 5. PMID: 21886384; PMCID: PMC3031347
2. Fary RE, Briffa NK. Monophasic electrical stimulation produces high rates of adverse skin reactions in healthy subjects. Physiother Theory Pract. 2011;27(3):246–51. https://doi.org/10.3109/09593985.2010.487926.
3. Egger F, Hofer C, Hammerle FP, Löfler S, Nürnberg M, Fiedler L, Kriz R, Kern H, Huber K. Influence of electrical stimulation therapy on permanent pacemaker function. Wien Klin Wochenschr. 2019;131(13-14):313–20. https://doi.org/10.1007/s00508-019-1494-5. Epub 2019 Apr 25
4. Crevenna R, Mayr W, Keilani M, Pleiner J, Nuhr M, Quittan M, Pacher R, Fialka-Moser V, Wolzt M. Safety of a combined strength and endurance training using neuromuscular electrical stimulation of thigh muscles in patients with heart failure and bipolar sensing cardiac pacemakers. Wien Klin Wochenschr. 2003;115(19-20):710–4.
5. Badger J, Taylor P, Swain I. The safety of electrical stimulation in patients with pacemakers and implantable cardioverter defibrillators: a systematic review. J Rehabil Assist Technol Eng. 2017; https://doi.org/10.1177/2055668317745498.
6. Kamiya K, Satoh A, Niwano S, Tanaka S, Miida K, Hamazaki N, Maekawa E, Matsuzawa R, Nozaki K, Masuda T, Ako J. Safety of neuromuscular electrical stimulation in patients implanted with cardioverter defibrillators. J Electrocardiol. 2016;49(1):99–101, ISSN 0022-0736. https://doi.org/10.1016/j.jelectrocard.2015.11.006.