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Bone Healing and Dynamic Interferential Current (DIC)

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First Study comparing Experiments on Sheep

Part I:
Experimental Procedure and Histological Results

Part II:
Physical and Chemical Results

presented by

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Bone Healing and Dynamic Interferential Current (DIC-Summary)

The aim of this investigation was to clarify the influence of dynamic interferential current (DIC). Two sinusoidal currents of medium frequency are superimposed within the body to determine the reactive changes of bone healing after an osteotomy. An osteotomy was performed on the radius and ulna of the right foreleg of 34 "back-head breeding sheep". The radius shaft was deperiostalized and instably fixed with a four-hole AO-plate leaving a gap of at least 1 mm width. DIC of different mA-values was used to treat 24 sheep 3 times per week for 10 minutes. The other 10 animals were not treated with DIC but used as control animals. The different results of our clinical, radiological, histological and chemical analyses to date indicate that callus formation is accelerated by the application of DIC. The fracture callus of treated animals is strongly mineralized.

Key Words: Experimental study – Sheep – Transversal osteotomy – Instable osteosynthesis – Influence of dynamic interferential current – Noninvasive procedure – Bone healing.

Introduction and Presentation of the Problem

Our knowledge regarding the influence of electric currents on callus formation in its various stages is still incomplete up to the present day. Since the discovery of the piezoelectric effect on the bone (15), experiments with direct currents (4, 14, 35), alternating currents (10), electrodynamic potentials (3, 4, 20, 22, 23, 25, 34) as well as interferential current (17) have been carried out. Experiments regarding the influence on bone healing performed with methods other than electrical energy will not be discussed. The various electrical stimulating processes and the differing approaches to experiments with frogs (33), rats (6), rabbits (13, 17, 24) and sheep (35) make comparisons regarding the behaviour of the electrically induced osteogenesis difficult. Furthermore the choice of parameter of many researchers ist not uniform. Clinical behaviour, X-ray series, comparative anatomical findings and histological criteria are just as important as electron microscopic, chemical analytic and biochemical evaluations of the tissue treated with electric current. For this reason experiments on animals with a standardized, reproducible, experimental set-up should put us in a position to make an assessment of the electrically stimulated tissue.

In this way the clinical picture was related with the corresponding fine structural cytomorphosis. It was to be clarified as to whether it was possible to intervene in the metabolism and to accelerate bone healing with the help of DIC compared with untreated control animals.

Our own clinical observations during the dynamic interferential current treatment (DIC) of patients with traumatic soft tissue changes, such as oedemas and haematomas and with fractures at the same time indicated this effect in many cases. In this experimental study an attempt was made to view objectively the clinical experience with patients by using animals.

Material and Methods

Animals

Thirty-four pure-bred 6 month old black-head breeding sheep with an average weight of 37.6 kg were used as experimental animals. It appeared to us to be important for the evaluation of the tests to use young, large animals with a pronounced desire to move around, so that on the one hand conditions were unfavourable for the bone healing process due to the constant exertion of the operated limb and on the other hand, we had tubular bones at our disposal, which more or less correspond to those of humans.

Procedure of the Transversal Osteotomy

The operation was performed under sterile conditions. Anaesthesia: Pentobarbital (Nembutal®). A clean-edged transversal osteotomy was carried out with an oscillating saw on the radius and ulna in the middle of the shaft of the right foreleg and was instably fixed with a four-hole AO-plate leaving a gap of at least 1 mm in width. A torque wrench was not used, as it does not belong to the standard instrumentarium of most hospitals.

The osteotomy gap produced instability due to the lack of interfragmental compression. In addition the intra-medullary and cortical as well as the periosteal blood supply of the bone was damaged, since the periosteum was pushed away circularly in the whole area of the radius shaft, without being removed. Thus a reproducible model was created, on which the effect of dynamic interferential current on the osteogenous repair was to be tested.

The Course of the Experiment after the Transversal Osteotomy

Group I: Control group, 10 animals; transversal osteotomy without DIC treatment.
Group II: 12 animals; transversal osteotomy with 12 mA DIC treatment (therapeutic range) 3 times a week for 10 minutes at a time.
Group III: 12 animals; transversal osteotomy with 60 mA DIC treatment (maximum output of the appliance) 3 times a week for 10 minutes at a time.

Dynamic Interferential Current and its Application

Dynamic interferential current (DIC) is generated in the body by means of the superimposition of two medium frequency, sinusoidal currents of similar frequencies, e.g. 4000 and 4100 Hz. These currents are fed to the body by laying two pairs of electrodes on the skin. These electrodes must be attached in such a way that the two circuits cross over one another. The therapeutically effective frequency difference of both currents lies generally between 0 and 100 Hz, which can be varied according to the adjustability of the appliance – following empirical experience. We used only a range of 90-100 Hz and chose a Nemectrodyn 8 as the DIC source (Manufacturer: Deutsche Nemectron GmbH, Karlsruhe, West Germany, 1978 model).

In order to observe the course of the repair process in the osteotomy gap, it was necessary to examine untreated animals and then animals treated with DIC.

For the group of animals treated with DIC it was our intention to establish the intensity and extent of the interferential current field in the osteotomy gap. For this purpose, during the operation we attached a two-pole microelectrode[1], which was specially designed for this, in the osteotomy gap before closing the skin, so that its tip lay on the transverse incision of the bone cavity of the radius. After taking measurements and X-rays the electrode was removed and not used throughout the rest of the experiment.

To avoid a postoperative angulation of the operated limb – especially during the critical waking up phase, when the animals made vigorous attempts to stand up – immediately after the operation we put on a plaster cast (tutor) from the pastern to the olecranon and cut it open after it had hardened. The plaster was held together with circular adhesive plaster turns and could be removed easily for the radiological follow-ups and the interferential current treatment and then be put back on again. For the application of the interferential current both pairs of electrodes were laid onto the intact and slightly dampened skin and fixed in such a way that the osteotomy area was at the crossing point of the two circuits (Fig. 1). During the treatment the sheep were lying on their backs. The animals in group II (12 mA) tolerated the DIC treatment in the therapeutic range[2] with physical calm and moreover showed absolutely no sign of a pain reaction.

In group III (60 mA – maximum output of the appliance) all animals were put under slight anaesthesia before the application of the DIC (Xylazine, Rompun®, Bayer), because the strength of the interferential current was *above the therapeutic range* and would have led to pain manifestations, agitation and extension cramps of the limbs.

1) Termistor, installed into an injection tube and sealed in with araldite
2) the therapeutic range of the DIC application is the intensity, which is *below* the level of pain sensation

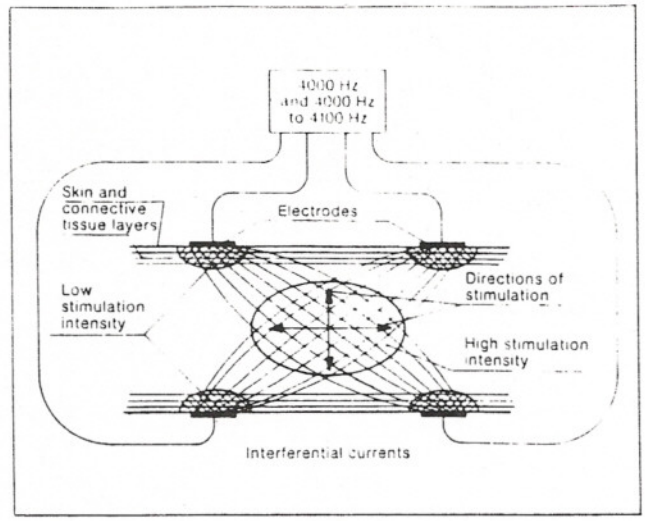

Fig. 1: Schematic representation of the electrode positioning and the DIC field arising in the limb (acc. to HANSJÜRGENS).

To judge the bone healing processes of the control group and the groups treated with dynamic interferential current *X-ray follow-ups* were carried out on *living animals*. We observed the healing of the wound and the *load behaviour* of the limb, on which the osteotomy was performed. The first DIC application followed after per primam healing of the wound on the 6th day (group II) and on the 7th day (group III) after the operation and was continued 3 times a week up to 6 weeks after the beginning of the DIC treatment. A series of maximum 19 DIC treatments resulted. The X-ray follow-ups were carried out immediately before each DIC treatment. The whole experiment lasted 16 weeks. During this period we dissected one animal from each group on the 13th, 15th, 17th, 21st, 25th and 28th day as well as after 5, 6, 7, 12 and 16 weeks.

Independent of the study of the behaviour of the osteogenesis during the bone repair of the osteotomy gap, we measured the temperature of the animals still alive at the end of the experiment in the sublingual area, on the skin and in the centre of the scar on the skin, as well as at the metallic implant after inserting a thermoprobe.

Preparation of the Tissue for Morphological and Chemical Examinations

Immediately *after death* the skin was removed from the exarticulated foreleg. After checking the flexibility of the operated limb bimanually, tissue was removed from the osteotomy gap and the callus mantle with the help of a drillpunch-cylinder for electromicroscopic and chemical examinations. The chemical analyses were made on fresh tissue or on shock-frozen, freeze-dried material, according to the specifications of ALTHOFF et al. (1, 2), QUINT and HÖHLING (27) and QUINT et al. (29). Both individual pieces from the osteotomy gap and homogenised callus tissue from the callus mantle were examined. The radius and ulna together with the surrounding soft parts were fixed in

10 % formalin for the purpose of the histological examination. We sawed longitudinal and cross sections out of the fracture area, decalcified them with RDO, prepared 5-7 µ thick paraffin sections and coloured them with HE (haematoxyline-eosine), azan, PAS (periodic acid-SCHIFF-reaction), as well as according to GOLDNER and LADEWIG.

Results

We were able to record the intensity and extent of the endogenous DIC field in the osteotomy area with an oscilloscope by means of the microelectrode. All the measurements in all animals quite clearly showed dependent on the direction, the greatest field intensity of interferential current in the osteotomy gap. It was discovered that both the inhomogeneities of the living tissue and the metallic implants with a high conductivity, which were put in place during osteosynthesis, had no noteworthy effect on the DIC field distribution, such as shadowing.

All the animals treated with DIC could put full weight on to the operated limb up to 6 days earlier than the animals in the control group. Correspondingly the X-rays showed a callus development, which led us to expect an earlier consolidation of the fracture (Fig. 2 and 3).

The histological findings confirmed this too. After the DIC application a cross section of the callus mantle showed, higher density and width of the trabeculae, a more homogeneous microarchitecture and a higher degree of mineralization (Fig. 5). Medullary and periphery bridgings of the osteotomy gap could already be seen in the longitudinal section of the animals in group II at a time, when larger proportions of connective and cartilage tissue could still be found in the osteotomy area of the control animals (Fig. 6 and 7). The cortical consolidation followed at a much later point in time.

The histomorphological findings in the proximal and distal resection area of the radius fragments showed differing behaviour with regard to the repair. In the cortex layer the continually progressing healing process began with cellular activity in the Haversian canals corresponding to the relatively better vascular supply to the *proximal* radius fragments. However, at the same point in time corresponding effective cellular activity was still not to be seen in the *distal* resection area. After 18 days, great osteoclastic activity could already be seen at the proximal lesion point of the treated animals, which was still absent distally at this point in time and did not occur until 14 days later. Parallel to this the Haversian systems only showed increased transformation in the proximal fragment. In perivascular fine connective tissue osteoclasts could be seen, which enlarged osteons in the direction of the resection area and together with osteoclasts of the osteotomy area "opened the osteons" (Fig. 8). The three layers of tissue in the osteotomy gap (Fig. 9), which could already be observed at this stage, remained visible during the whole repair process until the bony bridging over of the defect was complete. A proximal "trabecula layer" (zone I) and a distal "vacuolar layer" (zone III) border onto a wide, central "fibrocytic layer" (zone II). Here is a more detailed description of each zone:

Zone I: To the proximal resection area, which already has "opened osteons" in the outer general lamella area, is joined a layer taking in about a quarter of the osteotomy gap and containing spongiosa trabeculae. Signs of calcification and ossification both become evident.

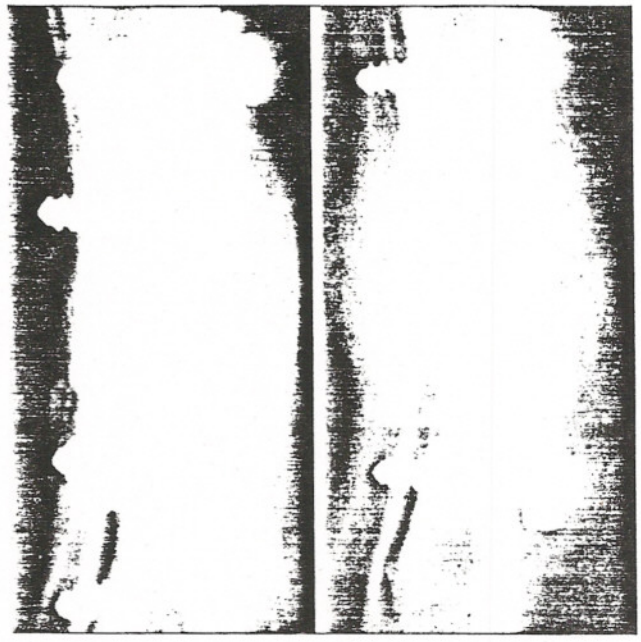

Fig. 2 and 3: Lateral X-rays of the radius and ulna obtained by means of a mediolateral beam path 48 days after the operation. Radius with 4-hole AO-plate (*right*) osteosynthesised.
Fig. 2: Animal from group II (12 mA DIC): Bony bridging over of the osteotomy gap, callus throughout.
Fig. 3: Animal from group I (without DIC): No bridging over of the osteotomy gap, fissuration on the callus.

Zone II: Here there is an expanded bipartite layer approximately over the middle of the osteotomy gap with highly active fibrocytic cell elements. The proximal half of this zone has wide fissures in the tissue (lymph?) without blood cells, whilst the distal part is highly vascularised (erythrocytes) again and is rich in pericapillary mitosis. Bone remains from the sawing (after the osteotomy) are to be found solely in the central distal part of the layer.

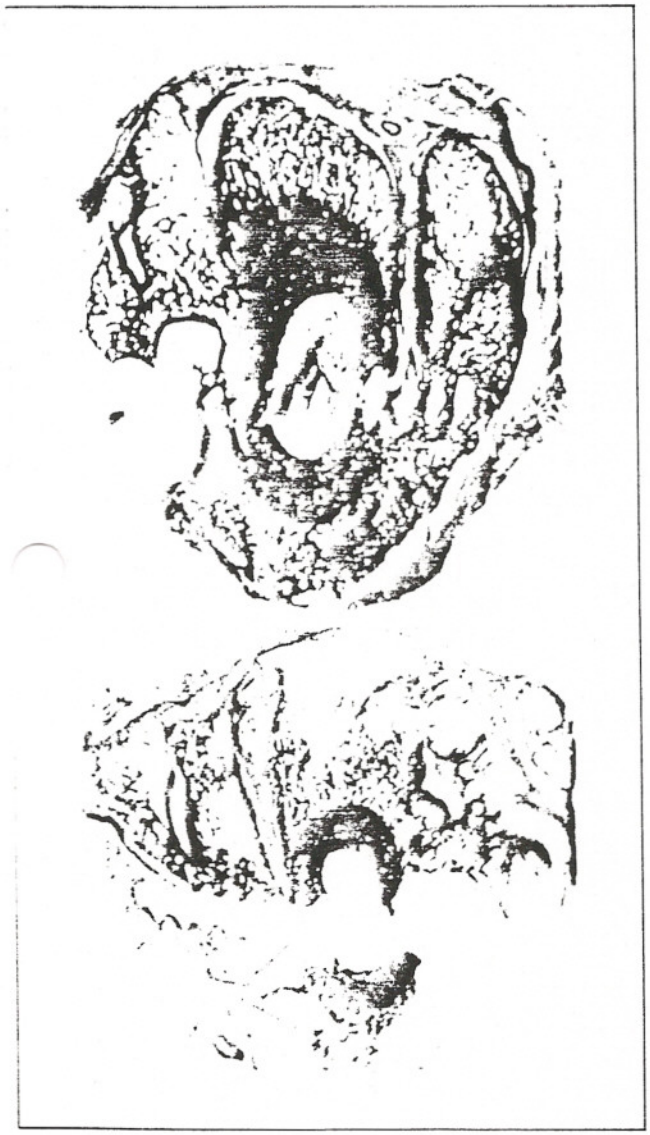

Fig. 4 and 5: Cross section of radius and ulna at the 3rd AO-screw proximally (same preparations for ill. 2 and 3), 48 days after the operation; colouring: azan; enlarged approx. twice

Fig. 4: (with DIC). The border between compact substance of the radius and the callus cannot be distinguished. Flowing transition between radius and callus with the same degree of mineralization. Even microarchitecture made up of *dense, wide trabeculae*; plate and screw-bearing embedded in a sheath of connective tissue.

Fig. 5: (without DIC). The border between compacta substance of radius and the less mineralized callus can be clearly distinguished. Uneven architecture with delicate trabeculae. Plate and screw-bearing ted on level of connective tissue

Zone III: The layer adjoining the distal resection area is characterised by a cell deficiency and an abundance of vacuoles. The collagen fibre parts of this zone stretch over the whole width of the cortex layer in a curve from the medulla to the periphery.

Figs. 6 and 7: Longitudinal section through the osteotomy zone 48 days after the operation; colouring. azan; 120 x (Same animals as in Fig. 2, 3, 4 and 5).

Fig. 6: Animal from group II (12 mA DIC). Distal resection area; bridging-over of the osteotomy gap with regenerated lamellar bone; transition into the Haversian systems of the compact substance of aligned, interfragmentary osteons, adjusted to the weight.

Fig. 7: Animal from group I (without DIC). Taut connective and cartilage tissue lies close to the distal resection area; no bony bridging-over; differing mineralisation of fasciculi of collagenous fibres in the callus blastema; only spongiosa trabeculae with network bone structure.

As the vascular supply in the distal zone near to the osteotomy zone increasingly improves, the proximal functions, which can be observed much earlier, recur in the same way. Right up until the end of the experiment there is no difference in the quality of the bone repair tissue. In the distal part of the interfragmental gap too network bone first of all develops, which, when the load is increased, only then shows lamella synthesis. In histological longitudinal sections (Fig. 10) a complete, continuous osteon connection can be seen over the whole cross section of the compact substance proximally, whilst at the distal fragment osteons remain receded from the bony connection at regular intervals. The osteoid lies on the latter as though it has been "poured over", as can be seen from the delicate, chink-like gaps in Fig. 10. In the reparative mesenchymal blastema of the osteotomy gap no cells with PAS-positive granulations can be detected. The osteocytes in the compact substance of the radius near the osteotomy show enlarged lacunae and ample PAS-positive granules in the animals treated with DIC. Bundles of collagenous fibre pass through the highly active fibrocytic repair tissue in the osteotomy gap leaving out individual areas, at first almost parallel to the surface of the osteotomy and later almost in the longitudinal direction of the radius adapted to the weight.

The collagenous fibres form a three dimensional network with fasciculi running longitudinally, transversely and in the 3rd dimension, so that the fibres are orientated in all directions of space.

Fig. 8: (with DIC) Longitudinal section through the proximal resection area 18 days after the operation. Colouring PAS 168 times. Considerably enlarged Haversian canals, partly opened towards the osteotomy zone. Loose, perivascular connective tissue accompanies a vessel branched out into the osteotomy gap, to which a polynuclear osteoclast adheres.

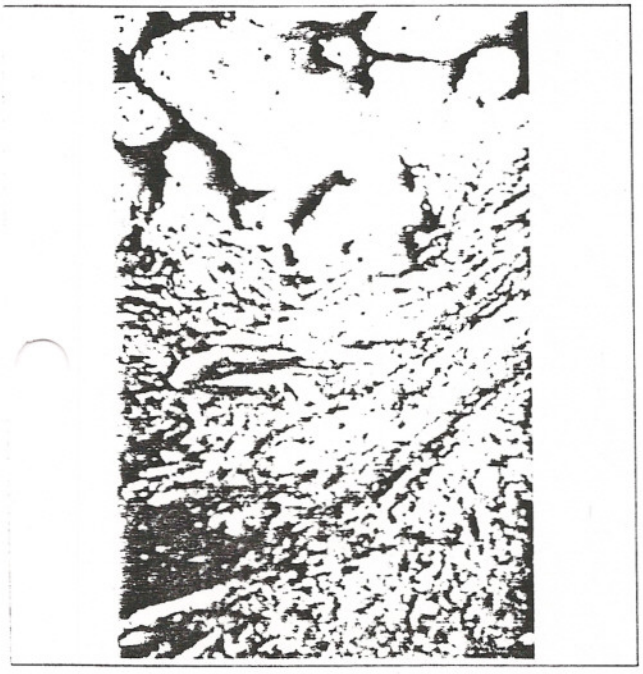

Fig. 9: (without DIC) Longitudinal section through the tissue of the osteotomy gap 18 days after the operation. Colouring Ladewig, 67 times. Synthesis in layers of the interfragmentary tissue with differentiation of the reparative blastema dependent on vascularisation: zone I with spongiosa trabeculae, zone II with predominantly fibrocytic cell elements; zone III with vacuoles with a small lumen

The ossification following the calcification progresses like a front together with the branching out of the capillaries. These grow from the medulla and/or periphery as well as from the Haversian systems of the proximal fragment and with a delay of 2-3 weeks from the distal cortex layer into the osteotomy gap. At the same time in the medulla and periphery vessels can be observed, which bridge over the defect together with the callus formations there

: early endosteal and peripheral bridging-over of the lesion, an additional reinforcement through at least 2 periosteal and 1 endosteal column has arisen from the instable osteosynthesis by means of unilateral lamina osteosynthesis

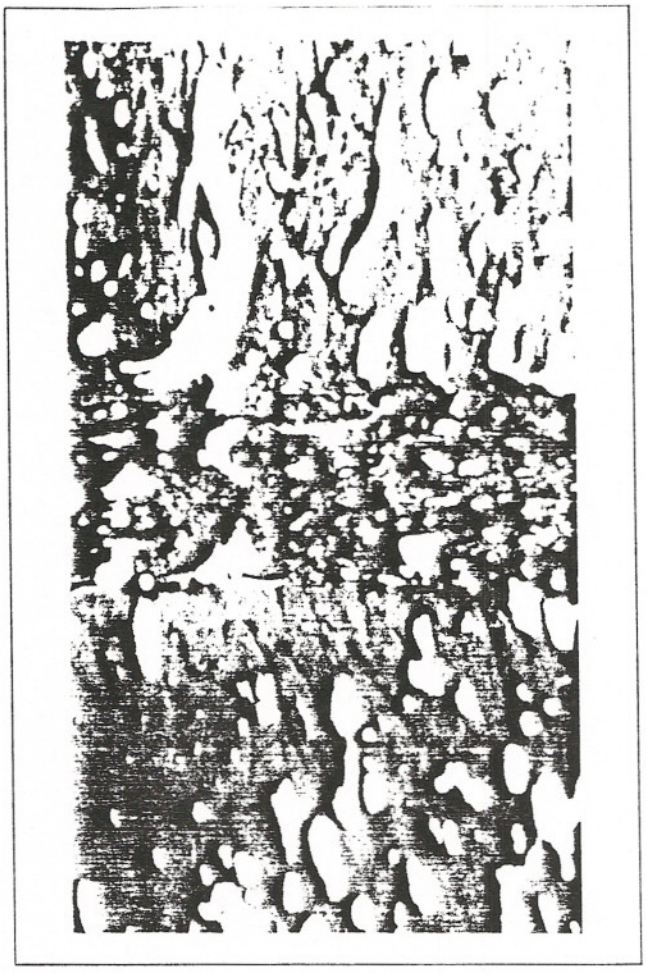

Fig. 10: Longitudinal section through the osteotomy gap 48 days after the operation (same animals as in Fig. 4). Colouring: azan; 24 times; partial decalcification with RDO. Joining of the fragment ends through regenerated, strongly vascularised bone tissue. Flowing transitions between proximal compact substance and intergramental callus. At the distal resection area communicating osteons and sharply defined parts, which are not bridged over, alternate with the compact substance of the radius.

The "callus supports" are formed at 2 opposing poles of the bone tube. If the almost oval cross section of the radius is compared with an ellipse, then these callus supports are attached to the compact substance around both intersecting points of the main axis. The bridging callus formed between the radius and ulna can also be regarded as a further column. These longitudinal stays protect the osteotomy zone from excessive rotatory, transversal and tractive forces, which are possible, when weight is put onto the limb. Severe ad axim dislocations are prevented by the tutor being cut open. The firm interlocking of the three outer general lamellae of the radius compact substance with the periphery callus in the statically important areas, corresponds to a sandwich structure with its characteristic stability.

The above mentioned callus stays manifest a fine structure which first of all has a lamella structure radially aligned to the compact substance (T-beam principle) and which does not have three-dimensional stays until later.

There are further callus formations between the above mentioned callus stays, which differ in structure, in that they do not have the formations mentioned. They have an uneven spongiosa architecture do not appear to have an essential statical function. This callus is decomposed earlier than the callus in the support areas.

The endosteal callus formation begins proximally earlier than it does distally. In both fragments the spongiosa trabeculae stays, filling up the bone cavity and dependent upon the vascular supply, can be seen. They can unite in the area of the osteotomy zone, if there are medullary callus formations in the proximal and distal bone cavity. If there are none distally, the trabeculae from the proximal medullary space traverse the osteotomy zone and unite with the inner surface of the compact substance of the distal fragment near the osteotomy.

In the proximal medullary space there are no cartilage cells to be found, but in the distal medullary space – in areas with insufficient capillarisation, i. e. in the area of the lesion and immediately below it. Thus proximally we find exclusively desmal ossification and distally both chondral and desmal bone formation side by side.

There was absolutely no indication that mechanical forces in this experiment would have damaged or destroyed the regenerated callus. The differentiation of the reparative callus is exclusively dependent upon the vascularisation.

The repair processes in the animals treated with DIC and the control animals do not differ regarding the course of the healing processes. However, they can be recognised earlier in the DIC animals and show a higher degree of cell activity at each phase.

Example

Whilst the cortex zone near the osteotomy of the untreated animals, e. g. after 13 days, still shows osteocytes almost without response and with pyknotic, eccentric nuclei in the narrow, oblong, spindle-shaped bone-cell cavity, highly enlarged lacunae can be observed both proximally and distally in the DIC animals. In these lacunae centrally positioned almost round nuclei (30) indicate their activity by the porous structure.

Part II: Physcial and Chemical Results

Bone Healing and Dynamic Interferential Current (DIC)

Summary: In the course of supplementary physical and chemical investigations of the influence of **D**ynamic **I**nterferential **C**urrent (DIC) on bone healing, 24 black-head sheep were subjected to transversal osteotomy of the radius. After an instable osteosynthesis the site was exposed to repeated therapy with DIC of varying mA intensity. (Methodological details are described in part I). DIC therapy resulted in altering the temperatures in the treated tissue, dependent on the mA intensity. Further associations were verified between DIC intensity and the occurrence of an alkaline phosphatase activity, which also reflected increased calcifying activity. Measurements of the calcium and phosphorous levels in the regenerated (newly forming) bone tissue documented full mineralization in the DIC-treated animals at a much earlier date than in the untreated control animals that had undergone similar operations. Whether DIC specifically stimulates osteogenesis within "healing" bones is still unclear.

Key words: Behaviour of tissue temperature under DIC – Hydroxyproline – Calcifying activity – Calcium – Phosporous levels – Degree of mineralization.

Investigation of the Temperature Behaviour during DIC-Therapy

No signs of damage to the tissue of the animals treated with DIC could be ascertained clinically or histologically, not even immediately surrounding the AO material. Transcutaneous measurements taken with highly sensitive probes over the whole duration of the DIC therapy showed reproducible temperature changes at the metallic implant and the soft tissue around it in the osteotomy zone. In order to eliminate possible disturbing effects due to the animals' restlessness, we took all the measurements on sedated animals (1 ml Xylazine, Rompun® i.m.). When the therapy was started using 12 mA, the course of the curve during the first minute always showed a temperature drop of 1.2° C ($n = 5$) on average and after 12 minutes treatment the temperature reached approximately the initial value again. (Fig. 11). One minute later (a longer break in the treatment did not produce any noteworthy differences, as the preliminary experiment showed) the maximum output of the device, approx. 60 mA, was applied to the animal. This always led to a temperature rise, which after 4 minutes was above the normal limits specific to animals (average normal temperature of sheep 38,5° – 39° C) and after 11 minutes reached 40.5° C. The skin temperature changed analogously to the temperature measured in the osteotomy zone.

These measurements were taken in addition to the above mentioned measurements with separate elec-

trodes for measuring skin temperatures. The temperature of the skin surface sank relatively rapidly after the end of the treatment.

No temperature fluctuations were registered in the o emperature, which was also checked.

The surface of the metallic implant itself, which was treated with DIC, showed no signs of corrosion or corresponding metallic changes.

Results of the Chemical Analyses

The results of the histological analyses can be quantified biochemically from the course of the calcifying activity and analytically and chemically through calcium and phosphorous analyses in the drill punch cylinders from the osteotomy zone.

The occurrence of an extracellular phosphatase, which can be determined biochemically, in the course of the hard tissue formation, most probably marks the moment of the first mineralization phase of the matrix rich in collagen. Consequently the activity of the enzyme per quantity of matrix rich in collagen from which it was extracted, can be regarded as calcifying activity. The matrix is put on a par with collagen here. The collagen content was established by means of a hydroxproline analysis (Hyp analysis). The illustration shows the course of the "calcifying activity" dependon time (Fig. 12). It is noticeable that *maximum activity in all three series of measurements occurs at the same time* after approximately 2.7 weeks. It is clear that the height of intensity of the calcifying activity varies. In the animals in group III (60 mA = maximum appliance output) it is approximately 10 times higher than that of the untreated animals and in the animals in group II (12 mA) it is twice as high.

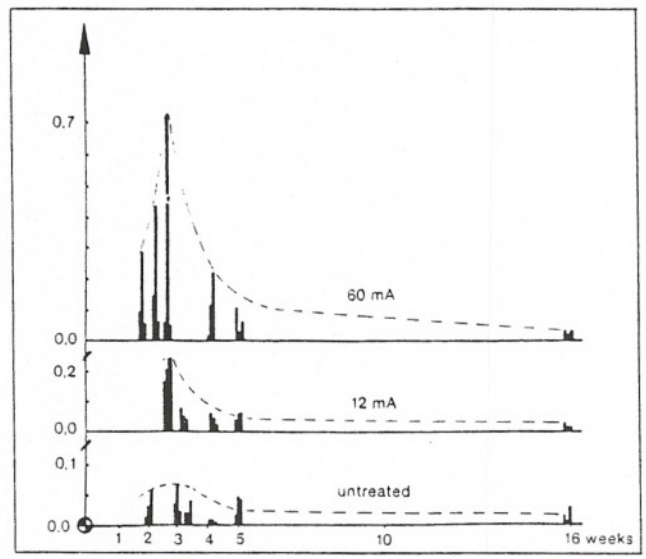

Fig. 12: Extracellular alkaline phosphatase activity in relation to the collagen matrix (shown through the hydrooxyproline content here) after dynamic interferential current treatment of different strengths dependent on time. This can be regarded as *a parameter for the calcifying activity*. Measurements were taken in the distal region near the osteotomy zone (left column of the triple block), in the osteotomy zone itself (middle column) as well as in the proximal region near the osteotomy zone (right column).

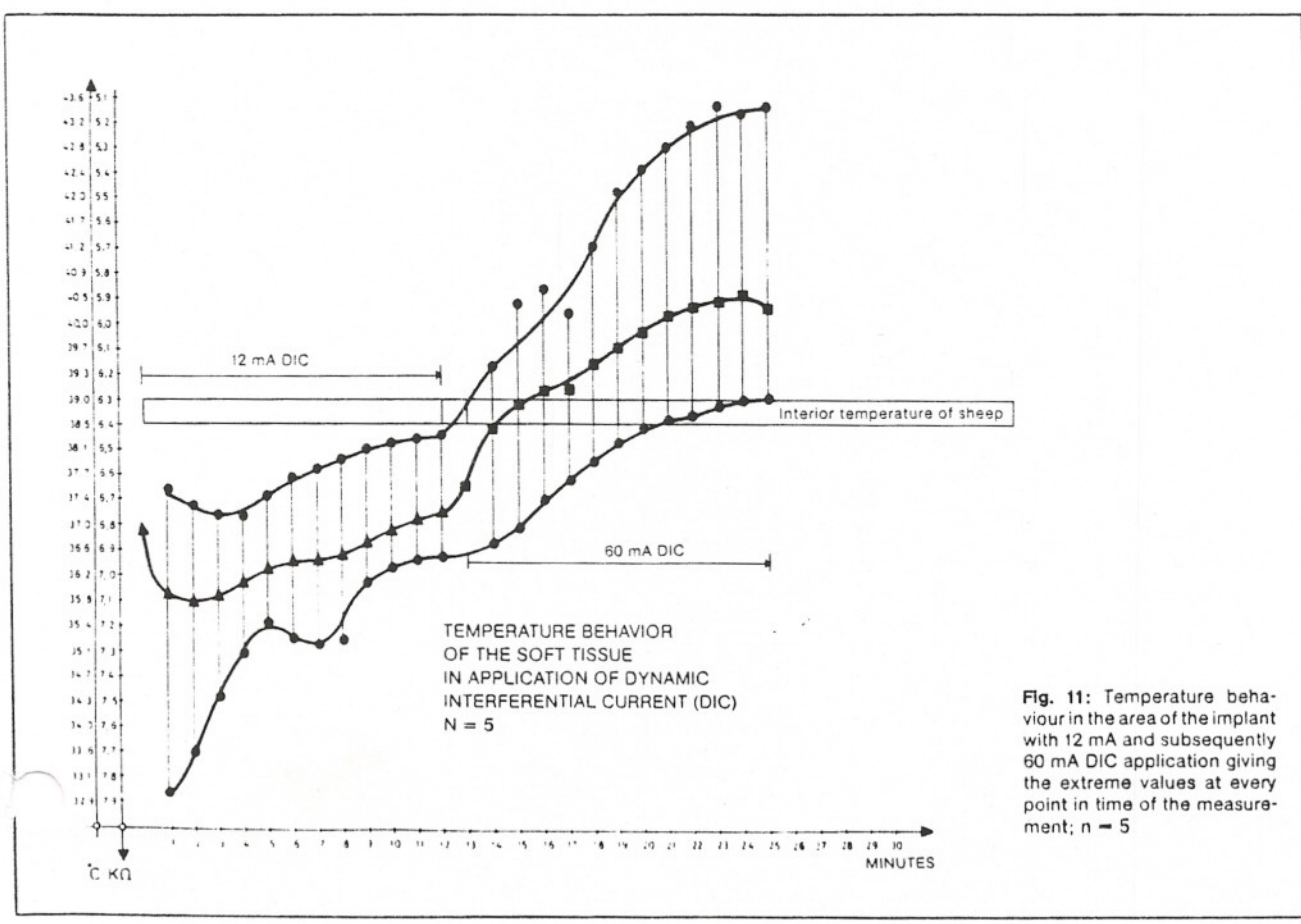

Fig. 11: Temperature behaviour in the area of the implant with 12 mA and subsequently 60 mA DIC application giving the extreme values at every point in time of the measurement; n = 5

The analytical chemical element analyses showed that the calcium and phosphorous levels of the callus in the osteotomy gap of the animals treated with DIC increase altogether faster than those of the control animals (Fig. 13). The early phase up to 3 weeks after the operation is excluded here, since during this period the mineralization is only initiated, shown by the increased activity of the alkaline phosphate. In the period of 3-6 weeks the calcium levels increase almost continuously after the application of DIC (12 mA). The Ca level is e.g. 6 weeks after the operation 18.5 % Ca (± 0.32 s, n = 8) and the phosphorus level is 8.5 % P (± 0.32 s). Thus these values almost correspond to those of the fully mineralized bone material. The clearly lower calcium level in the regenerated bone tissue of the control animals explained the strikingly lower degree of mineralization of the callus in this group compared to the animals treated with DIC. For example, 6 weeks after the operation only 7.4 % Ca (± 0.37 s, n = 8) and 3.4 % (± 0.31 s) were detected over the osteotomy zone in the callus of the control animals. A "full mineralization" could be seen in the animals treated with 12 mA in the 7th week with 20.4 % Ca (± 0.49 s, n = 6) and 9.2 % (± 0.51 s). In comparison, the callus of the untreated animals contained 13.2 Ca (± 0.51 s, n = 6) and 6.1 % P (± 0.45 s) at the same point in time.

In group III (60 mA = maximum appliance output) full mineralization of the callus already followed after 27 days with 19.0 % Ca (± 0.13 s, n = 8) and 9.5 % P (± 0.20 s).

At the end of the experiment after 16 weeks the calcium and phosphorus levels were the same in all 3 groups of animals. The tissue of group I contained 21.5 % Ca (± 0.14 s, n = 12) and 10.4 % P (± 0.14 s) and the callus of group III contained 21.5 % Ca (± 0.36 s, n = 12) and 10.1 P (± 0.05 s).

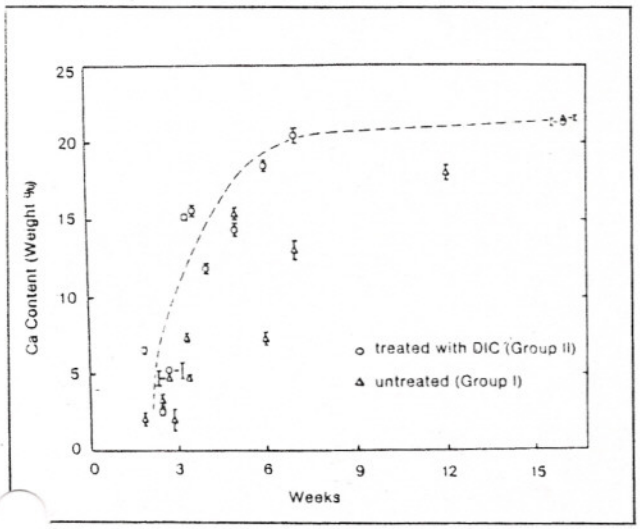

Fig. 13: Chemical analysis of the callus tissue over the osteotomy gap (Ca). Controlled course of mineralization in all animals. Degree of mineralization in the animals treated with DIC already reaches values similar to those in bones (approx. 20 % Ca) after approx. 5 weeks.

Discussion:

The influence of treatment with "electric current" on bone healing processes continues to be a subject of interest, since so far the known electric stimulation methods with direct and alternating currents have not actually fulfilled expectations, as hoped in clinical practice.

With the various methods mentioned at the beginning both direct and alternating currents as well as interferential currents were applied by means of electrodes, which were implanted into the bones and/or soft parts (7, 9, 17, 20, 22, 26, 35, 36). Only the device developed by BASSETT and his team (5) for the application of electromagnetic potentials works as a non-invasive therapy method, i.e. without surgically implanted electrodes.

The efficacy of electromagnetic potentials during the treatment of fractures and pseudoarthroses with retarded healing is regarded with controversy. ENZLER and his team (12) saw *"no effect* regarding the acceleration of bone healing" in beagle hounds treated with electromagnetic stimulation according to BASSETT'S method.

SCHMITT-NEUERBURG and his team (32) did not observe any effects on beagle hounds "with pure electromagnetic fields" either. However, they recommend "low frequency alternating current potentials with implanted transformers for treating fractures and oligotrophic pseudoarthroses in connection with appropriate surgical treatment (method according to KRAUS-LECHNER).

On the other hand environmental studies have shown that people who were subjected to strong electromagnetic fields in the environment have not shown "any signs of a biological reaction so far", which could be directly traced back to these fields.

In our study, in contrast to the above mentioned treatment methods, we wanted to produce a dynamic interferential current field in the osteotomy region by means of electrodes placed *on the skin.* This non-invasive method would be simple to apply and moreover would have the advantage that the risk of an operation and the danger of local infection would be eliminated.

Before the bone healing under the effects of dynamic interferential current could be investigated under these conditions, the interferential current in the soft tissue and at the bone lesion had to be verified first of all, since so far, despite 30 years of therapeutic application of interferential current on patients, there have been no investigations to discover whether the theoretically presumed interferential current field forms at all in living tissue. According to ENGELBRECHT "a final sure statement about the qualities of current actually present in the tissue cannot be made" (11).

Our investigations were intended to clarify this question too. With the help of microelectrodes, we were able to establish consistently by means of oscilloscope checks in vivo on 24 sheep, that an endogenous dynamic interferential current field actually develops in living tissue through superimposition of medium frequency currents from 2 electric circuits from the Nemectrodyn N 8 appliance, 1978 model. Convergences at pointed metallic implants could not be determined as opposed to information from SCOTT (1953). In contrast to ENGELBRECHT'S assumption, for the first time we were thus able to detect a dynamic interferential current field in the living body and give first indications regarding the behaviour around metallic implants. Thus we fulfilled FRIEDENBERG'S claim (13), that a "controlled system is necessary, in order to produce a constant flow of current over a longer period", if electrically stimulated osteogenesis is to be investigated.

It should be added here that MEYER-WAARDEN and HANSJÜRGENS (1980)[1] contributed to our experimental procedure. With computer-aided calculations and graphic presentation of these, they determined physically as well as mathematically that the field distribution of the dynamic interferential current, dependent on direction, was not influenced by the inhomogeneity of the living tissue nor by metallic osteosynthesis material. (This is to be reported on separately).

Swallowing of the osteotomy region as described by BASSETT and his co-workers (5) for electromagnetic fields in the presence of metallic implants, were not detected with the DIC method.

In addition to therapeutic effects, undesirable side effects have to be checked. No cell damage was observed in any of our experimental animals in the bone tissue or in the surrounding soft part mantle through the application of DIC (21), although we were able to measure typical temperature behaviour under the application of DIC at the metallic implant and its surroundings.

ENGELBRECHT and his co-workers (1978) believe they observed in a 75 year old patient, to take an example, "that through interferential current therapy a loosening of joint endoprotheses" takes place and regard it as being possible, that "the interferential current can cause mechanical abrasion, that is loosening, particularly between metal and plastic layers". On the contrary, after observing prosthesis loosening over a period of about 8 years in patients who were treated with dynamic interferential current after alloarthroplastic repair of the hip joints, we cannot confirm this statement.

The same applied to patients who had a metallic implant inserted after limb fractures and were then treated with dynamic interferential current.

On the contrary, after the application of dynamic interferential current (DIC) with Nemectrodyn appliances N 8 (models from 1973 and onwards) within the therapeutic range[2], the patients stated that they experienced pain relief and relatively speedily increasing mobility of the operated joints, which also continued. If a "mechanical factor plays a decisive role in the upper therapeutic range", which according to ENGELBRECHT and his co-workers (1978) can be explained through "fine and coarse, very frequent muscle twitching, which could lead to vibrations in the metal,", then this effect must also apply to all limbs treated correspondingly, regardless of whether it concerns a joint with an endoprothesis or a limb fracture osteosynthesized with metal implants.

Our experiment was arranged, so that this "mechanical factor" would arise in the animals treated with 60 mA DIC, since our Nemectrodyn appliance was "set at full power" following the information from ENGELBRECHT and his co-workers (1978). The application of the highest intensity of dynamic interferential current (60 mA) produced by the appliance was only tolerated by the animals, after they had been made unconscious (Xylazine, Rompun®), and extension spasms of the limbs and trunk occurred for about 1-2 minutes in all animals. Under this type of extreme strain of the bone and osteosynthesis material through rhythmic maximum contraction and relaxation of the limb muscles, the "alternating tension", which the above authors give as being the cause for the loosening, could have occurred at the borders between implanted metal and bone. Under these experimental conditions, a mechanism comparable to the "micro-abrasion" between metal and bone cement is to be expected at the border area between AO-screws and the tubular bone.

However, we were able to establish that in the animal experiments our clinical observations were confirmed, i. e. the osteotomies healed up without complications and no loosening of the implants arose.

Furthermore, after animal experiments on Göttingen minipigs, ENGELBRECHT and his co-workers only observed a "connective tissue layer between metal and palacos in the 3 protheses treated with the Nemectrodyn" and not in the 4 control animals. However, he saw a connective tissue casing of the same width around the AO-material in all animals, regardless of which group they belonged to and of the dynamic interferential current treatment, i. e. in all 55 operated animals including the control group (without DIC), which were examined with a view to answering other questions, which are not being discussed here.

In clinical practice, osteosynthesis material on the level of connective tissue after operations, which took place quite a while ago, are just as well known as connective tissue membranes between the prothesis shaft and palacos, which can be detected, if the shaft

[1] Personal communication

[2] The therapeutic range used by us for the dynamic interferential current treatment was an mA intensity, which was below pain sensation

can be pulled out of the palacos position effortlessly, when a prothesis is being changed. This has been experienced in cases where no interferential current treatment was used. We found no indication, neither clinically nor in the animal experiment, that the layer of connective tissue around the metal could have formed especially due to the effect of interferential current. In their monograph about "alloarthroplasty of the hip-joint", HUGGLER and SCHREIBER (1978) give a total of ten "possible causes of implant loosening", significantly without any indication of interferential current. One important reason for prothesis loosening between the prothesis shaft, palacos and bone tissue is without doubt, basically due to instability, whereby some causes cannot be explained, in particular "the initial occurrence of the prothesis loosening" of the implant in the minipigs treated with interferential current in ENGELBRECHT'S study, insufficient contact between the palacos and prothesis or fractures or infractions of the palacos-mantle could be considered. Furthermore, a "specially made complete knee prothesis" could cause specific problems in the animal chosen, especially with such a low number as 8 implanted protheses of this kind, including the 3 treated with interferential current. In our opinion, ENGELBRECHT'S assumption, that "damage to joint protheses comes from interferential current" is invalid.

Since no indication was made about the type of interferential current (static interferential current, dynamic interferential current) applied to the animals, the question remains open regarding the sort of electricity and the type of appliance (year of construction) used to obtain the results. It is possible that an interferential current appliance was used, which no longer corresponds to today's technical standards. Thus the results could not be compared, whereby we are aware of the problems of comparing results gained from animal experiments amongst themselves and with different species and, in particular, when transferring these results to humans.

We were not able to find any signs of osteolytic processes in our material, as observed by DIGBY, WEIGERT (8, 35) and others, e. g. after the application of direct current at the implanted anode. There were no electrolytic changes in the metal implants in the control animals nor in the animals treated with DIC, which are being discussed the same as ever with regard to the application of middle frequency alternating current (19).

It is more difficult to demonstrate that DIC has a therapeutic effect on fracture healing. From the results of our own histomorphological and chemical investigations we have come to the conclusion, that in the experiment presented here, each phase of the bone fracture healing is identical in all of our animals examined.

The development of the healing bone tissue with a more dense structure and higher degree of mineralization could be detected about 6 days earlier in the animals treated with DIC. It was observed in all groups regardless of the DIC treatment, that, as the callus was increasingly mineralized, particular element ratios change characteristically in almost the same way as found with other mineralization systems rich in collagen. In this way, after the transfer from a non-mineralized to a mineralized condition, the Mg/Ca and CO_2 ratios decrease in the same way and the Ca/P ratios increase, as QUINT and his co-workers (28) found with cartilage mineralization of the epiphyseal cartilage, tendon mineralization of a turkey tibia and mineralization of predentin (29, 30).

The start of the calcification of the tissue rich in collagen in the whole regeneration zone of the transversal osteotomy is marked by the development of a specific alkaline phosphatase (16). Increased collagenic synthesis correlates with increased hydroxyproline values. Under a high DIC intensity (group III, 60 mA) values with a factor of 10 and under the application of 12 mA with a factor of 2 can be verified as opposed to the control group.

After all that has been said up to now, in all cases – whether treated or untreated – the healing of a bone fracture obviously needs a constant starting phase, which cannot be influenced by DIC treatment. An acceleration of the bone healing process does not occur until the second phase, which can only be explained by a large increase in the activity of the cells "responsible" for calcification.

The reason for the full load-bearing capacity occurring up to 6 days earlier in a sheep under the influence of DIC, which we discovered from the results of our clinical, radiological, histological and chemical investigations, is apparently due to the faster development of a better constructed callus. In particular, as opposed to the control group, in the animals treated with DIC a callus form developed, which was characterized by lamellar callus supports in "column-shaped reinforcements" at the craniomedial and caudolateral periphery with thicker and more dense trabeculae with a more even micro-architecture and increased mineralization. The medullary space, the compact substance and the tissue between the detached periosteum and outer surface of the compact substance of the radius shaft all take an active part in the bone regeneration processes.

From the medullary space and the subperiosteal area ingrowing connective tissue cells enlarged in the osteotomy gap and did not appear here as osteoactive cells, i. e. osteoblasts and osteoclasts, until they reached the surface of the resection points in the radius. Independent of the relatively better vascular supply a slow substitution and lacunary decomposition of the bone could have occurred at the proximal cut surface and thus earlier than at the distal surface. Here the "opening" and enlargement of the osteons made it possible for the vessels in the connective tissue to connect to the vascular system of the inner compact substance. This could explain a more

speedy absorption of the haematoma, which surrounded the bone lesion, a process, which was more apparent in the animals treated with DIC. The subdivision of the bony regeneration tissue in the osteotomy gap to 3 zones could be interpreted as an expression of the different conditions of activity of the cell-populations, not ossifying at the same time, dependent on the vascularisation density relevant in each case.

We associate these findings with the effect of the dynamic interferential current. GÜTTLER and KLEDITZSCH (17) reached similar results. They also observed a speedier and more distinct callus formation in rabbits under interferential current stimulation, however, with *implanted screw electrodes* and only by evaluation of X-ray pictures.

To summarize, we have ascertained from investigations with animal experiments that it is not yet clear, whether dynamic interferential current (DIC) exerts "specific stimulation" on the osteogenesis of healing bones and where its starting point is to be found. So far it can be said that the quality of the "phases" of bone healing, which cannot be completely separated from one another, is the same in all groups, whereby it was seen in the animals treated with DIC that the course of healing occurred earlier. In quantity the animals treated with DIC differed amongst themselves independent of the DIC intensity applied as well as in comparison with the control animals. In this animal experiment an accelerated and controlled mineralization process of the callus tissue under the application of DIC was assumed.

The cause of our findings could be the increased stimulation of the vascular connective tissue. However, at the present time the question must remain open, as to whether dynamic interferential current has a direct or indirect effect.

Further results from our study with animal experiments will be reported on at a later date.

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