

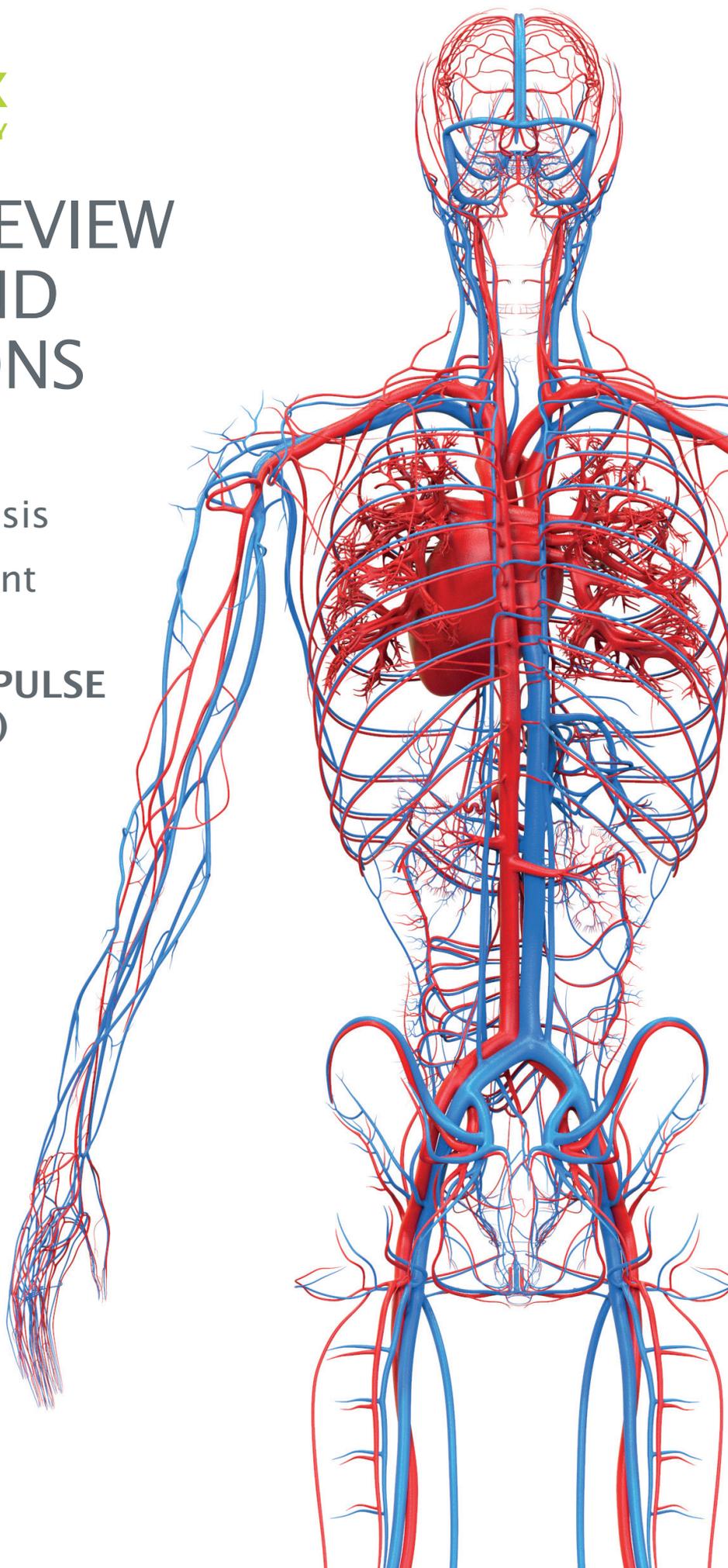
VADO[®] by OPED **plex**
VASCULAR IMPULSE TECHNOLOGY

CLINICAL REVIEW STUDIES AND PUBLICATIONS

Prophylaxis of
Deep Vein Thrombosis

Oedema Management

with
**INTERMITTENT IMPULSE
COMPRESSION (IIC)**



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STUDIES SHOWING EFFECTIVENESS OF IIC IN PREVENTION OF DEEP VEIN THROMBOSIS

PROSPECTIVE, RANDOMIZED TRIAL: COMPARISON OF INTERMITTENT IMPULSE COMPRESSION WITH LOW-MOLECULAR-WEIGHT HEPARIN TO PREVENT DEEP-VEIN THROMBOSIS IN PATIENTS WITH TOTAL HIP REPLACEMENT.

Warwick, D., Harrison, J., Glew, D., Mitchelmore, A., Peters, T. J., & Donovan, J. (1998).

Comparison of the use of a foot pump with the use of low-molecular-weight heparin for the prevention of deep-vein thrombosis after total hip replacement. A prospective, randomized trial.

The Journal of Bone and Joint Surgery. American Volume, 80(8), 1158–1166. <https://doi.org/10.2106/00004623-199808000-00009>

Device: **A-V Impulse System™**

Background

A prospective, randomised trial will compare the effectiveness of intermittent impulse compression (IIC) using the A-V Impulse System™ in preventing deep vein thrombosis (DVT) after total hip replacement with that of low molecular weight heparin (LMWH, Enoxaparin).

Design

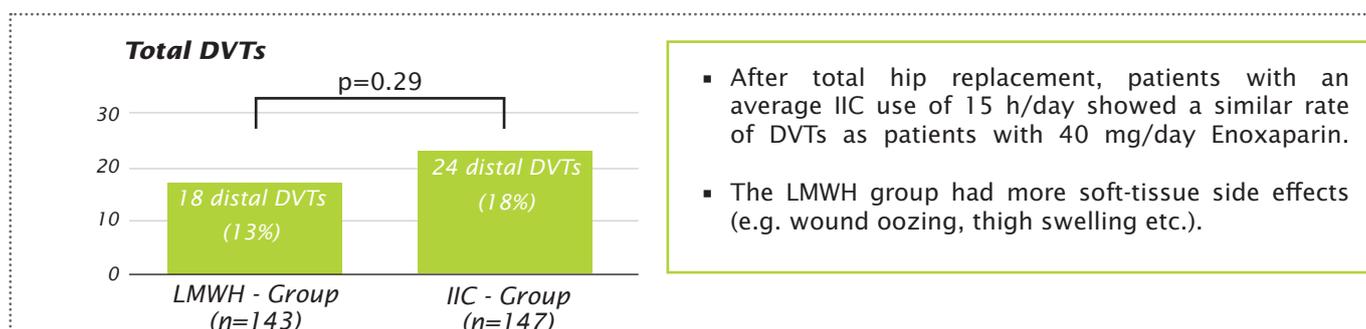
Of 290 patients with total hip replacement, 143 were randomly selected to receive Enoxaparin (40 mg/day, starting 12 hours pre-operatively; 7 days post-op), whereas 147 patients were treated with IIC for 7 days, starting post-operatively. Diagnosed by modified Rabinov-Paulin venography, the prevalence of DVT on the sixth, seventh, and eighth day post-surgery was defined as primary outcome. As secondary outcome, side effects regarding perioperative blood loss, post-operative drainage, blood parameter, transfusion requirements and the blood-loss index were calculated. Further, bruising of the thigh and oozing of the wound were subjectively assessed. Patient compliance regarding the A-V Impulse System™ was monitored using a built-in timer. The acceptance of the system was surveyed by means of a questionnaire.

Results

In the IIC group, 24 (18%) thromboses were identified compared to 18 (13%) in the Enoxaparin group (difference not significant $p=0.29$). None of these were located in the proximal deep leg veins. One symptomatic DVT occurred in the Enoxaparin group. One non-fatal pulmonary embolism was observed in the IIC group. There were no significant differences in known risk factors between the two groups. Both groups did not differ with respect to intraoperative blood loss, transfusion units and blood loss index. However, there were significant differences in post-operative drainage, wound oozing and bruising of the thigh in favour of IIC. Furthermore, the swelling of the thigh was significantly reduced in the IIC Group (10mm) compared to the Enoxaparin group (20mm). While soft-tissue lesions were more common in the Enoxaparin group, the clinical significance of this is unclear. Two patients, one treated with Enoxaparin and one treated with the A-V Impulse System™, were readmitted into hospital due to symptomatic DVTs on the 15th and 17th post-operative day, although there were no indication of DVT before discharge.

Conclusions

The authors designed this study as an equivalence trial (to show equivalent effect of 2 interventions on outcome measures). They found that IIC is a suitable alternative to LMWH to prevent DVTs in patients with total hip replacement. Additionally, IIC had less soft-tissue complications.



¹ The technology of VADoplex® or A-V Impulse system™ foot pump can be described as “intermittent impulse compression (IIC)”, a further development of the intermittent pneumatic compression (IPC). The pressure from the compression pad on the sole of the foot is developed in less than 0.4 seconds, whereby the blood from the venous plexus is accelerated like an impulse (see Gardner, A. M., & Fox, R. H. (1992). The venous footpump: influence on tissue perfusion and prevention of venous thrombosis. *Annals of the Rheumatic Diseases*, 51(10), 1173–1178. <https://doi.org/10.1136/ard.51.10.1173>)

RANDOMIZED CONTROLLED CLINICAL TRIAL: COMPRESSION THERAPY VS. LOW-MOLECULAR-WEIGHT HEPARIN FOR PREVENTION OF DEEP VEIN THROMBOSIS AFTER TOTAL HIP REPLACEMENT

Pitto, R. P., Hamer, H., Heiss-Dunlop, W., & Kuehle, J. (2004).

Mechanical prophylaxis of deep-vein thrombosis after total hip replacement: A randomised clinical trial. *The Journal of Bone and Joint Surgery*, 86-B(5), 639-642. <https://doi.org/10.1302/0301-620x.86b5.14763>

Device: **A-V Impulse System™**

Background

Although pneumatic compression has shown to reduce the risk of thromboembolic disease as an alternative to chemical prophylaxis, there were too few clinical trials that proved its equivalence in patients with total hip replacement (THR). The aim of this randomised clinical trial was to compare the effectiveness in DVT prophylaxis and safety of intermittent impulse compression (IIC)¹ using the A-V Impulse System™ with low-molecular weight heparin (LMWH) in patients after THR.

Design

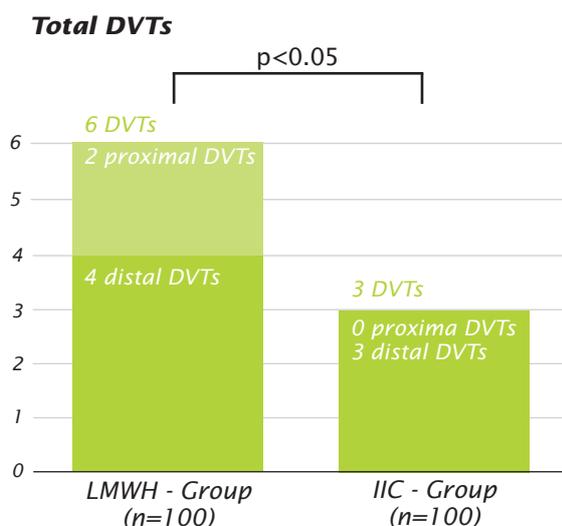
All 200 patients received LMWH against thromboembolism 12h before operation. After surgery, patients were randomly allocated in one of two groups continuing chemical DVT prophylaxis with LMWH or using intermittent pneumatic compression, specifically IIC, for mechanical DVT prophylaxis. Compression therapy was continuously applied (day and night) throughout the treatment period. Using serial duplex sonography, all patients were monitored with regard to DVT 3, 10, and 45 days after surgery. In addition, the daily measurement of thigh swelling a bruising, the post-operative drainage volume and the oozing of the wound were used as parameters.

Results

Venous thrombosis was detected in 3 of 100 patients in the IIC group (all distal DVTs) and in 6 of the 100 patients of the LMWH group (2 proximal, 4 distal DVTs). This difference was significant ($p < 0.05$). Prophylaxis with IIC reduced the post-operative drainage volume by 69 ml in average (259 ± 14.6 vs 328 ± 20.4 $p < 0.05$). The thigh swelling of the operated side was also significantly reduced (10 mm versus 15 mm, $p \leq 0.001$). However, 16 patients did not tolerate the IIC, while in the LMWH group one patient developed thrombocytopenia type 1.

Conclusions

The study compared the efficiency of post-operative mechanical and chemical DVT prophylaxis. With significant less DVTs, the effectiveness and safety of pneumatic compression as DVT prophylaxis could be shown. The use of foot impulse compression is further associated with significantly less surgery induced side effects such as soft-tissue swelling.



- The mechanical thromboprophylaxis was associated with significantly fewer DVTs compared to pharmaceutical anticoagulation.
- No pulmonary embolisms were detected in any group.

RETROSPECTIVE REGISTRY ANALYSIS: RESULTS OF RISK STRATIFICATION, MECHANICAL PROPHYLAXIS AND EARLY MOBILISATION IN 13,384 JOINT REPLACEMENTS

Gill, S. K., Pearce, A. R., Everington, T., & Rossiter, N. D. (2020)

Mechanical prophylaxis, early mobilisation and risk stratification: as effective as drugs in low-risk patients undergoing primary joint replacement. Results in 13,384 patients.

The Surgeon: Journal of the Royal Colleges of Surgeons of Edinburgh and Ireland, 18(4), 219–225.

<https://doi.org/10.1016/j.surge.2019.11.002>

Device: **A-V Impulse System™ & VADOPlex®**

Background

Chemical thromboprophylaxis is recommended in NICE guidance for all patients undergoing hip or knee arthroscopy. The aim of the retrospective registry analysis was to compare mechanical thromboprophylaxis alone to combined chemical and mechanical thromboprophylaxis with regard to the occurrence of venous thromboembolism (VTE) events, i.e., deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as complications after total hip/knee arthroplasty (THA/TKA) after risk stratification.

Design

Between 1999 and 2016, all patients undergoing THA/TKA were prospectively included in the local joint registry database. During the anamnesis, a review of the following risk factors for risk stratification took place: (1) personal or strong family history of DVT/PE, (2) myocardial infarction or stroke within 6 months, (3) continuous intake of oestrogens via oral contraceptives or hormone replacement therapies, (4) concomitant use of Tamoxifen/Zoladex®/similar drugs, (5) inherited thrombophilias, (6) paraproteinaemia, (7) obesity (BMI >35), (8) nephrotic syndrome, (9) myeloproliferative disease, (10) Behcet's disease, (11) active malignancy or treatment, and (12) antiphospholipid syndrome. If there was no additional risk factor, these patients were considered as low-risk patients and they received only mechanical thromboprophylaxis via intermittent impulse compression (initially A-V Impulse System™, more recently VADOPlex; IIC)¹. If patients had at least one additional risk factor, they received mechanical and chemical thromboprophylaxis based upon their high-risk stratification. A clinical examination was carried out after 2, 6 and 52 weeks. Further, the patients received annual questionnaires as well as clinical and radiological examinations after 5 and 10 years.

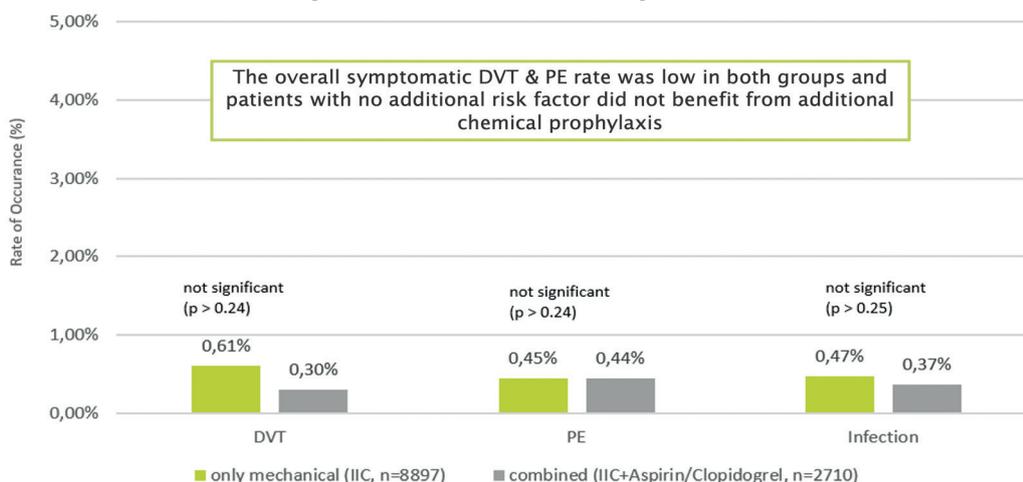
Results

There was an overall DVT rate of 0.48% as well as an overall PE rate of 0.42% in 13,384 patients after THA (n=6533) and TKA (n=6851). 86.16% of registered patients were assessed as low-risk patients. IIC alone was applied in 76.7% of the low-risk patients, while the other 23.3% received additional Aspirin®/Clopidogrel. The appearance of VTE events was not significantly affected by additional chemical prophylaxis in low-risk patients ($p > 0.24$). Further, there was no significant difference in infection rates ($p > 0.25$).

Conclusions

Because only symptomatic VTE events and no surrogate parameters were reported, the reported clinical rates of DVT and PE were lower than in comparable studies. It was shown, that additional chemical thromboprophylaxis had no effect on VTE rates when mechanical prophylaxis, concrete IIC, and early mobilisation were applied in low-risk patients. Thus, a targeted thromboprophylaxis strategy in terms of a risk stratification might question the need for chemical thromboprophylaxis for all patients undergoing THA or TKA.

DVT, PE and Infection Rates in all Patients with no additional Risk Factors (referred as "low-risk" Group n=11.607)



STUDIES SHOWING EFFECTIVENESS OF IIC IN OEDEMA MANAGEMENT

PROSPECTIVE RANDOMIZED CONTROLLED STUDY: EFFECTIVENESS OF VASCULAR IMPULSE TECHNOLOGY TO REDUCE SWELLING OF LOWER EXTREMITY JOINT FRACTURES

Schnetzke, M., El Barbari, J., Schüler, S., Swartman, B., Keil, H., Vetter, S., Gruetzner, P. A., & Franke, J. (2021).

Vascular impulse technology versus elevation for the reduction of swelling of lower extremity joint fractures: Results of a prospective randomized controlled study.

The Bone & Joint Journal, 103-B(4), 746–754. <https://doi.org/10.1302/0301-620X.103B4.BJJ-2020-1260.R1>

Device: **VADOPlex®**

Background

Complex joint fractures of the lower extremities represent a challenge in everyday inpatient life due to the soft-tissue swelling and associated complications. Compression therapy is known to enhance venous blood flow and assist lymphatic removal. Thus, compression therapy, specifically the use of vascular impulse technology (VIT)², can complement conventional methods to reduce swelling and at the same time shorten the perioperative admission time. The study compared the effectiveness of VIT treatment with elevation of the extremities as a measure to reduce swelling.

Design

Between 2016 and 2019, 100 patients were enrolled. 40 patients were diagnosed with a dislocated upper ankle fracture or intraarticular calcaneal fracture and 20 with a tibial pilon fracture. Randomisation was 1:1, with the active group receiving the pre- and post-operative VIT intervention (6-8 hours/day). The control group positioned the injured limb above heart level during the period stated. By using the VADOPlex system (OPED GmbH, Oberlindern, Germany), compression (130 mmHg) was generated at 20 second intervals. The venous plexus in the sole of the foot is stimulated and triggers a pulse-like venous return, which corresponds to the effect of normal walking with full weight bearing. The primary endpoint was the duration from admission until the patient was ready for surgery (in days). The suitability for surgery was assessed daily by independent doctors („skin folds“). As secondary endpoint, tissue swelling was determined daily as the circumference difference of both legs (smallest circumference of the calf). Pain (VAS pain scale), required pain medication and any occurring complications were additionally recorded.

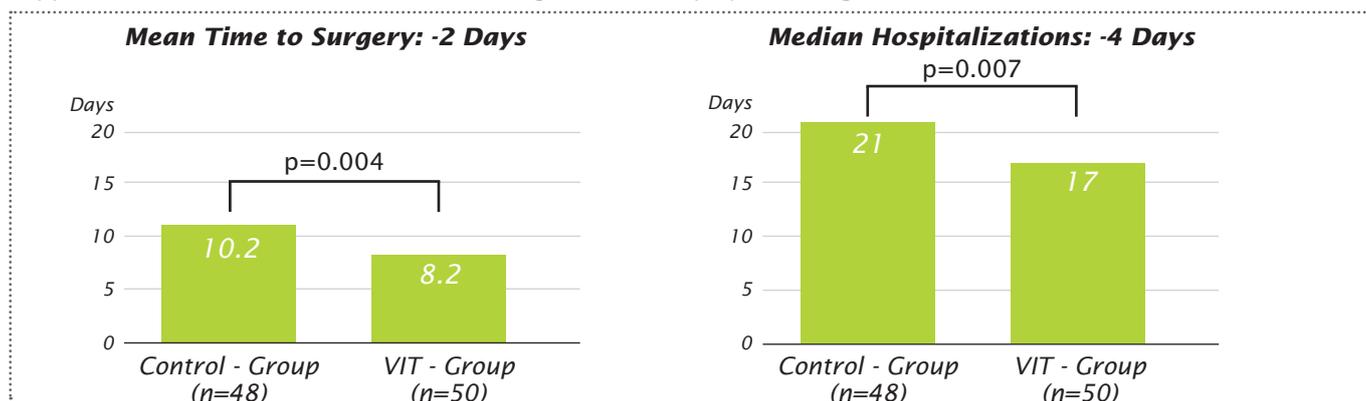
Results

Demographic variables and fracture severity were comparable in both groups. The time suitable for surgery after intervention with VIT therapy was 8.2 ± 3.0 days, significantly different from the control group (10.2 ± 3.7 days; $p=0.004$). The time suitable for surgery is significantly reduced by 2.6 days after intervention for upper ankle joint fractures and calcaneal fractures (8.6 ± 2.2 days vs. 10.6 ± 3.6 days; $p=0.043$). Pilon fractures of patients in the intervention group were considered ready for surgery after 9.8 ± 4.1 days and after 12.5 ± 5.1 days after elevation of the limb ($p=0.205$).

The intervention of using a compression system reduced swelling by 77.8% pre-operatively and 12.4% post-operatively ($p<0.001$). While the complication rate of the intervention group was 10% (5/50), a rate of 18.8% (9/48) was observed with elevation of the limb ($p=0.216$). The revision rate was 12% in the control group, reduced to 2% by active compression. Patients in the intervention group reported significantly less pain pre-operatively (-0.51 points on VAS pain scale, $p=0.050$), post-operatively (-0.93 points on VAS pain scale, $p=0.013$) and on the day of discharge (-0.71 points on VAS pain scale, $p<0.001$).

Conclusions

Compared to conventional soft-tissue conditioning (elevation), VIT treatment achieves time suitable for surgery about two days faster, reduces the hospitalization time and supports pain relief. Moreover, there is a trend towards reduced soft-tissue-related revision rates and swelling compared to the control group. The application of VIT can be used as a supplement to conventional methods (cooling, elevation, lymph drainage).



² The term "VIT" used in the publication relates to the subtitle of the manufacturer's product logo "VADOPlex® - Vascular Impulse Technology" and refers to the principle of intermittent impulse compression (IIC).

CLINICAL AUDIT: EFFECTIVENESS OF “IN-CAST” PNEUMATIC INTERMITTENT PEDAL COMPRESSION FOR THE PRE-OPERATIVE MANAGEMENT OF CLOSED ANKLE FRACTURES

Dodds, M. K., Daly, A., Ryan, K., & D’Souza, L. (2014).

Effectiveness of ,in-cast’ pneumatic intermittent pedal compression for the pre-operative management of closed ankle fractures: A clinical audit.

Foot and Ankle Surgery : Official Journal of the European Society of Foot and Ankle Surgeons, 20(1), 40–43.

<https://doi.org/10.1016/j.fas.2013.09.004>

Device: **A-V Impuls System™**

Background

Prolonged waiting times until a patient with ankle fracture is ready for surgery can impact the outcomes. This study investigated the efficacy of an in-cast intermittent impulse compression (IIC)¹ using the A-V Impulse System™.

Design

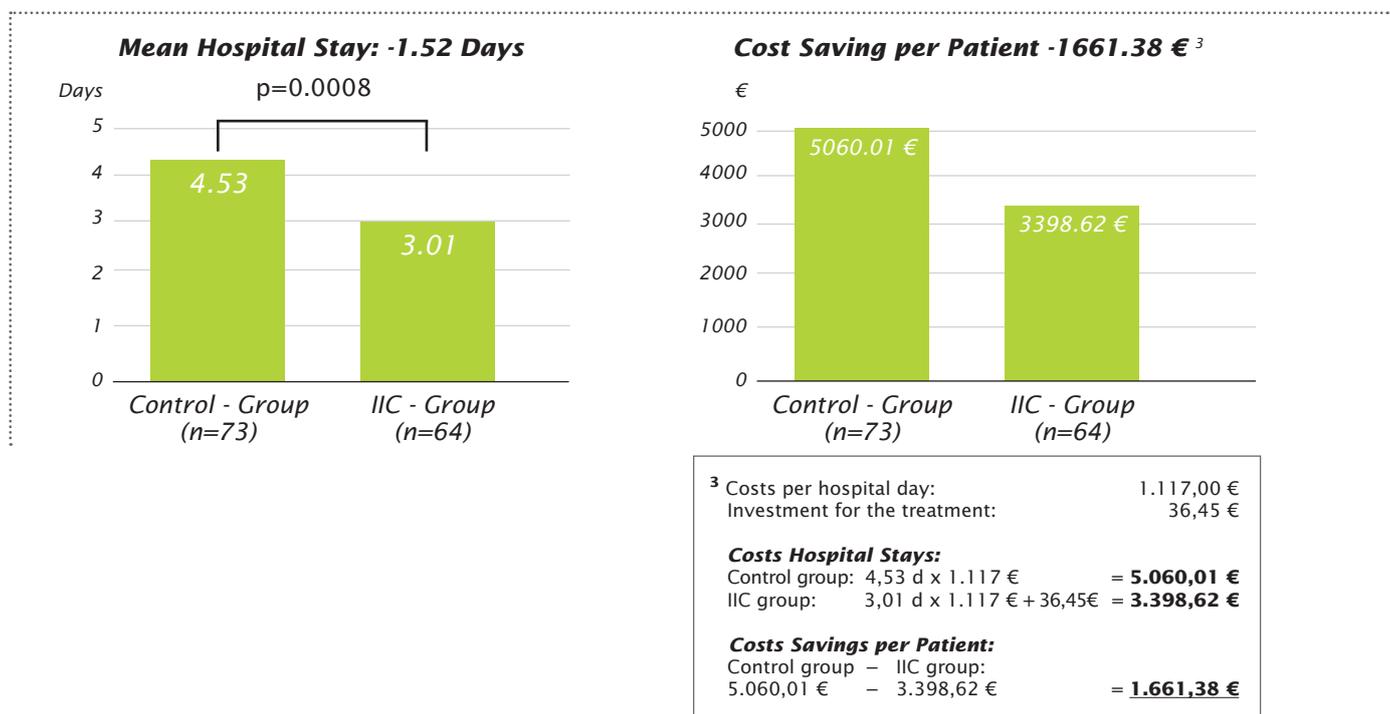
This study was performed in a clinical audit design. The control group consisted of 73 patients with closed ankle fractures that had been admitted for surgical treatment between January 2007 and December 2007 and whose data were retrospectively reviewed. The standard treatment included the ankle’s early relocation in the emergency department with following application of a backslab splint and pain medication. Additionally, elevation and cryotherapy were implemented for soft-tissue conditioning. The prospectively observed study group consisted of 64 patients (consecutive series) with closed ankle fractures who were treated with an in-cast artero-venous impulse device between November 2008 and October 2009 (IIC group). Time to surgery, length of inpatient treatment and appearance of wound infection were defined as study outcomes.

Results

The median pre-operative length of stay was 2 days (Range: 0-10) in the control group and 1 day (Range: 1-3) in the IIC group which represents a significant difference in the distribution between the two groups (p=0.0025). Regarding the total length of hospital stay, the IIC group also showed better results: The median length of hospital stays were 4 days (Range: 1–28) in the control group and 3 days (Range: 2–7) in the IIC group. The differences between the two groups were also significant (p=0.0008). Furthermore, the study was able to show a clinically significant reduction in the rate of surgical site infections that required antibiotics (3% in the IIC group vs. 11% in the control group).

Conclusions

Controlling and managing soft-tissue oedema is helpful to avoid soft-tissue complications and surgical infections. As this study shows, using an in-cast IIC device can reduce the length of hospital stay in patients with closed ankle fractures. The reduction of the inpatient treatment duration is mostly based on the reduced pre-operative phase. The authors believe that „the routine use of in-cast AV [artero-venous] compression foot pumps has practical benefits to the patient as well as economic benefits to trauma units and resource providers.“ (p. 43)



STUDY SHOWING EFFECTIVENESS OF SWELLING REDUCTION WITH IIC

COMPARISON OF INTERMITTENT IMPULSE COMPRESSION AND CONTINUOUS CRYOTHERAPY IN RELATION TO THE REDUCTION OF POSTTRAUMATIC OEDEMA

Stöckle, U., Hoffmann, R., Schütz, M., von Fournier, C., Südkamp, N. P., & Haas, N. (1997).

Fastest Reduction of Posttraumatic Edema: Continuous Cryotherapy or Intermittent Impulse Compression?

Foot & Ankle International, 18(7), 432-438. <https://doi.org/10.1177/107110079701800711>

Device: **A-V Impulse System™**

Background

In patients with foot and/or ankle injuries, surgery and post-operative mobilisation are often delayed due to swelling. The aim of this prospective study was to compare 3 treatments to reduce posttraumatic/post-operative swelling of the foot: intermittent impulse compression (A-V Impulse System™, Novamedix Services Ltd., England; IIC)¹, continuous cryotherapy (Polar Care 500, Breg Inc., Vista, CA) and cold packs (Coldhot pack, 3m Company, St. Paul, MN).

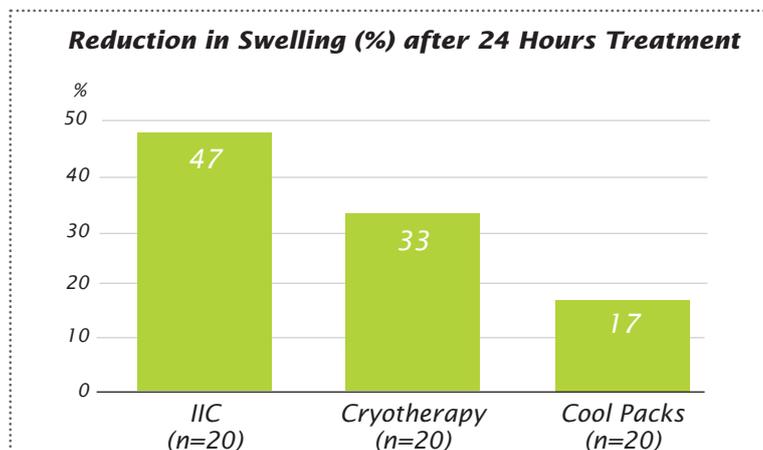
Design

60 patients with foot or ankle trauma were divided into three groups (n=20 each) in accordance with the randomisation procedure. One group received ICC, the second group received continuous cryotherapy, the third group received cold packs. Intermittent impulse compression applies a pneumatic pressure pulse (130 mmHg for 1 second) to the arch of the foot, rapidly releasing 20-30 ml of blood from the venous plexus. during the 20-second cycle, the venous plexus refills. IIC was applied almost continuously during the day, and the compression controller was allowed to be switched off at night. In continuous cryotherapy, ice water circulated permanently between the ice box and the cooling pad. The ice water was changed once a day. Cold packs were fixed with an elastic dressing and were changed four times a day. The circumferences of the ankle, scaphoid and forefoot were measured every 24 hours after the patient was admitted to hospital to determine the degree of swelling.

Conclusions

Both IIC and continuous cryotherapy reduced swelling significantly faster than conventional cold packs. However, IIC showed the fastest reduction in swelling before and after surgery. Due to savings of nursing staff time and possible shorter hospital stays, the authors assume that despite the higher initial costs, there might be an additional improved cost-benefit ratio in favor of IIC therapy.

Results



Abbreviations

- DVT** Deep Vein Thrombosis
- IIC** Intermittent Impulse Compression
- LMWH** Low Molecular Weight Heparin
- VIT** Vascular Impulse Technology

