

Hyiodine[®]

ACTIVATES HEALING NATURALLY

SUMMARY OF CLINICAL EVIDENCE

Hyiodine®

Hyiodine is a medical device intended for healing wide range of chronic, non-healing wounds.

It is used for healing diabetic foot ulcers, leg ulcers, dehisced wounds after surgery, or pressure ulcers. Thanks to its excellent healing properties, Hyiodine finds its application also in healing acute or traumatic wounds, where it speeds up the healing process, protects the wound against infection and helps to reduce scarring.

The product efficacy is based on the synergistic wound healing effect of hyaluronic acid and iodine complex. The unique combination of these two substances links the excellent regenerative properties of hyaluronic acid and the antimicrobial properties of iodine, making Hyiodine suitable also for the treatment of chronic infected wounds.



CHRONIC AND ACUTE WOUNDS

Author

Sobotka et al, 2003

Prospective, observational study

Study group

136 patients with wide range of chronic and acute wounds. The structure of wounds in the study: large surgical dehisced wounds complicated by infection (n=35), sternal dehiscence after cardio surgery (n=6), diabetic ulcers (n=32) including cases complicated by osteomyelitis - 3rd Wagner grade (n=20), pressure ulcers (n=22), leg ulcers (n=20), fistulae (n=12), and acute wounds (n=9) including burns, erosive lesions or cuts.

	Surgical Dehisced Wounds	Sternal Dehiscence	Diabetic Ulcers	Pressure Ulcers	Leg Ulcers	Fistulae	Acute Wounds
Complete healing	74.3 % (26)	100 % (6)	71.9 % (23)	77.3 % (17)	70.0 % (14)	91.7 % (11)	100 % (9)
Significant improvement	25.7 % (9)	0 %	15.6 % (5)	22.7 % (5)	30.0 % (6)	8.3 % (1)	0 %
No effect	0 %	0 %	12.5 % (4)	0 %	0 %	0 %	0 %

Main results

78 % wounds completely healed and 19 % significantly improved. The study revealed positive effect of Hyiodine on granulation growth and speed of the healing process in wide range of wounds. No allergic reactions or adverse effects were noticed during the study.

Pressure ulcer



Day 0



Day 120

Non-healing wound after venous graft removal



Day 0



Day 54

CHRONIC AND ACUTE WOUNDS

Author

Ott et al, 2011

Case series

Study group

Patients with diabetic ulcers, venous ulcers or infected traumatic lesions (n=15). Previous treatment included hydroactive dressings in majority of wounds.

Main results

Improved granulation growth and very good quality of newly formed skin was reported by the author. In two cases Hyiodine treatment prevented major amputation and in one case minor amputation. Application of autograft was not necessary in many patients. Significant reduction of pain was noticed as side effect in some cases.

Diabetic ulcer after amputation of metatarsals



Day 0



Day 98

Recurrent erysipelas of the right lower leg in association with venous insufficiency and peripheral arterial occlusion.



Day 0



Day 30

CHRONIC AND ACUTE WOUNDS

Author Brenes et al, 2011 Prospective, non-controlled, observational study

Study group Patients which failed previous treatment or had delayed healing with other wound healing modalities. 19 difficult to heal wounds with following structure: venous ulcers (n=4), postoperative wound infections (n=5), diabetic foot ulcers (n=5), traumatic wounds (n=3), one peranal fistula with abscess (n=1).

Main results 14 wounds progressed to complete healing and 4 wounds were close to complete healing at the end of the study. The author concluded that healing rates varied among the different types of the wounds, depending on their complexity and presence of infection, but they were generally better than those obtained with previous, unspecified treatment.

Chronic traumatic pretibial wound

Venous stasis ulcer



CHRONIC WOUNDS

Author Durante et al, 2010 Prospective, non-controlled, observational study

Study group Patients with delayed wound healing having recalcitrant complex wounds complicated with fistulae, colonized bone or high level of exudate (n=18). Previous mean treatment was 12,6 months.

Main results Of eighteen wounds 6 wounds completely healed and 8 wounds significantly reduced within two months. In 3 wounds there was improvement of wound bed and reduction in size of fistulae. The author concluded that Hyiodine treatment accelerated healing process, reduced bacteria burden, and high levels of exudate.

Vascular leg ulcer

Fistulae



Day 0

Day 166

Day 0

Day 69

CHRONIC WOUNDS

Author Wild et al, 2010 Observational report

Study group Chronic non-healing wounds with signs of infection (n=49)

Main results The author recorded that within 2 weeks of Hyiodine treatment granulation tissue was increased by 11% and wound size was reduced by 21% on average. Wounds infected by Pseudomonas were successfully treated without inhibition of healing process.

DIABETIC FOOT ULCERS

Author Sobotka et al, 2006 Observational, open study

Study group Severe diabetic foot ulcers (n=63) including ulcers complicated by osteomyelitis (n=22) and vascular occlusive disease (n=37)

Main results The author reported that 49 % of wounds were completely healed and 19 % significantly reduced. Introduction of Hyiodine treatment led to significant improvement of the healing process.

Diabetic foot ulcer



Day 0



Day 96

Black necrotic diabetic foot ulcer



Day 0



Day 180

DIABETIC FOOT ULCERS

Author Sobotka et al, 2007 Prospective, non-controlled, observational study

Study group Patients with complicated diabetic foot ulcers (n=18) suffering with peripheral neuropathy. Distribution of Wagner grades in the study group: Wagner IV (n=2), Wagner III (n=8), Wagner II (n=7), Wagner I (n=1)

Main results Complete healing was achieved in 15 wounds in a mean time of 133 days following commencement of therapy. Four patients with arterial stenoses or gangrene of toes had to undergo amputation.

Diabetic foot ulcer complicated by several fistulae



Day 0



Day 94

Deep diabetic foot ulcer probing to the heel bone



Day 0



Day 98

WOUND DEHISCENCE

Author Brenes et al, 2011 Non-controlled, observational study

Study group Patients with sternal wound dehiscence after median sternotomy (n=8). All wounds were infected and involved underlying osseous structures.

Main results The author reported that within 3 to 4 weeks all wounds were free of necrotic tissue and mucopurulent exudate, and growth of new granulation tissue was started. Time required for complete healing varied among patients, with a mean healing time of 136 days. After 2 months all patients were treated in the outpatient clinic. 7 patients completely healed, 1 underwent reconstructive surgery. Despite long period of treatment no allergic reactions or adverse effects were noticed.

Sternectomy with complete wound healing in 165 days

After 48 days of healing the patient sent for reconstructive surgery



Day 0



Day 165



Day 0



Day 48

WOUND DEHISCENCE

Author Sobotka et al, 2008 Non-controlled, observational study

Study group Patients with abdominal wound dehiscence (n=54) including wounds complicated by intestinal fistulae (n=27)

Main results The study showed positive effect of Hyiodine treatment on all wounds included in the study. Improved granulation growth and accelerated healing was observed by the author. Wounds without intestinal fistulae completely healed within 32.1 ± 21.3 days. Wounds complicated with intestinal fistulae significantly decreased in their size, what enabled surgical procedure or usage fo colostomy device. No allergic reactions or adverse effects noticed.

Large abdominal dehiscence after complicated gastric resection and subsequent operations; wound complicated by 8 intestinal fistulae.



Day 0



After 5 months of treatment, stage of the wound before surgery



Stage of the wound 3 days after surgery



Stage of the wound 2 weeks after surgery

SKIN GRAFTING

Author **Cap et al, 2008** Case reports

Study group Venous ulcers after skin transplantation (n=14)

Main results Use of Hyiodine before and after skin grafting led to good adherence of the graft to the wound bed and improved healing inspite of persistent infection in the wound. Positive side effect was reduction of pain which was claimed within several days after skin transplantation. The author showed that use of Hyiodine increased rate of successfully healed wounds after skin grafting from 50 % to 90 %.



Before skin grafting



Day 2 after skin grafting



Day 7 after skin grafting



20 days after skin grafting

WAR INJURIES

Author **Plodr et al, 2008** Case reports

Study group Soldiers suffering from shrapnel injury treated in the field hospital in Afghanistan. Wounds were infected by MRSA.

Main results The author reported improved rate of healing in traumatic war wounds treated by Hyiodine. Wound bed was clean of infection in 4 days of injury what enabled primary delayed suture and fast healing.



Day 0



Day 4



Day 4



Day 5

ANIMAL WOUND MODEL

Author **Slavkovsky et al, 2009** Prospective, controlled study

Study group Full-thickness wounds made on the back of rats.

Main results The study demonstrated accelerated wound contraction in the first five days of healing. By day 3 Hyiodine-treated wounds had reduced to 63 % of the original area, whereas the wound area in saline treated animals was 75 %. By day 7, it was found that proliferating epidermis was thicker in Hyiodine-treated animals. The author concluded that Hyiodine supports wound healing by stimulating wound contraction and epidermal proliferation.

REFERENCES

BRENES, Robert, et al. Hyaluronate-Iodine Complex. A new adjunct for the management of complex sternal wounds after a cardiac operation. *Archive of Surgery*. 2011; 146:11, 1323-1325

BRENES, Robert, et al. Initial experience using a hyaluronate-iodine complex for wound healing. *The American Surgeon*. 2011; 77, 355-359.

CAP, Robert, et al. Effect of Hyaluronate-iodine-complex in Skin Grafting of Chronic Infected Wounds. Presented at EWMA 2008, May 14-16, 2008, Lisbon, Portugal.

DURANTE, Colonel Corrado, et al. Influence of hyaluronate-iodine gel on recalcitrant wounds. Presented at EWMA 2010, 26-28 May, Geneva, Switzerland.

OTT, Kerstin, et al. Treatment of therapeutical resistant wounds with hylauronan combined with bactericidal agent (Hyaluronan Iodine Complex)-First time experience in Switzerland. Presented at 98th congress of Swiss surgery in Geneva 2011.

PLODR, Michal, et al. Complex of Hyaluronan Acid and Iodine in War Soft Tissue Injuries – First Experience (Case Reports). Presented at EWMA 2008, May 14-16, 2008, Lisbon, Portugal.

SLAVKOVSKY, Rastislav, et al. Effects of hylauronan and iodine on wound contraction and granulation tissue formation in rat skin wounds. *Clinical and Experimental Dermatology*. 2010; 35:4, 373-379.

SOBOTKA, Lubos, et al. A Case Report of the Treatment of Diabetic Foot Ulcers Using a Sodium Hyaluronate and Iodine Complex. *Lower Extremity Wounds*. 2007; 6:3, 143-147.

SOBOTKA, Lubos, et al. Complex Approach to the Treatment of Diabetic Foot Ulcers. Presented at EWMA 2006, May 18-20, 2006, Prague, Czech Republic

SOBOTKA, Lubos, et al. New Method for Healing of Large Abdominal Wound Using Sodium Hyaluronate-Iodine Complex. Presented at EWMA 2008, May 14-16, 2008, Lisbon, Portugal.

SOBOTKA, Lubos, et al. Successful treatment of surgical abdominal wounds complicated by multiple bowel fistulas with a combination of total parenteral nutrition, hyaluronan –iodine complex and delayed surgery: results of monocentric experience. *Nutritional Therapy & Metabolism*. 2008; 26:4, 177-183.

SOBOTKA, Lubos, 2003 (study not published) Study conducted at the Department of Metabolic Care and Gerontology, Medical Faculty – Charles University and Faculty Hospital, Hradec Kralove, Czech Republic.

WILD, Thomas, et al. New galenic antiseptic substance containing iodine (KI3 complex) and hyaluronic acid for treatment of chronic, hardly healing wounds. *Journal of Wound Technology*. 2010; 7, 63-65.

www.hyiodine.com



CONTIPRO
PHARMA

Contipro Pharma a.s., Czech Republic

Phone +420 465 520 035 Fax +420 465 524 098 E-mail sales@contipro.com

www.contipro.com