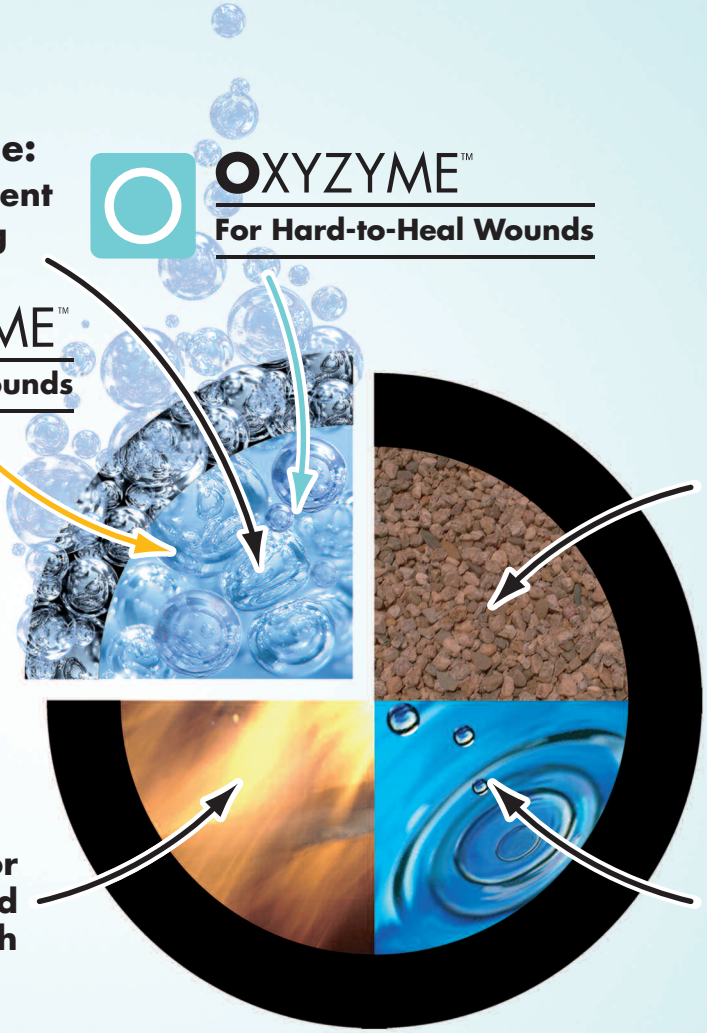
Oxygen Balance:
The missing element in wound healing

OXYZYME™
For Hard-to-Heal Wounds

IODOZYME™
For Infected Wounds



Wound bed preparation

Energy for healing and tissue re-growth

Moist wound healing and exudate management

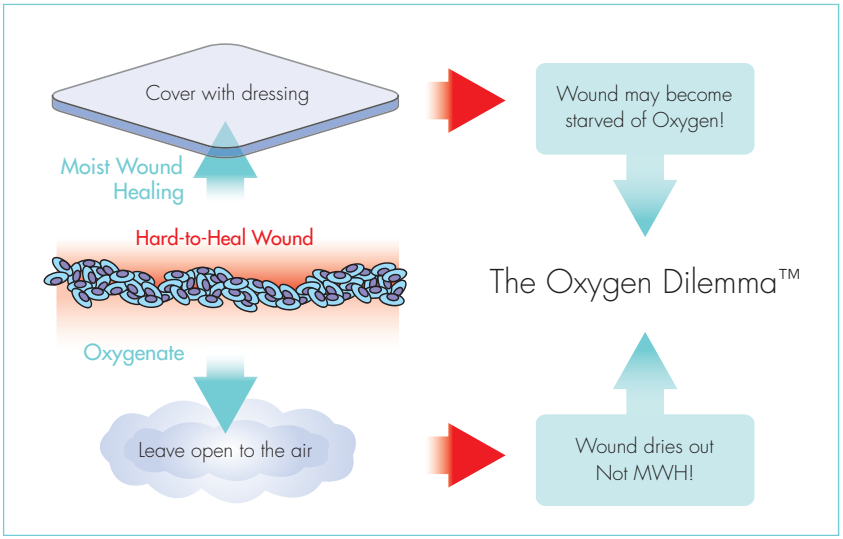
A breath of fresh air in wound care

Archimed™
www.archimed.co.uk

THE EFFECTS OF OXYGEN IN WOUND HEALING

Oxygen is vital for many cellular functions including cell repair and regeneration, and there is a growing body of research on oxygen's role in wound healing, in areas including:

- Signalling and control
- Metabolic support
- Matrix repair
- Antisepsis



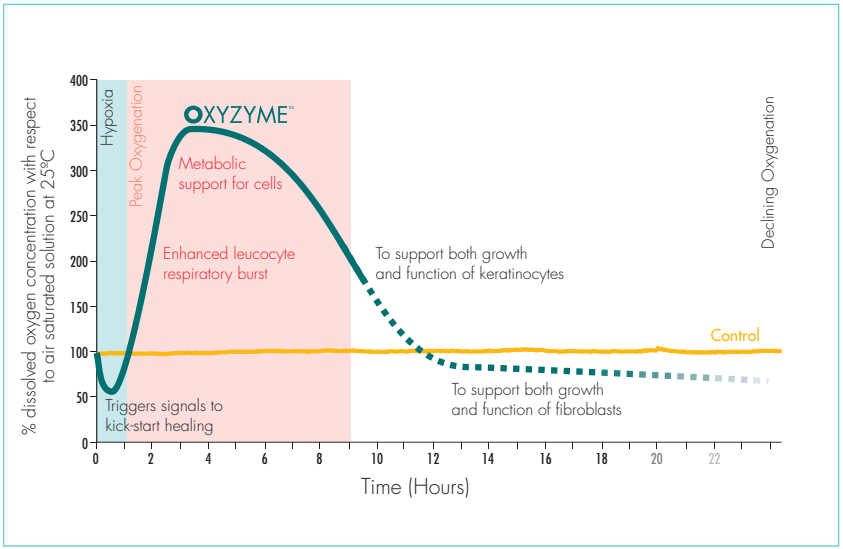
THE MISSING ELEMENT IN WOUND HEALING

In vitro tests show that whilst conventional moist wound healing dressings can lower oxygen levels, Oxyzyme™ and Iodozyme™ can significantly increase them[1].

Some processes in the wound need lower oxygen levels. Oxyzyme™ therefore varies the amount of oxygen provided, to manage the oxygen balance.

PARTNERING THE WOUND

Leucocyte activity increases as oxygen levels increase, to increase antimicrobial activity.

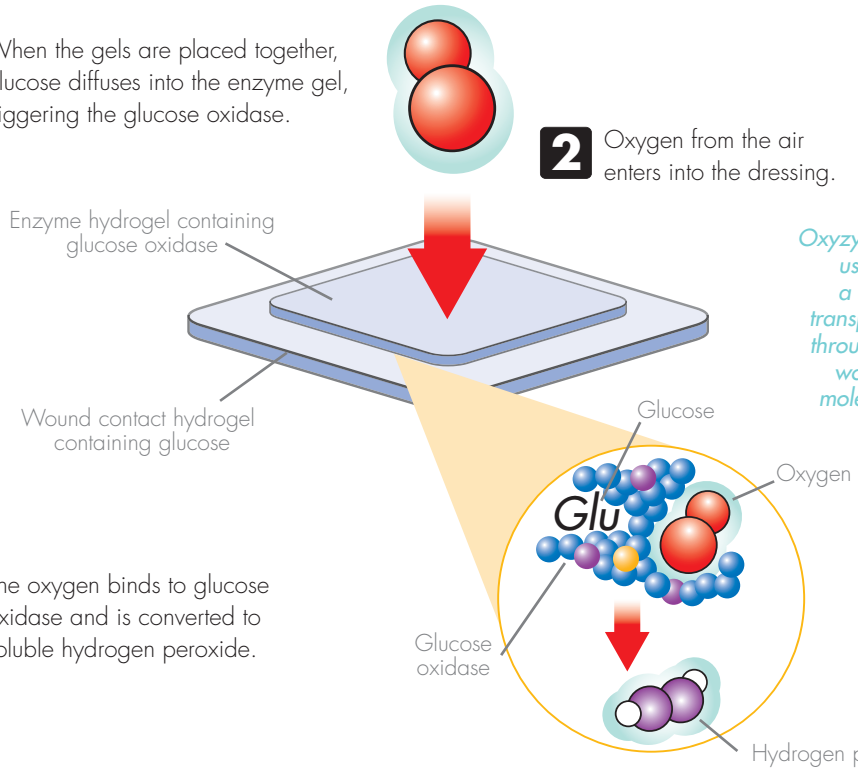


1. In Vitro data on file at Insense Ltd.

MODE OF ACTION FOR OXYZYME™ AND IODOZYME™

1 When the gels are placed together, glucose diffuses into the enzyme gel, triggering the glucose oxidase.

2 Oxygen from the air enters into the dressing.



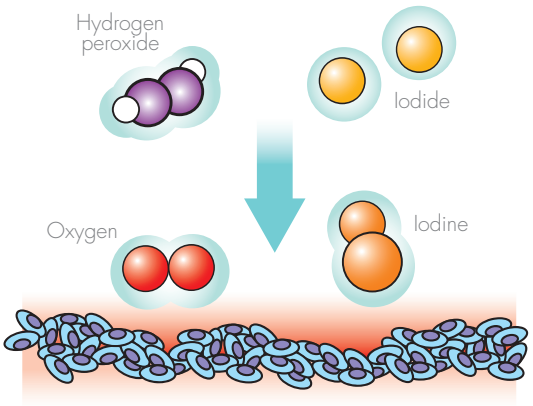
Oxyzyme™ and Iodozyme™ use glucose oxidase, a natural enzyme, to transport dissolved oxygen through the dressing to the wound surface, like a molecular oxygen pump.

3 The oxygen binds to glucose oxidase and is converted to soluble hydrogen peroxide.

The relative amounts of oxygen and iodine have been tuned to the needs of the wound.

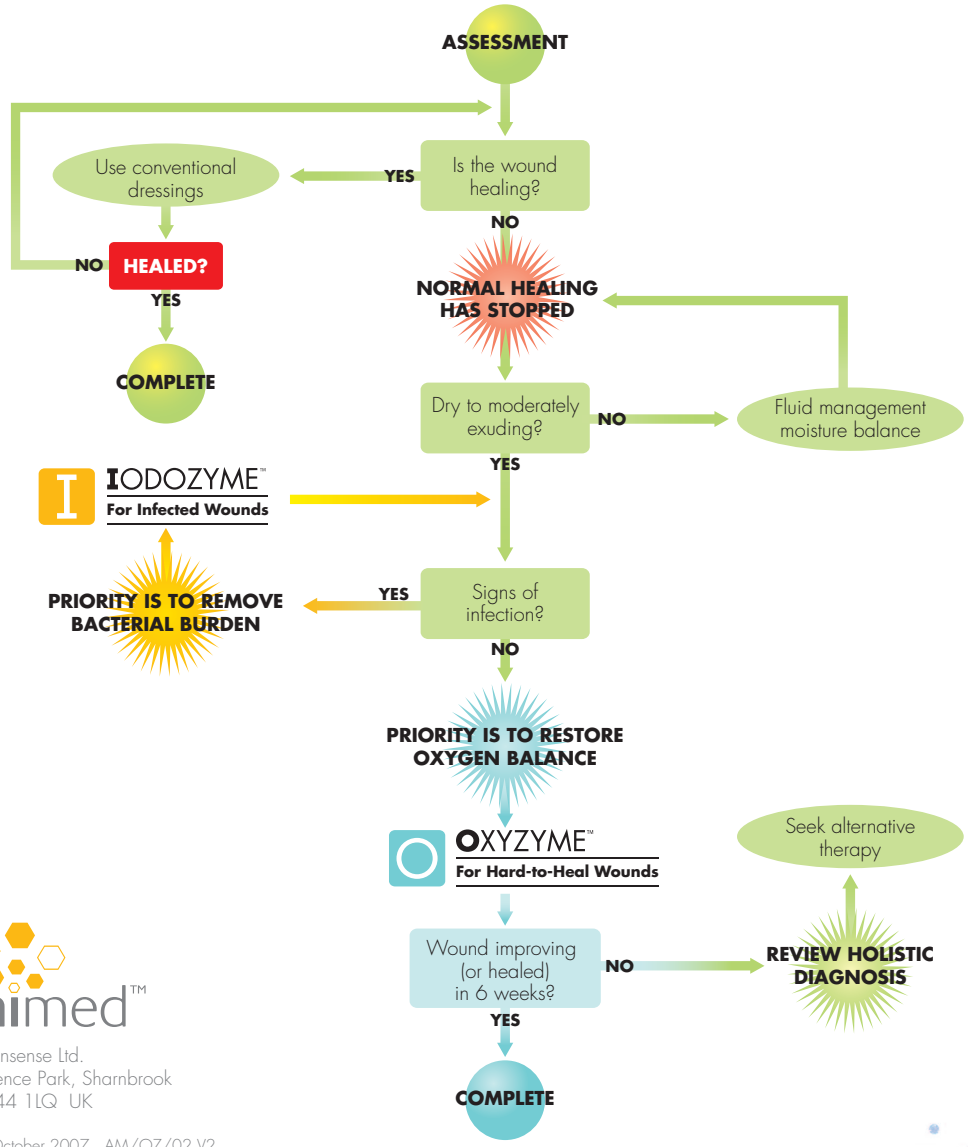
Oxyzyme™ generates dissolved oxygen and a small amount of iodine.

Iodozyme™ also creates oxygen, but a significantly higher level of iodine, for use on infected wounds.



4 Peroxide diffuses through the dressing encountering iodide ions. These can react to form dissolved oxygen, and iodine. Any residual hydrogen peroxide is instantly converted to oxygen at the wound surface.

TREATMENT SELECTION ALGORITHM FOR OXYZYME™ AND IODOZYME™



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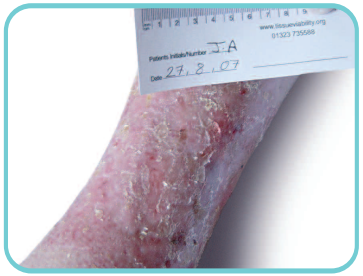
OXYZYME™ CASE STUDY PROGRAMME RESULTS

- **This previously static wound reduced in size by 80% in 7 weeks**
- **The wound continued to be treated with OXYZYME™ and had healed completely by 11 weeks**

The patient is a 90 year old female with shallow left lateral leg ulcer that had been present for 12 months. The wound was static, with a distinct margin, and entirely covered in slough. OXYZYME™ was used and PU film was used as a secondary dressing. Flamazine was applied to previously macerated periwound skin.



Photographs of wound at the week 1 assessment, and healed after 11 weeks.

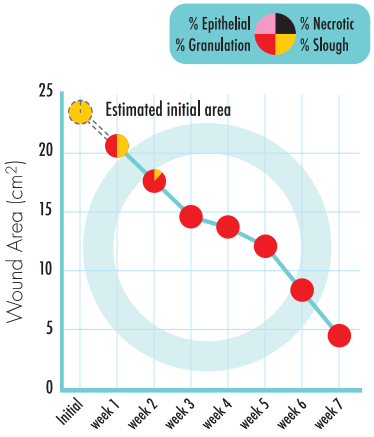
Week 1. After a week of treatment with OXYZYME™, the amount of slough had decreased to 50%. The exudate contained blood and the periwound skin was no longer macerated but still inflamed, and with less erythema.

Week 3. The wound bed was now composed entirely of healthy granulation tissue and had reduced in size by 38% since the start. Blood remained in the exudate, but the periwound skin was now healthy.

Week 7. The wound had reduced dramatically, by 80%, since the start.

Week 11. The wound had healed completely, and remained healed at the four week follow up.

Case Study Reference XY-CS-04/05. Full details of this and other case studies can be downloaded from our website at:
www.archimed.co.uk



Graph of change in wound area (measured by LUTM telemedicine software) with time. Circles indicate wound condition at each assessment.

CLINICAL TRIAL RESULTS[1] FOR THE TREATMENT OF MIXED ÆTIOLOGY WOUNDS WITH IODOZYME™

BACKGROUND

This was a 30 patient single-centre nonrandomised, prospective, open study with subjects in possession of a superficial wound that was clearly showing signs of elevated bacterial burden, and was suitable for treatment with a 10cm x 10cm wound dressing. This mixed trial included chronic venous leg ulcers (10), diabetic foot ulcers (5) and miscellaneous other wound ætiologies (15).

The objectives of the study were to gather evidence regarding the safety and performance of IODOZYME™ dressings when applied to wounds, for a period of 28 days or until healing (whichever occurred sooner), and to establish the general acceptability of the dressings in routine use, using patient and nurse scoring systems. The progress of the wound was measured against a number of standard characteristics of chronic wounds (e.g. size, state and condition of wound surface, patient comfort).

RESULTS

Of the 32 patients recruited, 30 completed, or healed during, the course of the trial. The remaining 2 were withdrawn from the trial, or withdrew for personal reasons.

Overall 3 patients (10%) proceeded to complete healing and a further 21 (70%) improved or gained benefit. 3 (10%) showed no improvement and 3 (10%) deteriorated.

Thus 80% of cases in this study showed improvement or healing. In a comparable clinical trial of Aquacel® Ag, carried out by the same researchers in 2005[2], only 56% of patients showed improvement or healing.

The investigating team commented favourably on the way the case of pilonidal sinus responded when treated with Iodozyme™, and the fact that of the two wounds infected with MRSA, one had reduced in size, and the other had begun a healing trajectory.

An assessment of the antimicrobial performance of IODOZYME™ was not possible due to poor patient compliance. However, the results of an in-vitro investigation into the microbiological properties of a number of dressings has been published previously[3].

	Ref.	Ætiology	Patient Age	Wound duration	Comments	Previous treatment
3 HEALED	JKT	Trauma	65	2 weeks	Healed by day 7	Compression
	GB	Dehisced Surgical	78	6 months	Healed after 7 days	VAC
	AG	Surgical	83	6.5 years	Healed by day 28	Betadine
21 IMPROVED (70%)	HS	Burn	48	New	Size reduced	-
	EAP	VLU	64	2 weeks	Size reduced, complete de-sloughing, excellent granulation	-
	SKC	VLU (sec. to Trauma)	31	3 weeks	Size increased as a result of de-sloughing, other wound parameters improved, reduction in pain.	-
	LTF	Trauma (sec. to Hæmatoma)	66	2 months	Size significantly reduced, increase in granulation tissue	Intrasite
	MC	Pilonoidal Sinus	36	2 months	Size significantly reduced, mild maceration, reduction in wound pain	Betadine
	CES	VLU	54	3 months	No change in size, wound bed condition improved, significant granulation	Biatain IBU, compression
	JK	VLU	57	6 months	Size reduced, wound bed condition improved	Acticoat, compression
	JS	Scleroderma	49	7 months	Size increased, good granulation reduction in wound pain	Mepilex Border
	WE	Radiation Ulcer	79	8 months	Size slightly reduced, increase in granulation tissue	Contreet
	FD	Diabetic Foot Ulcer	35	10 months	Similar in area but much reduced maceration. All other wound parameters improved	Viscopaste, Aquacel Ag
	ES	Pressure Ulcer	73	11 months	Size significantly reduced, mild maceration, wound bed condition improved	Mesalt, Iodosorb, Promogran
	MM	VLU	78	1 year	No change in size, de-sloughed, formation of granulation tissue	Dry dressing
	GH	Trauma	71	1 year	Size significantly reduced, mild maceration, increase in granulation tissue	Iodosorb, Mepilex
	MTG	VLU	60	1 year	Size reduced, and the wound had begun to heal, ***despite MRSA***	Kling, Comprilan
	WJ	VLU	83	1.3 years	No change in size, wound bed condition improved, granulation started	
	JT	Vasculitis	72	1.5 years	Size significantly reduced, excellent desloughing,increase in granulation tissue	Aquacel, Betadine
	EW	Diabetic Foot Ulcer	60	2 years	Size reduced. All other wound parameters improved	Prisma, Allevyn
	JR	Thalassemia	46	2.2 years	Size increased significantly as a result of major desloughing, other wound parameters improved	Flamazine
	WW	Surgical	40	3 years	Size slightly reduced, mild maceration, wound bed condition improved, increase in granulation tissue	Aquacel, Betadine
	EDR	Diabetic Foot Ulcer	55	3.5 years	Size significantly reduced and reduced maceration.	Silvercel
	OHR	VLU	70	6 years	Size remained the same, completely desloughed, formation of granulation tissue	Biatain IBU,
STATIC (10%)	MR	Pressure Ulcer	67	7 months	Size slightly reduced, mild maceration, reduction in wound pain	Iodosorb, Aquacel
	DS	Diabetic Foot Ulcer	62	10 months	Size slightly reduced, wound base clean. Began healing trajectory ***despite MRSA***	Mesalt, Aquacel Ag
	WRM	Trauma	85	3.4 years	Size increased, mild maceration, wound bed condition improved	Flamazine
Deteriorated	EF	VLU	75	5 months	Same size but shallower, begun to deslough, formation of granulation tissue	Mesalt, Iodosorb, Promogran
	RCC	VLU	71	1 year	Size increased significantly as a result of major de-sloughing, healing process had begun, granulation tissue observed	Biatain IBU, compression
	SP	VLU	66	1.5 years	Size increased, Distinct granulation	Iodosorb, Aquacel

1 "A non-comparative study to investigate the use of the Iodozyme™ wound dressing in the treatment of various wounds", Professor R. Gary Sibbald, Pat Coutts, RN, Marjorie Fierheller, RN, Connie Harris, RN, Dr. Douglas Queen, Toronto Wound Healing Centers, 210 – 1077 North Service Road, Mississauga, Ontario L4Y 1A6, Canada. April 2007. On file at Insense Ltd.

2 "The effect of a silver containing Hydrofiber® dressing on superficial wound bed and bacterial balance of chronic wounds", R. Gary Sibbald, Pat Coutts, RN. Int. Wound J. 2005, 2, 4, pp348-356.

3 "In vitro diffusion bed, 3-day repeat challenge 'capacity' test for antimicrobial wound dressings", John Greenman, Robin M.S. Thorn, Saliah Saad, Andrew J. Austin., Int. Wound J., 2006, 3, 4, pp322-329.