

Complex and Problem Wounds

ELECTIVE COURSE — but select on measured perfusion, not on the diagnosis

A selective adjunct for non-healing wounds with a demonstrable hypoxic component — not a universal wound therapy.

TREATMENT PROTOCOL

Pressure	2.0–2.5 ATA depending on facility practice (2.5 ATA in the anchor trial). In a monoplace chamber, in-chamber TcPO2 may guide the pressure
Duration	90–120 min (85 min in the anchor trial)
Frequency	5 days per week. UHMS: once or twice daily, 5–7 days per week
Sessions	40 in the trial. UHMS: an outpatient course is usually 30, many need up to 40; more is acceptable with objective utilisation review. Post-operative wounds may need fewer than 30
Review	Utilisation review after the initial 30 days (30 treatments for arterial ulcers), then at least as often; no TcPO2 improvement by 2–3 weeks should discourage further HBOT

PATIENT SELECTION

Who to treat	Chronic neuro-ischaemic or ischaemic diabetic foot ulcers (UHMS: Wagner 3 or higher not improving after 30 days, or after surgery; it suggests against Wagner 2) failing standard care, chronic lower-limb ulcers in peripheral arterial disease, and compromised surgical wounds. Selection should favour demonstrable tissue hypoxia. In-chamber TcPO2 of 200 mmHg or more predicted healing in Strauss 2002 (retrospective).
Who not to treat, or when to stop	Not for acute, uncomplicated or adequately perfused wounds that will heal with standard care. Baseline dorsal-foot TcPO2 below 25 mmHg: healing is unlikely — consider revascularisation first. HODFU completers: below 25 gave 0% healing; 26–50 gave 50%; 51–75 gave 73%. Room-air TcPO2 alone is a weak selector (Strauss 2002).
Mechanism	The wound bed is chronically hypoxic and hypoperfused. Intermittent hyperoxia raises the tissue oxygen tension needed for fibroblast function, collagen synthesis, angiogenesis and leukocyte oxidative killing.
Outcome measure	Complete healing; wound-area reduction; major amputation rate; transcutaneous oximetry.

WHAT THE NUMBERS SHOW

- **Löndahl 2010 HODFU RCT** (n=94, double-blind, sham-controlled, low risk of bias): complete healing at 1 year **52% vs 29% (p=0.03)**; **61% vs 27%** among those completing more than 35 sessions.
- **Faglia 1996 RCT** (n=68, severe ischaemic ulcers): major amputation **8.6% vs 33.3%, RR 0.26 (95% CI 0.08–0.84), P=0.016.**
- **Zhang 2022** (20 RCTs, 1,263 patients): healing **RR 1.90 (1.48–2.44)**; major amputation **RR 0.52 (0.32–0.83).**
- **Santema 2018 DAMOCLES RCT** (n=120): **intention-to-treat null** — limb salvage RD 0.10 (–0.04 to 0.23), not significant; per-protocol completers RD 0.26 (0.10–0.38).
- **Fedorko 2016 RCT** (n=103): **no amputation or healing benefit** over comprehensive wound care.

EVIDENCE BASE

Shape and certainty	Very large — 55 or more records, a dozen randomised trials, several meta-analyses and network meta-analyses, a Cochrane synthesis and the IWGDF 2023 guideline (conditional recommendation, low certainty).	
Study	Design	Result and risk of bias
Löndahl 2010 HODFU — PMID 20427683	Double-blind RCT, n=94	Positive ; RoB 2 low
Faglia 1996, Diabetes Care — PMID 8941460	RCT, n=68	Positive on amputation
Santema 2018 DAMOCLES — PMID 29074815	Multicentre RCT, n=120	Null on ITT ; 35% did not complete
Fedorko 2016 — PMID 26740639	RCT, n=103	Negative
Zhang 2022 — PMID 34376365	Meta-analysis, 20 RCTs	Positive

WHAT THE EVIDENCE DOES NOT SUPPORT

Cautions	Two randomised trials failed their primary endpoints. A 6,259-patient Medicare cohort found no healing or amputation benefit from routine, unselected treatment — which is the strongest argument for the oximetry selection rule above. The IWGDF states the amputation benefit is not established.
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STATUS IN SOUTH AFRICA

Status	Accepted indication in South Africa via the gangrene or severe-ischaemia presentation. A plain ulcer and peripheral vascular disease alone are not PMB-listed.
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Compiled from the **UHMS Hyperbaric Oxygen Therapy Indications Manual, 15th edition (2023)** and the appraised trial evidence held in an HBOT evidence library. All treatments are 100% oxygen. US Navy Treatment Table profiles are named, not reproduced — the US Navy Diving Manual is the operative document at the chamber. Session counts are largely guideline convention rather than dose-finding evidence. This card summarises published parameters and does not replace those source documents or clinical judgement for the individual patient. Generated 03 October 2026. Not a SAUHMA publication and carries no society endorsement.