



Clinical Summary

A review of published evidence on intraoperative graft preservation in CABG

2026 EDITION



01

Mechanism & Bench Research

How DuraGraft preserves vascular conduits at the cellular level.



A Novel Endothelial Damage Inhibitor (DuraGraft) Reduces Oxidative Stress and Improves Cellular Integrity in Radial Artery Grafts for Coronary Artery Bypass

AIM

To evaluate the protective effect of DuraGraft®, an endothelial damage inhibitor (EDI), on radial artery (RA) grafts.

METHODS

The effect of DuraGraft vs. Ringer's Lactate on endothelial damage was evaluated ex vivo and in vitro using histological analysis, immunofluorescence staining, Western blot, and scanning electron microscopy.

FINDINGS & CONCLUSIONS

DuraGraft treatment preserved the functionality and integrity of endothelial and intimal cells. The authors concluded that DuraGraft may have the potential to reduce graft disease and failure in RA grafts in CABG patients.

KEY FINDING

Preserved endothelial and intimal cell integrity in radial artery grafts vs. Ringer's Lactate.

AUTHORS

Aschacher T, Sandner S, et al.
Medical University of Vienna, Austria

JOURNAL

Frontiers in Cardiovascular Medicine, October 2021
(doi: 10.3389/fcvm.2021.736503)

COHORT

Ex vivo and in vitro analysis of radial artery (RA) graft segments

Efficacy of Intraoperative Vein Graft Storage Solutions in Preserving Endothelial Cell Integrity during Coronary Artery Bypass Surgery

AIM

To compare the efficacy of three solutions in maintaining the endothelial cell integrity of venous segments.

METHODS

Researchers tested physiological saline solution (PSS), heparinized autologous blood (HAB), and DuraGraft® for their ability to preserve the endothelium of vein segments by evaluating the degree of endothelial cell apoptosis.

FINDINGS & CONCLUSIONS

Within 2 hours of incubation, endothelial structural integrity depended on the incubating medium. DuraGraft better protected the saphenous vein graft against ischemic-induced apoptosis when compared to saline solution.

KEY FINDING

Better protection of SVGs against ischemic-induced apoptosis vs. saline.

AUTHORS

Toto F, Ferrari E, et al.
Cardiocentro Lugano, Switzerland

JOURNAL

Journal of Clinical Medicine, February 2022;11(4):1093
(doi: 10.3390/jcm11041093)

COHORT

Comparison of three intraoperative storage solutions

Effect of Different Storage Solutions on Oxidative Stress in Human Saphenous Vein Grafts

AIM

To assess the level of oxidative stress in human saphenous vein grafts (SVGs) following ischemic storage in three intraoperative solutions: saline (S), autologous heparinized blood (HB), and DuraGraft (DG).

METHODS

SVG segments from 50 patients were stored for 30 minutes in DG, S, or HB. Total oxidative status (TOS) and total antioxidant status (TAS) levels were determined for each group.

FINDINGS & CONCLUSIONS

SVGs stored in DuraGraft had a lower oxidative level, higher antioxidant level, and a lower oxidative stress index compared to saphenous vein grafts stored in saline or heparinized blood.

KEY FINDING

Lower oxidative stress index in SVGs stored in DuraGraft vs. saline or heparinized blood.

AUTHORS

Tekin I, Özdem S, et al.
Bahçeşehir University, Istanbul, Turkey

JOURNAL

Journal of Cardiothoracic Surgery, January 2022;17(1):7
(doi: 10.1186/s13019-022-01752-7)

COHORT

50 patients · saphenous vein graft segments

02

Clinical Outcomes

Patient-level evidence from CABG: troponin, MACE, patency, and survival.

Graft Preservation with DuraGraft Confers Myocardial Protection with Reduction of Postoperative Troponin Levels in CABG Patients

AIM

To assess the impact of DuraGraft versus saline/Bisecko on myocardial protection when flushed into the distal anastomosis during CABG.

METHODS

DuraGraft or 0.9% saline/Bisecko was applied during 272 CABG procedures. 166 patients were propensity-matched into two groups. Cardiac enzymes were evaluated through 7 days post-CABG.

FINDINGS & CONCLUSIONS

Repeated graft flushing of the distal anastomosis with DuraGraft during CABG was associated with significantly lower troponin postoperatively, suggesting better myocardial protection compared to saline/Bisecko.

KEY FINDING

Significantly lower postoperative troponin vs. saline/Bisecko in propensity-matched patients.

AUTHORS

Szalkiewicz P, Winkler B, et al.
Clinic Floridsdorf, Vienna, Austria

JOURNAL

Frontiers in Cardiovascular Medicine, July 2022;9:922357
(doi: 10.3389/fcvm.2022.922357)

COHORT

272 CABG procedures · 166 propensity-matched patients

Vein Graft Preservation with an Endothelial Damage Inhibitor in Isolated Coronary Artery Bypass Surgery: An Observational Propensity Score-Matched Analysis

AIM

To evaluate clinical outcomes of CABG patients with the use of DuraGraft vs. standard of care (saline). Subgroups were also defined for diabetic patients and patients who received more than one vein graft.

METHODS

The primary outcome was the rate of major adverse cardiac events (MACE) — defined as the composite of all-cause death and myocardial infarction (MI) — at 3 years.

FINDINGS & CONCLUSIONS

DuraGraft use significantly enhanced event-free survival at 3 years and reduced MACE events compared to the saline group. The benefit was pronounced in diabetic patients and patients who received multiple vein grafts.

KEY FINDING

Enhanced 3-year event-free survival vs. saline; benefit most pronounced in diabetics and multi-graft patients.

AUTHORS

Lopez-Menendez J, et al.
University Hospital Ramón y Cajal, Madrid, Spain

JOURNAL

Journal of Thoracic Disease, 2023;15(10):5549–5558
(Web. 9 Nov 2023)

COHORT

Propensity score-matched cohort, 3-year follow-up

Relationship between Intra-operative Vein Graft Treatment with DuraGraft or Saline and Clinical Outcomes after Coronary Artery Bypass Grafting

AIM

To compare the impact of intraoperative preservation of saphenous vein grafts (SVGs) with DuraGraft (GALA) versus heparinized saline on vein-graft-failure-related outcomes after CABG.

METHODS

2,436 patients underwent isolated CABG with ≥ 1 SVG. SVGs were consecutively treated with DuraGraft in 1,036 patients and heparinized saline in 1,400 patients. Short- and long-term outcomes were assessed.

FINDINGS & CONCLUSIONS

Intraoperative treatment of SVGs with DuraGraft was associated with a lower risk of long-term adverse events, suggesting that efficient intraoperative SVG treatment may reduce vein-graft-failure-related complications post-CABG.

KEY FINDING

Lower risk of long-term adverse events vs. heparinized saline in a cohort of 2,436 CABG patients.

AUTHORS

Haime M.
Veterans Affairs Boston, USA

JOURNAL

Expert Reviews in Cardiovascular Therapy, December 2018;16(12):963–970
(doi: 10.1080/14779072.2018.1532289)

COHORT

2,436 CABG patients (DuraGraft 1,036 / saline 1,400)

Sequential Multidetector Computed Tomography Assessments after Venous Graft Treatment Solution in Coronary Artery Bypass Grafting

AIM

To assess the effect of DuraGraft, an intraoperative graft treatment, on saphenous vein grafts (SVGs) in patients undergoing isolated CABG.

METHODS

Within patients, two SVGs were randomized to DuraGraft or heparinized saline. Multidetector CT angiography at 1, 3, and 12 months assessed change in wall thickness, lumen diameter, and maximum narrowing for the whole graft and the proximal 5-cm segment.

FINDINGS & CONCLUSIONS

DuraGraft demonstrated a favorable effect on graft wall thickness at 12 months, particularly in the proximal segment.

KEY FINDING

Favorable effect on SVG wall thickness at 12 months — most pronounced in the proximal segment.

AUTHORS

Perrault L, Emmert M, et al.
Montreal Heart Institute · German Heart Center Berlin

JOURNAL

J Thorac Cardiovasc Surg, November 2019
(doi: 10.1016/j.jtcvs.2019.10.115)

COHORT

Within-patient SVG randomization, CT at 12 mo

03

Registry & Real-World Evidence

Multicenter, prospective registry data from contemporary surgical practice.

1-Year Clinical Outcomes of CABG after Intraoperative Graft Treatment with DuraGraft — A Report from the European DuraGraft Registry

AIM

To determine the clinical outcomes of contemporary isolated CABG and combined CABG-and-valve procedures after intraoperative graft treatment with DuraGraft.

METHODS

The primary outcome measure was the rate of major adverse cardiac events (MACE), defined as the composite of all-cause death, myocardial infarction (MI), or repeat revascularization (RR) at 1 year.

FINDINGS & CONCLUSIONS

CABG patients treated intraoperatively with DuraGraft showed a promising mortality rate with low MI and repeat revascularization rates at 1 year.

KEY FINDING

Promising 1-year mortality with low MI and repeat-revascularization rates after intraoperative DuraGraft treatment.

AUTHORS

Sandner S, Emmert M, et al.
Medical University Vienna, Austria · German Heart Center
Berlin, Germany

JOURNAL

International Journal of Surgery, March 2023
(doi: 10.1097/JS9.0000000000000259)

COHORT

Multicenter European DuraGraft Registry

Clinical Event Rate in Patients with and without Left Main Disease Undergoing Isolated CABG — A Report from the DuraGraft Registry

AIM

To investigate clinical event rates at 1 year in patients with and without Left Main Disease (LMD) undergoing isolated CABG in contemporary practice.

METHODS

The primary endpoint was the incidence of a major adverse cardiac event (MACE), defined as the composite of death, myocardial infarction (MI), or repeat revascularization (RR) at 1 year.

FINDINGS & CONCLUSIONS

In this large prospective registry, LMD was demonstrated to be an independent risk factor for MACE after isolated CABG. Conversely, the risk of stroke was lower in LMD patients.

KEY FINDING

LMD is an independent risk factor for 1-year MACE after isolated CABG; stroke risk was lower in LMD patients.

AUTHORS

Caliskan E, Emmert M, et al.
Charité Berlin, Germany · German Heart Center Berlin,
Germany

JOURNAL

European Journal of Cardiothoracic Surgery, August 2022
(doi: 10.1093/ejcts/ezac403)

COHORT

DuraGraft Registry · Left Main Disease subgroup analysis

Surgical Revascularization Using DuraGraft for Graft Preservation in Patients with Diabetes Mellitus — A Report from the DuraGraft Registry

AIM

To evaluate the impact of DuraGraft on 1-year clinical outcomes in patients with and without diabetes mellitus (DM) undergoing CABG.

METHODS

A sub-group analysis of the multicenter European DuraGraft Registry (n = 2,544) of patients undergoing isolated CABG whose saphenous vein grafts and free arterial grafts underwent DuraGraft treatment.

FINDINGS & CONCLUSIONS

DM was not an independent risk factor for 1-year MACE in diabetic patients undergoing CABG. Intraoperative graft preservation with DuraGraft may be beneficial with regard to early clinical outcomes in diabetic patients undergoing CABG.

KEY FINDING

In a 2,544-patient registry analysis, DM was not an independent risk factor for 1-year MACE.

AUTHORS

Misfeld M, Emmert M, et al.
Heart Center Leipzig, Germany · German Heart Center Berlin, Germany

JOURNAL

Interdisciplinary Cardiovascular and Thoracic Surgery, in press 2024

COHORT

n = 2,544 isolated CABG patients · diabetic subgroup analysis

Transatlantic Analysis of Patient Profiles and Mid-term Survival after Isolated CABG: European DuraGraft Registry vs. US STS Registry

AIM

To conduct a transatlantic comparison of patient profiles (n = 2,522) and overall survival outcomes after isolated coronary artery bypass grafting (CABG) for up to 3 years.

METHODS

The researchers compared data between the European DuraGraft Registry and the US Society of Thoracic Surgeons (STS) Registry, focusing on differences in patient characteristics and outcomes — particularly survival rates.

FINDINGS & CONCLUSIONS

European patients who received CABG with DuraGraft showed significantly improved survival at 3 years compared to U.S. patients in the STS Registry, who typically used standard graft storage solutions. No significant difference in mortality was detected through 2 years; survival was significantly better in the European DuraGraft Registry at 3 years post-CABG, suggesting potential benefits in clinical practice.

KEY FINDING

Significantly improved 3-year survival in the European DuraGraft Registry vs. US STS Registry comparator.

AUTHORS

Emmert M, Caliskan E, Misfeld M.
German Heart Center Berlin · Charité Berlin · Heart Center
Leipzig, Germany

JOURNAL

Frontiers in Cardiovascular Medicine, September 2024

COHORT

n = 2,522 patients · 3-year follow-up

A Growing Body of Evidence

Peer-reviewed studies spanning bench research, clinical outcomes, and real-world registry data.

3

Mechanism & Bench Studies

Endothelial integrity, oxidative stress, cell viability

4

Clinical Outcomes Studies

Troponin, MACE, graft patency, long-term survival

4

Registry & Real-World Studies

European DuraGraft Registry; transatlantic comparisons

11 peer-reviewed publications, 2018 – 2024

Indication & Prescription Status

INDICATION FOR USE

DuraGraft® is indicated as a single-use intraoperative vascular conduit flushing and storage solution for adult patients undergoing coronary artery bypass grafting (CABG). It is intended for the flushing and storage of saphenous vein autografts for up to 4 hours prior to grafting, to maintain cell viability and structural integrity of the conduit.

PRESCRIPTION USE

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician (21 CFR 801.109).

REGULATORY STATUS

FDA De Novo granted (DEN230002); 510(k) K240925. First and only device in its classification for intraoperative flushing and storage of saphenous vein grafts in adult CABG.

Refer to the DuraGraft® Instructions for Use for complete indications, contraindications, warnings, precautions, and adverse events.