



# DuraGraft® Clinical Summary



# Transatlantic analysis of patient profiles and mid-term survival after isolated coronary artery bypass grafting: A head-to-head comparison between the European DuraGraft Registry and the US STS Registry

## Lead Authors:

- Max Emmert, German Heart Center Berlin, Germany. Emet Caliskan, Charite University Hospital Berlin, Germany. Martin Misfeld, Leipzig Heart Center, Leipzig, Germany

## Journal:

- Front. Cardiovasc. Med., 11 September 2024

## Aim of the Study:

- 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.

# 1-year clinical outcomes of CABG after intraoperative graft treatment with DuraGraft - A report from European DuraGraft Registry

## Lead authors:

- Dr. Sigrid Sandner, Medical University Vienna, Austria and Dr. Max Emmert, German Heart Center Berlin, Germany

## Target Journal:

- Int J Surg. 2023 Mar 14. doi: 10.1097/JS9.0000000000000259.

## Aim of the Study:

- 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 re-vascularization (RR) at 1 year

# Clinical event rate in patients with and without left main disease undergoing isolated CABG – A report from the DuraGraft Registry

## Lead authors:

- Dr. Etem Caliskan, Charite Berlin, Germany and Dr. Max Emmert, German Heart Center Berlin, Germany

## Journal:

- Eur J Cardiothorac Surg. 2022 Aug 5;ezac403. doi: 10.1093/ejcts/ezac403.

## Aim of the Study:

- 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

# Graft preservation with DuraGraft confers myocardial protection with reduction of postoperative Troponin levels in CABG patients

## Lead authors:

- Dr. Philipp Szalkiewicz and Dr. Bernhard Winkler, Clinic Floridsdorf, Vienna, Austria

## Journal:

- Front Cardiovasc Med. 2022 Jul 28;9:922357. doi: 10.3389/fcvm.2022.922357. eCollection 2022.

## Aim of the Study:

- 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 to seven days post-CABG.

# Vein graft preservation with an endothelial damage inhibitor in isolated coronary artery bypass surgery: an observational propensity score-matched analysis

## Lead authors:

- Dr Jose Lopez, University Hospital Ramon y Cajal. Madrid, Spain.

## Journal:

- Lopez-Menendez, Jose, "Vein graft preservation with an endothelial damage inhibitor in isolated coronary artery bypass surgery: an observational propensity score-matched analysis." *Journal of Thoracic Disease* [Online], 15.10 (2023): 5549-5558. Web. 9 Nov. 2023

## Aim of the Study:

- To evaluate clinical outcomes of CABG patients with the use of DuraGraft vs Standard of Care (saline) . Subgroups were also defined as Diabetic and Patients who received more than one vein graft.

## 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) at 3 years.

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

## Lead authors:

- Dr. Francesca Toto and Dr. Enrico Ferrari, Cardiocentro Lugano, Lugano, Switzerland

## Journal:

- J Clin Med. 2022 Feb 18;11(4):1093. doi: 10.3390/jcm11041093.

## Aim of the Study:

- The aim of the study was to compare the efficacy of three solutions in maintaining the endothelial cell integrity of venous segments.

## Methods:

- The efficacy of physiological saline solution (PSS), heparinized autologous blood (HAB) and DuraGraft® in preserving the endothelium of vein segments by evaluating the degree of endothelial cell apoptosis was tested.

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

## Lead authors:

- Dr. Thomas Aschacher and Dr. Sigrid Sandner, Medical University Vienna, Austria

## Journal:

- Frontiers Cardiovascular Medicine, published 06 October 2021 | <https://doi.org/10.3389/fcvm.2021.736503>

## Aim of the Study:

- To evaluate the protective effect of DuraGraft®, an endothelial damage inhibitor (EDI), on Radial Artery (RA) grafts

## Methods:

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



# Effect of different storage solutions on oxidative stress in human saphenous vein grafts

## Lead authors:

- Dr. Ilker Tekin and Dr. Sebahat Özdem, Faculty of Medicine, Bahçeşehir University, İstanbul, Turkey

## Journal:

- Journal of Cardiothoracic Surgery, published 2022 Jan 16;17(1):7. [doi: 10.1186/s13019-022-01752-7](https://doi.org/10.1186/s13019-022-01752-7).

## Aim of the Study:

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

## Methods:

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

# Relationship between intra-operative vein graft treatment with DuraGraft or saline and clinical outcomes after coronary artery bypass grafting

## Lead authors:

- Dr. Miguel Haime, Veterans Affairs Boston, USA

## Journal:

- Exp Reviews Cardiovasc Therapy, published 2018 Dec;16(12):963-970. [doi: 10.1080/14779072.2018.1532289](https://doi.org/10.1080/14779072.2018.1532289).

## Aim of the Study:

- To compare the impact of intraoperative preservation of Saphenous Vein Grafts (SVGs) in DuraGraft (GALA) versus heparinized saline on Vein Graft Failure related outcomes after CABG

## Methods:

- 2436 patients underwent isolated CABG with  $\geq 1$  SVG. SVGs were consecutively treated with DuraGraft in 1036 patients and heparinized saline in 1400 patients. Short- and long-term outcomes were assessed

# **Surgical revascularization using DuraGraft for graft preservation in patients with diabetes mellitus – A report from the DuraGraft Registry**

## **Lead authors:**

- Dr. Martin Misfeld, Heart Center Leipzig, Germany and Dr. Max Emmert, German Heart Center Berlin, Germany

## **Target Journal:**

- Accepted in Interdisciplinary Cardiovascular and Thoracic Surgery, in press 2024

## **Aim of the Study:**

- To evaluate the impact of DuraGraft on 1-year clinical outcome in patients with and without Diabetes Mellitus (DM) undergoing CABG.

## **Methods:**

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

# Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting

## Lead authors:

- Dr. Louis Perrault, Montreal Heart Institute, Canada and Dr. Max Emmert, German Heart Center Berlin, Germany

## Journal:

- J of Thoracic and Cardiovasc Surgery, publ 2019 Nov 9;S0022-5223(19)32503-6. [doi: 10.1016/j.jtcvs.2019.10.115](https://doi.org/10.1016/j.jtcvs.2019.10.115).

## Aim of the Study:

- To assess the effect of DuraGraft, an intraoperative graft treatment, on saphenous vein grafts (SVGs) in patients undergoing isolated coronary artery bypass grafting

## Methods:

- Within patients, 2 SVGs were randomized to DuraGraft or heparinized saline. Multidetector computed tomography 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

