EFFICACIOUS PREVENTION OF DEEP STERNAL WOUND COMPLICATIONS POST CARDIAC SURGERY BY THE POSTHORAX® VEST

FINAL RESULTS OF A PROSPECTIVE RANDOMIZED MULTICENTER TRIAL IN 2600 PATIENTS.

[1] Wagner FM, [2] Gorlitzer M, [3] Pfeiffer S, [1]Sprathof N, [1]Seiffert M, [2]Folkmann S, [3] Fischlein T, [2] Grabenwoeger M, [1]Reichenspurner H

Depts. for Cardiovascular Surgery
[1] Universitäres Herzzentrum Hamburg, [2] KH Hietzing, Wien, [3] KH Nürnberg

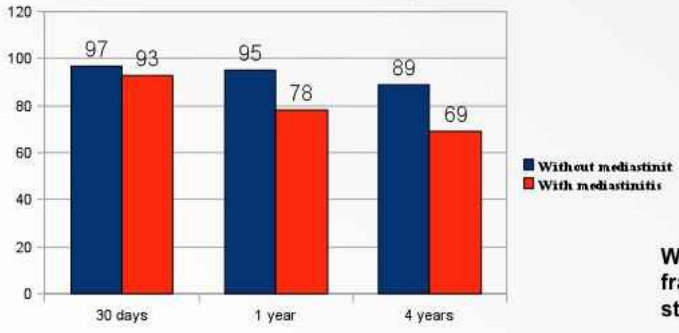


40th Annual Meeting of the German Society for Thoracic- and Cardiovascular Surgery

Background Literature

- Deep sternal infections: up to 5 %
- Mortality up to 25%
- Prolonged hospital stay
- Estimated additional cost 2,8 times higher

Braxton et al.: Postoperative survival rate after mediastinitis
Observation period: 4 years - 15.906 patients
Ann Thorac Surg 2000;70:2004-2007



ORTHOPEDIC LITERATURE:

Rabbit tibial fracture inoculated with S.aureus. Infection rates:
Compr. Plate (stable fixation): 35%
Loose rod (unstable fixation): 71%

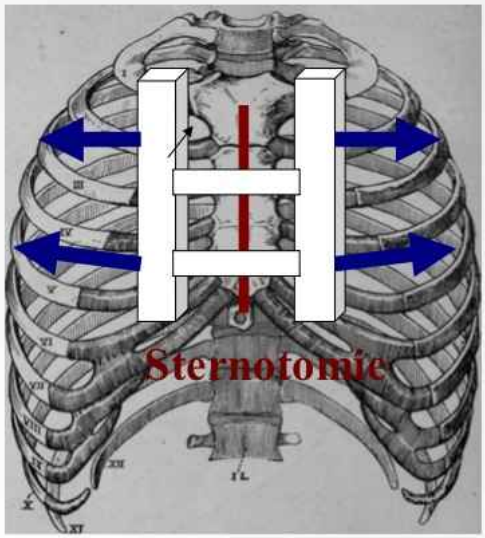
Worlock et al: The prevention of infection in open fractures: An experimental study of the effect of fracture stability. Internat J Care Injured 25:31-38, 1994

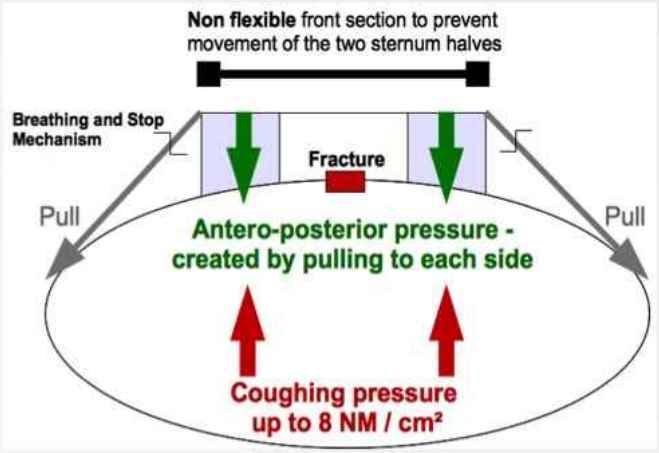
Aim of the Study

- Examine, if additional sternal stabilization by a specially designed sternal support vest, prevents wound complications (WHC) after median sternotomy
- Develop a risk score for postoperative sternal complications (dehiszence, mediastinitis etc.) based on a prospective randomized data collection

Posthorax® sternum support vest

Sternum Support Vest Design

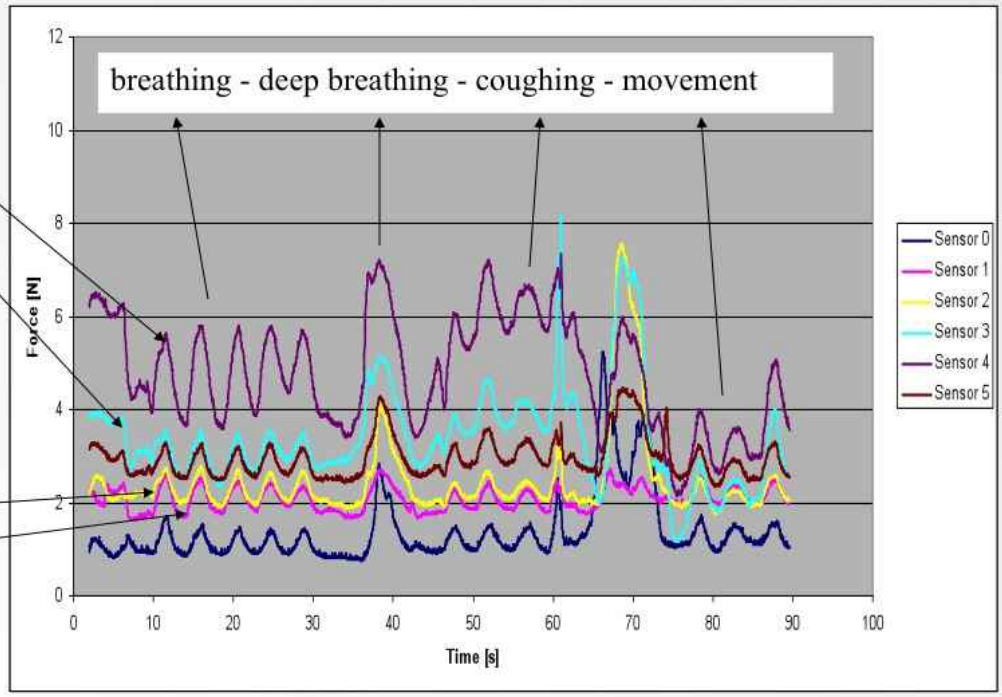




Anterio - posterior sternum fixation

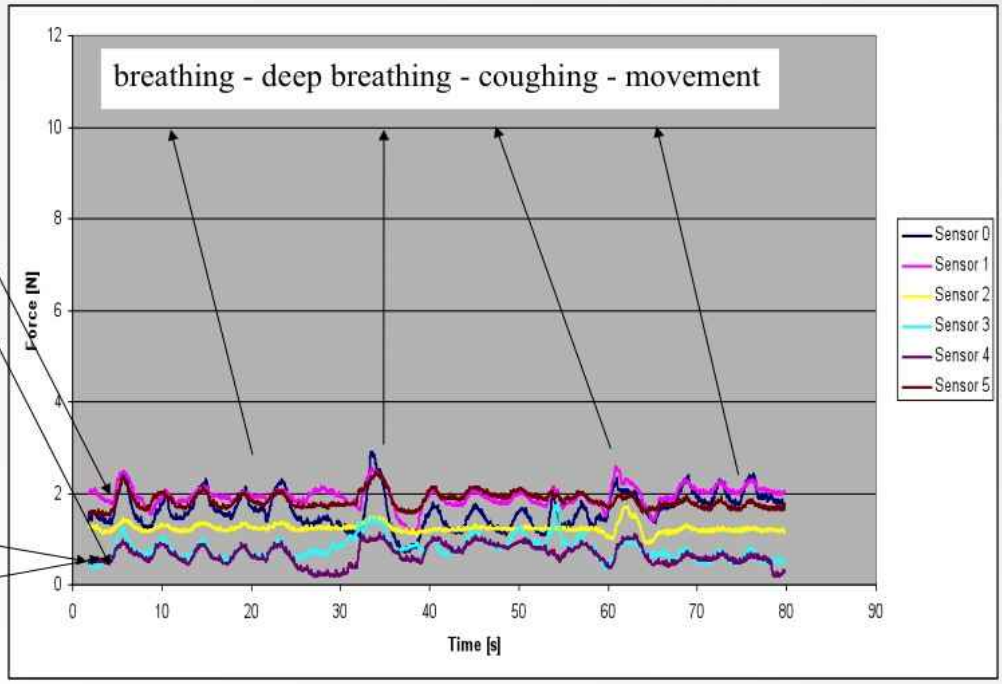
Pressure Sensor Measurement Posthorax® Vest

Biomechanical Institut, Med. University Vienna, M. Bijak, E. Unger



In Comparison: Pressure Sensor Measurement Elastic Bandage

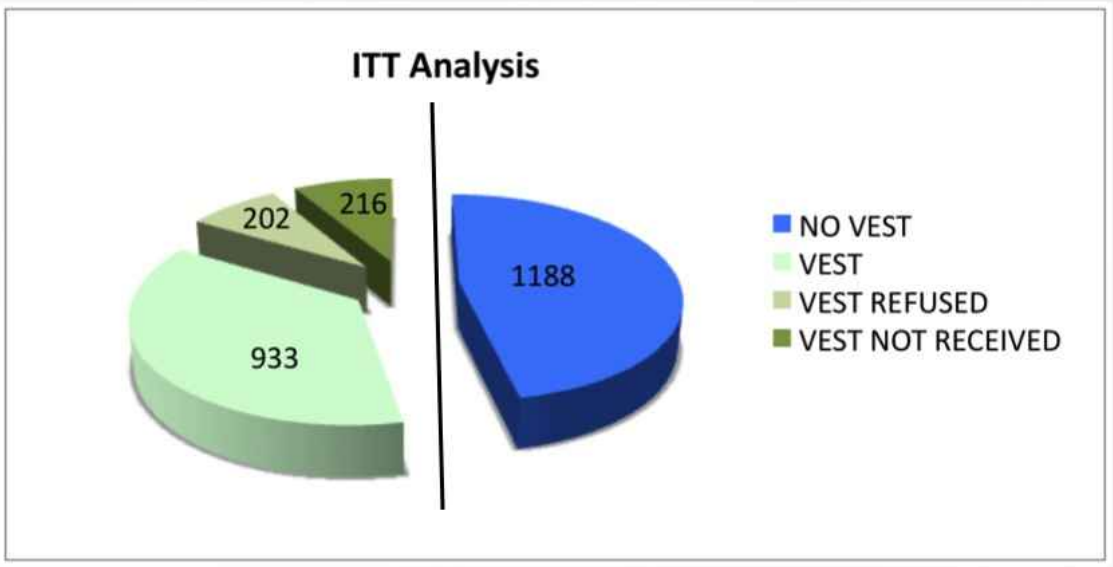
Biomechanical Institut, Med. University Vienna, M. Bijak, E. Unger



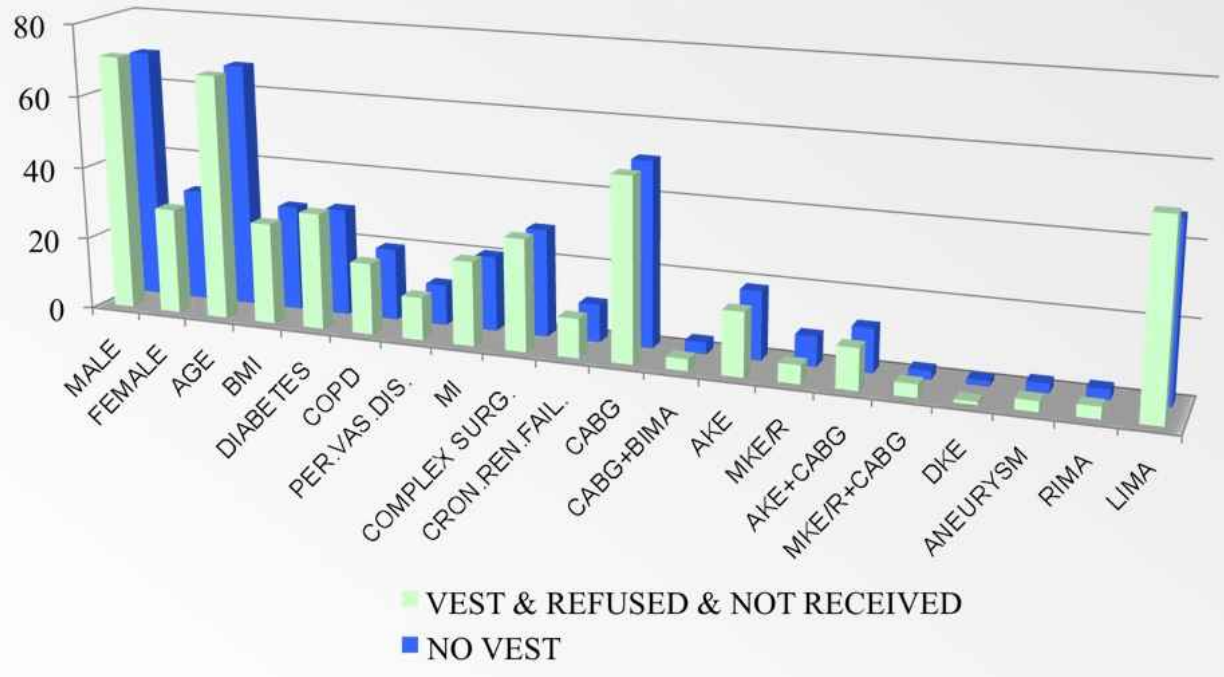
Study Design

- Prospective randomized
- 90 days follow-up
- Target: ≥n=2000
- Vest use for 6 weeks (24hrs/day)
- Exclusion criteria:
  - secondary thorax closure
  - Inability to carry the vest <72 hrs
- Study endpoint: Incidence of WHC
- Analysis : ITT (Intention to Treat)

Study Groups

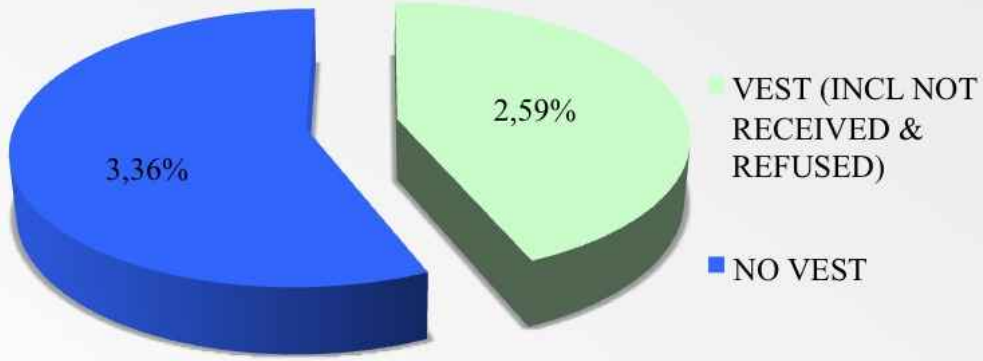


ITT: Risk Profile Vest – No Vest



Results: Overall Incidence of WHC

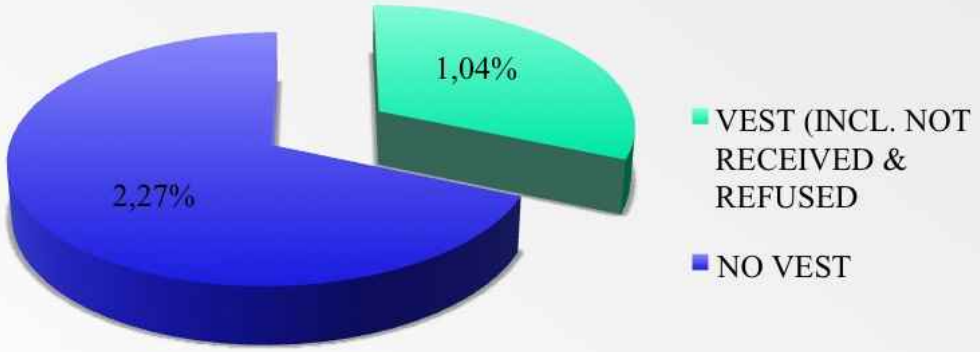
Superficial (SWI) and deep sternal wound infections (DSWI)



p = n.s.

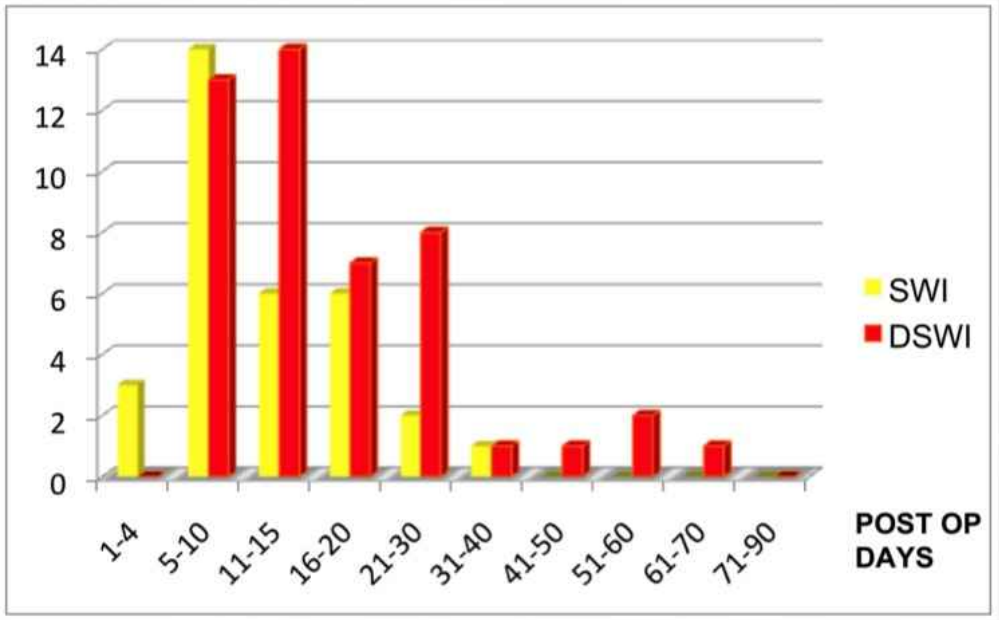
Incidence of Sternal Dehiscence & Mediastinitis

Deep sternal wound infections (DSWI) & mediastinitis

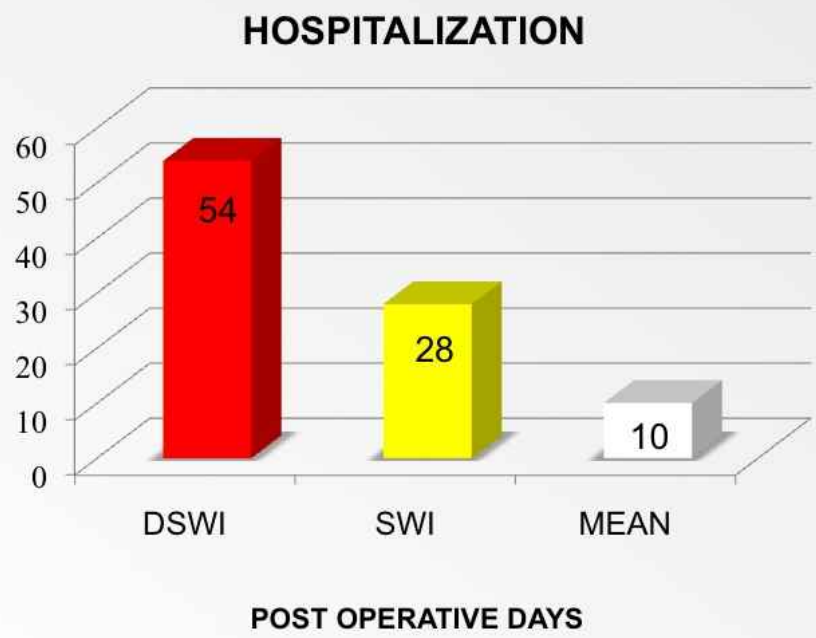


p < 0,0136

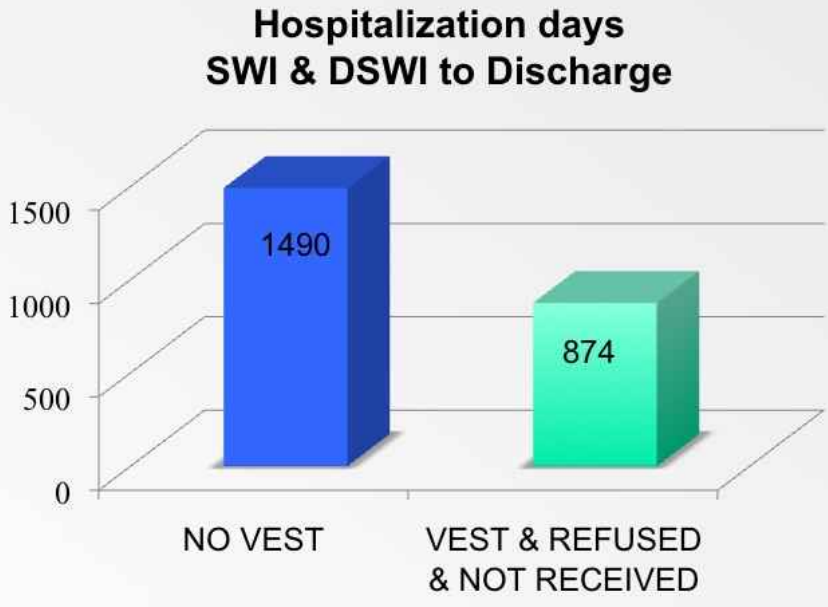
Time Pattern of WHC



Postoperative Hospital Stay

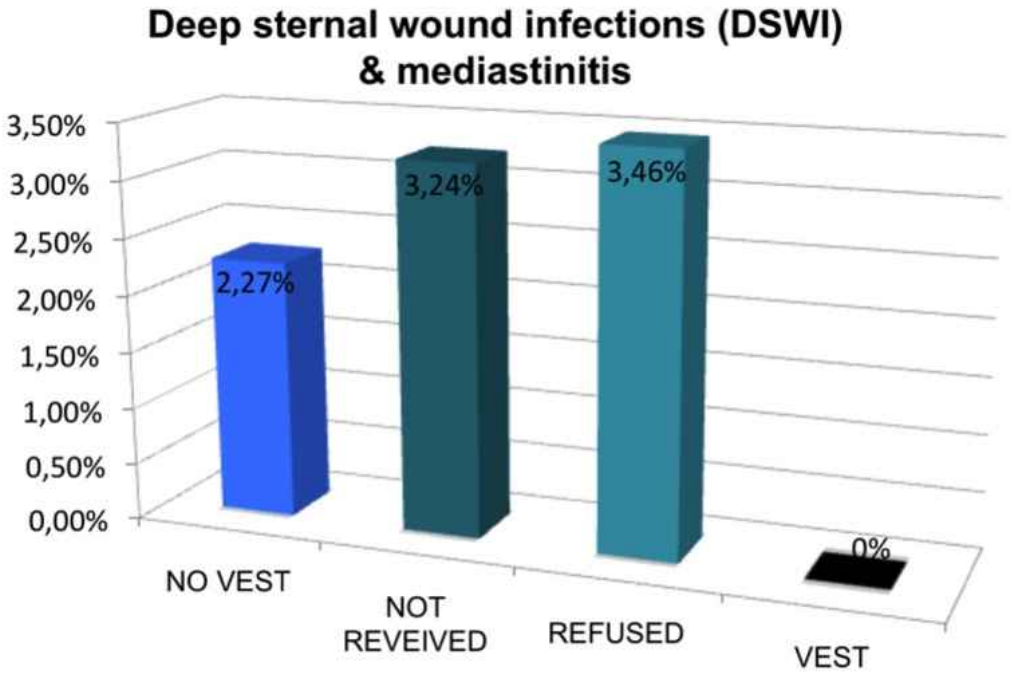


Infection related Cumulative Hospital Stay

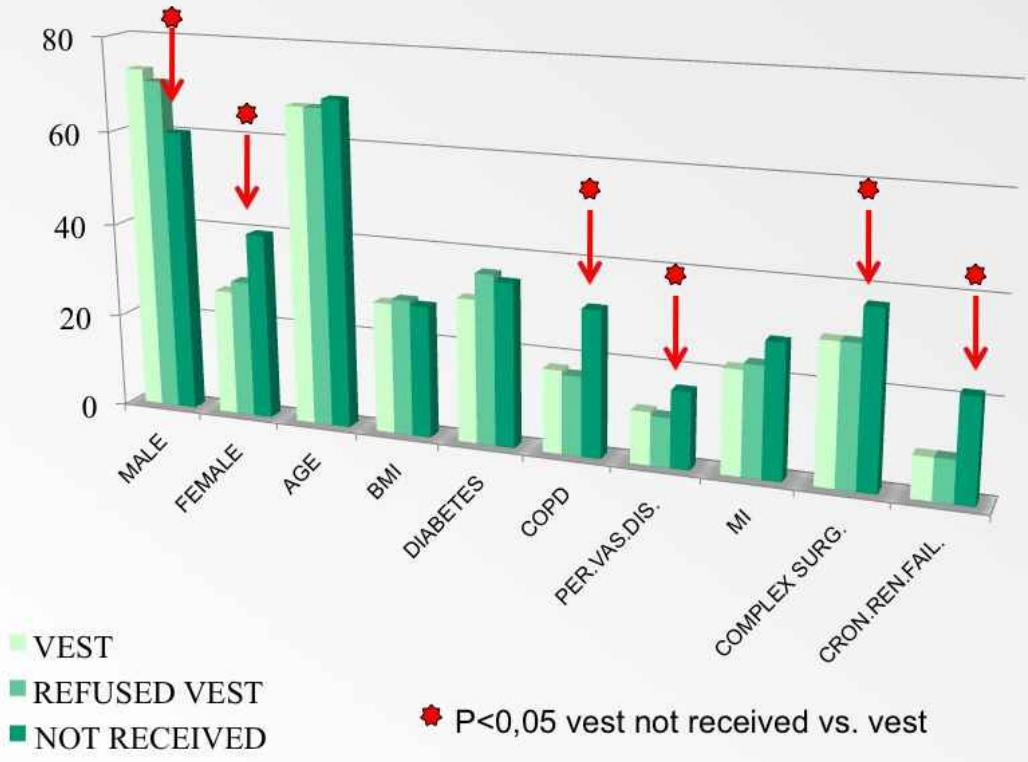


P < 0,00001

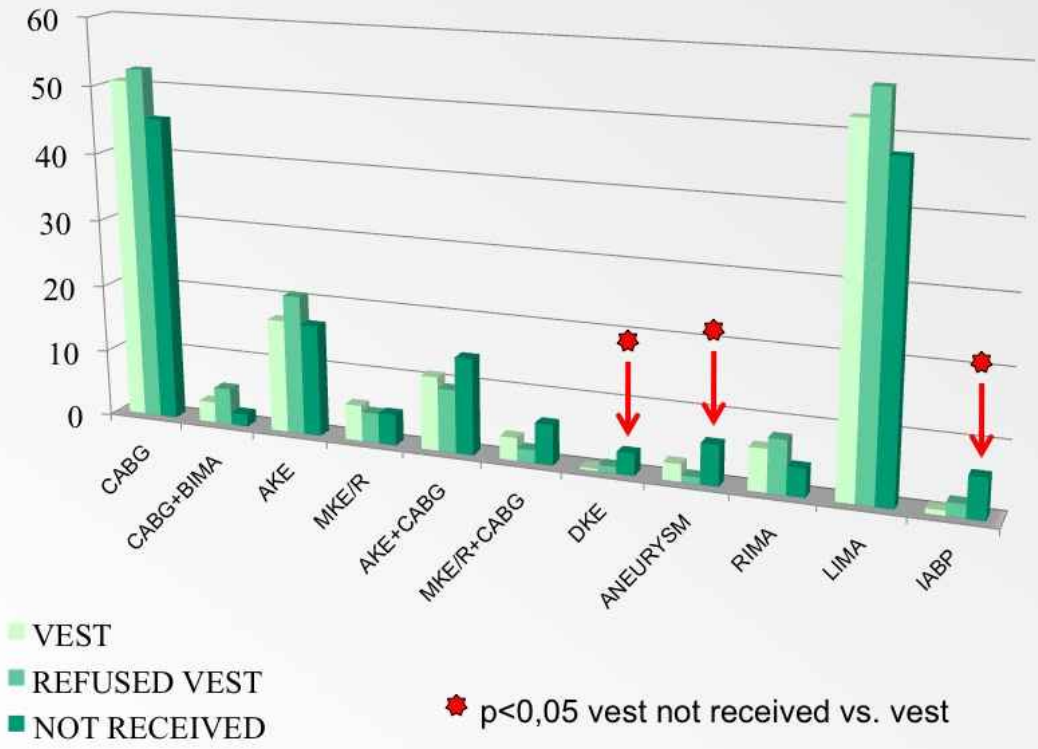
Incidence of WHC: Subgroup Analysis



Subgroup Analysis Preoperative Risk Profile



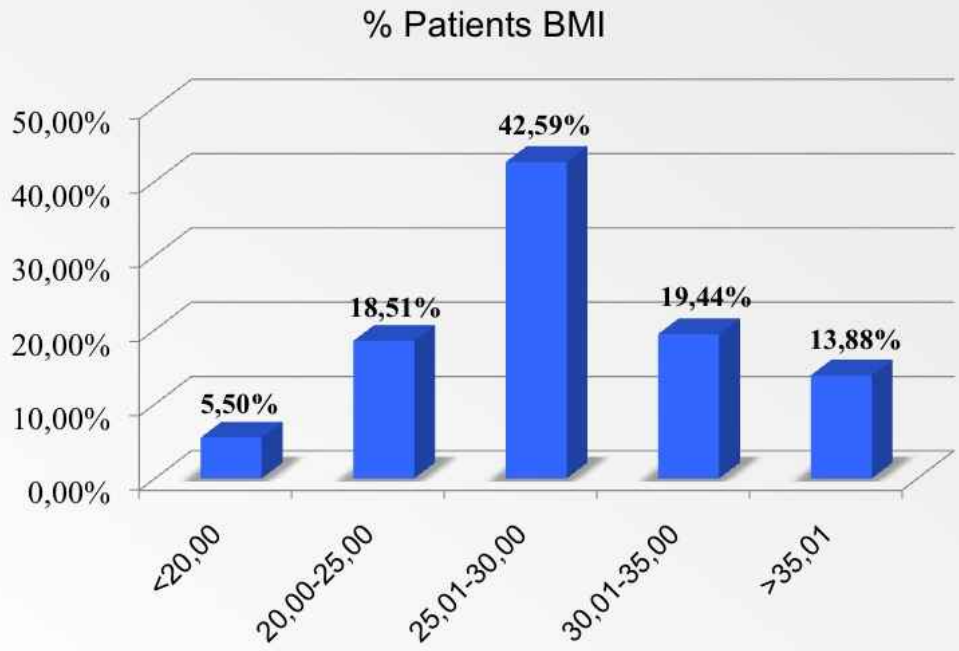
Subgroup Analysis: Surgical Risk Profile



Risk Factors for WHC: Multivariate Log. Regression Analysis

	Parameter	Regression Coefficient	Standard Error	WaldZ-Value (Beta=0)	Wald Prob. Level	Odds Ratio Exp (B)
1	WHC no vest	1,35387	0,42151	3,212	0,00132	3,87239
2	ComplexSurg.	0,57975	0,31481	1,842	0,06553	1,78560
3	Perif.Vasc.Disease	0,62841	0,35527	1,769	0,07693	1,87463
4	Diabetes	0,49811	0,30341	1,642	0,10065	1,64560
5	Age	0,02863	0,01661	1,724	0,08479	1,02904
x	BMI - no significance	0,00335	0,00572	0,586	0,55803	1,00336

Relationship Infection to BMI (Adipositas)



All patients with wound healing complications

Summary

- **Use of the Posthorax® vest**

  - led to a significant reduction, if worn according to protocol even eliminated sternal dehiszence and mediastinitis
  - led to a significant reduction of infection related hospital stay

- **Patient refusing the vest had identical preop. and surgical risk profile – key issue seems to be non-compliance**

- **Preoperative factors seem less important for the development of WHC**

- **Key risk factors rather related to prolonged surgery and postop. complications**

Conclusion

Sternal instability seems to be the single most important factor for deep wound healing infections and mediastinitis post cardiac surgery

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F.M. Wagner[1], M. Gorlitzer[2], S. Pfeiffer[3], R. Oeser[4], M. Seiffert[1], S. Folkmann[2], T. Fischlein[3], M. Grabenwöger[2], H. Reichenspurner[1]

[1] Dept. of Cardiovascular Surgery, University Heart Center Hamburg, Hamburg, Germany

[2] Dept. of Cardiovascular Surgery, Hospital Hietzing, Vienna, Austria

[3] Dept. of Cardiac Surgery, Heart Center, Nuernberg, Germany

[4] Institute for data analysis and statistics, Vienna, Austria

Dr. med.
F.M. Wagner

Objective:

Analyzing efficacy of a specifically designed vest (Posthorax) to prevent sternal wound infections post cardiac surgery and identify risk factors.

Methods:

From 07/2008 until 03/2010 n=2632 patients undergoing cardiac surgery via median sternotomy were randomized to receive or not a Posthorax® vest. Patients were instructed to wear the vest postoperatively 24 hrs/day for at least 6 weeks, follow-up was 90 days. Protocol drop out occurred if no vest was applied within 72 hrs. postoperatively. Main statistics are based on an intention-to-treat (ITT) analysis. Further analysis involved all subgroups including drop out patients.

Results:

Complete data were available for n=2539 patients (age 67±11 years, 45% female). N=1351 were randomized to a vest versus n=1188 to no vest. There was no significant difference between groups regarding age, gender, diabetes, BMI, COPD, renal failure, logEuroScore, surgery indication and bilateral mammary artery. Incidence of deep wound complications (dWC: mediastinitis, sternal dehiscence) was statistically significantly lower in vest n=14 (1,04%) vs. n=27 (2,27%) in no-vest (ITT, p<0,01), superficial complications(sWC) were no different between groups. Subanalysis of vest patients revealed only n=933 (Gr.A) wore the vest according to protocol, while n=202 (Gr.B-refused) refused wearing the vest (non-compliance), n=216 (Gr.B-drop out) dropped out of study (failed vest application <72 hours). All observed dWC occurred in groups B-refused (n=7) and B-drop out (n=7) despite identical preoperative risk profile with Gr.A. Postoperatively Gr.B-drop out revealed statistically elevated intubation time, length of ICU stay, use of IABP, incidence of COPD and percentage of patients with prolonged surgery.

Conclusion:

Consequent application of the Posthorax® vest eliminated deep sternal wound complications. Expected risk factors for wound complications did not prove to be relevant whereas complicated intra- and postoperative course seem of outstanding importance.