SECOND VIENNA SHOCK FORUM

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Heinz Redl

First Vienna Shock Forum

Part A: Pathophysiological Role of Mediators and Mediator Inhibitors in Shock

First Vienna Shock Forum

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Second Vienna Shock Forum

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Günther Schlag

Heinz Redl

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Contributors

Ansgar O. Aasen, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Oslo 4, Norway **[315,389,401,873]**

Homeros Aletras, Department of Surgery, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

Sefik Alkan, Department of Surgery, LMU Munich, Klinikum Grosshadern, D-8000 Munich 70, Federal Republic of Germany **[495]**

Athanasia Alvanou, Department of Histology, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

W. Amann, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[743]**

Paul L. Appel, Department of Surgery, King-Drew Medical Center, Los Angeles, CA 90059 **[133]**

Z. Atay, Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[51]**

Walter Aulitzky, Department of Internal Medicine, University of Innsbruck, Innsbruck A-6020, Austria **[467]**

Gernot Autenrieth, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[625]**

Ivo Baca, Department für Chirurgie, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany **[695]**

Björn Bäckstrand, Department of Surgery, Regionsjukhuset, S-581 85 Linköping, Sweden **[867]**

Andrea Bader, Institute of Immunology, University of Heidelberg, 6900 Heidelberg, Federal Republic of Germany **[299]**

Gregory J. Bagby, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[545]**

F. Bahlmann, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[1097]**

Soheyl Bahrami, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[931,977]**

A. Barjasic, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[743]**

The numbers in brackets are the opening page numbers of the contributors' articles.

Robert E. Barrow, Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 [377]

Jesse Basadre, Department of Anesthesiology and Surgery, The University of Texas Medical Branch and Division of Anesthesia Research, Shriners Burns Institute, Galveston, TX 77550 [815]

J.A. Bauer, Chirurg. Klinik Innenstadt und Chirug. Polikl. der Universität, D-8000 München 2, Democratic Republic of Germany [455]

Franz Bäumer, Chirurgische Universitätsklinik, Experimentelle Chirurgie, D-8700 Würzburg, Federal Republic of Germany [143]

I. Baumgartner, Abt. Klin. Chemie und Klin. Biochemie in der Chir. Klinik Innenstadt, Universität München, 8000 München 2, Federal Republic of Germany [731,763]

Gerard I.J.M. Beerthuizen, Department of General Surgery, University Hospital Nijmegen, 6500 HB Nijmegen, The Netherlands [137]

Anders Bengtson, Department of Anesthesiology, Sahlgren Hospital, University of Göteborg, 41345 Göteborg, Sweden [265,879]

Herbert Benzer, Clinic for Anaesthesia and General Intensive Care Medicine, A-6020 Innsbruck, Austria [783]

Rikard Berling, Department of Anaesthesiology, Malmö General Hospital, University of Lund, S-214 01 Malmö, Sweden [725]

Sandra Betti, Cardiovascular Surgery, University of Siena, 53100 Siena, Italy [73]

G. Beverley, The HA Grové Research Center of the University of Pretoria, Pretoria, South Africa [217]

Sucharit Bhakdi, Department of Microbiology, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany [67,283]

Ron Bilik, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 [535]

Timothy R. Billiar, Departments of Surgery and Biochemistry, University of Minnesota Medical School, Minneapolis, MN 55455 [563]

A. Billing, Chirurg. Klinik und Poliklinik der Universität München, Klinikum Grosshadern, 8000 München 70, Federal Republic of Germany [527]

Ulrich Birkenhauer, Klinik für Anaesthesiologie und Transfusionsmedizin der Universitaet Tuebingen, D-7400 Tuebingen, Federal Republic of Germany [175]

G. Bisiani, Department of Internal Medicine, University of Milan, 20122 Milan, Italy [277]

Giuliana Bisiani, Department of Emergency Surgery, University of Milan, Milan 20122, Italy [633]

Heiner Blanke, Department Hematology/ Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany [971]

Miguel Blazquez, Intensive Care Unit, Hospital N.S. del Pino, Las Palmas, Canary Islands, Spain [57,61]

Günther Blümel, Department of Experimental Surgery, Technical University, 8000 Munich 80, Federal Republic of Germany [339]

Gert Bokelmann, Institut für Laboratoriumsmedizin-Zentrallabor, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany [1043]

Giuseppe Boldrini, Centro di Studio per la Fisiopatologia dello Shock, CNR, Istituto di Clinica Chirurgica, Università Cattolica, Roma, Italy **[259,607,613,619]**

B. Bonavida, Department of Microbiology and Immunology, UCLA School of Medicine, Los Angeles, CA 90024 **[485]**

Roger C. Bone, Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL 60612 **[857]**

Gerhard Borkowski, Department of Internal Medicine, University of Giessen, 6300 Giessen, Federal Republic of Germany **[383]**

Emma Borrelli, Cardiovascular Surgery, University of Siena, 53100 Siena, Italy **[73]**

Ulrich Bosch, Department of Traumasurgery, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37]**

Bonno N. Bouma, Department of Hematology, University Hospital Utrecht, Utrecht, The Netherlands **[401]**

M. Brandl, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[743,1097]**

Pierre Braquet, I.H.B. Research Labs., 92350 Le Plessis-Robinson, France **[425,441,485]**

J. Mark Braughler, CNS Diseases Research, The Upjohn Company, Kalamazoo, MI 49001 **[891]**

G.G. Braun, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[1097]**

K.L. Brigham, Department of Medicine, The Center for Lung Research, Vanderbilt University Medical Center, Nashville, TN 37232 **[91]**

Volker Bühren, Department Trauma Surgery, University of Saarland, D-6650 Homburg/Saar, Federal Republic of Germany **[523]**

Hilmar Burchardi, Department of Anaesthesiology, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[323]**

Reinhard Burger, Robert Koch Institute, 1000 Berlin, Federal Republic of Germany **[299]**

R.D. Burrow, Department of Medicine, University of Oklahoma City, Oklahoma, OK 73104 **[207]**

Wim A. Buurman, Department of General Surgery, University of Limburg, Biomedical Center, 6200 MD Maastricht, The Netherlands **[463]**

Jorge Casals-Stenzel, Department of Pharmacology, Boehringer Ingelheim KG, D-6507 Ingelheim, Federal Republic of Germany **[925]**

Marco Castagneto, Centro di Studio per la Fisiopatologia dello Shock, CNR, Istituto di Clinica Chirurgica, Università Cattolica, Roma, Italy **[259,607,613,619]**

Matthias Cebulla, Department of Surgery, University Hospital Frankfurt/M., D-6000 Frankfurt/M. 70, Federal Republic of Germany **[517]**

Frank B. Cerra, Departments of Surgery and Biochemistry, University of Minnesota Medical School, Minneapolis, MN 55455 **[563]**

Huacui Chen, Department of Pathophysiology, Peking Union Medical College, Beijing 100700, China **[271]**

Li Chen, Department of Pathophysiology, Peking Union Medical College, Beijing 100700, China **[271]**

Osvaldo Chiara, Department of Emergency Surgery, University of Milan, 20122 Milan, Italy **[73,277]**

Carlo Chiarla, Centro di Sudio per la Fisiopatologia dello Shock, CNR, Istituto di Clinica Chirurgica, Università Cattolica, Roma, Italy **[259,607,613,619]**

J. Allen Coffey, Jr., Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 **[377]**

Bill Coleman, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

P. Conzen, Chirurg. Klinik Innenstadt und Chirurg. Polikl. der Universität, D-8000 München 2, Federal Republic of Germany **[455]**

Tore Curstedt, Department of Clinical Chemistry, Karolinska Hospital, Stockholm, Sweden **[791]**

Louis G. D'Alecy, Departments of Physiology and Surgery, The University of Michigan Medical School, Ann Arbor, MI 48109 **[891]**

Ying Dang, Department of Pathophysiology, Peking Union Medical College, Beijing 100700, China **[271]**

Reiner Dauberschmidt, Research Department of Intensive Care Medicine, Friedrichshain Hospital Berlin, DDR-1017 Berlin, Democratic Republic of Germany **[331]**

I.V. Deaciuc, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[575]**

D. De Backer, Department of Intensive Care, Erasme Hospital, Free University of Brussels, 1070 Brussels, Belgium **[181]**

Joop M.H. Debets, Department of General Surgery, University of Limburg, Biomedical Center, 6200 MD Maastricht, The Netherlands **[463]**

Peter J. Del Vecchio, Departments of Ophthalmology and Physiology, The Albany Medical College, Albany, NY 12208 **[101]**

R. Dennhardt, Klinik für Anästhesiologie, Krankenhaus Nordwest, 6000 Frankfurt 90, Federal Republic of Germany **[711,751]**

E.B. Rodriguez de Turco, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[575]**

R. de Winter, Medical Center Veterans Administration, Oklahoma City, OK 73104 **[207]**

Heinrich Ditter, Department of Internal Medicine, University of Giessen, 6300 Giessen, Federal Republic of Germany **[383]**

I.C. Dormehl, AEC Institute for Life Sciences, University of Pretoria, Pretoria, South Africa **[207,217]**

M. Dreher, Diagnostica Forschung, E. Merck, D-6100 Darmstadt, Federal Republic of Germany **[707]**

Detlev Drenckhahn, Department of Anatomy and Cell Biology (DD), Phillips University, D-3550 Marburg, Federal Republic of Germany **[127]**

Christel Dressler, Department of Anaesthesiology, Friedrichshain Hospital of Berlin, DDR-1017 Berlin, Democratic Republic of Germany **[331]**

Günter Dussing, Institute of Biochemistry, University of Graz, A-8010 Graz, Austria **[351]**

K.H. Duswald, Chirurgische Klinik Innenstadt, Universität München, 8000 München 2, Federal Republic of Germany **[731,763]**

Alexander Dwenger, Klinische Biochemie, Medizinischen Hochschule Hannover, D-3000 Hannover 61, Federal Republic of Germany **[673]**

Rudolf Egbring, Division of Internal Medicine, Department of Hematology, Philipps-University, D-3550 Marburg, Federal Republic of Germany **[965,971]**

Gerd Egger, Institute of Functional Pathology, University of Graz, A-8010 Graz, Austria **[351]**

Efthimios Eleftheriadis, Department of Surgery, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

O. Elert, Department of Thoracic and Cardiovascular Surgery, University Hospital, D-8700 Würzburg, Federal Republic of Germany **[1031]**

W. Engelhardt, Institute of Anaesthesiology, University Hospital, D-8700 Würzburg, Federal Republic of Germany **[1031]**

Rolf Erdmann, Institut für Laboratoriumsmedizin-Zentrallabor, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany **[695]**

Wolfgang Ertel, Department of Surgery, LMU Munich, Klinikum Grosshadern, D-8000 München 70, Federal Republic of Germany **[495,513]**

Vichra Evstatieva, Ludwig Boltzmann Institute, Department of Anaesthesia and Intensive Care, A-1090 Vienna, Austria **[803]**

Eugen Faist, Department of Surgery, LMU Munich, Klinikum Grosshadern, 8000 München 70, Federal Republic of Germany **[495,513]**

Luca Fattori, Department of Emergency Surgery, University of Milan, Milan 20122, Italy **[633]**

Walter Fierz, Section of Clinical Immunology, Department of Medicine, University Hospital Zurich, CH-8091 Zurich, Switzerland **[491]**

Peter C. Fink, Institut für Laboratoriumsmedizin-Zentrallabor, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany **[695,1043]**

Chryssi Foroglou, Department of Histology, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

Knut Frederking, Department of Surgery, University Hospital Frankfurt/M., D-6000 Frankfurt/M. 70, Federal Republic of Germany **[517]**

Reinhold Fretschner, Klinik für Anaesthesiologie und Transfusionsmedizin der Universität Tuebingen, D-7400 Tuebingen, Federal Republic of Germany **[185]**

M.A. Freudenberg, Max-Planck-Institut für Immunbiologie, Freiburg/Br., Federal Republic of Germany **[407]**

Nikolaus Freudenberg, Department of Pathology, University of Freiburg, D-7800 Freiburg, Federal Republic of Germany **[77,113,371,407]**

Stefan W. Frick, Surgical University Clinic Marienhospital Ruhr-University of Bochum, D-4690 Herne 1, Federal Republic of Germany **[1037]**

Elmar Friderichs, Department of Pharmacology, Grünenthal GmbH, 5100 Aachen, Federal Republic of Germany **[913]**

H.P. Friedl, Department of Traumatology, Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[775]**

Arno Friedlein, Progen Biotechnik, 6900 Heidelberg, Federal Republic of Germany **[299]**

Hans Fritz, Department of Surgery, Division of Clinical Chemistry and Clinical Biochemistry, University of Munich, D-8000 Munich 2, Federal Republic of Germany **[305,395,455,701]**

D. Fröhlich, Chirurg. Klinik und Poliklinik der Universität München, Klinikum Grosshadern, 8000 München 70, Federal Republic of Germany **[527]**

Thomas Fuchs, Department of Anatomy and Cell Biology (DD), Phillips University, D-3550 Marburg, Federal Republic of Germany **[127]**

Reinhold Függer, Department of Surgery 1, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

G. Fuhrer, Department of Cardiovascular Surgery, University of Tübingen, D-7400 Tübingen, Federal Republic of Germany **[737]**

J. Funovics, First Surgical University Clinic, Metabolic Research Laboratory, University Vienna, A-1090 Vienna, Austria **[589]**

Walter Fürst, Ludwig Boltzmann Institute for Experimental Traumatology, Vienna A-1200, Austria **[345]**

Manfred Gahr, Department of Pediatrics, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[689]**

Ralf Gahr, Unfallchirurgische Klinik, Städtische Kliniken Dortmund, D-4600 Dortmund 1, Federal Republic of Germany **[1087]**

C. Galanos, Max-Planck-Institut für Immunbiologie, Freiburg/Br., Federal Republic of Germany **[407]**

Wolfgang Gammer, Department of Orthopaedic Surgery, Ludvika Hospital, 771 00 Ludvika, Sweden **[879]**

M. Gardinali, Department of Internal Medicine, University of Milan, 20122 Milan, Italy **[277]**

Harald Gasser, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[447]**

J. Gebert, Zentrum für Anästhesie der Medizinischen, Hochschule Hannover, 3000 Hannover 51, Federal Republic of Germany **[643]**

R. Geiger, Abteilung für Klinische Chemie und Klinishche Biochemie in der Chirurgie Innenstadt, Ludwig-Mamimilians-Universität München, D-8000 München 2, Federal Republic of Germany **[945]**

Stephanos Geroulanos, Department of Surgery, University Hospital Zurich, CH-8091 Zurich, Switzerland **[491]**

Anders Gidlöf, Clinical Research Center, Faculty of Health Sciences, University Hospital, S-581 85 Linköping, Sweden **[157]**

Hubert Giertz, Department of Pharmacology, Grünenthal GmbH, 5100 Aachen, Federal Republic of Germany **[913]**

Nicolas Gilliard, Division of Pulmonary and Critical Care Medicine, Department of Medicine, University of California, San Diego, CA 92103 **[791]**

Pier P. Giomarelli, Cardiovascular Surgery, University of Siena, 53100 Siena, Italy **[73]**

Ivo Giovannini, Centro di Studio per Fisiopatologia dello Shock, CNR, Istituto di Clinica Chirurgica, Università Cattolica, Roma, Italy **[259,607,613,619]**

Werner Glinz, Section of Clinical Immunology, Department of Surgery, University Hospital, CH-8091 Zurich, Switzerland **[491,769]**

Oliver Gonschorek, Department of Trauma Surgery, University of Saarland, D-6650 Homburg/Saar, Federal Republic of Germany **[523]**

R. Jan A. Goris, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegen, The Netherlands **[137,419,827]**

Notker Graf, Department of Anaesthesiology, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[323]**

Hans Grajetzki, Central Resuscitation and Intensive Care Unit, Friedrichshain Hospital Berlin, DDR-1017 Berlin, Demorcratic Republic of Germany **[331]**

H.-J. Gramm, Klinik für Anästhesiologie und opertive Intensivmedizin, Klinikum Steglitz der Freien Universität Berlin, D-1000 Berlin 45, Federal Republic of Germany **[711,751]**

Wolfgang Graninger, Department of Chemotherapy, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

K.F. Gratz, Department of Nuclearmedicine, Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[775]**

Barbara Griess, Research Department of Intensive Care Medicine, Friedrichshain Hospital of Berlin, DDR-1017 Berlin, Democratic Republic of Germany **[331]**

Peter J. Grob, Section of Clinical Immunology, Department of Medicine, University Hospital, CH-8091 Zurich, Switzerland **[491,769]**

O. Gröber, Department of Cardiovascular Surgery, University of Tübingen, D-7400 Tübingen, Federal Republic of Germany **[737]**

A.B.J. Groeneveld, Medical Intensive Care Unit, Free University Hospital, Amsterdam **[163]**

R. Grundmann, Chirurgische Universitätsklinik Köln-Lindenthal, D-5000 Köln 41, Federal Republic of Germany **[637]**

Heinz Guggenberger, Klinik für Anaesthesiologie und Transfusionsmedizin der Universität Tuebingen, D-7400 Tuebingen, Federal Republic of Germany **[185]**

G. Gunzer, Diagnostica Forschung, E.Merck, D-6100 Darmstadt, Federal Republic of Germany **[707]**

C.E. Hack, Central Laboratory of the Netherlands Red Cross Bloodtransfusion Service and Laboratory for Experimental and Clinical Immunology, University of Amsterdam, Amsterdam **[163]**

Werner Hackl, Ludwig Boltzmann Institute, Department of Anaesthesia and Intensive Care, Vienna University School of Medicine, A-1090 Vienna, Austria **[809]**

Rainer Haeckel, Institut für Laboratoriumsmedizin-Zentrallabor, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany **[1043]**

Edward D. Hall, CNS Diseases Research, The Upjohn Company, Kalamazoo, MI 49001 **[891]**

Seth W.O. Hallström, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[225,231,345]**

Gerhard Hamilton, Experimental Surgery, University Clinic, Burn Care Unit, A-1090 Vienna, Austria **[995]**

A.F. Hammerle, Department of Anaesthesiology and General Intensive Care, University of Vienna, A-1090 Vienna, Austria **[715]**

Diane M. Hargrove, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[545]**

Henning Harke, Department of Anaesthesia, General Hospital of Krefeld, D-4150 Krefeld, Federal Republic of Germany **[959]**

Rolf Hartmann, Surgical University Clinic Marienhospital Ruhr-University of Bochum, D-4690 Herne 1, Federal Republic of Germany **[1037]**

Ruth Hartmann, Department of Internal Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[283]**

Mats Heideman, Department of Surgery, Sahlgren Hospital, University of Göteborg, 41345 Göteborg, Sweden **[265,879]**

A. Heidland, Department of Medicine, University of Wuerzburg, D-8700 Wuerzburg, Federal Republic of Germany **[757]**

R. Helger, Diagnostica Forschung, E. Merck, D-6100 Darmstadt, Federal Republic of Germany **[707]**

W. Heller, Department of Cardiovascular Surgery, University of Tübingen, D-7400 Tübingen, Federal Republic of Germany **[737]**

G. Hempelmann, Department of Anaesthesia and Intensive Care Medicine, Justus-Liebig Universität, D-6300 Giessen, Federal Republic of Germany **[897]**

Hermann August Henrich, Chirurgische Universitätsklinik, Experimentelle Chirurgie, D-8700 Würzburg, Federal Republic of Germany **[143]**

Friedrich Herbst, Department of Surgery 1, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

Stefan Hergenröder, Department of Pharmacology, Boehringer Ingelheim KG, D-6507 Ingelheim/Rhein, Federal Republic of Germany **[1091]**

J.B. Hermiller, Naval Medical Research Institute, Bethesda, MD 20814 **[575]**

David N. Herndon, Department of Anesthesiology and Surgery, The University of Texas Medical Branch and Division of Anesthesia Research, Shriners Burns Institute, Galveston, TX 77550 **[201,377,815,885]**

Thomas Hessz, Department of Anatomy and Cell Biology (DD), Phillips University, D-3550 Marburg, Federal Republic of Germany **[127]**

Hubert Heuer, Department of Pharmacology, Boehringer Ingelheim KG, D-6507 Ingelheim, Federal Republic of Germany **[919,925]**

Lerner B. Hinshaw, Oklahoma Medical Research Foundation, and University of Oklahoma Health Sciences Center, Oklahoma City, OK 73104 **[835]**

Herwig P. Hofer, Surgical Clinic, University of Graz, A-8010 Graz, Austria **[351]**

Ch. Hoffmann, Department of Internal Medicine, Division of Clinical Pathophysiology and Experimental Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[305]**

H. Hoffmann, Abteilung für Klinische Chemie und Klinische Biochemie in der Chirurgie Innenstadt, Ludwig-Maximilians Universität München, D-8000 München 2, Federal Republic of Germany **[395,937,945,983]**

Peter Hoffmann, Abteilung für Anästhesiologie, Städtische Kliniken Dortmund, D-4600 Dortmund 1, Federal Republic of Germany **[1087]**

James C. Hogg, Pulmonary Research Laboratory, University of British Columbia, St. Paul's Hospital, Vancouver, Canada V6Z 1Y6 **[27]**

G. Hohlbach, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Michael Holch, Department of Trauma Surgery, Medical School Hannover, 3000 Hannover 61, Federal Republic of Germany **[507]**

Michael W. Holch, Section of Clinical Immunology, Department of Medicine, University Hospital, CH-8091 Zurich, Switzerland **[491,769]**

Ralph T. Holman, Departments of Surgery and Biochemistry, University of Minnesota Medical School, Minneapolis, MN 55455 **[563]**

M. Hornung, Chirurgische Universitätsklinik Köln-Lindenthal, D-5000 Köln 41, Federal Republic of Germany **[637]**

David Hosford, I.H.B. Research Labs., 92350 Le Plessis-Robinson, France **[425,485]**

Christoph Huber, Department of Internal Medicine, University of Innsbruck, A-6020 Innsbruck, Austria **[467]**

N. Hugo, The HA Grové Research Center of the University of Pretoria, Pretoria, South Africa **[207,217]**

Elizabeth Husztik, Institute of Medical Biology, Albert Szent-Györgyi Medical University, Szeged, Hungary **[1001]**

Carlo Iannace, Centro di Studio per la Fisiopatologia dello Shock, CNR, Istituto di Clinica Chirurgica, Università Cattolica, Roma, Italy **[613]**

Michael Imhoff, Chirurgische Klinik, Städtische Kliniken Dortmund, D-4600 Dortmund 1, Federal Republic of Germany **[1087]**

Ingvar Jansson, Department of Surgery, Regionsjukhuset, S-581 85 Linköping, Sweden **[867]**

Marianne Jochum, Klinische Chemie und Klinische Biochemie, Chirurgische Klinik Innenstadt, Universität München, D-8000 München 2, Federal Republic of Germany **[527,673,701,731]**

J.E. Johnson, Department of Pathology, The Center for Lung Research, Vanderbilt University Medical Center, Nashville, TN 37232 **[91]**

Theo Joka, Department of Traumatology, University of Essen, D-4300 Essen 1, Federal Republic of Germany **[43,51,673]**

F. Joo, Biological Research Center of the Academy of Science of Hungary, Hungary **[291]**

Ch. Josten, Department of Surgery, Berufsgenossenschaftliche Krankenanstalten "Bergmannsheil", 4630 Bochum, Federal Republic of Germany **[989]**

Wolfgang G. Junger, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[953]**

W. Junginger, Department of Cardiovascular Surgery, University of Tübingen, D-7400 Tübingen, Federal Republic of Germany **[737]**

Stefan Kääb, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[1025]**

Karin Kaden, Paediatric Clinic, Friedrichshain Hospital Berlin, DDR-1017 Berlin, Demorcratic Republic of Germany **[331]**

M. Kahle, Department of General and Thoracic Surgery, Justus-Liebig Universität, D-6300 Giessen, Federal Republic of Germany **[897]**

J. Kalotai, Department of Traumatology, University of Essen, 4300 Essen 1, Federal Republic of Germany **[51]**

T. Kapsner, Department of Medicine I, Klinikum Grosshadern, University of Munich, 8000 Munich 70, Federal Republic of Germany **[247]**

M.R. Karim, Chirurgische Klinik, Städtisches Klinikum Karlsruhe, Karlsruhe, Federal Republic of Germany **[407]**

J. Karner, First Surgical University Clinic, Metabolic Research Laboratory, University Vienna, A-1090 Vienna, Austria **[589]**

József Kaszaki, Institute of Experimental Surgery, Szent-Györgyi Albert Medical University, H-6720 Szeged, Hungary **[253,291]**

Dezsö Kelemen, Department of Experimental Surgery, University of Medicine, Pécs, Hungary H-7643 **[907]**

Zafar Khakpour, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[225,231]**

J.G. Kilian, Department of Medicine, University of Pretoria, Pretoria, South Africa **[207,217]**

N. Kipping, Chirurgische Universitätsklinik Köln-Lindenthal, D-5000 Köln 41, Federal Republic of Germany **[637]**

R. Kirnbauer, Department of Anaesthesiology and General Intensive Care, University of Vienna, A-1090 Vienna, Austria **[715]**

Michael Kirschfink, Department of Immunology, University of Heidelberg, D-6900 Heidelberg, Federal Republic of Germany **[43]**

Werner J. Kleeman, Department of Forensic Medicine, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37]**

Thomas Kloess, Klinik für Anaesthesiologie und Transfusionsmedizin der Universitaet Tuebingen, D-7400 Tuebingen, Federal Republic of Germany **[175,185]**

R. Knoll, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[1097]**

G. Kolb, Department of Hematology/ Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany **[971]**

Wolfgang Koller, Clinic for Anaesthesia and General Intensive Care Medicine, A-6020 Innsbruck, Austria **[783]**

Peter Konold, Department of Surgery, University Hospital Frankfurt/M., D-6000 Frankfurt/M. 70, Federal Republic of Germany **[517]**

A. Kooistra, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Joop P. Koopman, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegen, The Netherlands **[827]**

H. Kortmann, Chirurg. Klinik und Poliklinik der Universität München, Klinikum Grosshadern, 8000 München 70, Federal Republic of Germany **[527]**

Bernd Kottler, Klinik für Anaesthesiologie und Transfusionsmedizin der Universitaet Tuebingen, D-7400 Tuebingen, Federal Republic of Germany **[175]**

Katerina Kotzampassi, Department of Surgery, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

E. Kovats, First Surgical University Clinic, Metabolic Research Laboratory, University Vienna, A-1090 Vienna, Austria **[589]**

Harry B. Kram, Department of Surgery, King-Drew Medical Center, Los Angeles, CA 90059 **[133]**

Sabine Krautschneider, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[447]**

H.G. Kress, Institute of Anaesthesiology, University Hospital, D-8700 Würzburg, Federal Republic of Germany **[1031]**

Ferdinand J.A. Kreuzer, Department of Physiology, University Hospital Nijmegen, 6500 HB Nijmegen, The Netherlands **[137]**

E. Kreuzfelder, Institute of Virology and Immunology, University of Essen, 4300 Essen 1, Federal Republic of Germnay **[51]**

Peter E. Krösl, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[225,231,237]**

Peter Kühnl, Institute of Immunohematology, University Hospital Frankfurt/M., D-6000 Frankfurt/M. 70, Federal Republic of Germany **[278]**

K. Kürten, Chirurgische Universitätsklinik Köln, 5000 Köln 41, Federal Republic of Germany **[601]**

Herbert Lamche, Ernst Boehringer Institute, A-1120 Vienna, Austria **[467]**

Charles H. Lang, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[545]**

Hermann Lang, Diagnostic Research, E. Merck Darmstadt, D-6100 Darmstadt, Federal Republic of Germany **[701,707]**

Åke Lasson, Departments of Surgery and Surgical Pathophysiology, Malmö General Hospital, University of Lund, S-214 01 Malmö, Sweden **[725]**

Z. Laszik, Institute of Pathology, Medical University of Szeged, Szeged, Hungary **[291]**

Martin Lausen, Department of Surgery, University of Freiburg, 7800 Freiburg, Federal Republic of Germany **[371]**

George Lázár, Institute of Pathophysiology, Albert Szent-Györgyi Medical University, Szeged, Hungary **[1001]**

George Lázár, Jr., Department of Surgery, Albert Szent-Györgyi Medical University, Szeged, Hungary **[1001]**

P. Lehmkuhl, Zentrum für Anästhesie der Medizinischen, Hochschule Hannover, 3000 Hanover 51, Federal Republic of Germany **[643]**

P. Lehnert, Med. Klinik Innenstadt, Universität München, 8000 München 2, Federal Republic of Germany **[763]**

Sten Lennquist, Department of Surgery, Regionsjukhuset, S-581 85 Linköping, Sweden **[867]**

L. Lerch, Department of Hematology/Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany **[971]**

David H. Lewis, Clinical Research Center, Faculty of Health Sciences, University Hospital, S-581 85 Linköping, Sweden **[157]**

Camille Lieners, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[345,467,953]**

Zhenyuan Liu, Department of Pathophysiology, Peking Union Medical College, Beijing 100700, China **[271]**

Hans J. Lübbesmeyer, Department of Anesthesiology and Operative Intensive Care, Westfaelian Wilhelms University, D-4400 Münster, Federal Republic of Germany **[815]**

Santiago Lubillo, Intensive Care Unit, Hospital N.S. del Pino, Las Palmas, Canary Islands, Spain **[57,61]**

Heribert Luig, Department of Nuclear Medicine, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[323]**

Mohammad Maghsudi, Department of Trauma Surgery, Medical School Hannover, 3000 Hannover 61, Federal Republic of Germany **[507]**

James Maguire, Department of Anesthesiology and Surgery, The University of Texas Medical Branch and Division of Anesthesia Research, Shriners Burns Institute, Galveston, TX 77550 **[815]**

Asrar B. Malik, Department of Physiology, The Albany Medical College, Albany, NY 12208 **[101]**

Jose L. Manzano, Intensive Care Unit, Hospital N.S. del Pino, Las Palmas, Canary Islands, Spain **[57,61]**

M. Maree, The HA Grové Research Center of the University of Pretoria, Pretoria, South Africa **[207,217]**

Claudio Marradi, Department of Emergency Surgery, University of Milan, Milan 20122, Italy **[633]**

F. Reinhard Matthias, Department of Internal Medicine, University of Giessen, 6300 Giessen, Federal Republic of Germany **[383]**

O. Mayrhofer, Department of Anaesthesiology and General Intensive Care, University of Vienna, A-1090 Vienna, Austria **[715]**

J.P. Mehegan, Naval Medical Research Institute, Bethesda, MD 20814 **[575]**

H. Meinhold, Abteilung für Nuklearmedizin, Klinikum Steglitz FU Berlin, D-1000 Berlin 45, Federal Republic of Germany **[711]**

K. Meinhold, Klinik für Anästhesiologie und operative Intensivmedizin, Klinikum Steglitz der Freien Universität Berlin, D-1000 Berlin 45, Federal Republic of Germany **[751]**

Günther Meissl, I. Surgery, University Clinic, Burn Care Unit, A-1090 Vienna, Austria **[995]**

S.M. Melnitzki, Department of Medicine I, Klinikum Grosshadern, University of Munich, 8000 Munich 70, Federal Republic of Germany **[247]**

Jean Michel Mencia-Huerta, I.H.B. Research Labs., 91952 Les Ulis, France **[441]**

T. Menges, Department of Hematology/Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany **[971]**

T. Allen Merritt, Department of Pediatrics, University of California, San Diego, CA 92103 **[791]**

Károly Mészáros, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[545]**

Birgit Metzler, Department of Occupational and Social Medicine, University of Tübingen, 7400 Tübingen, Federal Republic of Germany **[595]**

Angelika Mewes, Department of Surgery, LMU Munich, Klinikum Grosshadern, D-8000 Munich 70, Federal Republic of Germany **[495]**

Manfred Meyer, Research Department of Intensive Care Medicine, Friedrichshain Hospital Berlin, DDR-1017 Berlin, Democratic Republic of Germany **[331]**

Barbara Meyrick, Department of Pathology, The Center for Lung Research, Vanderbilt University, Nashville, TN 37232 **[91]**

M. Micksche, Institute for Applied and Experimental Oncology, University of Vienna, A-1090 Vienna, Austria **[715]**

Rusty A. Milhoan, Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 **[377]**

Jan Modig, Department of Anesthesiology and Intensive Care, University Hospital of Uppsala, S-751 85 Uppsala, Sweden **[17]**

Roland M.G.H. Mollen, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegen, The Netherlands **[827]**

Michael Möllmann, Department of Anesthesiology and Operative Intensive Care, Westfaelian Wilhelms University, D-4400 Münster, Federal Republic of Germany **[815]**

Helmut Molnar, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[345]**

Glenn Morris, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

Stephen E. Morris, Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 **[377]**

Heinz Mrochen, Research Department of Intensive Care Medicine, Friedrichshain Hospital Berlin, DDR-1017 Berlin, Democratic Republic of Germany **[331]**

G. Muhr, Department of Surgery, Berufsgenossenschaftliche Krankenanstalten "Bergmannsheil", 4630 Bochum, Federal Republic of Germany **[989]**

Frode Naess, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Oslo 4, Norway **[389,873]**

Sándor Nagy, Institute of Experimental Surgery, Szent-Györgyi Albert Medical University, H-6701 Szeged, Hungary **[253,291,907]**

Werner Naser, Progen Biotechnik, 6900 Heidelberg, Federal Republic of Germany **[299]**

D. Nast-Kolb, Chirurgische Klinik Innenstadt, Universität München, 8000 München 2, Federal Republic of Germany **[731,763]**

JoAnne E. Natale, Department of Physiology, The University of Michigan Medical School, Ann Arbor, MI 48109 **[891]**

Michael L. Nerlich, Department of Traumasurgery, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37,413, 507,775]**

Angelo Nespoli, Department of Emergency Surgery, University of Milan, 20122 Milan, Italy **[73, 277,633]**

Heinz Neuhof, Department of Internal Medicine, Division of Clinical Pathophysiology and Experimental Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[67,119,127,283,305]**

Josef Newald, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[237]**

J.H. Nuyens, Central Laboratory of the Netherlands Red Cross Bloodtransfusion Service and Laboratory for Experimental and Clinical Immunology, University of Amsterdam, Amsterdam **[163]**

Udo Obertacke, Department of Traumatology, University of Essen, D-4300 Essen 1, Federal Republic of Germany **[43,51]**

Kjell Ohlsson, Departments of Surgery and Surgical Pathophysiology, Malmö General Hospital, S-214 01 Malmö, Sweden **[725]**

L. Olivier, Department of Traumatology, University of Essen, 4300 Essen 1, Federal Republic of Germany **[51]**

Richard Pacher, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[683]**

N. Pacitti, Department of Physiology and Pharmacology, University of Strathclyde, Glasgow G1 1XW, Scotland **[357]**

Pietro Padalino, Department of Emergency Surgery, University of Milan, 20122 Milan, Italy **[73,277,633]**

Jacopo Pallavicini, Department of Emergency Surgery, University of Milan, 20122 Milan, Italy **[277,633]**

Alfred Pannike, Department of Surgery, University Hospital Frankfurt/M., D-6000 Frankfurt/M. 70, Federal Republic of Germany **[517]**

James R. Parratt, Department of Physiology and Pharmacology, Royal College, University of Strathclyde, Glasgow G1 1XW, Scotland **[357,1065]**

Joseph E. Parrillo, Critical Care Medicine Department, National Institutes of Health, Bethesda, MD 20892 **[191]**

Th. Pasch, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[743]**

Monique Paubert-Braquet, Centre de Traitement des Brûlés, Hôpital Percy, 92140 Clamart, France **[441,485]**

Eva Paul, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[477,467,931,977]**

Botond Penke, Institute of Medical Chemistry, Szent-Györgyi Albert Medical University, H-6701 Szeged, Hungary **[253]**

Ulrich Pfeiffer, Department of Experimental Surgery, Technical University, 8000 Munich 80, Federal Republic of Germany **[339]**

Bernadette Pignol, I.H.B. Research Labs., 91952 Les Ulis, France **[441]**

Johan Pillgram-Larsen, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Oslo 4, Norway **[389,874]**

Günter Pilz, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[247,625,1025]**

Susan Pollak, Department of Experimental Surgery, University of Medicine, Pécs, Hungary H-7643 **[907]**

G. Pöschl, Department of Anaesthesiology and General Intensive Care, University of Vienna, A-1090 Vienna, Austria **[715]**

J.P. Pretorius, AEC Institute for Life Sciences, University of Pretoria, Pretoria, South Africa **[207,217]**

E. Pscheidl, Institute of Anaesthesiology of the FAU Erlangen-Nürnberg, 8520 Erlangen, Federal Republic of Germany **[743]**

Christian Putensen, Clinic for Anaesthesia and General Intensive Care Medicine, A-6020 Innsbruck, Austria **[783]**

Günther Putz, Clinic for Anaesthesia and General Intensive Care Medicine, A-6020 Innsbruck, Austria **[783]**

Jose Quintana, Intensive Care Unit, Hospital N.S. del Pino, Las Palmas, Canary Islands, Spain **[61]**

Salah Rahman, Department of Anaesthesia, General Hospital of Krefeld, D-4150 Krefeld, Federal Republic of Germany **[959]**

Thomas Rath, I. Surgery, University Clinic, Burn Care Unit, A-1090 Vienna, Austria **[995]**

H.-G. Rau, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Heinz Redl, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[xli,3,231,345,447, 467,649,683,701,797,931,953,977]**

Gerd Regel, Department of Traumasurgery, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37,775]**

Richard Reichl, Department of Pharmacology, Boehringer Ingelheim KG, D-6507 Ingelheim/Rhein, Federal Republic of Germany **[1091]**

Hubert Reichle, Department of Anaesthesiology, Technical University, 8000 Munich 80, Federal Republic of Germany **[339]**

Susanne Reisser, Department of Traumasurgery, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37]**

Daniela Reitz, Department of Internal Medicine, University of Giessen, 6300 Giessen, Federal Republic of Germany **[383]**

Michaela Rethwilm, Department of Pediatrics, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[689]**

Albert W. Rettenmeier, Department of Occupational and Social Medicine, University of Tübingen, 7400 Tübingen, Federal Republic of Germany **[595]**

Elisabeth Reuschel-Janetschek, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[625]**

Paul Richman, Division of Pulmonary and Critical Care Medicine, Department of Medicine, University of California, San Diego, CA 92103 **[791]**

U.N. Riede, Department of Pathology, University of Freiburg, D-7800 Freiburg, Federal Republic of Germany **[113]**

Anne-Lise Rishovd, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, Oslo 4, Norway **[315]**

Avraham Rivkind, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

Bengt Robertson, Departments of Pediatrics and Pediatric Pathology, St. Goran's Children's Hospital, Stockholm, Sweden **[791]**

I.W. Rodger, Department of Physiology and Pharmacology, University of Strathclyde, Glasgow G1 1XW, Scotland **[357]**

Michael Rogy, Department of Surgery 1, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

Olav Røise, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Olso 4, Norway **[389,401,873]**

A. Roman, Department of Intensive Care, Erasme Hospital, Free University of Brussels, 1070 Brussels, Belgium **[181]**

B.L. Roth, Naval Medical Research Institute, Bethesda, MD 20814 **[575]**

E. Roth, First Surgical University Clinic, Metabolic Research Laboratory, University Vienna, A-1090 Vienna, Austria **[589]**

Elizabeth Röth, Department of Experimental Surgery, University of Medicine, Pécs, Hungary H-7643 **[907]**

K. Roth, Department of Cardiovascular Surgery, University of Tübingen, D-7400 Tübingen, Federal Republic of Germany **[737]**

Lennart Roxvall, Department of Surgery, Sahlgren Hospital, University of Göteborg, 41345 Göteborg, Sweden **[265]**

Günther Ruf, Department of Surgery, University of Freiburg, 7800 Freiburg, Federal Republic of Germany **[371]**

Tom E. Ruud, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Oslo 4, Norway **[389,873]**

Mohammed M. Sayeed, Department of Physiology, Loyola University, Stritch School of Medicine, Maywood, IL 60153 **[1053]**

Roland M. Schaefer, Department of Medicine, University of Wuerzburg, D-8700 Wuerzburg, Federal Republic of Germany **[757]**

H.-M. Schardey, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Erwin Schauenstein, Institute of Biochemistry, University of Graz, A-8010 Graz, Austria **[351]**

Rudolf J. Schaur, Institute of Biochemistry, University of Graz, A-8010 Graz, Austria **[351]**

C. Scheidewig, Institute of Anaesthesiology, University Hospital, D-8700 Würzburg, Federal Republic of Germany **[1031]**

Michael Schemper, Department of Surgery 1, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

Anna Schiesser, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[447,467,931]**

F.W. Schildberg, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Paul H.M. Schillings, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegan, The Netherlands **[419]**

Heinrich M. Schima, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[225]**

Günther Schlag, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[xli,3,231,237,345,447,467,649,797,931,953,977]**

Friedrich W. Schmahl, Department of Occupational and Social Medicine, University of Tübingen, 7400 Tübingen, Federal Republic of Germany **[595]**

Klaus-Peter Schmit-Neuerburg, Department of Traumatology, University of Essen, D-4300 Essen 1, Federal Republic of Germany **[43]**

Uwe Schmuckall, Department of Immunology, Medical School Hannover, 3000 Hannover 61, Federal Republic of Germany **[507]**

Johannes Schneider, Department of Pharmacology, Grünenthal GmbH, 5100 Aachen, Federal Republic of Germany **[913]**

Ulrich Schoeffel, Department of Surgery, University of Freiburg, 7800 Freiburg, Federal Republic of Germany **[371]**

Friedrich Schöndube, Department für Chirurgie, Zentralkrankenhaus, D-2800 Bremen 1, Federal Republic of Germany **[695]**

Robert J. Schott, Department of Surgery, The University of Michigan Medical School, Ann Arbor, MI 48109 **[891]**

W. Schramm, Medizinische Klinik Innenstadt, Ludwig-Maximilians Universität, 8000 Munich, Federal Republic of Germany **[395]**

A. Schultz, Zentrum für Anästhesie der Medizinischen, Hochschule Hannover, 3000 Hannover 51, Federal Republic of Germany **[643]**

Franz Schulz, Department of Surgery 1, University of Vienna Medical School, A-1090 Vienna, Austria **[719]**

L. Schweiberer, Chirurgische Klinik Innenstadt und Chirurgische Poliklinik, Ludwig-Maximilians-Universität München, D-8000 München 2, Federal Republic of Germany **[731,763,945]**

Werner Seeger, Department of Internal Medicine, Division of Clinical Pathophysiology and Experimental Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[67,119,127,283,305]**

Jochen W. Seidel, Department of Immunology, Medical School Hannover, 3000 Hannover 61, Federal Republic of Germany **[507]**

Rainer Seitz, Division of Internal Medicine, Department of Hematology, Philipps-University, D-3550 Marburg, Federal Republic of Germany **[965,971]**

Mohie Sharaf El Din, Institute of Biochemistry, University of Graz, A-8010 Graz, Austria **[351]**

William C. Shoemaker, Department of Surgery, King-Drew Medical Center, Los Angeles, CA 90059 **[133]**

William J. Sibbald, Critical Care Trauma Centre, The Victoria Hospital Corporation, and the University of Western Ontario, London, Ontario N6A 4G5, Canada **[1075]**

Matthias Siebeck, Chirurgische Klinik Innenstadt und Chirurgische Poliklinik, University of Munich, D-8000 Munich 2, Federal Republic of Germany **[395,937, 945,983]**

John H. Siegel, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

Rolf Edgar Silber, Chirurgische Universitätsklinik, Experimentelle Chirurgie, D-8700 Würzburg, Federal Republic of Germany **[143]**

A. Simmel, First Surgical University Clinic, Metabolic Research Laboratory, University Vienna, A-1090 Vienna, Austria **[589]**

Richard Simmons, Departments of Surgery and Biochemistry, University of Minnesota Medical School, Minneapolis, MN 55455 **[563]**

R. Sistermann, Department of Surgery, Berufsgenossenschaftliche Krankenanstalten "Bergmannsheil", 4630 Bochum, Federal Republic of Germany **[989]**

M. Spannagl, Medizinische Klinik Innenstadt, Ludwig-Maximilians Universität München, D-8000 München 2, Federal Republic of Germany **[395,937]**

Ron G.H. Speekenbrink, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegen, The Netherlands **[419]**

Christian P. Speer, Department of Pediatrics, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany [**689**]

John J. Spitzer, Department of Physiology, Louisiana State University Medical Center, New Orleans, LA 70112 **[545]**

Judy A. Spitzer, Department of Physiology, Louisiana State University Medical School, New Orleans, LA 70112 **[575]**

Paul Sporn, Ludwig Boltzmann Institute, Department of Anaesthesia and Intensive Care, Vienna University School of Medicine, A-1090 Vienna, Austria **[803,809]**

Roger G. Spragg, Division of Pulmonary and Critical Care Medicine, Department of Medicine, University of California, San Diego, CA 92103 **[791]**

Alexander Stäblein, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[625]**

Jan O. Stadaas, Department of Surgery and Institute for Experimental Medical Research, Ullevaal Hospital, University of Oslo, 0407 Oslo 4, Norway **[315, 389,401,873]**

Karl H. Staubach, Department of Surgery, University of Luebeck, 2400 Luebeck, Federal Republic of Germany **[821]**

Karl Steinbereithner, Ludwig Boltzmann Institute, Department of Anaesthesia and Intensive Care, Vienna University School of Medicine, A-1090 Vienna, Austria **[803,809]**

T. Stober, Department of Hematology/ Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany **[971]**

Theo Strasser, Department of Surgery, LMU Munich, Klinikum Grosshadern, D-8000 Munich 70, Federal Republic of Germany **[495]**

Wolfgang Strohmaier, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[797]**

Johannes Sturm, Unfallchirurgische Klinik, Medizinischen Hochschule Hannover, D-3000 Hannover 61, Federal Republic of Germany **[507,673,775]**

R. Südhoff, Department of Hematology/ Oncology, Philipps-University, D-3550 Marburg/Lahn, Federal Republic of Germany **[971]**

Kazuro Sugi, The University of Texas Medical Branch and Shriners Burns Institute, Galveston, TX 77550 **[237]**

Günther Sutter, Department of Trauma, University of Saarland, D-6650 Homburg/Saar, Federal Republic of Germany **[523]**

Norbert Suttorp, Department of Internal Medicine, Division of Clinical Pathophysiology and Experimental Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[67,119,127,305]**

Imre Szabó, Institute of Experimental Surgery, Szent-Györgyi Albert Medical University, H-6701 Szeged, Hungary **[253]**

Kornél Szabó, Burn Center of Central Hospital H.P.A., 1553 Budapest, Pf 1, Hungary **[1101]**

Ben E. Tall, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

Friedrich Tegtmeyer, Department of Pediatrics, Medical School of Lübeck, D-2400 Lübeck 1, Federal Republic of Germany **[689]**

M. Teschner, Department of Medicine, University of Wuerzberg, D-8700 Wuerzberg, Federal Republic of Germany **[757]**

L.G. Thijs, Medical Intensive Care Unit, Free University Hospital, Amsterdam **[163]**

Martin Thurnher, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[225,231,447, 931]**

D. Tirpitz, Department of Surgery I and Center for Hyperbaric Medicine, St. Joseph-Hospital, D-4100 Duisburg 12, Federal Rebublic of Germany **[1007]**

Bela Török, Department of Experimental Surgery, University of Medicine, Pécs, Hungary H-7643 **[907]**

Courtney M. Townsend, Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 **[377]**

Daniel L. Traber, Shriners Burns Institute and the Departments of Surgery and Anesthesiology, The University of Texas Medical Branch, Galveston, TX 77550 **[201,237,377,815,885]**

Lillian Traber, Department of Anesthesiology and Surgery, The University of Texas Medical Branch, and Division of Anesthesia Research, Shriners Burns Institute, Galveston, TX 77550 **[201,815,885]**

F. Trautinger, Institute for Applied and Experimental Oncology, University of Vienna, A-1090 Vienna, Austria **[715]**

Otmar Trentz, Department of Trauma Surgery, University of Saarland, D-6650 Homburg/Saar, Federal Republic of Germany **[523]**

Emmanouel Tzartinoglou, Department of Surgery, University of Thessaloniki, AHEPA Hospital, Thessaloniki GR-54006, Greece **[151]**

Ignas P.T. van Bebber, Department of General Surgery, St. Radboud University Hospital, 6500-HB Nijmegen, The Netherlands **[419,827]**

Cees J. van der Linden, Department of General Surgery, University of Limburg, Biomedical Center, 6200 MD Maastricht, The Netherlands **[463]**

Thomas C. Vary, Departments of Surgery, Physiology, and Medicine, University of Maryland, Baltimore, MD 21201 **[535]**

B. v. Borman, Department of Anaesthesiology and Intensive Care Medicine, Justus-Liebig Universität, D-6300 Giessen, Federal Republic of Germany **[897]**

G. Vermaak, The HA Grové Research Center of the University of Pretoria, Pretoria, South Africa **[217]**

Jesus Villar, Intensive Care Unit, Hospital N.S. del Pino, Las Palmas, Canary Islands, Spain; present address: Mount Sinai Hospital, Toronto, Ontario M5G 1X5,Canada **[57,61]**

JL. Vincent, Department of Intensive Care, Erasme Hospital, Free University of Brussels, 1070 Brussels, Belgium **[181]**

Christa Vogl, Ludwig Boltzmann Institute for Experimental Traumatology, A-1200 Vienna, Austria **[231,237,447, 931]**

K. Voigt, Klinik für Anästhesiologie und operative Intensivmedizin, Klinikum Steglitz der Freien Universität Berlin, D-1000 Berlin 45, Federal Republic of Germany **[751]**

K. Voigt, Institut für Normale und Pathologische Physiologie, Marburg, Federal Republic of Germany **[711]**

Hartmut Volkmann, Department of Anaesthesiology, University of Göttingen, D-3400 Göttingen, Federal Republic of Germany **[323]**

Bernd-Ulrich von Specht, Department of Surgery, University of Freiburg, 7800 Freiburg, Federal Republic of Germany **[371]**

Reinhard Voss, Department of Internal Medicine, University of Giessen, 6300 Giessen, Federal Republic of Germany **[383]**

Bernd Wagener, Klinik für Anaesthesiologie und Transfusionsmedizin der Universität Tuebingen, D-7400 Tuebingen, Federal Republic of Germany **[185]**

H. Wallasch, Institute of Anaesthesiology, University Hospital, D-8700 Würzburg, Federal Republic of Germany **[1031]**

Henrik Walter, Department of Internal Medicine, Justus-Liebig University, D-6300 Giessen, Federal Republic of Germany **[67]**

Sten Walther, Department of Anaesthesia and Intensive Care, Lasarettet, S-601 82 Norrköping, Sweden **[867]**

Alfred Walz, Department of Surgery, LMU Munich, Klinikum Grosshadern, D-8000 Munich 70, Federal Republic of Germany **[495]**

Ch. Waydhas, Chirurgische Klinik Innenstadt, Universität München, 8000 München 2, Federal Republic of Germany **[731,763]**

B. Weidler, Department of Anaesthesiology and Intensive Care Medicine, Justus-Liebig Universität, D-6300 Giessen, Federal Republic of Germany **[897]**

Joachim Weipert, Abteilung für Klinische Chemie und Klinische Biochemie in der Chirurgie Innenstadt, Ludwig-Maximilians-Universität München, D-8000 München 2, Federal Republic of Germany **[937,983]**

Peter Wendt, Department of Experimental Surgery, Technical University, 8000 Munich 80, Federal Republic of Germany **[339]**

Karl Werdan, Department of Medicine I, Klinikum Grosshadern, University of Munich, D-8000 Munich 70, Federal Republic of Germany **[247,625,1025]**

C. Wesoly, Chirurgische Universitätsklinik Köln-Lindenthal, D-5000 Köln 41, Federal Republic of Germany **[637]**

Michael West, Departments of Surgery and Biochemistry, University of Minnesota Medical School, Minneapolis, MN 55455 **[563]**

Eric T. Whalley, Department of Physiological Sciences, University of Manchester, Manchester, England **[983]**

Michael F. Wilson, Research Service, VA Medical Center and Department of Medicine, University of Oklahoma Health Sciences Center, Oklahoma City, OK 73104 **[207,217,847]**

Gisela Windus, Department of Forensic Medicine, University of Hannover Medical School, 3000 Hannover 61, Federal Republic of Germany **[37]**

Isolde Wodarz, Department of Occupational and Social Medicine, University of Tübingen, 7400 Tübingen, Federal Republic of Germany **[595]**

Martin Wolf, Division of Internal Medicine, Department of Hematology, Philipps-University, D-3550 Marburg, Federal Republic of Germany **[965]**

Wolfgang Woloszczuk, Ludwig Boltzmann Institute for Clinical Endocrinology, A-1090 Vienna, Austria **[683]**

Qixia Wu, Department of Pathophysiology, Peking Union Medical College, Beijing 100700, China **[271]**

K. Wurster, Chirurg. Klinik Innenstadt und Chirurg. Polikl. der Universität, D-8000 München 2, Democratic Republic of Germany **[455]**

Ernst Zadrobilek, Ludwig Boltzmann Institute, Department of Anaesthesia and Intensive Care, Vienna University School of Medicine, A-1090 Vienna, Austria **[803,809]**

G. Zeck-Kapp, Department of Pathology, University of Freiburg, D-7800 Freiburg, Federal Republic of Germany **[113]**

Gertrud Zilow, Department of Immunology, University of Heidelberg, D-6900 Heidelberg, Federal Republic of Germany **[43,299]**

T. Zimmermann, Surgical Department of the Medical College Dresden, Dresden, German Democratic Republic **[291]**

Gerald Zöch, I. Surgery, University Clinic, Burn Care Clinic, A-1090 Vienna, Austria **[995]**

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Validity of the Elastase Assay in Intensive Care Medicine

Hermann Lang [1], Marianne Jochum [2], Hans Fritz [2] and Heinz Redl [3] *)
1) Diagnostic Research, E. Merck Darmstadt, FRG
2) Department of Clinical Biochemistry, University Munich, FRG
3) Ludwig Boltzmann Institute for Experimental and Clinical Traumatology, Vienna, Austria
*) With cooperation of H. Dittmer, M. Dreher, A. Heubner, D. Inthorn, Th. Joka, D. Nast-Kolb, R. Pacher and W. Sandtner

Introduction

The role in the so called inflammatory response of the polymorphonuclear granulocyte (neutrophil) has been well established (Lang and Fritz, 1986). Excessive neutrophil stimulation in traumatic or infectious foci may cause deleterious effects to the organism, manifested by the failure of shock sensitive organs. The pathogenetic agents responsible for those actions mainly are lysosomal proteinases and oxidative molecules released by the neutrophil. Therefore, the possible use of neutrophil elastase (PMN Elastase) as a biochemical marker for pathologic granulocyte stimulation has been investigated during recent years (Jochum et. al., 1986).

In this paper, data on the validity of plasma PMN Elastase measurements as a prognostic marker for clinical complications in postoperative and posttraumatic intensive care patients are presented.

Methods

For PMN Elastase measurements, in recent years a heterogenous sandwich ELISA assay (Neumann et. al. 1984) has been used. Now, a homogenous "Immuno Activation" (IMAC) assay is available (Figure 1). This assay can be used for routine measurements of plasma elastase (inhibitor complex) levels. The characteristics of this assay are presented on page 708. The IMAC assay has been positively correlated to the ELISA assay. Due to improved protein purification techniques, the elastase calibrator used in the IMAC assay (in form of the elastase-α_1-proteinase inhibitor complex) has a 3 times higher purity than the calibrator of 1984. The elastase values of the IMAC assay, therefore, are lower than the values of the ELISA assay by the factor of 3.0. All raw data of the studies presented below have been recalibrated to the new calibrator before evaluation.

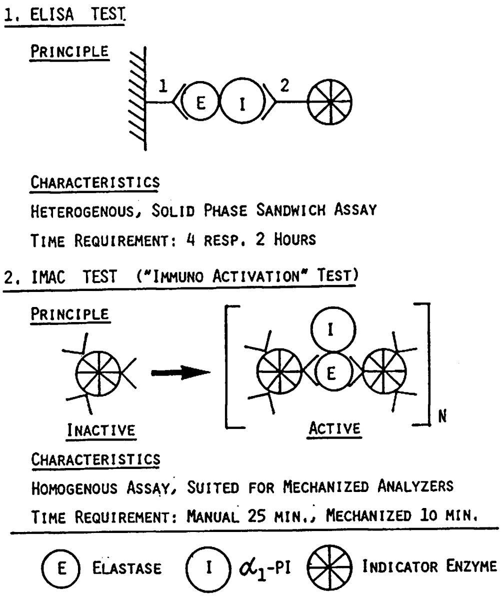

Figure 1. Assays for measurement of plasma concentrations of the elastase-α_1-PI complex

Patients

The studies evaluated in this paper are listed in Figure 2. The results of the different studies will be published in detail by the authors separately.

Study Center			Patients	Number
1	Inthorn	Munich	Postoperative	47
2	Nast-Kolb	Munich	Posttraumatic	33
3	Joka	Essen	Posttraumatic	14
4	Pacher	Vienna	Postoperative	12
5	Sandtner	Vienna	Posttraumatic	11
6	Dittmer	Frankfurt	Posttraumatic	8
			Total of Patients	125

Figure 2. Study centers and patients included in the evaluation

Results

The hypothesis to be tested was the question, whether or not plasma elastase measurements in postoperative and posttraumatic patients will yield prognostic information about eventually forthcoming complications in these patients. Daily plasma elastase values (daily mean from 1 to 6 measurements) were correlated, therefore, to the course of the disease on subsequent days.

1. Correlation to Physician's Classification

Plasma elastase values were correlated to the physicians classification, whether or not the patient had suffered complications on the subsequent days. 114 patient reports were accepted as adequately documented for the evaluation. The results of this semi-subjective evaluation are shown in Figure 3: The plasma elastase levels differentiate well between the two groups classified "Complications" vs. "No Complications" during the postoperative/posttraumatic period. A window exists from day 3 to day 7, where the elastase level has predictive quality.

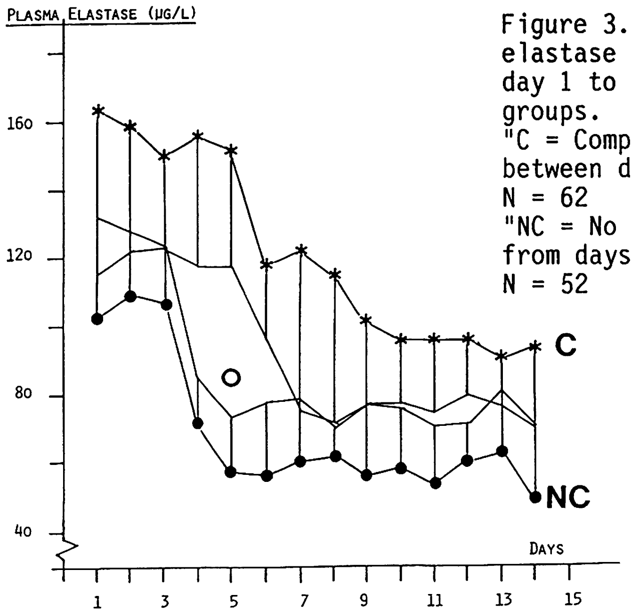

Figure 3. Mean plasma elastase levels from day 1 to 14 of patient groups.
"C = Complications between days 6 and 12", N = 62
"NC = No Complications from days 6 to 12", N = 52

The plasma elastase level on day 5 predicts whether or not a patient will suffer from complications within days 6 to 12, see Figure 4. An elastase discrimination level of 85 µg/l yields the following validity data: Diagnostic sensitivity = 94 %, diagnostic specificity = 79 %, predictive value of the positive test = 84 %, predictive value of the negative test = 91 %.

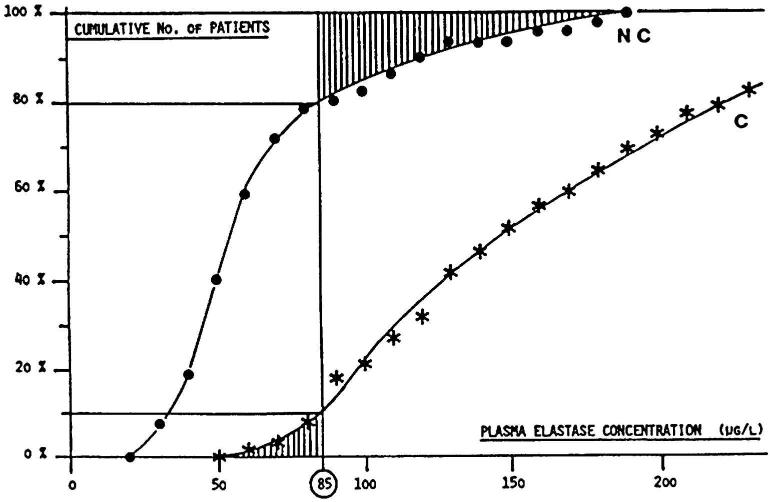

Figure 4. Discrimination on day 5 between the patient groups "Complications" (C) vs. "No Complications" (NC). Discriminatory plasma elastase level = 85 µg/l.

2. Correlation to the Multi Organ Failure (MOF) Score

To test fully objective criteria, the plasma elastase values were correlated against the MOF Score of Goris (1). In accordance to the work of Goris, a MOF Score of 5 was selected as discriminator between non critically ill vs. critically ill patients. 86 patient reports were accepted as adequately documented for the evaluation. The results are shown in Figure 5. The elastase value on day 5 discriminates between the patient groups "MOF ≥ 5 on days 7 to 12" vs. MOF < 5 on days 7 to 12. An elastase discrimination level of 135 µg/l (405 µg/l in the sandwich assay) yields the following validity data: Diagnostic sensitivity = 83 %, diagnostic specificity = 84 %, predictive value of the positive test = 66 %, predictive value of the negative test = 93 %.

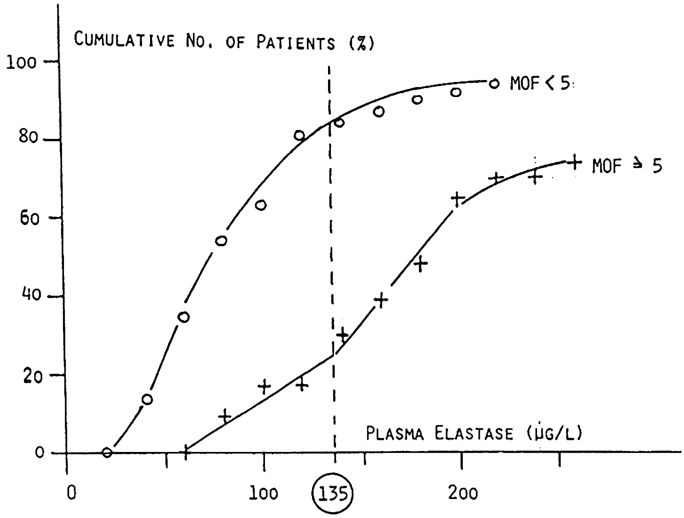

Figure 5. Discrimination between patients groups "MOF ≥ 5 on days 7 to 12" (N = 23) vs. "MOF < 5 on days 7 to 12" (N = 63). Discriminatory elastase level = 135 µg/l.

Discussion

This exploratory data analysis is being followed up by a transnational multicenter study. Nevertheless, the data presented already document the diagnostic validity of plasma elastase measurements as a prognostic marker for postoperative/posttraumatic complications. The clinician's classification of a patients situation is a more sensitive criterium (discriminatory elastase level 85 µg/l) than the MOF Score of 5 (discriminatory elastase level 135 µg/l). Intensive care patients at risk for complications (e. g. organ failure, septicemia) can be identified from day 5 (4th postoperative/posttraumatic day) on for a period of 1 to 6 days in advance. By selecting a suitable discriminatory elastase level, a predictive value of the positive test of 90 % can be acchieved. Using a discriminatory elastase level of 85 µg/l, no risk patients can equally be identified with a security of over 90 % (predictive value of the negative test).

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