CorCap™ Cardiac Support Device
REFERENCES

MANUSCRIPTS

ABSTRACTS

For detailed information describing use, warnings, precautions and contraindications, refer to the instructions with each device, or contact the manufacturer.

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CAUTION: In the United States, the CorCap™Cardiac Support Device is limited by USA law to investigational use.

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MANUSCRIPTS

Clinical Trial Experience

A. Charité Safety Study

1. Lembcke A, et al. Evaluation of Left and Right Ventricular Diastolic Function by Electron-beam Computed Tomography in Patients With Passive Epicardial Constraint. J Comput Assist Tomogr 2007;00:00Y00

2. Lembcke A, et al. Early and late effects of passive epicardial constraint on left ventricular geometry: ellipsoidal re-shaping confirmed by electron-beam computed tomography. J of Heart and Lung Transplantation Jan 2006;25(1):90-8.

3. Lembcke A, Dushe S, Enzweiler CN, Kloeters C, Wiese TH, Hermann KG, Hamm B, Konertz WF. Passive external cardiac constraint improves segmental left ventricular wall motion and reduces akinetic area in patients with non-ischemic dilated cardiomyopathy. Eur J Cardiothorac Surg. 2004 Jan;25(1):84-90.

4. Lembcke A, Dushe S, Sonntag S, Kloeters C, Enzweiler CN, Wiese TH, Hamm B, Kleber FX, Konertz WF. Changes in right ventricular dimensions and performance after passive cardiac containment. Ann Thorac Surg. 2004 Sep;78(3):900-5.

5. Lembcke A, Wiese TH, Dushe S, Hotz H, Enzweiler CNH, Hamm B, Konertz WF. Effects of passive cardiac containment on left ventricular structure and function: verification by volume and flow measurements. J of Heart and Lung Transplantation 2004;23:11-19.

6. Lembcke A, Hotz H, Dushe S, Ensweiler CNH, Wiese TH, Kivelitz DE, Rogalla P, Konertz W, Hamm B. Evaluierung der passiven Kardiomyoplastie mittels links- und rechtsvertrikularer EBCT- und MRT-Volumetrie bei Patienten mit chronischer Herzinsuffizienz. Fortschr Rontgenstr 2003; 175: 1086-1092.

7. Konertz WF, Dushe S, Hotz H, Spies C, Enzweiler C, Kleber FX. Cardiac Support Device: Novel surgical option for heart failure. Asian Cardiovasc Thorac Ann 2001;9:167-70.

8. Konertz WF, Shapland JE, Hotz H, Dushe S, Braun JP, Stantke K, Kleber FX. Passive containment and reverse remodeling by a novel textile Cardiac Support Device. Circulation 2001;104(Suppl I):I-270-I-275.

9. Hotz H, Dushe S, Konertz W. Indikationen, Technik und Erste Ergebnisse der Passiven Kardiomyoplastie. Z Kardiol 2001;90 (Suppl 1):16-21.

B. Melbourne Safety Study

10. Raman JS, Hata M, Storer M, Power JM, Buxton BG, Alferness C, Hare D. The Mid-term Results of Ventricular Containment (ACORN WRAP) for End-stage Ischemic Cardiomyopathy. Ann Thorac Cardiovasc Surg 2001;7(5):278-81.

11. Raman JS, Power JM, Buxton BF, Alferness C, Hare D. Ventricular Containment as an Adjunctive Procedure in Ischemic Cardiomyopathy: Early Results. Ann Thorac Surg 2000;70:000-00.

C. Acorn Clinical Trial

12. Douglas L. Mann, MD, Michael A. Acker, MD, Mariell Jessup, MD, Hani N. Sabbah, PhD, Randall C. Starling, MD and Spencer H. Kubo, MD. Clinical Evaluation of the CorCap Cardiac Support Device in Patients With Dilated Cardiomyopathy. The Annals of Thoracic Surgery 2007; 84: 1226-35.

13. Randall C. Starling, MD, MPH, Mariell Jessup, MD, Jae K. Oh, MD, Hani N. Sabbah, PhD, ACC, Michael A. Acker, MD, Douglas L. Mann, MD and Spencer H. Kubo, MD. *Sustained Benefits of the CorCap Cardiac Support Device on Left Ventricular Remodeling: Three Year Follow-up Results from the Acorn Clinical Trial.* The Annals of Thoracic Surgery 2007; 84:1236-42.

14. Michael A. Acker, MD, Steven Bolling, MD, Richard Shemin, MD, James Kirklin, MD, Jae K. Oh, MD; Douglas L. Mann, MD, Mariell Jessup, MD, Hani N. Sabbah, PhD, Randall C. Starling, MD, and Spencer H. Kubo, MD, for the Acorn Trial Principal Investigators and Study Coordinators: Mitral valve surgery in heart failure: Insights from the Acorn Clinical Trial. The Journal of Thoracic and Cardiovascular Surgery Volume 132, Number 3 568-577.

15. Hauptman P, Rector T, Wentworth D, Kubo S. Quality of life in advanced heart failure : Role of mitral regurgitation. Am Heart Journal Jan 2006 ;151 :213-8.

16. Mann D et al. Rationale, Design and Methods for a Pivotal Randomized Clinical Trial for the Assessment of the CorCap™ Cardiac Support Device in Patients with NYHA II-IV Heart Failure. J Card Failure. 2004; 10(3):185-192.

17. Kubo S et al. Development and Validation of a Patient Questionnaire to Determine NYHA Classification. J Card Failure, 2004; 10(3):228-235.

D. Implant Technique

18. Oz MC. Surgical Implantation of the Acorn Cardiac Support Device. Operative Techniques in Thoracic and Cardiovascular Surgery. Vol 7(2) May 2002; 107-110.

19. Badhwar V, Bolling SF. The Acorn Procedure: Operative Techniques in Thoracic and Cardiovascular Surgery. Vol 7(2) May 2002; 84-89.

20. Dullum MKC, Carlos BD, Oz MC, Chon CD, Bafi AS, Cooke RH, Harrison J, Bither C, Peel GK. Less Invasive Surgical Management of Heart Failure by Cardiac Support Device Implantation on the Beating Heart. The Heart Surgery Forum 2001-1818. 4(4):361-363, 2001.

21. Oz MC. Passive ventricular constraint for the treatment of congestive heart failure. Ann Thorac Surg 2001;71:S185-7.

E. Global Experience/Review

22. Spoor, Martinus T., Bolling, Steven F. Nontransplant Surgical Options for Heart Failure. Card. Surg. Adult 2008 3: 1639-1648.

23. Valli, Nathalie, Labrousse, Louis, Reant, Patricia, Dos-Santos, Pierre. Significant improvement of cardiac sympathetic function following cardiac support device implantation: illustration by 123I-MIBG scintigraphy. Eur. J. Cardiothorac. Surg. 2007 32: 943-944.

24. Bredin F, Olsson A, Franco-Cereceda A. No additive effect of passive containment surgery in patients with aortic regurgitation and left ventricular dilation. Ann Thorac Surg. 2007 Aug;84(2):514.

25. Bredin F, Franco-Cereceda A. Reversed remodeling in dilated cardiomyopathy by passive containment surgery is associated with decreased circulating levels of endothelin-1. Eur J Cardiothorac Surg. 2006 Mar;29(3):299-303. Epub 2006 Jan 26.

26. Bredin F, Franco-Cereceda A. Experiences of levosimendan as an inotropic agent in conjunction with passive containment surgery. Scand Cardiovasc J. 2007 Jun;41(3):197-200.

27. Labrousse, Louis, MD. Barandon, Laurent, Numis, Flora, Deville, Claude. Parachute-like technique for off-pump implantation of cardiac support device in isolated and combined procedure. Eur. J. Cardiothorac. Surg. 2007 32: 807-809.

28. Oz MC. Passive ventricular constraint for the treatment of congestive heart failure. Ann Thorac Surg 2001;71:S185-7.

29. Schroder JN, Lima B, Rogers JG, Milano CA. Department of Surgery, Division of Cardiothoracic Surgery, Duke University Medical Center, Durham, NC 27710, USA.Cardiac transplantation following ACORN CorCap device implantation. Eur J Cardiothorac Surg. 2006 May;29(5):848-50. Epub 2006 Apr 4.

30. Serri K, Labrousse L, Reant P, Lafitte S, Roudaut R. Significant improvement of myocardial function following cardiac support device implantation: Illustration by two-dimensional strain. Eur J Echo doi:10.1016/j.euje.2005.09.006.

31. Franco-Cereceda, A, Lockowandt, U, Liska, J, Alsson, A. Reversal of Ventricular Dilatation in Aortic Regurgitation After Valve Replacement and Cardiac Support Implant Surgery Using the CorCap Cardiac Support Device. Ann Thorac Surg 2005;80:315-316.

32. Franco-Cereceda A, Runsio M, Liska J. Passiv volymreducerande kirurgi vid hjärtsvikt och dilaterad Kardiomyopati Resultat från pilotstudie ger anledning till försiktig optimism. Läkartidningen Nr 34 2005 Volym 102.

33. Thelin S. Polyesternät stramar till sviktande hjärta Kan bli del av framtida behandlingsarsenal vid avancerad hjärtsvikt. Läkartidningen Nr 34 2005 Volym 102.

34. Oz MC, Konertz WF, Raman J, Kleber FX. Reverse remodeling of the failing ventricle: surgical intervention with the Acorn Cardiac Support Device. Congest Heart Fail. 2004 Mar-Apr;10(2):96-104; discussion 105.

35. Lembcke, Alexander, Dushe, Simon, Sonntag, Steffen, Kloeters, Christian, Enzweiler, Christian N. H., Wiese, Till H., Hamm, Bernd, Kleber, Franz-Xaver, Konertz, Wolfgang F.
Changes in right ventricular dimensions and performance after passive cardiac containment
Ann Thorac Surg 2004 78: 900-905

36. Lembcke, Alexander, Dushe, Simon, Enzweiler, Christian N.H., Kloeters, Christian, Wiese, Till H., Hermann, Kay-Geert A., Hamm, Bernd, Konertz, Wolfgang F.
Passive external cardiac constraint improves segmental left ventricular wall motion and reduces akinetic area in patients with non-ischemic dilated cardiomyopathy
Eur. J. Cardiothorac. Surg. 2004 25: 84-90

37. Livi U, et al. One-year clinical experience with the Acorn CorCap™ Cardiac Support Device: results of a limited market release safety study in Italy and Sweden. Ital Heart J. 2005 Jan;6(1):59-65.

38. Cohn JN. New Therapeutic Strategies for Heart Failure: Left Ventricular Remodeling as a Target. J Card Failure 2004; 10 (6):200-201.

39. Mann DL. Basic Mechanisms of Left Ventricular Remodeling : The Contribution of Wall Stress. J Card Failure 2004; 10 (6):202-206 .

40. Acker MA. Surgical Therapies for Heart Failure. J Card Failure 2004; 10 (6):220-224.

41. Starling RC, Jessup M. Worldwide Experience With the CorCap™ Cardiac Support Device. J Card Failure 2004; 10 (6):225-233.

42. Gummert JF, Rahmel A, Bossert T, Mohr FW. Socks for the dilated heart: Does passive cardiomyoplasty have a role in long-term care for heart failure patients?. Z Kardiol 93:849-854 (2004).

43. Franco-Cereceda Anders, Lockowandt U, Olsson A, Bredin F, Forssell G, Owall A, Runsio M, Liska J. Early results with cardiac support device implant in patients with ischemic and non-ischemic cardiomyopathy. Scand Cardiovasc J 2004; 38:159-163.

44. Oz MC, Konertz WF, Kleber FX, Mohr FW, Gummert JF, Ostermeyer J, Lass M, Raman J, Acker MA, Smedira N. Global Surgical Experience with the Acorn Cardiac Support Device. J Thor and CV Surg. 2003; 126:4:983-91.

45. Power JM, Byrne M, Raman J, Alferness C. Review: Passive ventricular constraint. Progress in Biophysics & Molecular Biology 82(2003) 197-206.

Pre-clinical Experience

F. Global Cardiac Function/Structure

46. Ravi K. Ghanta, Aravind Rangaraj, Ramanan Umakanthan, Lawrence Lee, Rita G. Laurence, John A. Fox, R. Morton Bolman, III, Lawrence H. Cohn, and Frederick Y. Chen : Adjustable, Physiological Ventricular Restraint Improves Left Ventricular Mechanics and Reduces Dilatation in an Ovine Model of Chronic Circulation 115: 1201-1210; published online before print as doi:10.1161/CIRCULATIONAHA.106.671370

47. Zaca V, Brewer R, Khanal S, Imai M, Jiang A, Wang M, Goldstein S, Sabbah HN. Department of Medicine, Division of Cardiovascular Medicine, Henry Ford Heart & Vascular Institute, Detroit, Michigan 48202, USA. Left atrial reverse remodeling in dogs with moderate and advanced heart failure treated with a passive mechanical containment device: an echocardiographic study. J Card Fail. 2007 May;13(4):312-7.

48. Cheng A, Nguyen TC, Malinowski M, Langer F, Liang D, Daughters GT, Ingels NB Jr, Miller DC. Department of Cardiothoracic Surgery, Stanford University School of Medicine, 300 Pasteur Dr, Stanford, California 94305-5247, USA Passive ventricular constraint prevents transmural shear strain progression in left ventricle remodeling. Circulation. 2006 Jul 4;114(1 Suppl):I79-86.

49. Sabbah H. Commentary: Passive Ventricular Containment in Dilated Ventricular Heart Failure: Experimental insights into clinical benefits. Braunwald's on line 7th edition Jan 2006.

50. Mann D. Cardiac Remodeling as Therapeutic Target: Treating Heart Failure with Cardiac Support Devices. HF Reviews, 10, 93-94, 2005.

51. Mann D. Left Ventricular Size and Shape: Determinants of Mechanical Signal Transduction Pathways. HF Reviews, 10, 95-100, 2005.

52. Walsh R. Design and Features of the Acorn CorCap™ Cardiac Support Device: The Concept of Passive Mechanical Diastolic Support. HF Reviews, 10, 101-107, 2005.

53. Sabbah HN. Global Left Ventricular Remodeling with the Acorn Cardiac Support Device: Hemodynamic and Angiographic Findings in Dogs with Heart Failure. HF Reviews, 10, 109-115.

54. Power JM, Raman J, Byrne M, Alferness C. Efficacy of the Acorn Cardiac Support Device in Animals with Heart Failure Secondary to High Rate Pacing. HF Reviews, 10, 117-123, 2005.

55. Sabbah HN. Effects of Cardiac Support Device on Reverse Remodeling: Molecular, Biochemical, and Structural Mechanisms. J Card Failure 2004; 10 (6):207-214.

56. Kass DA, Saavedra WF, Sabbah HN. Reverse Remodeling and Enhanced Inotropic Reserve From the Cardiac Support Device in Experimental Cardiac Failure. J Card Failure 2004; 10 (6):215-219.

57. Sabbah HN. The Acorn Cardiac Support Device and the Myocor Myosplint: treating heart failure by targeting left ventricular size and shape. Ann Thoracic Surg 2003 Jun;75(Suppl 6):S13-9.

58. Saavedra F, Tunin R, Mishima T Suzuki G, Chaudhry PA, Anagnostopoulos PV, Paolocci N, Sabbah HN, Kass DA. Reverse remodeling and enhanced adrenergic reserve from a passive external ventricular support in experimental dilated heart failure. J Am Coll Cardiol 2002;39:2069-76.

59. Chaudhry PA, Anagnostopouls PV, Mishima T, Suzuki G, Nair H, Morita H, Sharov VG, Alferness C, Sabbah HN. Acute Ventricular Reduction with the Acorn Cardiac Support Device: Effect on Progressive Left Ventricular Dysfunction and Dilation in Dogs with Chronic Heart Failure. J Card Surg Mar/Apr 2001; 16(2):118-126.

60. Chaudry PA, Mishima T, Suzuki G, Sharov VG, Anagnostopoulos PV, Undrovinas AI, Nass O, Sabbah HN. Acute ventricular reduction with Acorn's Cardiac Support Device prevents left ventricular dysfunction and remodeling in dogs with advanced heart failure. Surgical Forum 2000;51:146-148.

61. Chaudhry PA, Mishima T, Sharov VG, Hawkins J, Alferness CA, Paone G, Sabbah HN. Passive epicardial containment prevents ventricular remodeling in heart failure. Ann Thorac Surg 2000;70:1275-80.

62. Power JM, Raman J, Dornom A, Farish SJ, Burrell LM, Tonkin AM, Buxton B, Alferness CA. Passive ventricular constraint amends the course of heart failure: A study in an ovine model of dilated cardiomyopathy. Cardiovascular Research 1999;44:549-555.

G. Cellular/Molecular

63. Sharov VG, Todor AV, Sabbah HN. Left Ventricular Histomorphometric Findings in Dogs with Heart Failure Treated with the Acorn Cardiac Support Device. HF Reviews, 10, 141-147, 2005.

64. Gupta RC, et al. Improvement of Cardiac Sarcoplasmic Reticulum Calcium Cycling in Dogs with Heart Failure Following Long-Term Therapy with the Acorn Cardiac Support Device. HF Reviews, 10, 149-155, 2005.

65. Rastogi S, et al. Reversal of Maladaptive Gene Program in Left Ventricular Myocardium of Dogs with Heart Failure Following Long-Term Therapy with the Acorn Cardiac Support Device. HF Reviews, 10, 157-163, 2005.

66. Blom AS, Mukherjee R, Pilla JJ, Lowry AS, Yarbrough WM, Mingoia JT, Hendrick JW, Stroud RE, McLean JE, Affuso J, Gorman RC, Gorman III JH, Acker MA, Spinale FG. Cardiac Support Device Modifies Left Ventricular Geometry and Myocardial Structure After Myocardial Infarction. Circ 2005;112:1274-1283.

67. Shah PK. Preservation of Cardiac Extracellular Matrix by Passive Myocardial Restraint: An Emerging New Therapeutic Paradigm in the Prevention of Adverse Remodeling and Progressive Heart Failure. Circ 2005;112:1245-1247.

68. Sabbah HN, Sharov VG, Gupta RC, Mishra S, Rasogi S, Undrovinas AL, Chaudhry PA, Todor A, Mishima T, Tanhehco EJ, Suzuki G. Reversal of Chronic Molecular and Cellular Abnormalities Due to Heart Failure by Passive Mechanical Ventricular Containment. Circ Res. 2003; 93:1095-1101.

H. Acute Myocardial Infarction

69. Blom, Aaron S., Pilla, James J., Arkles, Jeffrey, Dougherty, Larry, Ryan, Liam P., Gorman, Joseph H., III, Acker, Michael A., Gorman, Robert C. Ventricular Restraint Prevents Infarct Expansion and Improves Borderzone Function After Myocardial Infarction: A Study Using Magnetic Resonance Imaging, Three-Dimensional Surface Modeling, and Myocardial Tagging. Ann Thorac Surg 2007 84: 2004-2010.

70. Pilla JJ, et al. Early postinfarction ventricular restraint improves borderzone wall thickening dynamics during remodeling. Ann Thorac Surg 2005;80:2257-62.

71. Blom AS, et al. Infarct Size Reduction and Attenuation of Global Left Ventricular Remodeling with the CorCap™ Cardiac Support Device Following Acute Myocardial Infarction in Sheep. HF Reviews, 10, 125-139, 2005.

72. Blom AS, et al. A cardiac support device modifies left ventricular geometry and myocardial structure following myocardial infarction. Circulation 2005;112:1274-1283.

73. Olsson A, Bredin F, Franco-Cereceda A. Echocardiographic findings using tissue velocity imaging following passive containment surgery with the Acorn CorCap™ cardiac support device. EU Journal of Card-thoracic Surg 28 (2005) 448-453.

74. Pilla JJ, Blom AS, Brockman DJ, Bowen F, Yuan Q, Giammarco J, Ferrari VA, Gorman JH, Gorman RC, Acker MA. Ventricular Constraint Using the Acorn Cardiac Support Device Reduces Myocardial Akinetic Area in an Ovine Model of Acute Infarction. Circulation. 2002;106[suppl I]:I-207-I-211.

ABSTRACTS

Clinical Trial Experience

A. Charité Safety Study

1. Dushe, S, Kleber, FX, Konertz, W. The Impact of Passive Diastolic Constraint on Functional Mitral Regurgitation in Patients with Dilative Cardiomyopathy. Society for Heart Valve Disease June 2005

2. Konertz WF, Sonntag S, Dushe S, Hotz H. Efficacy trends with the Acorn Cardiac Support Device: 3-Year Follow-Up. American Heart Association Scientific Sessions 2003. Nov 9.

3. Dushe S, Kleber FX, Sonntag S, Konertz W. Passive Diastolic Containment by a Mesh-Like Device as an Option for Surgical Heart Failure Therapy. EACTS 2003

4. Lembcke A, Wiese TH, Dushe S, Hotz H, Enzweiler CNH, Hamm B, Konertz WF. Changes in both left- and right-ventricular volumes and function after passive cardiomyoplasty assessed by electron beam computed tomography. European Heart Journal Vol 4, Abstract Suppl. August 2002:145.

5. Konertz WF, Dushe S, Enzweiler C, Hamm B. Evidence of decreasing LV size and volume after Cardiac Support Device (CSD) implantation. The Journal of Heart and Lung Transplantation;21:150.

6. Konertz WF, Kleber FX, Dushe S, Hotz H, Stanke K, Austin L, Walsh R. Efficacy trends with the Acorn Cardiac Support Device: Two year follow-up. Journal of American College of Cardiology;39(Suppl A):142A.

7. Konertz WF, Kleber FX, Dushe S. Hotz H, Stanke K. Efficacy trends with the Acorn Cardiac Support Device: One year follow-up. Circulation 2001;104(Suppl II):II-357.

8. Dushe S, Hotz H, Bottner D, Kleber FX, Konertz WF. Passive ventricular constraint for the treatment of heart failure patients - One year follow-up. EACTS/ESTS Joint Meeting Abstract Book September 2001:584.

9. Konertz WF, Kleber FX, Dushe S, Hotz H, Stantke K. Efficacy trends with the Acorn Cardiac Support Device in patients with advanced heart failure. Journal of Cardiac Failure 2001;7(Suppl 2): 39.

10. Kleber FX, Sonntag S, Krebs H, Stantke K, Konertz W. Influence of the cardiac support device on left ventricular function. European Journal of Heart Failure 2001;3(Suppl 1): S65.

11. Konertz W, Kleber FX, Dushe S, Hotz H, Stantke K. Efficacy trends with the acorn cardiac support device in patients with advanced heart failure. European Journal of Heart Failure 2001;3(Suppl 1): S93.

12. Kleber FX, Sonntag S, Krebs H, Stantke K, Konertz W. Follow-up on passive cardiomyoplasty in congestive heart failure: Influence of the Acorn Cardiac Support Device on left ventricular function. J Am Coll Cardiol 2001;37(Suppl A):143A.

13. Konertz W, Kleber FX, Dushe S, Hotz H, Stantke K. Initial efficacy trends with the Acorn Cardiac Support Device in patients with advanced heart failure. J Am Coll Cardiol 2001;37(Suppl A):143A.

14. Sabbah HN, Kleber FX, Konertz W. One year follow-up of the Acorn Cardiac Support Device in patients with heart failure: efficacy trends. European Journal of Heart Failure 2001;3(Suppl 1): S65.

15. Sabbah HN, Kleber FX, Konertz W. Efficacy trends of the Acorn Cardiac Support Device in patients with heart failure: A one year follow-up. J of Heart and Lung Transplantation 2001;20:217.

16. Konertz W, Hotz H, Dushe S, Braun JP, Stantke K, Kleber FX. Passive containment and reverse remodeling by a novel textile cardiac support device. Circulation 2000;102(Suppl):II-683.

17. Dushe S, Hotz H, Stantke K, Kleber FX, Konertz W. Mid-term follow up of patients after Cardiac Support Device implantation for dilated cardiomyopathy. J of Cardiac Failure 2000;6(suppl 2):35.

18. Kleber FX, Sonntag S, Krebs H, Stantke K, Konertz W. Passive cardiomyoplasty in congestive heart failure: influence of the passive Acorn Cardiac Support Device on left ventricular function. European Heart Journal 2000;21(suppl):533.

19. Konertz W, Kleber FX, Rombeck B, Hotz H, Zytowski M, Sonntag S, Stantke K, Sabbah HN. Safety results and initial efficacy trends with the Acorn Cardiac Support Device in patients with advanced heart failure. European Heart Journal 2000;21(suppl):533.

20. Dusche S, Rombeck B, Hotz H, Stantke K, Sabbah HN, Kleber FX, Konertz W. Initial safety and efficacy results of Acorn's Cardiac Support Device in patients with advanced heart failure. Cardiovascular Surgery 2000;ESCVS Abstracts:11.

21. Konertz W, Rombeck B, Zytowski M, Hotz H, Sabbah HN, Alferness CA, Kleber FX. Clinical and hemodynamic short term results with passive cardiomyoplasty. J of Heart and Lung Transplantation 2000;19:68.

22. Konertz W, Rombeck B, Hotz H, Zytowski M, Sonntag S, Kleber FX, Sabbah HN. Short-term safety of the Acorn Cardiac Support Device in patients with advanced heart failure. J Am Coll Cardiol 2000;35(Suppl A):182A.

23. Kleber FX, Sonntag S, Krebs H, Stantke K, Rombeck B, Konertz W. Influence of the passive Acorn Cardiac Support Device on systolic and diastolic left ventricular function. J Am Coll Cardiol 2000;35(Suppl A):182A.

24. Rombeck B, Zytowski M, Hotz H, Kleber FX, Konertz W. Cardiomyoplasty with Acorn Cardiac Support Device in patients with Chronic Heart Failure. Poster presentation on October 1-2, 1999 at the Heart Failure Summit V Meeting.

B. Melbourne Safety Study

25. Raman J, Hata M, Hare DL, Power JM, Jones E, Buxton BF, Alferness CA. Ventricular containment as an adjunct to coronary artery surgery amends the course of heart failure in patients with ischemic cardiomyopathy. Circulation 2000;102(Suppl):II-502.

26. Raman J, Seevanayagam S, Power JM, Hare D, Buxton BF, Alferness CA. Ventricular containment as an adjunctive procedure in ischemic cardiomyopathy – Results of the Phase I study. The J of Heart Failure 2000;6:121.

C. Acorn Clinical Trial

27. Mann DL, et al. Randomized Clinical Assessment of a Cardiac Support Device (CSD) in Advanced Heart Failure Patients Not Requiring Concomitant Valve Surgery. Heart Failure 2005 (Lisbon) 13 June 2005.

28. Mann D, et al. Results of a Multicenter Randomized Clinical Trial for the Assessment of a Cardiac Support Device in Patients with Heart Failure. J of Heart and Lung Transp. Feb, 2005: S74.

29. Acker M, et al. Mitral Valve Surgery in Heart Failure: Results of the Acorn CorCap™ Randomized Trial. AATS Scientific Session April 11, 2005.

30. Mann D, et al. Results of a Multicenter Randomized Clinical Trial for the Assessment of a *Cardiac Suppo*rt Device in Patients with Heart Failure. ISHLT 2005 Plenary Session April 8, 2005

31. *Mann D*. Clinical Evaluation of the CorCap™ Cardiac Support Device in Patients with Dilated *Cardiomyop*athy. 2004 AHA Scientific Session Nov. 7, 2004.

32. Bhat G, Kubo SH. *Gender Diffe*rences in Heart Failure : Baseline Characteris*tics from the* Acorn Clinical Trial. 2004 HF Society of America poster presentation Sept 14, 2004.

33. Aranda JM, Beaver TM, Schofield RS, Leach DD, Staples ED, Kubo SH. Predictors of Hospital Length of Stay in a Surgical Approach to the Failing Heart : The ACORN Cardiac Support Device Randomized Trial Experience. 2004 HF Society of America poster presentation Sept 13, 2004.

34. Hauptman PJ, Wentworth D, Kubo S. Correlates of Quality of Life in Advanced Heart Failure: Insights from the Acorn Trial. Journal of American College of Cardiology;41(Suppl):212A.

D. Implant Technique

35. Valerio Zaca, Mengjun Wang, Gaetano Paeone, Alice Jiang, Robert Brewer, Aaron Hjelle, and Hani N Sabbah. Abstract 1763: Efficacy of the Generation-2 Acorn Cardiac Support Device in Dogs with Chronic Heart Failure Circulation 116: II_373.

36. Labrousse L, et al. Implantation of a cardiac support device by the “parachute-like” technique throughsternal and trans-abdominal approach. EACTS: Abstract ID: 25254.

37. Oz MC, Konertz WF, Kleber FX, Mohr FW, Gummert JF, Ostermeyer J, Lass M, Raman J, Acker MA, Smedira N. Global surgical experience with the Acorn Cardiac Support Device. AATS Annual Meeting Program Guide 2002:236.

38. Dullum MKC, Carlos BD, Oz MC, Chou CD, Bafi AS, Cooke RH, Harrison J, Bither C, Peel GK, Salah Zaki M. Surgical management of heart failure with the Cardiac Support Device: Implantation on the beating heart. Journal of Cardiac Failure 2001;7(Suppl 2): 45.

E. Global Experience/Review

39. Dullum MKC. Update of Restraint Devices for Congestive Heart Failure. TECH-CON 2005 Scientific Session

40. Castel MA, Kotetishvilli N, Schomburg R, Lass M. Implantation of a Cardiac Support Device as Adjunct to CABG in Ischemic Cardiomyopathy. ISHLT Annual Meeting; 9-12 April, 2003.

41. Sabbah HN, Chaudhry PA, Mishima T, Sharov VG, Maltsev VA, Undrovinas AI, Kleber FX, Konertz W. Passive constraint of the failing ventricle: Impact on ventricular function and remodeling. Proceedings, Cardiomyopathy 2000, page 93.

Pre-clinical Experience

F. Global Cardiac Function/Structure

42. Walsh RG, Shapland JE, Wojcik LJ. Pre-clinical Histologic Evaluation of a Proprietary Polyester Device for the Treatment of Dilated Cardiomyopathy (Acorn Cardiac Support Device [CSD]): Multiple Species Comparison. Trans Soc Biomaterials 2003;29:701.

43. Fanous NH, Paone G, Morita H, Suzuki G, Haithcock BE, Sharov VG, Todor A, Brewer R, Sabbah HN. Reverse left ventricular remodeling with the Acorn cardiac support device in dogs with advanced heart failure: A randomized, placebo controlled study. Circulation, Abstract Suppl. 2002:II-550.

44. Sabbah HN, Suzuki G, Morita H, Chaudhry PA, Mishima T. Chronic therapy with the Acorn Cardiac Support Device in dogs with heart failure affords adequate response to increased demands on the left ventricle. The Journal of Heart and Lung Transplantation;21:153.

45. Power JM, Raman J, Byrne MJ, Esler M, Kaye D, Alferness C. Passive ventricular constraint significantly lowers left ventricular wall stress in an experimental model of degenerative heart failure and dilated cardiomyopathy. European Heart Journal 2001;22(Suppl): 411.

46. Sabbah HN, Sharov VG, Chaudhry PA, Suzuki G, Morita H, Todor A. Six months hemodynamic, histologic, and ultrastructural findings in dogs with chronic heart failure treated with the Acorn Cardiac Support Device. European Journal of Heart Failure 2001;3(Suppl 1): S71.

47. Sabbah HN, Sharov VG, Chaudhry PA, Suzuki G, Todor A, Morita H. Chronic Therapy with the Acorn Cardiac Support Device in dogs with chronic heart failure: Three and six months hemodynamic, histologic and ultrastructural findings. J of Heart and Lung Transplantation 2001;20:189.

48. Saavedra F, Tunin R, Mishima T, Suzuki G, Chaudhry PA, Anagnostopoulos PV, Paolocci N, Sabbah HN, Kass DA. Reverse remodeling and enhanced adrenergic reserve from a passive external ventricular support in experimental dilated heart failure. Circulation 2000;102(Suppl):II-501.

49. Power JM, Raman J, Byrne MJ, Alferness CA. Passive ventricular constraint is a trigger for a significant degree of reverse remodeling in an experimental model of degenerative heart failure and dilated cardiomyopathy. Circulation 2000;102(Suppl):II-501.

50. Sabbah HN, Chaudhry PA, Kleber FX, Konertz W. Passive cardiac support: A surgical approach to the treatment of heart failure. Presented October 13, 2000 at the Mechanical Circulatory Support Meeting.

51. Shapland E, Raman J, Byrne M, Power JM, Alferness CA. Passive ventricular constraint is a trigger for a significant degree of reverse remodeling in an experimental model of degenerative heart failure and dilated cardiomyopathy. J of Cardiac Failure 2000;6(suppl 2):32.

52. Chaudhry PA, Mishima T, Suzuki G, Sharov VG, Anagnostopolos P, Undrovinas AI, Nass O, Alferness CA, Sabbah HN. Acute ventricular reduction with the Acorn Cardiac Support Device prevents progressive left ventricular dysfunction and remodeling in dogs with advanced heart failure. European Heart Journal 2000;21(suppl):534.

53. Byrne M, Raman J, Power JM, Alferness CA. Passive ventricular constraint; an effective intervention for the treatment of both moderate and severe cardiomyopathy. The J of Heart Failure 2000;6:120.

54. Power JM, Raman J, Byrne B, Alferness CA. Passive ventricular constraint performed in advanced heart failure prevents mortality in an experimental model of progressive, malignant dilated cardiomyopathy. European J of Heart Failure 2000;2(suppl 2):46.

55. Power JM, Raman J, Byrne M, Alferness CA. Passive ventricular constraint in advanced heart failure prevents a further decline in cardiovascular function. J Am Coll Cardiol 2000;35(Suppl A):233A.

56. Byrne M, Raman J, Power JM, Alferness CA. Passive ventricular constraint; an effective intervention for the treatment of both moderate and advanced dilated cardiomyopathy. European Heart Journal 2000;21(suppl):293.

57. Sabbah HN, Chaudhry PA, Kleber FX, Konertz W. Passive mechanical containment of progressive left ventricular dilation: a surgical approach to the treatment of heart failure. The J of Heart Failure 2000;6:115.

58. Power JM, Raman J, Burrell LM, Buxton BF, Alferness CA. Passive ventricular constraint in dilated cardiomyopathy does not induce a constrictive cardiovascular pattern. J of Cardiac Failure 1999;5(Suppl 1):32.

59. Raman J, Power JM, Buxton BF, Alferness CA. Passive ventricular containment in the treatment of experimental dilated cardiomyopathy. Presented May 30, 1999 at the 7th Annual Meeting of the Asian Society for Cardiovascular Surgery.

60. Chaudhry PA, Paone G, Sharov VG, Mishima T, Hawkins J, Alferness CA, Sabbah HN. Passive ventricular constraint with the Acorn prosthetic jacket prevents progressive left ventricular remodeling and functional mitral regurgitation in dogs with moderate heart failure. AATS 79th Annual Meeting, program page 66, 1999.

61. Raman J, Power JM, Buxton BF, Alferness CA. Passive ventricular containment in the treatment of experimental dilated cardiomyopathy. J Am Coll Cardiol 1999;33(Suppl A):208A.

62. Sabbah HN, Chaudhry PA, Paone G, Mishima T, Alferness CA. Passive ventricular constraint with the Acorn prosthetic jacket prevents progressive left ventricular dilation and improves ejection fraction in dogs with moderate heart failure. J Am Coll Cardiol 1999;33(Suppl A):207A.

63. Power JM, Raman J, Farish SJ, Burrell LM, Tonkin AM, Alferness CA. A novel device for the treatment of rapid pacing induced dilated cardiomyopathy in sheep. J of Cardiac Failure 1998;4(Suppl 1):27.

G. Cellular/Molecular

64. Rastogi S, Gupta RC, Imai M, Brewer R, Walsh R, Sabbah HN. Chronic Therapy with the *Acorn* Cardiac Support Device normalizes mRNA Gene Expression of Fatty Acid Oxidation Regulatory Enzymes in dogs with heart failure. ISHLT 2006 Annual Meeting, ACC 2006 Annual Meeting.

65. Rastogi S, Mishra S, Gupta RC, Morita H, Sabbah HN. Chronic Therapy with the Acorn Cardiac Support Device Normalizes Gene Expression of Vascular Endothelial and Basic Fibroblast Growth Factors in Dogs with Heart Failure. ISHLT Annual Meeting; 9-12 April, 2003.

66. Rastogi S, Gupta RC, Mishra S, Morita H, Sabbah HN. Chronic Therapy with the Acorn Cardiac Support Device Reduces Gene Expression of MMP2 and MMP9 in Dogs with Heart Failure. Journal of American College of Cardiology;41(Suppl):175A.

67. Rastogi S, Gupta RC, Mishra S, Morita H, Sabbah HN. Long-term therapy with the Acorn cardiac support device normalizes gene expression of □-myosin heavy chain in dogs with chronic heart failure. Circulation, Suppl. 2002:II-384.

68. Rastogi S, Gupta R, Mishra S, Suzuki G, Morita H, Sabbah HN. Therapy with the Acorn Cardiac Support Device reduces mRNA expression of brain and atrial natriuretic peptides in left ventricular myocardium of dogs with heart failure. Journal of American College of Cardiology;39(Suppl A):140A.

69. Sabbah HN, Gupta RC, Mishra S, Suzuki G, Morita H. Prevention of progressive left ventricular dilation with the Acorn Cardiac Support Device normalizes protein phosphatase activity in dogs with chronic heart failure. Circulation 2001;104 (Suppl II):II-556.

70. Sabbah HN, Gupta RC, Sharov VG, Todor A, Mishra S, Chaudhry PA, Suzuki G, Morita H. Prevention of progressive LV dilation with the acorn cardiac support device downregulates stretch response proteins and improves sarcoplasmic reticulum calcium cycling in dogs with heart failure. European Heart Journal 2001;22(Suppl): 95.

71. Gupta RC, Sharov VG, Mishra S, Todor A, Sabbah HN. Chronic therapy with the Acorn Cardiac Support Device (CSD) attenuates cardiomyocyte apoptosis in dogs with heart failure. J Am Coll Cardiol 2001;37(Suppl A):478A.

72. Sabbah HN, Gupta RC, Sharov VG, Todor A, Mishra S, Chaudhry PA, Suzuki G. Prevention of progressive left ventricular dilation with the Acorn Cardiac Support Device downregulates stretch-response proteins and improves sarcoplasmic reticulum recycling in dogs with chronic heart failure. J Am Coll Cardiol 2001;37(Suppl A):474A.

73. Sabbah HN, Gupta RC, Sharov VG, Todor A, Mishra S, Chaudhry PA, Nair H. Prevention of progressive left ventricular dilation with the Acorn Cardiac Support Device (CSD) downregulates stretch-mediated p21ras, attenuates myocyte hypertrophy and improves sarcoplasmic reticulum calcium cycling in dogs with heart failure. Circulation 2000;102(Suppl):II-683.

74. Sabbah HN, Maltsev VA, Chaudhry PA, Mishima T, Undrovinas AI. Contractile function of cardiomyocytes isolated from dogs with heart failure is enhanced after chronic therapy with passive ventricular constraint using the Acorn Cardiac Support Device. Circulation 1999;100(Suppl):439.

H. Acute Myocardial Infarction

75. Pilla JJ, Brockman DJ, Blom AS, Yuan Q, Acker MA. Passive ventricular constraint improves myocardial energetics in a model of heart failure secondary to acute infarction. AATS Annual Meeting Program Guide 2002:76.

76. Pilla JJ, Brockman DJ, Blom AS, Bowen F, Yuan Q, Gorman JH, Gorman RC, Acker MA. Prevention of dilatation using the Acorn Cardiac Support Device (CSD) results in reversed remodeling and improvement of function. Circulation 2001;104 (Suppl II):II-440.

77. Pilla JJ, Blom AS, Brockman DJ, Bowen F, Yuan Q, Giammarco J, Gorman JH, Gorman RC, Acker MA. Ventricular constraint using the Acorn Cardiac Support Device (CSD) limits infarct expansion in an ovine model of acute myocardial infarction. Circulation 2001;104(Suppl II):II-480.

78. Pilla JJ, Brockman DJ, Blom, AS, Bowen F, Gorman, III JH, Gorman RC, Axel L, Acker MA. Placement of the Acorn Cardiac Support Device (CSD) results in left ventricular reversed remodeling and improvement of function in a model of heart failure secondary to acute myocardial infarction. EACTS/ESTS Joint Meeting Abstract Book September 2001:482.

79. Pilla JJ, Brockman DJ, Blom AS, Yuan Q, Gorman III, JH, Gorman RC, Acker MA. Prevention of dilatation using the Acorn Cardiac Support Device (CSD) results in reversed remodeling and improvement of function in a model of heart failure secondary to myocardial infarction. Journal of Cardiac Failure 2001;7(Suppl 2): 10.

80. Pilla JJ, Blom AS, Brockman DJ, Bowen FW, Yuan Q, Giammarco J, Gorman III, JH, Gorman RC, Acker MA. Ventricular constraint using the Acorn Cardiac Support Device (CSD) limits infarct expansion in an ovine model of acute myocardial infarction. Journal of Cardiac Failure 2001;7(Suppl 2): 40.

81. Pilla JJ, Brockman DJ, Blom AS, Yuan Q, Dougherty L, Bowen FW, Giammarco J, Ferrari V, Acker MA. Limiting dilatation results in reversed remodeling and improvement of function in an acute infarct model of heart failure. European Heart Journal 2001;22(Suppl): 679.