Ventricular Remodeling Operation (Batista Procedure) and Surgical Ventricular Restoration (Dor Procedure)

I. Aetna considers the Batista ventricular remodeling procedure, also known as partial left ventriculectomy, experimental and investigational because its effectiveness has not been established.

II. Aetna considers surgical ventricular restoration, also known as the Dor procedure, experimental and investigational because its effectiveness has not been established.

III. Aetna considers the Acorn CorCap Cardiac Support Device for the treatment of heart failure experimental and investigational because its effectiveness has not been established.

See also CPB 0586 - Heart Transplantation, CPB 0599 - Autologous Skeletal Myoblast/Mononuclear Bone Marrow Cell Transplantation, CPB 0610 - Biventricular Pacing (Cardiac Resynchronization Therapy)/Combination Resynchronization-Defibrillation Devices for Congestive Heart Failure.
Background

Ventricular Remodeling Operation (Batista Procedure)

The ventricular remodeling operation (also known as the Batista procedure, partial left ventriculectomy, heart reduction surgery, and wedge resection of the heart) has been proposed as a surgical procedure to replace or postpone heart transplantation in patients with dilated non-ischemic cardiomyopathy. It involves removing a viable portion of the enlarged left ventricle and repair of the resultant mitral regurgitation with a valve ring. It attempts to augment systemic blood flow through improvement in the mechanical function of the left ventricle by restoring its chamber to optimal size. In most cases, partial left ventriculectomy is accompanied by mitral valve repair.

Although initial reports on the Batista procedure lacked significant information on its safety and effectiveness, overall clinical impression was that the operation may serve as a bridge to heart transplantation especially in patients with idiopathic dilated cardiomyopathy. However, recent reports indicated that further investigation is needed.

In a prospective evaluation of the Batista procedure, Weston et al (2000) reported that at 3, 6, and 12 months post-surgery the ejection fractions of patients who had undergone the operation were not significantly better than prior to surgery. Moreover, there was no survival benefit with 60 % of the patients expiring within 6 months after the Batista procedure.

In a prospective study, Starling and associates (2000) reported the clinical outcomes of 59 patients with cardiomyopathy and advanced heart failure who have undergone partial left ventriculectomy (PLV). The authors concluded that PLV could provide structural remodeling of the heart that might result in temporary improvement in clinical compensation. However, perioperative failures and the return of heart failure limit the propriety of this procedure. In an accompanying editorial, Ratcliffe (2000)
stated that the clinical results of PLV have been disappointing -- event-free survival is poor. He noted that although PLV is able to reduce left ventricular volume and probably decreases ventricular wall stress, reduction of volume and stress is insufficient to improve ventricular function.

Doenst et al. (2001) concluded that although the Batista procedure is well-tolerated by most patients with dilated cardiomyopathy and results in immediate improvement of contractile function, the long-term benefits of this technique for patients with dilated cardiomyopathy are uncertain. Thus, the technique is currently not an alternative for heart transplantation. Abe et al. (2001) stated that further study is required to determine the exact role of the Batista procedure in the treatment of congestive heart failure. This would have to be a multi-center, randomized, and long-term follow-up study.

In an editorial on the Batista procedure, Dreyfus and Mihealainu (2001) believed that no more than 20% of idiopathic cardiomyopathies are appropriate for this procedure, and that further investigation is needed to define a suitable candidate in this regard. The authors stated that heart failure surgery is at its early phase, especially for palliative procedure, and further elaboration and investigation are required before any definitive conclusions can be drawn. In an overview on the surgical management of heart failure, Zeltsman and Acker (2002) stated that direct surgical approaches to restoring normal geometry and size to failing hearts, such as left ventricular reduction (Batista procedure) are under clinical investigation.

The National Institute of Clinical Excellence (NICE, 2004) concluded that "current evidence on the safety and efficacy of partial left ventriculectomy (PLV) does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research." NICE (2003) has stated that "publication of safety and efficacy outcomes will be useful in reducing the current uncertainty."

The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology (Swedberg et al., 2005) stated that partial left ventriculectomy (Batista procedure) can not be recommended
for the treatment of heart failure. Furthermore, the Batista procedure should not be considered an alternative to heart transplantation.

Frey et al (2014) tested, for the first time, the feasibility of intra-coronary delivery of an innovative, injectable bioabsorbable scaffold (IK-5001), to prevent or reverse adverse left ventricular remodeling and dysfunction in patients after ST-segment-elevation myocardial infarction (MI). Patients (n = 27) with moderate-to-large ST-segment-elevation MI, after successful re-vascularization, were enrolled. Two milliliters of IK-5001, a solution of 1% sodium alginate plus 0.3% calcium gluconate, was administered by selective injection through the infarct-related coronary artery within 7 days after MI. IK-5001 is assumed to permeate the infarcted tissue, cross-linking into a hydrogel and forming a bioabsorbable cardiac scaffold. Coronary angiography, 3 minutes after injection, confirmed that the injection did not impair coronary flow and myocardial perfusion. Furthermore, IK-5001 deployment was not associated with additional myocardial injury or re-elevation of cardiac biomarkers. Clinical assessments, echocardiographic studies, 12-lead electrocardiograms, 24-hour Holter monitoring, blood tests, and completion of Minnesota Living with Heart Failure Questionnaires were repeated during follow-up visits at 30, 90, and 180 days after treatment. During a 6-month follow-up, these tests confirmed favorable tolerability of the procedure, without device-related adverse events, serious arrhythmias, blood test abnormalities, or death. Serial echocardiographic studies showed preservation of left ventricular indices and left ventricular ejection fraction (LVEF). The authors concluded that this first-in-man pilot study showed that intra-coronary deployment of an IK-5001 scaffold is feasible and well-tolerated. They stated that these findings have promoted the initiation of a multi-center, randomized controlled trial to confirm the safety and effectiveness of this new approach in high-risk patients after ST-segment-elevation MI.

Surgical Ventricular Restoration Procedure

Surgical ventricular restoration (SVR), also known as the Dor procedure, left ventricular reconstruction, and surgical anterior ventricular endocardial restoration (SAVER), is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic segments of the heart, secondary to either dilated
cardiomyopathy or post-infarction left ventricular aneurysm. In general, SVR is delayed for at least 3 months after myocardial infarction to allow the healing of infarcted tissue. It is usually performed after coronary artery bypass grafting (CABG) and may proceed or be followed by mitral valve repair or replacement. A principal difference between SVR and ventriculectomy (i.e., for aneurysm removal) is that in SVR the ventricle is reconstructed using patches of autologous or artificial material that are placed to close the defect while maintaining the desired ventricular volume and contour. In addition, SVR is distinct from partial left ventriculectomy (Batista procedure), which does not attempt to specifically resect akinetic segments and restore ventricular contour.

While SVR has been performed for many years, available evidence is insufficient to allow conclusions regarding health outcomes associated with this approach. In particular, the lack of randomized controlled studies comparing SVR to other surgical or medical treatments does not permit assessment of the effectiveness of SVR. Furthermore, patient selection criteria and optimal surgical techniques are still undetermined.

Joyce et al (2003) stated that as techniques for the management of patients with ischemic heart failure have evolved, controversy has arisen with respect to the roles of revascularization and ventricular restoration procedures. These investigators noted that although the basis for improved survival with CABG lies in the viability of ischemic myocardium, nuclear medicine studies and stress echocardiography have failed to adequately select for tissues that are capable of recovery. Furthermore, recent studies have suggested an additional benefit to combining ventricular restoration with bypass surgery. However, the role for these techniques has not been definitively established. They concluded that the currently enrolling Surgical Treatment for Ischemic Heart Failure (STICH) trial promises to address these issues and thereby improve the management of patients with this disease. Furthermore, Menicanti and Di Donato (2004) stated that SVR is a safe and effective surgical option for post-infarction ischemic cardiomyopathy resulting in improvement of pump function, functional class and survival. Observational data now need to be confirmed by randomized data and the STICH trial will definitely ascertain if SVR adds any health benefits to CABG alone in patients with left ventricular dysfunction and dilated ventricle.
De Bonis et al (2004) noted that myocardial revascularization, left ventricular restoration, mitral valve repair, passive containment device implantation, as well as surgical ablation of atrial fibrillation represent some of the "conventional" procedures which are currently in use or under development for the surgical treatment of ischemic cardiomyopathy. For several of them, the exact indications and results are not yet established and significant changes and improvements should reasonably be waited over the next few years. As techniques are refined and more data become available, the optimum surgical strategy for patients with advanced ischemic heart failure is likely to become clearer and more effective. Additionally, McConnell and Michner (2004) stated that there are several surgical treatments (SVR, autologous skeletal myoblast, and stem cell transplantation) now under clinical investigation that appear promising in the effort to reverse or restore the remodeled left ventricle. Although these emerging therapies remain in the early stages of study and development, they hold promise in providing options to those patients with end-stage congestive heart failure.

Ribeiro et al (2006) stated that there are subsets of patients with ischemic cardiomyopathy for whom the optimal treatment strategies are not clear. These investigators studied the relationship between clinical outcomes and surgical procedure in patients who were treated either with a CABG or with a CABG and additional SVR. The study population comprised 137 consecutive patients with anterior myocardial infarction. All patients had an ejection fraction less than 50 % and left ventricle end-systolic volume index greater than 80 ml/m². The patients were divided into a viable and a non-viable group according to anterior myocardium viability, which was determined by a thallium-201 test. The viable group underwent a revascularization and was randomized into two groups for additional SVR. Group 1a comprised 35 patients with viable anterior wall who underwent surgical revascularization. Group 1b comprised 39 patients with viable anterior wall who underwent surgical revascularization and SVR. Group 2 comprised 69 patients with non-viable anterior wall who underwent revascularization and SVR. The pre-operative and post-operative ejection fractions, end-systolic volume, mitral regurgitation, mortality, and heart failure symptoms were compared among groups. Complete 2-year follow-up was achieved in 127 (92.7 %) patients. Ejection fraction improved in all groups compared with pre-operative values and it was greater in group 1b than in group 1a (p < 0.001) at 2
years. There were no post-operative deaths in group 1a, 1 in group 1b, and 2 in group 2. After 2 years, group 1b was significantly smaller than group 1a (p < 0.01) in relation to mitral regurgitation of grades 1 to 2+.

End-systolic volume was significantly smaller in group 1b than in group 1a (p < 0.001), it was smaller in group 1a than in group 2 (p < 0.001), and it was smaller in group 1b than in group 2 (p < 0.001). Heart failure class (New York Heart Association [NYHA]) was reduced in all groups and events were significantly smaller in patients with end-systolic volume lesser than 120 ml/m$^2$ (p < 0.05). The authors concluded that the short-term and mid-term outcomes of CABG alone in patients with a large left ventricle are inferior to CABG plus SVR.

Ratcliffe (2006) stated that while CABG plus SVR provided significant improvement in left ventricular volumes compared to CABG alone, the number of patients in the study by Ribeiro and colleagues (2006) was small and the follow-up short-term. Recurrence of heart failure is likely to occur at higher rates after more time has passed.

Di Donato and colleagues (2007) evaluated the effectiveness of SVR and un-repaired mild ischemic mitral regurgitation on left ventricular geometry, cardiac and functional status, and survival. These investigators analyzed 55 patients with previous anterior infarction (age 65 +/- 10 years) and mild chronic functional mitral regurgitation who underwent SVR and CABG without mitral repair. Left ventricular volumes, ejection fraction, and geometric parameters were measured before and after surgery. Even mild ischemic mitral regurgitation is characterized by abnormal left ventricular geometry when compared with that of patients without mitral regurgitation at comparable ventricular volumes and ejection fraction. Surgical ventricular restoration induced a significant decrease in left ventricular volumes, left ventricular diameters, and papillary muscle distance; and an improvement in ejection fraction and NYHA class. Ischemic mitral regurgitation significantly decreased in the majority of patients. Survival is 93% at 1 year and 88% at 3 years. The authors concluded that SVR improved mitral functioning by improving geometry abnormalities. Survival is optimal and greater than would be expected in patients with post-infarction dilated ventricles and depressed left ventricular function. These findings indicated that mitral repair in conjunction with SVR is unnecessary in such patients.
Lee et al (2007) stated that an association of mitral regurgitation (MR) with ischemic cardiomyopathy (I-CMP) increases the risk of heart failure and its surgical management remains controversial. These researchers reported their findings of a total of 49 patients with I-CMP who underwent SVR and coronary revascularization with or without concomitant mitral annuloplasty (MAP). The mean age was 59.8 years, and all patients had NYHA class III or IV heart failure (mean LVEF = 24.8 %). Nineteen patients had MR greater than grade 3 (MR group). Surgical ventricular restoration and CABG were performed in all patients, and concomitant MAP was performed in the MR group. Echocardiography was performed pre-operatively, post-operatively, and at mean of 19 months after operation. Pre-operative left ventricular (LV) end-diastolic and endsystolic dimensions, left atrial volume index, and MR grade were statistically significantly increased in the MR group. On the early post-operative echocardiogram, mean LVEF was significantly improved, with reduction of LV dimensions, in both groups; however, at follow-up, these parameters were more significantly improved in the MR group, but unchanged in non-MR group, reaching almost the same levels as the non-MR group. The authors concluded that in patients with I-CMP, MR increased early and late mortality; however, after SVR and concomitant MAP, LV function seems to continuously improve with more significant reduction in the LV dimensions than in the non-MR group.

Ogawa and co-workers (2007) examined if the determination of myocardial viability by pre-operative delayed-enhanced magnetic resonance imaging (DE-MRI) would be useful for planning SVR. A total of 8 consecutive patients with poor cardiac function (ejection fraction less than 30 %) due to ischemic cardiomyopathy underwent surgical treatment based on findings of pre-operative cine-MRI and DE-MRI. The surgical strategy consisted of: (i) complete revascularization on viable segments; (ii) SVR in patients with extensive non-viable segments; and (iii) mitral valve plasty in patients with a more than moderate degree of mitral regurgitation. Based on the MRI findings, 4 patients (group A) underwent isolated coronary bypass surgery, and the remaining 4 patients (group B) underwent SVR and mitral valve plasty concomitantly with coronary bypass surgery. Peri-operative changes in ventricular function were quantitatively assessed in each group. The mean end-diastolic volume index was reduced from 115 +/- 29 ml/m2 to 95 +/- 14
ml/m2 in group A and from 163 +/- 35 ml/m2 to 125 +/- 28 ml/m2 in group B. The mean end-systolic volume index was reduced from 91 +/- 25 ml/m2 to 68 +/- 16 ml/m2 in group A and from 135 +/- 36 ml/m2 to 98 +/- 28 ml/m2 in group B. The mean ejection fraction increased from 20 % +/- 6 % to 28 % +/- 9 % in group A and from 17 % +/- 6 % to 22 % +/- 5 % in group B. The mean NYHA functional class was reduced from 3.0 +/- 0.8 to 1.8 +/- 0.6 in group A and from 3.5 +/- 0.5 to 2.2 +/- 0.2 in group B.

The authors concluded that DE-MRI was highly effective in helping to select which patients and which areas of the left ventricle are indicated for SVR, which contributed to excellent early clinical outcomes.

Tulner et al (2007) examined the clinical effectiveness of heart failure surgery in patients with severe heart failure. A total of 33 patients NYHA class III/IV, left ventricular ejection fraction less than or equal to 35 % were included. Patients with moderate-to-severe mitral regurgitation underwent restrictive mitral annuloplasty (RMA) (85 %) and patients with antero-septal aneurysm underwent SVR (52 %). A combined procedure was performed in 12 patients, and additional CABG in 27 patients. Clinical and echocardiographic parameters were assessed at baseline and 6 months after surgery. Operative mortality was 3 % (n = 1), in-hospital mortality was 9 % (n = 3), and there was no late mortality. All clinical parameters were significantly improved at 6 months' follow-up (p < 0.001); NYHA class improved from 3.4 +/- 0.5 to 1.5 +/- 0.5, Quality-of-life score improved from 44 +/- 22 to 16 +/- 12, and 6-minute walking distance increased from 248 +/- 134 m to 422 +/- 113 m. Left ventricular end-diastolic volume decreased from 107 +/- 32 to 80 +/- 20 ml/m(2) (p < 0.001) and end-systolic volume decreased from 78 +/- 32 to 53 +/- 15 ml/m(2) (p < 0.001), whereas ejection fraction improved from 29 +/- 9 to 35 +/- 7 % (p < 0.01). The authors concluded that surgical treatment of severe heart failure by SVR or RMA was associated with 12 % mortality at 6 months. Surviving patients showed highly significant functional and clinical improvements.

Sartipy et al (2007b) prospectively examined changes in brain natriuretic peptide (BNP) and amino terminal pro-BNP (NT-pro-BNP) in relation to functional status after SVR. A total of 29 patients (20 men and 9 women, mean age of 65 years, mean ejection fraction of 24 %) with post-infarction left ventricular aneurysm and depressed left ventricular function underwent SVR according to the Dor technique. Twenty-two patients (76
% were in NYHA functional class III or IV. Multi-vessel disease was present in 26 patients. Natriuretic peptides, functional status, ejection fraction and left ventricular volumes were analyzed at baseline, after 6 months, and late post-operatively. There was no early mortality. Survival at 24 months was 93%. Six months post-operatively 25/29 (86%) patients were in NYHA class I and II (p < 0.001) and at late (mean 21 months) follow-up, all patients were in NYHA class I and II. There was a persistent reduction of NT-pro-BNP (2406 pg/ml versus 1510 pg/ml; p = 0.03 and 975 pg/ml; p = 0.03) and BNP (312 pg/ml versus 228 pg/ml; p = 0.12 and 191 pg/ml; p = 0.20) 6 months post-operatively and at late follow-up, respectively. Ejection fraction improved from 24% to 37% (p < 0.001) at 6 months. End-diastolic (110 ml/m² versus 90 ml/m², p = 0.009) and end-systolic (75 ml/m² versus 52 ml/m², p = 0.006) volume index were reduced at 6 months. Functional improvement correlated significantly with reduction in BNP (r = 0.61, p = 0.01) and NT-pro-BNP (r = 0.58, p = 0.003) 6 months after surgery. Ejection fraction correlated inversely with BNP (r = -0.58, p = 0.02) and NT-pro-BNP (r = -0.51, p = 0.04), and end-systolic volume correlated with BNP (r = 0.65, p = 0.03) and NT-pro-BNP (r = 0.62, p = 0.03) 6 months after surgery. The authors concluded that heart failure secondary to post-infarction left ventricular remodeling can be reversed by SVR. Improvement in these patients was associated with reduced levels of B-type natriuretic peptides 6 months after surgery. Clinical improvement was maintained and peptide levels were further reduced at late follow-up. The same group of investigators (Sartipy et al, 2007c) also noted that functional status and quality of life improved 6 months after SVR, and the improvement was sustained at late follow-up almost 2 years after surgery.

Sartipy and associates (2007a) also assessed the effectiveness of SVR and direct surgery for ventricular tachycardia in patients with left ventricular aneurysm or dilated ischemic cardiomyopathy. The procedure includes a non-electrophysiologically guided subtotal endocardectomy and cryoablation in addition to endoventricular patch plasty of the left ventricle. Coronary artery bypass surgery and mitral valve repair are performed concomitantly as needed. The authors stated that, in their personal experience, the procedure yields a 90% success rate in terms of freedom from spontaneous ventricular tachycardia, with an early mortality rate of 3.8%.
Menicanti et al (2007) reported operative and long-term mortality in patients submitted to anterior SVR; changes in clinical and cardiac status induced by SVR; as well as predictors of death in a large cohort of patients. A total of 1161 consecutive patients (83 % men, 62 +/- 10 years) had anterior SVR with or without CABG and with or without mitral repair/replacement. A complete echocardiographic study was performed in 488 of 1,161 patients operated on between January 1998 and October 2005 (study group). The indication for surgery was heart failure in 60 % of patients, angina, and/or a combination of the two. Thirty-day cardiac mortality was 4.7 % (55/1161) in the overall group and 4.9 % (24/488) in the study group. Determinants of hospital mortality were mitral valve regurgitation and need for a mitral valve repair/replacement. Mitral regurgitation (greater than 2+) associated with a NYHA class greater than II and with diastolic dysfunction (early-to-late diastolic filling pressure greater than 2) further increased mortality risk. Global systolic function improved post-operatively: ejection fraction improved from 33 % +/- 9 % to 40 % +/- 10 % (p < 0.001); end-diastolic and end-systolic volumes decreased from 211 +/- 73 to 142 +/- 50 and 145 +/- 64 to 88 +/- 40 ml, respectively (p < 0.001) early after surgery. New York Heart Association functional class improved from 2.7 +/- 0.9 to 1.6 +/- 0.7 (p < 0.001) late after surgery. Long-term survival in the overall population was 63 % at 120 months. The authors concluded that SVR for ischemic heart failure reduced ventricular volumes, improved cardiac function and functional status, carried an acceptable operative mortality, and resulted in good long-term survival. Predictors of operative mortality are mitral regurgitation of 2+ or more, NYHA class greater than II, and diastolic dysfunction (early-to-late diastolic filling pressure greater than 2).

Williams et al (2007a) compared outcomes in 69 consecutive patients 65 years and older (n = 27) and younger than 65 years (n = 42) to determine the utility of SVR in an elderly population with end-stage heart failure. The investigators found similar outcomes from SVR in the elderly as in younger patients. Patients 65 years and older showed significant improvements in ejection fraction (p = 0.01) and left ventricular end-systolic volume index (p = 0.07) following SVR, which were similar to the improvements seen in patients younger than 65 years. Sixty percent (15 of 25) of patients 65 years and older in pre-operative NYHA class III/IV improved to class I/II at follow-up (p < 0.0001). Actuarial survival was 68.8 % at 2.5 years.
Williams et al (2007b) evaluated the impact of advanced stage of congestive heart failure (NYHA IV) on survival after SVR. A retrospective review was conducted of SVR patients at our institution between January 2002 and December 2005. A total of 78 patients underwent SVR during the study period; 34 patients were NYHA IV and 44 patients were NYHA II/III before surgery. NYHA IV patients had significantly worse pre-operative ejection fraction (EF), left ventricular end systolic volume index (LVESVI), and stroke volume index (SVI). The investigators reported that both groups demonstrated significant improvement in EF and LVESVI after SVR, and that there were no differences between the groups with regard to post-operative EF, LVESVI, or SVI. There were 3 operative deaths in each group (p = 1.00). Sixty-five percent (p < 0.0001) of NYHA IV patients and 82 % (p < 0.0001) of NYHA II/III patients improved to NYHA class I or II at follow-up. NYHA IV patients trended toward reduced Kaplan-Meier survival at 32 months (68 % versus 88 %, p = 0.08), although NYHA IV was not a significant predictor of mortality. The authors concluded that NYHA IV patients demonstrated similar improvements in cardiac function with acceptable, although decreased, survival after SVR when compared with those with less severe clinical disease. The investigators stated that these outcomes are superior to those reported for medical management, indicating that patients with clinically advanced congestive heart failure who are appropriate candidates should be considered for SVR irrespective of pre-operative NYHA class.

These investigators (Patel et al, 2007) also examined the impact of lateral wall MI (LMI) on SVR outcomes in the same group of patients. Patients were grouped into those with and without LMI. Lateral wall myocardial infarction patients were further subdivided into those with anterior-lateral and anterior-inferior-lateral MI. Extent of LMI was assessed intra-operatively as less than 25 %, 25 % to 49 %, 50 % to 75 %, and more than 75 % of the lateral wall. Follow-up was 100 %. The investigators concluded that cardiac function is improved after SVR for patients with and without LMI. However, anterior-inferior-lateral MI and LMI involving 50 % or more of the lateral wall may predict mortality.

The same group of investigators (Patel et al, 2008) also assessed the impact of the extent of septal myocardial infarction (SMI) on outcomes after SVR. Patients were stratified based on the extent of SMI assessed
by magnetic resonance imaging and intra-operative findings; SMI was graded as less than 50 %, 50 % to 74 %, and 75 % or greater of the length or height, or both, of the septum. Follow-up was 100 %. The investigators concluded that the findings of this study showed similar survival as well as significant functional and clinical improvement after SVR regardless of the extent of SMI.

Available studies of SVR, although promising, are small, uncontrolled, and largely retrospective. The major study of SVR is the Surgical Treatment of Congestive Heart Failure (STICH) trial funded by the National Institutes of Health. The STICH investigators are prospectively and randomly selecting patients with akinetic, low–EF ventricles to receive CABG versus CABG and SVR. After prolonged follow-up, the results provide reliable evidence of the effectiveness of SVR in these patients.

Cotrufo et al (2008) evaluated quality-of-life functional capacity after the 2 treatment strategies of SVR and transplantation for severe left ventricular dysfunction of ischemic cause. The 75-patient study population with severe heart failure included 35 patients undergoing SVR (mean age of 62.6 +/- 8.7 years), sometimes together with CABG or mitral surgery, and 40 cardiac transplant recipients (mean age of 55.6 +/- 7.7 years). Pre-operative and 6-month post-operative function (peak VO(2), the anaerobic threshold, and the slope of minute ventilation/carbon dioxide uptake), cardiac catheterization parameters (left and right), and hospital and early outcomes were evaluated. The 2 groups had comparable baseline functional impairment and experienced similar hospital stay and early outcomes. They also showed similar improvements in left ventricular volume indexes and hemodynamic parameters and sustained significant improvements of median VO(2), anaerobic threshold, and minute ventilation/carbon dioxide uptake values. The authors concluded that both surgical strategies resulted in a significant and comparable improvement of functional capacity at the 6-month evaluation. However, these early studies must be repeated to determine the long-term benefits of SVR because maximal VO(2) and ventilatory efficiency lose their prognostic survival role after transplantation.
Allen and Felker (2008) discussed emerging surgical therapies in heart failure. The most widely established surgical therapy for heart failure is cardiac transplantation, but its impact is limited due to the limited number of donors. The Surgical Treatment for Ischemic Heart Failure study, a landmark evaluation of the role of CABG and SVR in patients with ischemic heart disease and heart failure, has recently completed enrollment. Improvements in device design and patient selection appear likely to continue to improve outcomes with mechanical cardiac support in patients who are not deemed transplant candidates (destination therapy).

Surgical repair of secondary mitral regurgitation is undergoing evaluation in the soon to be launched Surgery versus Medical Treatment Alone for Patients with Mitral Regurgitation and Non-ischemic study. The authors concluded that a variety of surgical therapies for heart failure are currently undergoing evaluation in randomized controlled trials. Data from these landmark studies will guide the application of surgical therapy in heart failure for the foreseeable future.

Jones et al (2009) reported on the results of the Hypothesis 2 substudy of the Surgical Treatment for Ischemic Heart Failure (STICH) trial, which compared coronary artery bypass grafting (CABG) alone with the combined procedure of CABG with surgical ventricular reconstruction in 1,000 patients with coronary artery disease. Patients were required to have coronary disease amenable to CABG, a LVEF of 35% or less, and a dominant anterior region of myocardial akinesia or dyskinesia that was amenable to treatment with surgical ventricular reconstruction. All patients received standard medical and device therapy for heart failure. The patients in the 2 study groups were closely matched in terms of demographic characteristics, co-existing illnesses, the proportion who were receiving specific heart-failure medications, the Canadian Cardiovascular Society (CCS) angina class, the NYHA heart-failure class, coronary anatomy, and the extent of anterior myocardial akinesia or dyskinesia. Both CABG alone and the combined procedure were equally successful in improving the post-operative CCS angina class and NYHA heart-failure class. The 2 groups had similar improvements in the 6-min walk test and similar reductions in symptoms. There was a greater reduction in the end-systolic volume index with the combined procedure (16 ml per square meter of body-surface area), as compared with CABG alone (5 ml per square meter). The primary outcome of the trial was a composite of death from any cause or hospitalization for cardiac causes.
There was no difference in the occurrence of the primary outcome between the CABG group (59%) and the combined-procedure group (58%). The 30-day surgical rates of death for CABG alone (5%) and for the combined procedure (6%) were similar and low overall, and no difference in the rate of death from any cause was observed in a median follow-up period of 48 months. Subgroup analyses showed no individual variables interacting significantly with study-group assignment. An accompanying editorial (Eisen, 2009) concluded that, "on the basis of this trial, the routine use of surgical ventricular reconstruction in addition to CABG cannot be justified."

Mark et al (2009) compared CABG plus SVR with CABG alone in 1,000 patients with ischemic heart failure, an anterior wall scar, and a LVEF less than or equal to 0.35. In 991 subjects (99% of eligible), these researchers collected a battery of quality of life (QOL) instruments. The principal, pre-specified QOL measure was the Kansas City Cardiomyopathy Questionnaire, which evaluates the effects of heart failure symptoms on QOL using a scale from 0 to 100 with higher scores indicating better QOL. Structured QOL interviews were conducted at baseline, 4, 12, 24, and 36 months post randomization and were greater than or equal to 92% complete. Cost data were collected on 196 (98%) of 200 patients enrolled in the United States. Heart-failure-related QOL outcomes did not differ between the 2 treatment strategies out to 3 years (median Kansas City Cardiomyopathy Questionnaire scores for CABG alone and CABG plus SVR, respectively: baseline 53 versus 54, p = 0.53; 3 years 85 versus 84, p = 0.89). There were no treatment-related differences in other QOL measures. In the United States patients, total index hospitalization costs averaged over $14,500 higher for CABG plus SVR (p = 0.004) due primarily to 4.2 extra post-operative, high-intensity care days in the hospital. The authors concluded that addition of SVR to CABG in patients with ischemic heart failure did not improve QOL, but significantly increased health care costs.

Shimamoto et al (2013) noted that the impact of diastolic function on the clinical outcome of SVR remains controversial. In this study, a total of 71 patients undergoing SVR between 1999 and 2012 were investigated. Peri-operative echocardiographic parameters were compared, risk factors for deaths and cardiac events were analyzed, and actuarial freedom from death and cardiac events was computed. Pre-operatively, the left
ventricular end-systolic volume index was 77 ± 40 ml·m⁻² and LVEF was 33 % ± 11 %. Post-operatively, left ventricular systolic function was significantly improved (end-systolic volume index 49±31 ml·m⁻², LVEF 42.1 % ± 11.7 %) with a 33.8 % ± 21.9 % reduction in left ventricular end-systolic volume index. The trans-mitral filling deceleration time decreased from 198 ± 54 to 150 ± 46 ms, and the ratio of early peak filling velocities increased significantly postoperatively (from 16 ± 10 to 21 ± 17). Freedom from death and cardiac events at 5 years was 78 % ± 5 % and 64 % ± 6 %, respectively. Multi-variate analyses revealed that age was a significant risk factor for all-cause death, post-operative trans-mitral inflow pattern for cardiac death, and pre-operative mitral regurgitation and post-operative trans-mitral inflow pattern for cardiac events. The authors concluded that despite its positive impact on systolic function, SVR negatively affects post-operative diastolic function. Post-operative severe diastolic dysfunction may correlate with late mortality and cardiac events.

Athanasuleas and Buckberg (2015) stated that the surgical treatment for ischemic heart failure (STICH) trial concluded that the addition of SVR to coronary bypass grafting did not lead to improved survival in patients with dilated ischemic cardiomyopathy. Observational studies at multiple centers over the last 15 years have shown consistent improvement in global ventricular function and approximately 70 % long-term survival. These investigators reviewed the causes of this discrepancy; which likely relate to how the STICH trial was conducted. Recent subset analyses from the STICH investigators have provided some additional data relating ventricular volumes to outcomes. However, including patients with unsuitable entry criteria and operations confounded the data. The authors recommended an analysis of the STICH data based on the trial's initial design in order to determine if there are patients who may benefit by SVR.

Shen and colleagues (2016) compared the mid- to long-term outcomes of patients receiving isolated CABG versus SVR plus CABG for left ventricular aneurysms. The clinical data were retrospectively analyzed in 205 patients with left ventricular aneurysms admitted to the authors’ hospital between January, 1997 and December, 2012, including 115 patients receiving SVR plus CABG and 90 undergoing isolated CABG. By matching pre-operative echocardiographic parameters including aneurysm size, LVEF, LVESVI and EuroSCORE risk factors, 32 patients...
receiving SVR plus CABG and another 32 with isolated CABG were enrolled in this study. The patients were compared for survival rates, major adverse cardiac or cerebrovascular events (MACCEs), left ventricular geometry and function at 1, 3 and 5 years of follow-up. Compared with the patients receiving isolated CABG, those receiving SVR and CABG showed greater improvements in echocardiographic parameters and NYHA functional class. The differences in the echocardiographic parameters between the 2 groups gradually reduced with time and became comparable at 5 years after the operation (p > 0.05). No significant difference was found in the mid- to long-term survival or the incidence of MACCEs between the 2 groups (p > 0.05). The authors concluded that compared with isolated CABG, SVR plus CABG did not reduce the incidence of MACCEs or improve the mid- to long-term survival rate of patients with left ventricular aneurysm with a LVESVI less than 60 ml/m^2.

Doulamis and colleagues (2018) systematically reviewed the existing literature reporting on patients recruited during the past 20 years regarding the role of LV reconstruction in ischemic cardiomyopathy in terms of efficacy and mortality and provided an updated overview of the current evidence. The PubMed and Cochrane bibliographical databases were thoroughly searched for the following MeSH terms: "ventricular reconstruction" or "ventriculoplasty" or "ventricular aneurysm" or "ventricular restoration". Original studies recruiting patients during the past 20 years on LV reconstruction surgery in more than 5 cases and reporting on the associated peri- or post-operative mortality were deemed eligible. A total of 27 studies were included and provided data for 3,220 patients with a mean age of 61 years. Angina was present in 66.6 % (510/766) of the patients, while 90 % (635/699) had a history of MI. Average pre-operative EF was 29.9 % and ESVI was 93.6 ml/m2. With respect to complications, low cardiac output syndrome and the need for intra-aortic balloon pump were prevalent in 9.3 % (79/850) and 18.8 % (334/1,773), respectively. The 30-day mortality was 7.1 % (230/3,220) and late-mortality (mean follow-up of 36.9 months) was 19.6 % (548/2,791), while the rate of MACCE was 40.1 % (367/915); 5-year mortality was 29 % (340/1,171). The authors concluded that these findings provided a current perspective of the role of LV reconstruction in the treatment of ischemic cardiomyopathy suggesting its benefit in
survival. These researchers stated that taking into consideration the existing debate, further studies are needed so that a solid conclusion to be made.

The CorCap Cardiac Support Device

Left ventricular remodeling is related to adverse outcomes in heart failure. The CorCap Cardiac Support Device (CSD; Acorn Cardiovascular, Inc., St. Paul, MN) is an implantable device that attenuates left ventricular remodeling. It is designed to treat heart failure by constraining the heart to prevent further dilation. The CorCap resembles a net that is placed around and attached to the heart to support the damaged heart muscle and limit further enlargement. It provides passive support that reduces the stress on the ventricular wall.

Mann et al (2007) assessed the safety and effectiveness of the CSD in 300 heart failure patients. Patients needing mitral surgery (n = 193) were randomized to mitral surgery alone or mitral surgery plus CSD. Patients who did not need mitral surgery (n = 107) were randomized to medical therapy or medical therapy plus CSD. The primary endpoint was a clinical composite based on changes in patient vital status, the need for major cardiac procedures for worsening heart failure, and a change in NYHA class. The proportional odds ratio for the primary endpoint favored treatment with the CSD (1.73 confidence interval [CI]: 1.07 to 2.79; p = 0.024). The CSD-treated patients received significantly (p = 0.01) fewer cardiac procedures indicative of worsening heart failure and had an improvement in NYHA class (p = 0.049). There was no significant difference in survival between groups (p = 0.85). Treatment with the CSD led to a decrease in left ventricular end-diastolic (LVED) (p = 0.009) and end-systolic volumes (p = 0.017), an increase in the LV sphericity index (p = 0.026), an improvement in the Minnesota Living with Heart Failure score (p = 0.04), and the Short Form-36 Questionnaire (p = 0.015). There was no evidence for a significant difference (p = 0.43) in serious adverse events between the treatment and control groups. The authors concluded that these findings supported the hypothesis that preventing LV remodeling with a CSD favorably impacts the untoward natural history of heart failure.
Speziale et al (2011) conducted a prospective study of the clinical outcomes and health-related quality of life after implantation of the CorCap CSD for dilated cardiomyopathy. The criteria adopted for CorCap implantation were dilated cardiomyopathy (LVED diameter greater than or equal to 60 mm, LVEF less than or equal to 0.30 and greater than 0.10), and NYHA functional class II or III despite maximal medical therapy. Echocardiographic follow-up and evaluation with the Short Form-36 questionnaire were performed. Included were 39 patients: 5 in NYHA class II and 32 in class III. At 13.3 +/- 2.5 months of follow-up, a statistically significant improvement was evident in mean left ventricular volume (left ventricular end-systolic volume from 202 +/- 94 to 138 +/- 72 ml, p = 0.005) and systolic function (LVEF from 0.26 +/- 0.05 to 0.36 +/- 0.05, p < 0.001). The mean LV sphericity index was significantly increased at the end of the follow-up (p = 0.009). Ischemic etiology, diabetes, advanced age, and LVEF of less than 0.15 predicted lesser reversal of the LV alterations. Operative mortality was 5.1%. Cumulative follow-up mortality was 10.2%. The average Physical Health domain scores (Physical Functioning, Role Physical, General Health) were improved. Average Mental Health domain scores were also increased. The authors concluded that the cardiac support device obtains reverse remodelling of the LV and is useful to improve the quality of life of patients with dilated cardiomyopathy and NYHA class III symptoms of heart failure. They stated that the integration of different and complementary strategies (cardiac support device and resynchronization therapy) may represent the key to success for more complex patients, although further studies are needed.

Mann et al (2012) previously reported outcomes from the Acorn randomized trial to a common closing date (22.9 months of follow-up). This report summarized results of extended follow-up to 5 years. A total of 107 patients were enrolled in the no-mitral valve repair/replacement stratum including 57 in the CorCap treatment group and 50 in the control (optimal medical therapy alone) group. Patients were assessed every year, until completing 5 years of follow-up, for survival, adverse events, major cardiac procedures, NYHA functional status, and echocardiograms, which were read at a core laboratory. Overall survivals were similar between the treatment and control groups, demonstrating no late adverse effect on mortality. The treatment group had significant reductions in LVED volume (p = 0.029) as well as a small increase in sphericity index.
More patients in the treatment group improved by at least 1 NYHA functional class (p = 0.0005). There was no difference in rates of adverse events. In a subgroup of patients with an intermediate LVED dimension, there was a significant reduction in the Kaplan-Meier estimate of the freedom from the composite end point of death and major cardiac procedures (p = 0.04). The authors concluded that these cumulative data demonstrated the sustained reverse remodeling of the LV and the long-term safety and efficacy of the CorCap CSD as an adjunctive therapy for patients with heart failure who remain symptomatic despite optimal medical therapy.

Shafy et al (2013) stated that ventricular constraint devices made of polyester and nitinol have been used to treat heart failure patients. Long-term follow-up has not demonstrated significant benefits, probably due to the lack of effects on myocardial tissue and to the risk of diastolic dysfunction. The goal of this experimental study was to improve ventricular constraint therapy by associating stem cell intra-infarct implantation and a cell-seeded collagen scaffold as an interface between the constraint device and the epicardium. In a sheep ischemic model, 3 study groups were created: Group 1: coronary occlusion without treatment (control group); Group 2: post-infarct ventricular constraint using a polyester device (Acorn CorCap); and Group 3: post-infarct treatment with stem cells associated with collagen matrix and the polyester device. Autologous adipose mesenchymal stem cells cultured in hypoxic conditions were injected into the infarct and seeded into the collagen matrix. At 3 months, echocardiography showed the limitation of LVED volume in animals both treated with constraint devices alone and associated with stem cells/collagen. In Group 3 (stem cell + collagen treatment), significant improvements were found in ejection fraction and diastolic function evaluated by Doppler-derived mitral deceleration time. In this group, histology showed a reduction of infarct size, with focuses of angiogenesis and minimal fibrosis interface between CorCap and the epicardium due to the interposition of the collagen matrix. The authors concluded that myocardial infarction treated with stem cells associated with a collagen matrix and ventricular constraint device improves systolic and diastolic function, reducing adverse remodelling and fibrosis. The application of bioactive molecules and the recent development of nanobiotechnologies should open the door for the creation of a new semi-
degradable ventricular support bioprosthesis, capable of controlled stability or degradation in response to physiological conditions of the left or right heart.

Atluri and Acker (2013) noted that heart failure is a global epidemic with limited therapy. Abnormal LV wall stress in the diseased myocardium results in a biochemical positive feedback loop that results in global ventricular remodeling and further deterioration of myocardial function. Mechanical myocardial restraints such as the Acorn CorCap and Paracor HeartNet ventricular restraints have attempted to minimize diastolic ventricular wall stress and limit adverse ventricular remodeling. Unfortunately, these therapies have not yielded viable clinical therapies for heart failure. Cellular and novel biopolymer-based therapies aimed at stabilizing pathologic myocardium hold promise for translation to clinical therapy in the future.

According to the National Institutes of Health’s clinical trial website, there is a study on the Acorn CorCap Cardiac Support Device. The objective of the trial is to evaluate patients when they have the CorCap placed around their heart for the treatment of heart failure at the same time as their mitral valve surgery. However, the recruitment status of this study is unknown because the information has not been verified since June 2009. The CorCap has not received approval from the Food and Drug Administration.

CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
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<tbody>
<tr>
<td>33542</td>
<td>Myocardial resection (eg, ventricular aneurysmectomy)</td>
</tr>
<tr>
<td>33548</td>
<td>Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedures)</td>
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</tbody>
</table>

Other CPT codes related to the CPB:
Ventricular Remodeling Operation (Batista Procedure) and Surgical Ventricular Restoration (Dor Procedure) - Medical Clinical Policy Bulletin

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33426</td>
<td>Valvuloplasty, mitral valve, with cardiopulmonary bypass; with prosthetic ring</td>
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ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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</thead>
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<tr>
<td>I42.0</td>
<td>Dilated cardiomyopathy</td>
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</table>

Acorn CorCap Cardiac Support Device (no specific code):

ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

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<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I50.1 - I50.9</td>
<td>Heart failure</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

**Ventricular Remodeling Operation (Batista Procedure)**


**Surgical Ventricular Restoration Procedure**


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0182
Ventricular Remodeling Operation (Batista Procedure) and Surgical Ventricular Restoration (Dor Procedure)

“Myocardial resection” will be considered on a case by case basis for Medicaid recipients.