

Iliac Artery Disease: A Case-Based Approach To Stent Selection

Annotated Cited Reference Material

(2002). "MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial." Lancet 360(9326): 7-22.

BACKGROUND: Throughout the usual LDL cholesterol range in Western populations, lower blood concentrations are associated with lower cardiovascular disease risk. In such populations, therefore, reducing LDL cholesterol may reduce the development of vascular disease, largely irrespective of initial cholesterol concentrations. **METHODS:** 20,536 UK adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabetes were randomly allocated to receive 40 mg simvastatin daily (average compliance: 85%) or matching placebo (average non-study statin use: 17%). Analyses are of the first occurrence of particular events, and compare all simvastatin-allocated versus all placebo-allocated participants. These "intention-to-treat" comparisons assess the effects of about two-thirds (85% minus 17%) taking a statin during the scheduled 5-year treatment period, which yielded an average difference in LDL cholesterol of 1.0 mmol/L (about two-thirds of the effect of actual use of 40 mg simvastatin daily). Primary outcomes were mortality (for overall analyses) and fatal or non-fatal vascular events (for subcategory analyses), with subsidiary assessments of cancer and of other major morbidity. **FINDINGS:** All-cause mortality was significantly reduced (1328 [12.9%] deaths among 10,269 allocated simvastatin versus 1507 [14.7%] among 10,267 allocated placebo; $p=0.0003$), due to a highly significant 18% (SE 5) proportional reduction in the coronary death rate (587 [5.7%] vs 707 [6.9%]; $p=0.0005$), a marginally significant reduction in other vascular deaths (194 [1.9%] vs 230 [2.2%]; $p=0.07$), and a non-significant reduction in non-vascular deaths (547 [5.3%] vs 570 [5.6%]; $p=0.4$). There were highly significant reductions of about one-quarter in the first event rate for non-fatal myocardial infarction or coronary death (898 [8.7%] vs 1212 [11.8%]; $p<0.0001$), for non-fatal or fatal stroke (444 [4.3%] vs 585 [5.7%]; $p<0.0001$), and for coronary or non-coronary revascularisation (939 [9.1%] vs 1205 [11.7%]; $p<0.0001$). For the first occurrence of any of these major vascular events, there was a definite 24% (SE 3; 95% CI 19-28) reduction in the event rate (2033 [19.8%] vs 2585 [25.2%] affected individuals; $p<0.0001$). During the first year the reduction in major vascular events was not significant, but subsequently it was highly significant during each separate year. The proportional reduction in the event rate was similar (and significant) in each subcategory of participant studied, including: those without diagnosed coronary disease who had cerebrovascular disease, or had peripheral artery disease, or

had diabetes; men and, separately, women; those aged either under or over 70 years at entry; and--most notably--even those who presented with LDL cholesterol below 3.0 mmol/L (116 mg/dL), or total cholesterol below 5.0 mmol/L (193 mg/dL). The benefits of simvastatin were additional to those of other cardioprotective treatments. The annual excess risk of myopathy with this regimen was about 0.01%. There were no significant adverse effects on cancer incidence or on hospitalisation for any other non-vascular cause.

INTERPRETATION: Adding simvastatin to existing treatments safely produces substantial additional benefits for a wide range of high-risk patients, irrespective of their initial cholesterol concentrations. Allocation to 40 mg simvastatin daily reduced the rates of myocardial infarction, of stroke, and of revascularisation by about one-quarter. After making allowance for non-compliance, actual use of this regimen would probably reduce these rates by about one-third. Hence, among the many types of high-risk individual studied, 5 years of simvastatin would prevent about 70-100 people per 1000 from suffering at least one of these major vascular events (and longer treatment should produce further benefit). The size of the 5-year benefit depends chiefly on such individuals' overall risk of major vascular events, rather than on their blood lipid concentrations alone.

Bosch, J. L. and M. G. Hunink (1997). "Meta-analysis of the results of percutaneous transluminal angioplasty and stent placement for aortoiliac occlusive disease." Radiology 204(1): 87-96.

PURPOSE: To estimate and compare the results of percutaneous transluminal angioplasty (PTA) and stent placement to treat aortoiliac occlusive disease. **MATERIALS AND METHODS:** A meta-analysis was performed of data in six PTA studies (1,300 patients) and eight stent placement studies (816 patients) published in 1990 or later that met the inclusion criteria. Proportions were combined by means of a random-effects model. Failure-time data were pooled with and pooled without adjustment for differences in case mix.

RESULTS: The immediate technical success rate in the PTA group was 91%; the rate was higher in the stent group (96%), but the difference was not statistically significant [corrected]. Complication and mortality rates were not statistically significantly different. Analyzed data included technical failures and were adjusted for lesion type and disease severity. Four-year primary patency rates were 65% for stenoses versus 54% for occlusions after PTA to treat claudication and were 53% for stenoses versus 44% for occlusions after PTA to treat critical ischemia. These rates were 77% for stenoses versus 61% for occlusions after stent placement to treat claudication and 67% for stenoses versus 53% for occlusions after stent placement to treat critical ischemia. The risk of long-term failure was reduced by 39% after stent placement compared with PTA.

CONCLUSION: Stent placement and PTA yielded similar complication rates, but the technical success rate was higher after stent placement and the risk of long-term failure was reduced.

Bosiers, M., et al. (2013). "BRAVISSIMO: 12-month results from a large scale prospective trial." J Cardiovasc Surg (Torino) 54(2): 235-253.

The BRAVISSIMO study is a prospective, non-randomized, multi-center, multi-national, monitored trial, conducted at 12 hospitals in Belgium and 11 hospitals in Italy. This manuscript reports the findings up to the 12-month follow-up time point for both the TASC A&B cohort and the TASC C&D cohort. The primary endpoint of the study is primary patency at 12 months, defined as a target lesion without a hemodynamically significant stenosis on Duplex ultrasound (>50%, systolic velocity ratio no greater than 2.0) and without target lesion revascularization (TLR) within 12 months. Between July 2009 and September 2010, 190 patients with TASC A or TASC B aortoiliac lesions and 135 patients with TASC C or TASC D aortoiliac lesions were included. The demographic data were comparable for the TASC A/B cohort and the TASC C/D cohort. The number of claudicants was significantly higher in the TASC A/B cohort, The TASC C/D cohort contains more CLI patients. The primary patency rate for the total patient population was 93.1%. The primary patency rates at 12 months for the TASC A, B, C and D lesions were 94.0%, 96.5%, 91.3% and 90.2% respectively. No statistical significant difference was shown when comparing these groups. Our findings confirm that endovascular therapy, and more specifically primary stenting, is the preferred treatment for patients with TASC A, B, C and D aortoiliac lesions. We notice similar endovascular results compared to surgery, however without the invasive character of surgery.

Dyet, J. F., et al. (2000). "Mechanical properties of metallic stents: how do these properties influence the choice of stent for specific lesions?" Cardiovasc Intervent Radiol 23(1): 47-54.

PURPOSE: To assess selected balloon-expandable and self-expanding stents for radial force, flexibility, radio-opacity, and trackability, and to relate these physical characteristics to potential indications for placement. **METHODS:** Force-strain curves were plotted for each stent and the force required to produce 50% luminal narrowing was recorded. The ability of the stent to show elastic recoil following deformation was also noted. Flexibility was measured by bending the stents against a force transducer and recording the force required per degree of flexion. Radio-opacity was measured by comparing each stent against a standard aluminum step wedge. Trackability was measured by testing the ability of the stent on its delivery system to track over angles of 90 degrees and 60 degrees. **RESULTS:** The balloon-expandable stents showed greater radial strength and radio-opacity but, apart from the AVE Iliac Bridge stent, showed poorer flexibility and trackability. The self-expanding stents showed less radial force but were able to re-expand following deformity. They were generally more flexible and had better trackability but lower radio-opacity. **CONCLUSION:** There is no stent which exhibits all the ideal properties required and therefore the interventionist will need to keep a range of stents available if all lesions are to be addressed.

Freeman, J. W., et al. (2010). "A link between stent radial forces and vascular wall remodeling: the discovery of an optimal stent radial force for minimal vessel restenosis." Connect Tissue Res 51(4): 314-326.

Coronary and peripheral artery disease (PAD) continue to be primary causes of morbidity and mortality in western nations; percutaneous transluminal angioplasty (PTA) with stenting has become a popular treatment. Unfortunately, restenosis is a significant problem following intravascular stent placement. This study considers the contribution of stent forces in vascular stenosis and remodeling to develop an equation for identifying the optimal stent force. z-Type stents of three radial forces [low (3.4 N), high (16.4 N), and ultrahigh (19.4 N)] were deployed into the iliac arteries of a juvenile porcine model. Vessel diameters were measured before, after deployment, and again at 30 days. At 30 days animals were killed and the vessels fixed in situ. After implantation, there was a significant increase in total thickness and neointimal hyperplasia with increasing stent force. The model for vessel radius and experimental data was in agreement. The model shows that maximum late-term radius is achieved with a stent deployment stress of 480 kPa, which occurs at the end of the stress-strain curve nonlinear domain and beginning of the high-strain collagen domain. The results and calculations suggest that an optimal stent force exists that is subject to the geometry, structure, and mechanics of the target vessel. To achieve maximum late-term dilatation, stents should not produce stress in the vessel wall greater than the end of the transitional domain of the vessel's stress-strain curve. This finding is extremely important for vascular stent development and will be expanded to preliminary vessel wall injury and atherosclerotic models.

Goode, S. D., et al. (2013). "Randomized clinical trial of stents versus angioplasty for the treatment of iliac artery occlusions (STAG trial)." *Br J Surg* 100(9): 1148-1153.

BACKGROUND: The management of total iliac artery occlusion is now undertaken routinely using percutaneous techniques but there are no controlled data to indicate whether either balloon angioplasty or stent placement is preferable. This was a multicentre randomized trial to assess whether stents confer any safety or efficacy advantage over balloon angioplasty for complete iliac artery occlusion. **METHODS:** Six participating centres recruited patients with symptoms of lower limb peripheral arterial disease due to iliac artery occlusion 8 cm or less in length. Patients were assigned randomly to either percutaneous transluminal angioplasty (PTA group) or primary stent placement (stent group) alone after the lesion had been traversed with a guidewire. **RESULTS:** There were 118 patients recruited to the study; six were excluded from the analysis owing to major protocol violations, leaving a total of 112 patients for analysis. Some 55 patients had PTA and 57 had a primary iliac stent. Technical success was achieved in 46 patients (84 per cent) in the PTA group and 56 (98 per cent) in the stent group ($P = 0.007$). There were 11 (20 per cent) major procedural complications after PTA compared with three (5 per cent) after primary stenting ($P = 0.010$). There were no significant differences in primary or secondary patency between the groups after 1 and 2 years. **CONCLUSION:** Primary stent placement for iliac artery occlusion increased technical success and reduced major procedural complications (predominantly distal embolization) compared

with balloon angioplasty. Registration number: ISRCTN 48145465 (<http://www.controlled-trials.com>).

Greenhalgh, R. M., et al. (2008). "The adjuvant benefit of angioplasty in patients with mild to moderate intermittent claudication (MIMIC) managed by supervised exercise, smoking cessation advice and best medical therapy: results from two randomised trials for stenotic femoropopliteal and aortoiliac arterial disease." Eur J Vasc Endovasc Surg 36(6): 680-688.

BACKGROUND: Uncertainty exists on whether there is adjuvant benefit of percutaneous transluminal angioplasty (PTA) over supervised exercise and best medical therapy in the treatment of intermittent claudication. **METHODS:** Patients with symptoms of stable mild to moderate intermittent claudication (MIMIC) were randomised in two multi-centre trials, for femoropopliteal and aortoiliac arterial disease, to receive either PTA or no PTA against a background of supervised exercise and best medical therapy and followed up for 24 months. Initial claudication distance (ICD) and absolute walking distance (AWD) on treadmill were compared between randomised groups adjusting for the corresponding measure at baseline. Secondary outcomes included ankle-brachial pressure index (ABPI) and quality of life. **FINDINGS:** A total of 93 patients were randomised into the femoropopliteal trial (48 into PTA) and 34 into the aortoiliac trial (19 to PTA). The mean (standard deviation, SD) age was 66(9) years for the femoropopliteal trial (63% male) and 63(9) for the aortoiliac trial (65% male). At 24 months, there were significant improvements in both AWD and ICD in the PTA groups for both trials. The adjusted AWD was 38% greater in the PTA group for the femoropopliteal trial (95%; CI 1-90) ($p=0.04$) and 78% greater in the PTA group for the aortoiliac trial (95%; CI 0-216) ($p=0.05$). Further benefits were demonstrated for ABPI but not for quality of life. **INTERPRETATION:** PTA confers adjuvant benefit over supervised exercise and best medical therapy in terms of walking distances and ABPI 24 months after PTA in patients with stable mild to moderate intermittent claudication.

Holm, J., et al. (1991). "Chronic lower limb ischaemia. A prospective randomised controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty (PTA)." Eur J Vasc Surg 5(5): 517-522.

In a prospective randomised study, performed over a 6-year period, 102 patients with severe lower limb ischaemia or claudication resistant to exercise training were randomised either to percutaneous transluminal angioplasty (PTA) or vascular surgery. Only patients who could be treated by both methods were included, constituting only 5% of the total number of patients treated during this period. The two groups were similar regarding age, severity of symptoms and diabetes. The immediate and 1-year results showed similar success and complication rates. There was, however, a significantly shorter hospital stay for patients treated with PTA. Due to early complications and initial failures PTA should, however, only be used in institutions where vascular surgical facilities are available since PTA demands access to such treatment.

Leung, D. A., et al. (2003). "Selection of stents for treating iliac arterial occlusive disease." J Vasc Interv Radiol 14(2 Pt 1): 137-152.

Intravascular stents play an increasingly important role in the treatment of iliac artery occlusive disease and their use has expanded the indications for percutaneous endoluminal therapies. The past several years have seen a sharp increase in the number of commercially available covered and uncovered stents. Knowledge of their design and mechanical properties is crucial for selecting the appropriate stent for a particular type of lesion. In this article, the indications for and results of iliac artery stent placement are reviewed and the various characteristics of the currently available stents that may influence operator choice for use in specific lesions are discussed.

Mouanoutoua, M., et al. (2003). "Endovascular intervention of aortoiliac occlusive disease in high-risk patients using the kissing stents technique: long-term results." Catheter Cardiovasc Interv 60(3): 320-326.

Endovascular intervention deploying a kissing stents (KS) technique has been used as an alternative to surgical intervention in treating symptomatic aortoiliac occlusive disease. However, the long-term results on high-risk patients are unknown. We retrospectively analyzed data on high-risk patients who underwent endovascular intervention using the KS technique at our institution. Fifty high-risk patients aged 62 +/- 6.4 years with severe aortoiliac stenosis underwent stent-supported angioplasty using the KS technique. Thirty percent of the patients had total occlusion of the distal aorta and/or the iliac arteries. Twelve patients received thrombolytics prior to stenting. The procedure was successful in all 50 patients. There was a 4% acute complication rate (distal embolization). However, there were no vascular complications, myocardial infarction, or perioperative death. Primary patency during follow-up of 20 +/- 12.3 months was 92%, while secondary patency rate was 100%. Amputation-free survival was 100%. Ninety-two percent remained free of lifestyle-limiting claudication.

Murphy, T. P., et al. (2012). "Supervised exercise versus primary stenting for claudication resulting from aortoiliac peripheral artery disease: six-month outcomes from the claudication: exercise versus endoluminal revascularization (CLEVER) study." Circulation 125(1): 130-139.

BACKGROUND: Claudication is a common and disabling symptom of peripheral artery disease that can be treated with medication, supervised exercise (SE), or stent revascularization (ST). **METHODS AND RESULTS:** We randomly assigned 111 patients with aortoiliac peripheral artery disease to receive 1 of 3 treatments: optimal medical care (OMC), OMC plus SE, or OMC plus ST. The primary end point was the change in peak walking time on a graded treadmill test at 6 months compared with baseline. Secondary end points included free-living step activity, quality of life with the Walking Impairment Questionnaire, Peripheral Artery Questionnaire, Medical Outcomes Study 12-Item Short Form, and cardiovascular risk factors. At the 6-month follow-up, change in peak walking time (the primary end point) was greatest for SE, intermediate for ST, and least with OMC (mean change versus baseline, 5.8+/-

4.6, 3.7+/-4.9, and 1.2+/-2.6 minutes, respectively; $P < 0.001$ for the comparison of SE versus OMC, $P = 0.02$ for ST versus OMC, and $P = 0.04$ for SE versus ST). Although disease-specific quality of life as assessed by the Walking Impairment Questionnaire and Peripheral Artery Questionnaire also improved with both SE and ST compared with OMC, for most scales, the extent of improvement was greater with ST than SE. Free-living step activity increased more with ST than with either SE or OMC alone (114+/-274 versus 73+/-139 versus -6+/-109 steps per hour), but these differences were not statistically significant. CONCLUSIONS: SE results in superior treadmill walking performance than ST, even for those with aortoiliac peripheral artery disease. The contrast between better walking performance for SE and better patient-reported quality of life for ST warrants further study. CLINICAL TRIAL REGISTRATION: URL: <http://clinicaltrials.gov/ct/show/NCT00132743?order=1>. Unique identifier: NCT00132743.

Norgren, L., et al. (2007). "Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II)." *J Vasc Surg* 45 Suppl S: S5-67.

Nygaard, M., et al. (2007). "The Oslo balloon angioplasty versus conservative treatment study (OBACT)--the 2-years results of a single centre, prospective, randomised study in patients with intermittent claudication." *Eur J Vasc Endovasc Surg* 33(1): 3-12.

OBJECTIVES: To compare the effect of optimal medical treatment only (OMT) with OMT combined with percutaneous transluminal angioplasty (OMT+PTA) in patients with intermittent claudication (IC). DESIGN: A single centre prospective, randomised study. Quality of life (QoL) was the primary outcome measure. Secondary measures were ankle-brachial-index (ABI), treadmill walking distances and mortality. METHODS: From a total of 434 patients considered for inclusion into the trial, only 56 patients with disabling IC fulfilled the inclusion criteria. The patients were randomised into treatment groups consisting of 28 patients each and followed for 2 years. ABI and treadmill walking distances were measured in addition to the visual analogue scale (VAS) for pain evaluation, and QoL assessment using the Short Form (SF-36 and Claudication Scale (CLAU-S). RESULTS: The demographic data in the 2 groups were almost identical. After 2 years of follow-up the ABI, the treadmill walking distances and the VAS were significantly improved in the group treated with OMT+PTA, compared to the group treated with OMT only ($p < 0.01$ for all). Furthermore, some variables from the QoL assessment also showed a significant improvement in favour of the OMT+PTA group ($p < 0.05$ for all). CONCLUSION: The advantage of conducting a single centre study and adhering to very strict inclusion criteria was illustrated by the homogenous demographic data of the two groups. This partly outweighed the disadvantage of having included a relatively small number of patients. Early intervention with PTA in addition to OMT seems to have a generally more positive effect compared to OMT only, on haemodynamic, functional as well as QoL aspects during the first 2 years in patients with IC.

Ormiston, J. A., et al. (2000). "Stent longitudinal flexibility: a comparison of 13 stent designs before and after balloon expansion." Catheter Cardiovasc Interv 50(1): 120-124.

Longitudinal flexibility is an important property of coronary stents, facilitating delivery and allowing the expanded stent to conform to vessel contour. Subjective descriptions of flexibility abound, but there are few independent quantitative data to aid stent selection. A three-point bend test was employed to measure stiffness, the reciprocal of flexibility, for 13 stent designs in the unexpanded (bare) state, then after expansion with a 3.5-mm balloon. For eight of the designs, stiffness of the proprietary stent/balloon delivery system was also measured. In the unexpanded state, there was a wide spread of stiffness, which ranged from 0.5+/-0.2 to 91.5+/-10.0 g force/mm, depending on design. Stiffness was least for the coil (Wiktor and Crossflex) and hybrid (AVE GFX and Bard XT) designs. The MultiLink was the most flexible and the Crown the stiffest of the slotted tube designs. All stents became stiffer upon expansion. For most manufacturer-mounted stents, the delivery balloon was the main determinant of stent/balloon delivery system stiffness. Manufacturer-mounted stent profile ranged from 1.15+/-0.11 mm for the Jostent to 1.53 +/- 0.05 mm for the MultiLink system. Independent quantitative assessment of characteristics such as flexibility and profile should aid rational comparison of stent designs.

Scheinert, D., et al. (2011). "A novel self-expanding interwoven nitinol stent for complex femoropopliteal lesions: 24-month results of the SUPERA SFA registry." J Endovasc Ther 18(6): 745-752.

PURPOSE: To examine the efficacy and integrity of a novel interwoven self-expanding nitinol stent system for the treatment of complex femoropopliteal lesions in a "real world" medical practice. **METHODS:** This retrospective analysis included 107 consecutive patients (77 men; mean age 68.9 years) with atherosclerotic femoropopliteal lesions (occlusions in 31%) who underwent implantation of 137 SUPERA stents. The patients were followed for up to 24 months by Doppler ultrasound examinations, radiography of the stent, and assessments of Rutherford-Becker class and ankle-brachial index (ABI). **RESULTS:** The mean implanted stent length was 111+/-50 mm (range 40-270). Procedure success (residual stenosis <30%) was achieved in 99% of procedures. The 6-, 12-, and 24-month cumulative primary patency rates (+/- standard error) were 93.1%+/-2.5%, 84.7%+/-3.6%, and 76.1%+/-4.5%, respectively, and the secondary patency rates were 99.0%+/-0.1%, 94.8%+/-0.2% and 91.9%+/-0.3%, respectively. Between baseline and 24 months, mean ABI increased from 0.68+/-0.14 to 0.87+/-0.10 and the mean Rutherford-Becker class decreased from 3.3+/-0.7 to 2.0+/-1.0 (p<0.0001 for both). Radiographs performed in 91 patients at a mean of 16.8+/-7.0 months found no stent fractures. **CONCLUSION:** Over a 2-year surveillance period, excellent durability without stent fractures was documented after implantation of the SUPERA stent in complex femoropopliteal lesions. In addition, significant improvements were observed in symptom classification and hemodynamics.

Scheinert, D., et al. (2001). "Stent-supported recanalization of chronic iliac artery occlusions." Am J Med 110(9): 708-715.

PURPOSE: Iliac artery occlusions that are more than a few centimeters in length are normally treated with surgical bypass grafting. The aim of this study was to evaluate the results of primary stent implantation after Excimer laser-assisted recanalization of iliac artery occlusions. **SUBJECTS AND METHODS:** We studied 212 consecutive patients with chronic unilateral iliac artery occlusions (mean [\pm SD] length 8.9 \pm 3.9 cm) who were treated with Excimer laser-assisted recanalization and stent implantation. Based on the criteria of the Society of Cardiovascular and Interventional Radiology, lesions were graded as class III occlusions (<5 cm) in 46 patients and as class IV (\geq 5 cm) in 166 patients. A total of 527 stents (Palmaz stent, 346; Wallstent, 94; Strecker stent, 38; covered stents, 49) were implanted. **RESULTS:** Technical success was achieved in 190 (90%) patients. There was a clinical improvement of three grades in 112 (53%) patients and of two grades in 67 (32%) patients. The rate of major complications was 1.4%, which included arterial rupture (1) and embolic events (2). Primary patency rates were 84% at 1 year, 81% at 2 years, 78% at 3 years, and 76% at 4 years. Secondary patency rates were 88% at 1 year, 88% at 2 years, 86% at 3 years, and 85% at 4 years. **CONCLUSION:** Stent-supported angioplasty is an effective treatment for iliac artery occlusions, with less morbidity and mortality than is associated with surgery. However, reported long-term patency rates after bypass surgery are greater than those we observed with interventional treatment. The value of primary stenting as compared with angioplasty alone should be evaluated in a randomized trial.

Smith, V. L., et al. (2012). "External iliac artery stenting: high incidence of concomitant revascularization procedures." Vasc Endovascular Surg 46(3): 246-250.

OBJECTIVES: To review immediate results, patency rates, hemodynamic success, and incidence of concomitant procedures with external iliac artery stenting (EIAS). **METHODS:** Demographic features, category and clinical grade, Trans-Atlantic Inter-Society Consensus II classification lesion type, pre- and postprocedure ankle-brachial indices, and primary patency were compared between group 1 (EIAS without distal revascularization) and group 2 (EIAS with concomitant distal revascularization). **RESULTS:** No mortality and a 100% immediate technical success rate was recorded in group 1 (n = 12) and group 2 (n = 24). Eleven patients (30.6%) also had stenting of the adjacent common iliac artery. Two thirds of group 2 patients required concomitant femoral or distal revascularization. **CONCLUSIONS:** No difference in stent patency rates was found between patients in group 1 versus group 2. Patients requiring EIAS tend to have more diffuse arterial disease necessitating complicated open reconstruction and/or distal revascularization, as well as more proximal iliac stenting.

Timmins, L. H., et al. (2007). "Stented artery biomechanics and device design optimization." Med Biol Eng Comput 45(5): 505-513.

The deployment of a vascular stent aims to increase lumen diameter for the restoration of blood flow, but the accompanied alterations in the mechanical environment possibly affect the long-term patency of these devices. The primary aim of this investigation was to develop an algorithm to optimize stent design, allowing for consideration of competing solid mechanical concerns (wall stress, lumen gain, and cyclic deflection). Finite element modeling (FEM) was used to estimate artery wall stress and systolic/diastolic geometries, from which single parameter outputs were derived expressing stress, lumen gain, and cyclic artery wall deflection. An optimization scheme was developed using Lagrangian interpolation elements that sought to minimize the sum of these outputs, with weighting coefficients. Varying the weighting coefficients results in stent designs that prioritize one output over another. The accuracy of the algorithm was confirmed by evaluating the resulting outputs of the optimized geometries using FEM. The capacity of the optimization algorithm to identify optimal geometries and their resulting mechanical measures was retained over a wide range of weighting coefficients. The variety of stent designs identified provides general guidelines that have potential clinical use (i.e., lesion-specific stenting).

Vorwerk, D., et al. (1995). "Primary stent placement for chronic iliac artery occlusions: follow-up results in 103 patients." Radiology 194(3): 745-749.

PURPOSE: To report results of primary stent placement for treatment of chronic iliac artery occlusions. **MATERIALS AND METHODS:** The authors placed 154 primary stents in 103 patients with iliac artery occlusions of at least 3 months duration. Mean length of the occluded segments was 5.1 cm. All patients had symptoms, with claudication or trophic changes. Mean ankle-arm index at rest was 0.48. Follow-up included angiography, Doppler ultrasound, and clinical examination. **RESULTS:** Ninety-nine patients demonstrated clinical improvement, with relief or improvement of claudication. Complications that required percutaneous or surgical intervention occurred in six patients; minor complications occurred in another six. Embolization occurred in five patients. Primary patency was 87% after 1 year, 83% after 2 years, and 78% after 4 years; secondary patency was 94%, 90%, and 88% at 1 year, 2 years, and 4 years, respectively. **CONCLUSION:** Primary stent placement should be the treatment of choice in unilateral chronic iliac artery occlusion.

Wilson, S. E., et al. (1989). "Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis. Report of a prospective randomized trial in a selected group of patients." J Vasc Surg 9(1): 1-9.

A prospective, randomized comparison of percutaneous transluminal angioplasty (PTA) with surgery in the treatment of occlusive disease of the iliac, superficial femoral, or popliteal arteries began in 1983. Radiologists and vascular surgeons independently assessed index lesions on arteriograms to decide whether their respective treatments were appropriate. Of 263 male patients randomized, 255 received vascular intervention (surgery, 126 patients; PTA, 129 patients). The groups were comparable when stratified for systemic risk factors and anatomic distribution of disease. Because eligibility criteria required that all

lesions randomized for treatment be suitable for PTA, the severity of disease was less than that of the general population having vascular disease. Claudication was the principal indication for intervention. The immediate failure rate for PTA was 15.5% (20 of 129 patients). Surgery was performed with one in-hospital death (0.8%) and 17 complications (13.5%). There were two late deaths ascribable to surgical complications and none to PTA. At 4.5 years, 50 deaths (20%) (28 from surgery; 22 with PTA) and 24 major amputations of legs included in the study (13 with surgery; 11 with PTA) have occurred. The baseline ankle-brachial indexes (ABIs) of 0.51 +/- 0.02, respectively, after treatment and was not different between the groups through 36 months (surgery, 0.28 +/- 0.04; PTA, 0.30 +/- 0.05). The 17 patients undergoing surgery after unsuccessful PTA had a mean ABI increase of 0.32 +/- 0.07; the durability of hemodynamic improvement was similar in both groups of patients.

Yusuf, S., et al. (2000). "Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. The Heart Outcomes Prevention Evaluation Study Investigators." N Engl J Med 342(3): 145-153.

BACKGROUND: Angiotensin-converting-enzyme inhibitors improve the outcome among patients with left ventricular dysfunction, whether or not they have heart failure. We assessed the role of an angiotensin-converting-enzyme inhibitor, ramipril, in patients who were at high risk for cardiovascular events but who did not have left ventricular dysfunction or heart failure. **METHODS:** A total of 9297 high-risk patients (55 years of age or older) who had evidence of vascular disease or diabetes plus one other cardiovascular risk factor and who were not known to have a low ejection fraction or heart failure were randomly assigned to receive ramipril (10 mg once per day orally) or matching placebo for a mean of five years. The primary outcome was a composite of myocardial infarction, stroke, or death from cardiovascular causes. The trial was a two-by-two factorial study evaluating both ramipril and vitamin E. The effects of vitamin E are reported in a companion paper. **RESULTS:** A total of 651 patients who were assigned to receive ramipril (14.0 percent) reached the primary end point, as compared with 826 patients who were assigned to receive placebo (17.8 percent) (relative risk, 0.78; 95 percent confidence interval, 0.70 to 0.86; $P < 0.001$). Treatment with ramipril reduced the rates of death from cardiovascular causes (6.1 percent, as compared with 8.1 percent in the placebo group; relative risk, 0.74; $P < 0.001$), myocardial infarction (9.9 percent vs. 12.3 percent; relative risk, 0.80; $P < 0.001$), stroke (3.4 percent vs. 4.9 percent; relative risk, 0.68; $P < 0.001$), death from any cause (10.4 percent vs. 12.2 percent; relative risk, 0.84; $P = 0.005$), revascularization procedures (16.3 percent vs. 18.8 percent; relative risk, 0.85; $P < 0.001$), cardiac arrest (0.8 percent vs. 1.3 percent; relative risk, 0.62; $P = 0.02$), [corrected] heart failure (9.1 percent vs. 11.6 percent; relative risk, 0.77; $P < 0.001$), and complications related to diabetes (6.4 percent vs. 7.6 percent; relative risk, 0.84; $P = 0.03$). **CONCLUSIONS:** Ramipril significantly reduces the rates of death, myocardial infarction, and stroke in a broad range of high-risk patients who are not known to have a low ejection fraction or heart failure.

Zhao, H. Q., et al. (2009). "Late stent expansion and neointimal proliferation of oversized Nitinol stents in peripheral arteries." Cardiovasc Intervent Radiol 32(4): 720-726.

For peripheral endovascular intervention, self-expanding (SE) stents are commonly oversized in relation to target arteries to assure optimal wall apposition and prevent migration. However, the consequences of oversizing have not been well studied. The purpose of this study was to examine the effects of SE stent oversizing (OS) with respect to the kinetics of late stent expansion and the long-term histological effects of OS. Pairs of overlapped 8 x 28-mm Nitinol SE stents were implanted into the iliofemoral arteries of 14 Yucatan swine. Due to variations in target artery size, the stent-to-artery ratio ranged from 1.2:1 to 1.9:1. Lumen and stent diameters were assessed by quantitative angiography at the time of implantation. Following angiographic assessment at 6 months, stented arteries were perfusion-fixed, sectioned, and stained for histological analysis. Immediately following implantation, the stents were found to be expanded to a range of 4.7-7.1 mm, largely conforming to the diameter of the recipient target artery. The stents continued to expand over time, however, and all stents had enlarged to nearly their 8-mm nominal diameter by 6 months. The histological effects of OS were profound, with marked increases in injury and luminal area stenosis, including a statistically significant linear correlation between stent-to-artery ratio and area stenosis. In this experimental model of peripheral endovascular intervention, oversized Nitinol SE stents are constrained by their target artery diameter upon implantation but expand to their nominal diameter within 6 months. Severe OS (stent-to-artery ratio >1.4:1) results in a profound long-term histological response including exuberant neointimal proliferation and luminal stenosis.

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