This thesis focuses on various aspects of quality control in vascular surgery, both from a patient’s and a physician’s perspective.

In Chapter 2, we performed a retrospective, cross-sectional study on quality of life in patients with neurogenic thoracic outlet syndrome, treated with either surgical decompression of the thoracic outlet or non-operative therapy. For this purpose, 46 patients diagnosed with N-TOS between 1999 and 2008 were identified. Twenty-four operated and 22 conservatively treated patients were sent questionnaires on their current symptoms and QoL (Euroqol [EQ-5D] questionnaire). A matched control group (n=24) of healthy individuals was selected for QoL comparison. Analysis between groups demonstrated that all patients with N-TOS-like symptoms have a lower QoL than healthy controls (p=0.001 resp. p≤0.000). No difference was found between conservatively and surgically treated patients (p=0.26). EQ-5D response rate was 83%. Of the 24 surgically treated patients, 15 would choose surgery again in a similar situation, although 4 of them did not benefit in terms of symptom reduction. Symptom relief and VAS pain scores in the conservatively and surgically treated patients did not show significant differences (p=0.95 resp. p=0.40).

Conclusions: All patients with N-TOS have a significantly decreased QoL compared with healthy individuals, regardless of the type of therapy they receive. In this small study, surgical decompression failed to improve QoL in patients with N-TOS to the level measured in the healthy control group, despite symptom reduction consistent with previous reports. Variables significantly associated with outcome were duration of symptoms and localization. From a QoL perspective, the benefit of decompressive surgery is questionable. Improving patient selection seems imperative in order to achieve better results in our surgically treated patients.

Chapter 3 focuses on the long-term results of three different strategies for treatment of patients with primary (spontaneous or effort related)
subclavian vein thrombosis (PSVT) in terms of residual symptoms/ post-thrombotic syndrome and QoL.
Forty-five consecutive patients were included in this case-control study. They had received either oral anticoagulant therapy only (n=14, group 1); thrombolysis followed by anticoagulant therapy (n=14, group 2) or thrombolysis, transaxillary first rib resection and anticoagulant therapy (n=17, group 3). End points were persisting symptoms and quality of life (Euroqol, cross-sectional assessment) at the end of follow up. Patients in group 2 and 3 experienced significantly less pain, swelling and fatigue in the afflicted limb at 6 weeks. There was no difference in pain (p=0.90), swelling (p=0.58), fatigue (p=0.61), functional impairment (p=0.61), recurrence (p=0.10) or QoL (P=0.25) between groups at the end of follow up (mean follow up 57 months (range 2-176, SD±46). Treatment strategy was not predictive of QoL (P=0.91, ANOVA). No differences in long-term symptoms or QoL between patients with successful and unsuccessful thrombolysis was present.

**Conclusions:** Thrombolysis with or without first rib resection does not appear to contribute to lasting symptom reduction and improvement of QoL in this study. The effect of thrombolysis may be limited to short term symptom relief. Transaxillary first rib resection was not associated with improved late outcome (symptoms, QoL) and did not reduce recurrence rate.

The applicability of contrast enhanced magnetic resonance angiography (ce-MRA) as a first stage imaging tool for individual treatment planning in patients with lower extremity arterial occlusive disease was studied in **Chapter 4**.

128 consecutive patients (182 extremities) between August, 2003 and June, 2004, with clinical manifestations of lower limb ischemia treatment was planned based on clinical assessment, ankle/brachial pressure index measurements combined with ce-MRA. Additional duplex ultrasononography (DUS) or digital subtraction angiography (DSA) was done when necessary.
Ce-MRA findings were compared with findings during open surgical, endovascular or combined procedures. In 28 extremities (15%) ce-MRA was found inconclusive and additional imaging was performed. In the remaining patients (85%) treatment was initiated as planned. However, in 19 (11%) the treatment plan was altered. In 7 of them, procedural findings did not correspond with those at the time of ce-MRA.

**Conclusions:** We conclude that in the majority of patients treatment can be planned based on ce-MRA images, although sometimes additional DUS or DSA may be required.

In **Chapter 5** we compare cost-utility of treatment strategies using either contrast enhanced magnetic resonance angiography (MRA) or intra-arterial digital subtraction angiography (DSA) as the principal imaging tool, related to quality of life (QoL), in patients with peripheral arterial occlusive disease (PAOD). In a prospective subgroup analysis of patients randomized between MRA and DSA (n=79), quality of life (QoL) measurements (SF-36) were obtained at randomization and at 4 months follow-up. Cost-effectiveness from hospital perspective was subsequently compared between groups and the difference in gained or lost QoL per Euro spent assessed using bootstrap analysis. No difference in quality of life was found. A treatment trajectory employing MRA as the principal imaging modality was almost 20 % cheaper, leading to a better cost-utility ratio in favor of MRA.

**Conclusion:** A treatment plan for peripheral arterial occlusive disease employing MRA as the principal imaging modality yields a better cost/QoL ratio.

The aim of the study presented in **Chapter 6** was to assess intraoperative transit-time volume flow measurements (VFM) as a tool for intraoperative evaluation of lower extremity arterial bypass grafts and to predict their patency. For this purpose, we analyzed 273 consecutive patients who had
an infrainguinal bypass procedure using greater saphenous vein from 1998 until 2008. In 103 of them the intraoperative VFM was performed. Patency and revision rates were compared between those with and without intraoperative VFM. Primary patency at 1 and 2 years was 75 and 67%, respectively, in patients receiving intraoperative VFM versus 72 and 69 % in those not without VFM (P=0.79). In the VFM-group, 12% had an immediate revision versus 6% without VFM (P=0.06). In the VFM-group, 4% underwent revision to salvage the bypass within the first postoperative 30 days versus 6% without VFM (P=0.32). Patency was not associated with the use of VFM. ROC- curve was significant for occlusion at 30 days postoperatively, but with a low predictive value (P=0.019, area under the curve; 0.648)

**Conclusions:** VFM may be helpful in selecting bypasses requiring immediate revision in order to prevent postoperative occlusion. The use of VFM was not significantly associated with patency.

In **Chapter 7** we aimed to determine the influence of patient and surgery related risk factors and antibiotic prophylaxis on prosthetic graft infection in patients undergoing arterial reconstructions in the groin area. In a cohort of 202 consecutive patients, we performed a case-control analysis comparing two groups of patients: with or without graft infection (GI), considering baseline characteristics, risk factors, the use of antibiotic prophylactics and , as a major end point, occurrence of graft infection with or without graft explantation . Multivariate analysis indicated that early revision surgery was independently associated with the occurrence of graft infection (p=0.002, OR 23.0, 95%CI 3.25-163.0), whereas the use of rifampicin-bonded grafts was associated with the absence of graft infection (p=0.002, OR 0.02, 95%CI 0.002-0.224).

**Conclusion:** Reduction of graft infections and the need for subsequent graft explantation can be achieved with the use of rifampicin-soaked grafts.
In Chapter 8 we studied the late quality of life and mobility after prosthetic femoropopliteal bypass grafting. Consecutive patients with claudication, ischemic rest pain or gangrene receiving above knee prosthetic bypass grafting between December, 1997 and January, 2003 were included in this observational study. Data used were recorded in a prospectively collected database of patients receiving Dacron and PTFE supragenicular bypasses for lower limb ischemia. Primary outcomes were quality of life and mobility, secondary outcomes were patency and patient survival. Quality of life was measured with the EuroQol questionnaire. Mobility was assessed with the Walking Impairment Questionnaire (WIQ). One hundred and forty patients were treated during the study period. Sixty nine (50%) died during follow up, leaving 71 survivors who were asked to complete the EQ-5D/EQ-VAS and WIQ questionnaires (response rate 89%). None of the primary outcome parameters (WIQ, EQ-5D, EQ-VAS) were affected by primary bypass occlusion (P=0.34, P=0.44 and P=0.27, respectively) or long-term patency (P=0.07, P=0.54 and P=0.36, respectively). Male sex was significantly associated with a better outcome on all primary outcome parameters. Patients with Dacron versus PTFE grafts had WIQ scores of 0.49 and 0.26, respectively (P=0.01). EQ-5D scores of patients with Dacron and PTFE were 0.576 and 0.409 (P= 0.08) and EQ-VAS scores were 61 and 54, respectively (P=0.95). Graft type was not independently associated with occlusion but run off was. Five- and ten-year patient survival rates were 58% and 51%, respectively.

Conclusions: In this study, long-term quality of life and mobility appear not to be associated with bypass patency, as assessed in a single late follow up. Revision of bypasses did not contribute to long-term quality of life and walking ability. Therefore, the necessity of graft surveillance and subsequent revision and/or thrombectomy in case of synthetic bypass failure in absence of critical limb ischemia appears to be questionable.

In Chapter 9 we reviewed the literature to investigate the effect of revascularisation (bypass surgery, angioplasty) and primary amputation on
health related quality of life (QoL) in patients with critical limb ischemia. A systematic review of the literature (1985-2012) was performed by two independent investigators to identify articles in the English literature investigating health related QoL in regard to CLI. Three observational studies were identified describing a comparison between primary amputation and revascularisation and their effects on QoL in patients with CLI. Due to the impossibility to combine outcome parameters data pooling was omitted and a separate analysis of each article presented.

**Conclusions:** Patients suffering from CLI have poor health prospects and life expectancy, irrespective of what treatment is received. Randomized trials on health-related QoL after revascularisation versus primary amputation are missing. Also, the available observational studies do not allow sound conclusions, due to small numbers and methodological imperfections. Therefore, no recommendations to either therapy in patients with CLI can be made, with respect to an anticipated benefit in QoL.

In **Chapter 10** we investigate the use of aluminium stump wrapping in patients suffering from phantom pain after lower limb amputation. Phantom pain is a painful sensation perceived in the missing limb after amputation, of which the underlying mechanism remains unclear. So far, only opioid analgetics have been proven to be effective in prospective studies. Anecdotally, phantom pain patients employ self-help measures, sometimes including “wrapping-up” or rubbing their stump with aluminium foil for relief of phantom pain. We hypothesized that wrapping an amputation stump with aluminium foil perioperatively will prevent phantom pain in the postoperative period. From September 2007 to September 2009, 32 consecutive patients were included in a cross-over double-blind randomized clinical trial. Perioperative fitting of an aluminium stump bandage was compared with a placebo paper foil. Scores were noted daily in a variable diary. The observation period was 2 weeks: first week double blinded, second week change of bandage: aluminum to placebo or
vice versa. A visual analogue scale (VAS) score was used as primary research variable. Secondary variables were use of analgetics, VAS measure of wound pain and wound infections. A period effect (p=0.84) and treatment-period interaction (p=0.79) were not present. There was no significant difference (mean difference 0.42) between both treatments in VAS pain scores (95% CI -2.56–1.81, p=0.71). VAS measurements of wound pain showed no significant difference (95% CI -2.32–1.66, p=0.72). Also the other secondary endpoints did not differ. For a variety of reasons, only 20 of the original 32 patients included in this study could be analysed. **Conclusion:** Patients receiving an aluminum foil stump wrapping do not experience less phantom pain as compared with a placebo.