CHAPTER I

Chapter I describes the outline and rationale of this thesis.

CHAPTER II

- ***Background***
  The main goal of performing a vascular anastomosis is to achieve maximal patency rates. An important factor to achieve that goal is to minimise damage to the vessel walls. Sutures inevitably induce vascular wall damage, which influences the healing of the anastomosis. Over time, several alternatives to sutures have become available. This chapter reviews these non-suture techniques exactly one century after Carrel's pioneering work on the vascular anastomosis.

- ***Materials and methods***
  A Medline literature search was performed to locate English, German and French language articles pertinent to non-suture methods of vascular anastomosis. Manual cross-referencing was also performed and many historical articles were included.

- ***Results and conclusion***
  The non-suture techniques can be categorised into five groups based upon the materials used: rings, clips, adhesives, stents and laser welding. With all these techniques a faster and less traumatic anastomosis can be made compared with sutures. However, each device is associated with technique-related complications. As a consequence, suturing continues to be the standard approach. The disadvantages of the non-suture techniques include: rigidity and a non-compliant anastomosis with rings; toxicity, leakage, and aneurysm formation with adhesives; early occlusion with stents; costs, reduced strength in larger-sized vessels, and demand for surgical skills with laser welding. Further refinement will be essential before widespread adoption of these techniques can be reached. Clips, however, have fewer disadvantages. They can be considered promising in view of the growing number of publications in the last five years reporting on their successful use for vascular anastomoses. Long-term evaluations are required to determine their value compared to conventional suturing and to assess for which kind of vascular procedures they are suited best.

CHAPTER III

- ***Background***
  Due to the development of less invasive surgical techniques there is an increasing demand for vascular anastomosing techniques that require less exposure of the operating field. This chapter reviews the most important representatives of mechanical clipping and stapling devices for vascular anastomosing described over the last five decades.

- ***Materials and methods***
  This report is organized in two parts: (1) the history of clipping and stapling devices, and, (2) development of the VCS clips. A Medline literature search was conducted and publications on the use of staples and/or clips for the creation of vascular anastomoses identified with extensive cross-referencing.

- ***Results***
  The first literature description of a mechanical vascular stapling device was by Gudov in 1950. This and other reports from the Soviet Union stimulated brisk, competitive development of vascular anastomotic devices in Europe, North America, and Japan. Fasteners included staples, penetrating pin-rings, or toothed stainless steel clips, none of which gained acceptance because of their complexity and inability to facilitate end-to-side anastomoses. A more convenient and less traumatic anastomotic system (VCS clip applier system®) was introduced into clinical practice in 1995. This system is easy to use and it differs from staples in that it is non-penetrating. It is marketed worldwide as of 1997.

- ***Conclusions***
  A steady evolution of mechanical vascular anastomotic devices has sought to eliminate the technical and biological disadvantages of conventional suturing. Though the conventional hand sewn, overcast non-absorbable suture remains the 'gold' standard, newer techniques such as the non-penetrating arcuate legged VCS clips are gaining acceptance as a useful addition to the vascular surgeons' armamentarium.

■ CHAPTER IV

- ***Background***
  In the search for better anastomosing techniques, an improved vascular stapler device (VCS clip applier system®) has been introduced. The system uses non-penetrating clips to approximate everted vessel walls. The objective of this study was to determine the effects of non-penetrating vascular clips on endothelial wound healing.

- ***Materials and methods***
  Aortic end-to-end anastomoses were performed in male Wistar rats. A comparison was made between clipped (n = 12) and conventional hand-sewn (n = 6) anastomoses. Patency rates were verified at different time intervals (after one, four, and eight weeks), after which the anastomotic sites were removed. Morphological evaluation was carried out using scanning electron microscopy.

- ***Results***
  All rats survived the procedure. Closure with clips took less time than closure with conventional sutures, with decreasing aortic clamping times for the clipped procedures during the course of the experiments. Patency rates were 100 per cent

in both the clipped and sutured groups. Microscopic examination showed favorable endothelial healing at the clipped anastomotic sites, with less inflammatory reaction at one week, and a more complete endothelial regeneration at four and eight weeks follow-up, as compared with the sutured anastomoses.

- ***Conclusions***
  The clip applier holds the promise of a useful device in anastomosing small caliber vessels, since clip closure takes less time than suturing, while patency rates are identical, and morphological results are favorable. Training is mandatory to obtain technical skills and to achieve optimal results.

■ CHAPTER V

- ***Background***
  Vascular repair with sutures is associated with disruption of the endothelial lining and subsequent thrombus formation on the intraluminal lesions. This experimental study was designed to determine whether the use of non-penetrating clips improves endothelial preservation.

- ***Materials and methods***
  In ten female pigs, 25-mm arteriotomies were made in both carotid arteries. The arteriotomies were repaired with jugular vein patches. On the left side, the repair was done with 1.4-mm titanium clips, and on the right side with two running 6/0 polypropylene sutures. Next, the aorta was divided and subsequently repaired with 2-mm clips in five of these pigs, and with two running 5/0 polypropylene sutures in the remaining five pigs. Endothelial function was studied at the anastomotic site of the carotid arteries by determination of endothelium-dependent and -independent relaxatory responses. Histomorphological studies included morphometric examination of the carotid arteries and inspection of the aortic endothelium using scanning electron microscopy.

- ***Results***
  Maximal endothelium-dependent relaxation to adenosine 5'-diphosphate was better in clipped than in sutured carotid arteries ($P < 0.05$), while there was no difference in maximal endothelium-independent relaxation to sodium nitrite. This result in clipped carotid arteries was not accompanied by less intimal hyperplasia. Screening of the aortic anastomotic line showed better preservation of endothelial architecture after clip anastomosis. Mean cross-clamp time for carotid patch repair was significantly less when using clips than with sutures.

- ***Conclusion***
  The use of non-penetrating clips for vascular anastomoses preserves endothelial function and structural integrity better than running sutures, although the degree of intimal hyperplasia is similar.

■ CHAPTER VI

- ***Background***
  To date, the gold standard for performing a microvascular anastomosis has been the penetrating suture with attached needle. During the last two decades the advancement of non-penetrating techniques included the Unilink system® for end-to-end anastomoses, and the VCS clip applier system® for both end-to-end and end-to-side anastomoses. The aim of the study was to compare the results of different techniques used to create microvascular anastomoses in free-flap reconstructions.

- ***Materials and methods***
  Between January 1995 and October 1999 we performed 474 microvascular anastomoses in 216 consecutive free-tissue transfers. The anastomosis techniques included manual sutures (42 per cent), Unilink rings (34 per cent) and VCS clips (24 per cent). Seven combined sutured-clipped anastomoses were excluded from further analysis.

- ***Results***
  The mean anastomotic time when rings were applied was significantly shorter than when using clips ($P < 0.0001$) or sutures ($P < 0.0001$). Venous anastomoses using clips took less time than those using sutures ($P < 0.05$). There were 19 anastomotic failures, all of which lead to early flap failure. Ten flaps were salvaged by early reoperation; nine flaps were lost. Three more flaps were lost as a result of other causes, bringing the flap survival rate down to 94.4 per cent. Early flap failure was caused by arterial anastomotic failure in eight cases; all of them were sutured (these represented 5 per cent of all arterial anastomoses with sutures). None of the clipped arterial anastomoses failed. Early flap failure was caused by failure of the venous anastomosis in 11 patients. Three of these anastomoses were sutured (representing 6 per cent of all venous anastomoses with sutures), 7 were anastomosed with rings (representing 5 per cent of all venous anastomoses with rings), and one was clipped (representing 2 per cent of all venous anastomoses with clips).

- ***Conclusion***
  Both the VCS clip applier system® and the Unilink system® allow a fast microvascular anastomosis without intraluminal penetration. The patency rate of clipped vessels is at least as good as the patency rates of vessels anastomosed using sutures or rings.

■ CHAPTER VII

- ***Background***
  Despite several modifications to the original design, patency rates of radiocephalic arteriovenous fistulas have not essentially improved since their first report in 1966. Non-penetrating clips, a relatively new vascular anastomosing technique, may

favourably influence the outcome of such fistulas. The effects of these clips were studied.

- ***Materials and methods***
  Between January 2000 and August 2003, 107 primary radiocephalic fistulas were constructed in 98 patients. All vascular anastomoses were divided randomly to be performed with sutures (n = 56) or clips (n = 51).

- ***Results***
  Six-months primary patency was 60.7 per cent with sutures and 68.6 per cent with clips (P = 0.393). The mean primary patency was 315(s.d. 306) and 285(s.d. 285) days for clipped and sutured fistulas, respectively. The mean primary assisted patency was 354(s.d. 330) and 312(s.d. 295) days for clipped and sutured fistulas, respectively. Although there were trends for better primary and primary assisted patencies of clipped fistulas, the differences were not statistically significant. With regard to secondary patency, clipped fistulas did considerably better than sutured constructs (log rank test, P = 0.009). The mean secondary patency was 435(s.d. 376) and 344(s.d. 316) days for clipped and sutured fistulas, respectively. There were no significant differences in flow characteristics, number of revisions, or other morbidity.

- ***Conclusion***
  This prospective randomized trial provides further evidence that the use of vascular clips rather than conventional running sutures may improve the patency rate of radiocephalic arteriovenous fistulas for haemodialysis. The beneficial effects can be explained by the interrupted and non-penetrating characteristics of the clip technique.

■ CHAPTER VIII

- ***Background***
  A new sutureless technique has been introduced clinically to facilitate the process of vascular reconstruction and improve patency. The VCS (Vessel Closure System®) is non-penetrating, creates an elastomeric everted anastomosis, and is easily and reproducibly applied. The objective of this report is to review the published world experience that has accrued regarding these clips with attention to the assets, liabilities, and pitfalls associated with the new technology.

- ***Materials and methods***
  Medline search and manual cross-referencing were performed, after which 62 original articles were identified on the use of VCS clips for vascular anastomoses.

- ***Conclusions***
  Advantages of the clips compared to sutures include the technical ease of application, the reduced anastomotic time, the superior haemodynamics and the

improved healing pattern of the anastomosis. Disadvantages include the potential problems in atherosclerotic vessels and initial costs. The best clinical results have been achieved in microvascular repair, as well as with vascular access and transplantation surgery. In summary, the VCS clip technology has become an accepted vascular anastomosing technique, which in future could lead to the use of clips as a standard approach and the use of sutures only in case of severe atherosclerosis and other circumstances in which vessel edges are difficult to evert.