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Detecting disease and designing treatment. Duplex and the diagnosis of diseased leg vessels

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Abstract In hospital Z, a Dutch university hospital, a new protocol for the diagnosis of vascular patients has been introduced. It requires vascular surgeons to rely sometimes on a non-invasive diagnostic technique, called duplex, in place of a previously used invasive one, called angiography. This article is a multivocal account of the protocol's introduction. It focuses on the intricate ways in which two aspects of diagnosis, the detection of disease and the design of treatment, relate.

Key words: diagnosis, decision, technology, disease, treatment, protocol

Introduction

Is diagnosis a matter of detecting disease or designing treatment? Can these two activities be separated, or do they form a single whole? In this article we explore these questions by looking at an example. The example is the use of duplex, a non-invasive, ultrasound technique, in the assessment of diseased blood vessels. The site of our investigation is a Dutch university hospital and our focus in on the way duplex is used to assess the arteries that supply blood to the legs. The legs of human bodies.

'Our' focus is composite, as is this writing. Sometimes you'll hear one voice in this text, and sometimes another. You may hear them singing the same tune, like an alto and a tenor. You may also hear different tunes, in counterpoint. And then again, you may detect dissonance, though only rarely so – given that this article is the joint product of an empirical philosopher and a surgeon.

An empirical philosopher is someone who engages in empirical studies

in order to come out of them with theoretical findings. She draws upon and mingles with history, anthropology, sociology and philosophy without bothering about disciplinary boundaries (Foucault 1963, Latour 1984). And a surgeon? Just one? But surgeons are never found alone. They operate in groups (Hirschauer 1991, Bosk 1979). An arrangement that we disrupt here. It is like this. Parts of this text were originally written for a surgical journal. To mark them off, we put these in italics. But they are not quotations – for we claim their authorship. This seems to be fair because one of us – the surgeon – actually wrote them. But then: in their original context they are signed by six people. The five that are omitted find themselves relegated to a mere thank you note. This text, after all, is published in a social science journal. And going from one genre to another isn't simply a matter of adding words. It implies larger changes. Even the nature of writing and authoring alter.

Ultrasonographic duplex scanning has become a valuable diagnostic technique in detecting and grading stenoses and occlusions in the aortoiliac and femoropopliteal arteries. However, the question remains as to whether a treatment strategy can be designed without diagnostic angiography.

The question asked, suggests that diagnostic techniques are expected to support two tasks: detecting and grading diseases on the one hand, and designing treatment on the other. It also suggests that there is a difference between these tasks. What kind of difference is this? That is our question.

The lines in italics include additional important words. 'Stenoses' and 'occlusions' are diseases that need to be assessed. The first is the partial loss of vessel lumen, and the second an entire closure of the vessel. 'Aortoiliac' and 'femoropopliteal' arteries are, respectively, the vessels leading to and in the upper leg. And 'angiography' is a technique for taking X-ray pictures of the inside of arteries that have been rendered opaque by a dye. Until very recently angiography was the most important technique used in the diagnosis of patients with 'lower limb arterial disease'. In many places it still is. But in others, like hospital Z, duplex is coming on.

Diagnosis is often presented as if it were synonymous with the detection of disease: with answering the question 'what is the matter?' Then, once this is established and diagnosis is complete, a form of therapy can be chosen, preferably from a range of options.[2] Recently, however, it has been argued that doctors ask themselves 'what to do?' from the very moment they first meet a patient. The detection of disease and the design of treatment cannot be separated. Instead, they form a single process, sometimes called the 'work up' of patients or the 'construction of a medical disposal'.[3]

If, as the first of these approaches suggests, diagnosis equals the detection of disease, it comes as no surprise that the diagnostic tool duplex

detects and grades stenoses and occlusions. But a diagnostic technique like duplex would not be expected to have a role in the design of treatment if design were to follow diagnosis. The second approach, which argues that the design of therapy is what a diagnostic procedure is all about, would expect duplex to be involved in that. That latter approach, however, cannot make much sense of the fact that there may be a moment when duplex is already able to 'detect and grade' disease while it is still uncertain whether 'a treatment strategy can be designed' in the absence of angiography. Thus both approaches fail. It turns out that the detection of disease and the design of treatment are neither entirely different, nor simply the same.

In this article we argue that diagnosis is a composite activity. We explore the complicated relation between its composite parts empirically, and find that the detection of disease and the design of therapy are simultaneously separable and intertwined; that at one moment they divide, while at another they join together again; that at one location they are contrasted while they are interdependent at another. We suggest that they are not so much phases in, as aspects of, a diagnosis. Having said this, we also need to say that other examples would yield slightly different pictures. For the shapes taken by the relations between the various components of diagnosis can only be understood if we analyse the intricacies of specific diagnostic procedures, as well as the clinical and research practices of which they form a part.

What is the relevance of this argument? First, there is the matter of epistemology and the social character of knowledge. If detection and design were separable, then the first phase, detection, might be a matter of finding facts, pure and simple, while pragmatic considerations (social factors, values, culture, you name it) would enter the scene only in the second phase, the design of treatment. It is precisely to undermine this assumption that those who hold detection and design to be inseparable, stress the impact of practicalities (social factors, values, culture) from the moment of the patient's first encounter with medicine.

We agree with that. Our empirical approach to the relation between the detection of disease and the design of treatment is certainly not intended to show that there is a way to isolate facts from social factors, values or culture. After all, practicalities are involved in what happens in every corner of the hospital, even in its research labs (Latour and Woolgar 1979). But it is not only the need to design a therapy that is of relevance in understanding diagnostic procedures. The list of relevant variables is long, it includes money, time, professional hierarchies, but also such things as the exact effects of dye, X-ray, needles, or ultrasound on the vessels, the kidneys, the DNA – let us say: the bodies – of patients. How to get a grasp on such matters? Our object is to contribute to the unraveling of the technicalities of medicine without attributing their shapes either to the body and its diseases or to social circumstances. We would

like to avoid having to choose between taking what medicine tells about the body as a series of unquestionable facts on the one hand and on the other bracketing the flesh. Therefore we try to study medical practice and the body it treats without distinguishing between them. We try to tell what disease is by unraveling the way it operates in practice (See also Law and Mol 1995; Mol forthcoming).

But our argument is also directly relevant to medicine. For if sociologists, anthropologists and philosophers argue that in current medicine the detection of disease is a step towards the design of treatment, many physicians worry that too often this is not the case. They worry as they watch their colleagues using diagnostic techniques to little purpose. Why make a duplex or an angiography if this does not help in the treatment of the patient? This might, perhaps, be justified under research conditions, but not in routine practice. For even if there are some cases where a diagnosis is all medicine has to offer, and thus may be a good in itself, the level of detail required in such cases is limited. Diagnostic procedures that give more and more detail but do not have an effect on therapy, may be an unnecessary burden, or even risk, for the patient. They moreover waste scarce resources. Thus, to be rigorous: diagnostic techniques should be appropriate to what is done with their results. They should not be overdone. Fine tuning is required. Such fine tuning might be facilitated by a more detailed insight into the difference between, and the interdependence of, the detection of disease and the design of treatment.

Material and method

This article reports on two studies which explored the use of duplex as a diagnostic technique in different ways. The first established a protocol for the use of duplex in a Dutch university hospital and assembled data for all the patients diagnosed according to this protocol over a period of several months. *Patients with intermittent claudication, rest pain or ischaemic ulceration of the lower limb who were eligible for invasive treatment were studied. If treatment was considered necessary, a duplex scan was performed instead of diagnostic angiography. The surgeon made a therapeutic decision based on clinical assessment and information obtained from the duplex scan. If it was felt that duplex scanning gave insufficient information, diagnostic angiography was performed. A group of 112 consecutive patients were studied prospectively; 12 patients were excluded for logistical reasons. The 100 remaining patients (intermittent claudication in 69, rest pain in 16, ischaemic ulceration in 15) were evaluated.*

The second study consisted of ethnographic observation over several years in the same hospital of surgeons, internists, technologists, radiologists and the machinery involved in the diagnosis of vascular patients. The observations of people and machines were supplemented by the ana-

lysis of texts in the relevant research literature. Moreover, interviews were held with sixteen patients who had undergone invasive treatment of their leg vessels.[4] The ongoing work for study number one was among the objectives of study number two. The material gathered throughout that study (stories based on observations and quotes from people, letters, files and articles) is presented here in indented passages. The professionals concerned are referred to as 'he' and 'him'. This is a fairly accurate description of a matter of fact.

In order to analyse the content of medicine, the empirical philosopher who engaged herself in study number two did not follow doctors around in an attempt to uncover their style of thinking and working (Hahn 1985). Nor did she explore what is transmitted in teaching situations and how this is accomplished (Atkinson, 1988). The object of study number two was not people and how they conceive the world, but techniques and the worlds they contain and imply. Thus study number two didn't take reality as waiting for people to come and observe it, nor take it to be the outcome of a process of social construction. Instead it took reality to be an interactive part of practices. Something performed (Hacking 1983, Butler, 1993, Mol and Berg 1994).

In mixing the results of these two studies, this article follows Bruno Latour's advice to sociologists of science to cross-over. Climbing onto the shoulders of Michael Lynch (who stated that there is a lot of sociology contained in the technical work of scientists) Latour writes: 'One possible formulation of Lynch's marvellous insight is that we strive for *equality* with the discipline we study. Instead of explaining it, we want to *cross-over* it – as in genetic cross-over We want to learn our sociology from the scientists, and we want to teach the scientists their science from our sociology' (Latour 1988:175, referring to Lynch 1985, passim. Italics in original).

Some filters first

The protocol said that the patients to be studied had *intermittent claudication, rest pain or ischaemic ulceration of the lower limb.*

When the vascular surgeons interviewed them in the consulting room, these patients told stories about walking for short distances and then stopping to rest: *intermittent claudication.* Or they said they hardly walked at all but their legs still hurt: *rest pain.* Or inspection of the skin of their feet or lower legs revealed that they had done with too little oxygen for quite a while: wounds did not heal any more, but stayed open: *ischaemic ulceration.*

So before a patient is included in the protocol study a lot has already happened. He or she has taken the initiative to go to a general practitioner – filter number one. The general practitioner has judged the

complaints to be sufficiently serious to refer the patient to a specialist – filter number two. And the surgeon has interviewed the patient and done a physical examination to be sure about the vascular origin of the complaints – filter number three.

If the patient tells about complaints that only start upon resting, or that vary enormously from one day to another, a physical examination is hardly necessary. The problems have some other cause, not a vascular one. Even so all patients who enter the surgeon's consulting room are not just questioned, but also physically examined. The pulse of their leg vessels is felt, as is the warmth of their feet and the texture of their skin. In this way, it is determined whether patients have *intermittent claudication, rest pain or ischaemic ulceration of the lower limb.*

> Quote from a letter sent by a surgeon to a general practitioner:
> 'Interview: There was an aggravating intermittent claudication with a walking distance of 250 metres with pain in the left calf. There was no pain at rest. The cardiac history was clean except for hypertension. Physical examination: in the left leg the femoral artery was palpable. Distal from this there was no pulse. Capillary refill in the left foot was slower than in the right.'

Having vasculair disease, however, is not enough to be enrolled in the study. For this, it is required to be *eligible for invasive treatment.* To determine who is or who isn't eligible for invasive treatment vascular surgeons want more information than they can easily acquire in the consulting room. So patients are sent to the vascular laboratory, where their arm and ankle pressures are measured. Then they walk on a treadmill for a while and the measurement is repeated. Numbers are noted on a form. This form invites the technologist to divide the blood pressure measured at the ankle by that measured at the arm. The product is called the ankle/arm index.

A bad ankle/arm index proves that the right story is indeed about wrong blood vessels. If the complaints are serious and the ankle/arm index is bad too, invasive treatment is considered. However, when there are only mild complaints, a poor showing on the index does not indicate a need to cut. However poor the index, as long as there is no rest pain or ulceration, the walking distance that a patient may gain from an intervention has to be balanced against other factors: the risk that treatment will bring about deterioration – or even death; the burdens of a hospital admission; the patient's 'motivation'.

> The man sits on a chair facing the surgeon. He is 84. He lives in a home. 'Listen, Mr. Winters', the doctor says, 'there's indeed something wrong with your blood vessels. That is what we've found out by this examination you've had. I've got the numbers here. They're not very

bad, but they're bad. So. Now we might be able to do something about it. I can't promise you. But it could be. Either with a small balloon, that is blown inside your vessel, or with an operation. To find that out, we need more information. So you'd need another examination. But we're only going to do that if you would want treatment. So maybe you could think about that, about whether you want that.'[5]

A patient in an interview, a few days after his operation: 'So he said: what do you want? And I said: whatever you think is best, doctor. Yes, it was nice, it was. They let you make your own decisions.'

Angiography and duplex

Patients *eligible for invasive treatment* can be treated in several invasive ways. There is PTA (percutaneous transluminal angioplasty) in which radiologists blow a balloon inside a stenotic vessel. And there are also several possible surgical interventions. Somehow patients have to be distributed between treatments. The protocol study was designed to investigate how well the diagnostic technique duplex measures up to this task. *This prospective study evaluated the impact of duplex scanning on therapeutic decision making.* Evaluating how well duplex allows surgeons to differentiate between patients who will profit from PTA and those who need surgical treatment is important because duplex is a relatively new technique. It is not well established. Angiography is the established technique for deciding how to intervene in the case of blood vessels.

Biplanar angiography is still the 'gold standard' in detecting and grading lesions in patients with atherosclerotic occlusive disease. Angiography provides information on the location and extent of lesions, and serves more or less as a 'roadmap' for the surgeon or radiologist. Therefore in usual clinical practice a diagnostic Seldinger angiography is carried out before therapeutic intervention.

Let us have a look at how angiography is done. In the room where the X-rays are taken everyone wears a heavy lead apron, apart from the patient who lies on an examination table. Several people (a radiologist, some residents) dressed in sterile green, are grouped around the patient's groin. They make a small cut in the skin, push a large hollow needle through it, find the artery, open it. Some blood squirts out of the vessel. An assistant, also dressed in green, wipes it off. One of the residents injects a small amount of dye which appears as a white shadow on the monitors hanging above the table. The inside of the vessel shows lumen, in two dimensions. Then another resident inserts a catheter – a plastic tube with a metal thread inside it – and pushes it 'up' inside the vessel. When the catheter is in position, the metal thread

is withdrawn. An automatic injector is attached to the remaining tube. Suddenly one of the doctors raises his voice and talks to the head of the patient. 'It's alright, Mr. Jansen, it went alright. The tube is in your vessel. Now we're going to the other room and you will feel your leg get warm. Don't worry about it. If it hurts, call us. Don't hesitate, we're near, we can hear you. Okay?' The drowsy patient nods. The doctors and assistant retreat. Behind the glass of the control room, they push some buttons. The dye injector operates and click, click, click, a row of X-ray pictures is shot. The assistant goes in again, removes the plates from the X-ray apparatus and takes them to the darkroom to be developed. The white shadows of the dye will be visible among the white shadows of the bones. Wherever the vessel diameter gets smaller, so, too, will the vessel's shadow. Such a location is called a stenosis. And where the lumen disappears altogether, there may be an occlusion.

A patient in interview: 'It isn't too bad. It doesn't really hurt. They make a small cut in your groin and inject a dye. It feels warm, you get all hot inside. Then there is a rail above your head with a camera. And they move the camera on the rail and quietly take their pictures. Bit by bit. And this radiologist said: 'Would you like to see it?' And I said I did. It was interesting. And it was easy to see. There was this branch going off, all clogged up.

Another patient: 'It takes quite a while, it does. Lying on your back all the time. The angio takes ages to make and afterwards you have to lie flat, really completely flat, for eight hours. Eight! So all in all you're lying in the same position for like ten hours. That's hard. It's almost impossible'.

The angiographic pictures are evaluated by radiologists who then dictate a description that is typed by a secretary and put into the patient's file. Since the pictures are stored the evaluation can always be called into question. Decisions about how to treat can be made with the pictures put on the light box, radiologists and surgeons pointing their fingers to the stenosis under suspicion.

The decision making meeting. A surgeon walks up to the light box on which three pictures of the left leg of Mrs. Tzomar are firmly clasped. 'What did you make of that?' he says, addressing the radiologist, '70 per cent, did you say 70 per cent? It doesn't look like 70 per cent to me'. The interpretation of the radiologist is doubted by the surgeon. The talk then goes from the diameter reduction of the vessel, to the treatment required and back again. Others join in. Until either a consensus is reached or the chairman says to the surgeon responsible for Mrs. Tzomar's treatment: 'Well, alright then, it's clear some of us would go for another option. But it's your patient'.[6]

Interpretation has a place. And then, in the end, after a while, there is a decision. So there seems to be no reason even to consider another diagnostic technique. But there is. *This policy has several disadvantages, not least that angiography is an invasive procedure with the risk of complications and often the need for hospital admission.* Hospital admission costs a lot of money and means that another three days of someone's life will be spent as a patient. And another ten hours will be spent in 'supine position'. But the fact that once in a while something goes wrong is taken more seriously. The small wound made in the vessel wall doesn't close but goes on bleeding, leaving the patient with a bruised and painful groin. A vessel is ruptured. A vessel clogs up. A patient has an allergic reaction to the injected dye.

These are practical factors that legitimate the search for alternatives. Duplex, for instance. *Detailed information about the location and extent of a lesion in the aortoiliac and femoropopliteal arteries can also be obtained non-invasively by duplex ultrasonography.*

In the hospital where these studies were conducted duplex is done in a small room with no windows. Much of this room is taken up by a large apparatus with many control buttons. On top of it there are two small screens. A technician looks at the screens, now and then adjusting a button with his left hand. His right hand holds a probe, moving it over the skin of the lower belly and the leg of the patient who is lying on an examination table.

The probe emits ultrasound, a sound too high to be audible. But some gel between probe and skin is all that is required for this sound to reach the vessels. Once in a while the technician's right hand stops moving. The white shadows on the screen are arteries. A colour appears inside them, flashing in red and blue. This is flowing blood. Red is made to mean the blood is moving away from the probe, blue that is flowing towards it. A graph appears on the other screen. The curve peaks. And lowers. And peaks again. Like the colours in the image, it shows the difference between the ultrasound emitted by the probe and the ultrasound reflected by the flowing blood and received back again. The machine is also able to make this difference audible. 'Pshew, pshew, pshew.' Since the angle between the ultrasound wave and the vessel can be adjusted, the velocity of the blood flow can be calculated.

A patient in an interview: 'Yes, I know about duplex. They have this broad pen, well, a pen is smaller, so with this broad thing they go after all your vessels. And on their screen they can see the blood flowing. And if they think 'well, that looks kind of odd' then they push a button. And then they've got a picture. So that allows them to see what's the matter. Later on. Like: I didn't think that was good, what was it?'

> Another patient (whose vessels were so bad her leg was amputated in order to prevent the development of gangrene): 'This is a good hospital. They have very good modern apparatus, here, too. A few weeks ago, when I still had my leg, I had to go downstairs and they had this new apparatus, they were proud of it. For they said: 'Do you want to see it, too, Mrs Martens?' And I said "sure" and I saw those thick vessels and the smaller ones and it flashed all the time, the blood that came through. So it was open, then. It is clever, it is, what all they do, can see, do with those vessels.'[7]

The technician records pictures of a standard series of vessel parts, and of any flaw he finds. Disease that goes undetected is lost for ever. If the technician's interpretations do not accord with those of others, there is no possibility to talk about it. Or to even find it out. But when technician and duplex detect a stenosis, they record numbers on paper. Moreover, the technician later draws a picture of the locations and extensions of the stenoses and occlusions he has found with a pen on a preprinted form. Even surgeons who cannot read a duplex graph, can take in these drawings at a single glance. Since the technicalities behind them are quite complicated, few vascular surgeons are currently capable of negotiating duplex findings. But even if the interpretation of duplex outcomes tend to go unquestioned, their relevance remains open to doubt. 'Yeah, this looks kind of bad, this duplex. But remember we're not treating numbers. We're treating patients'.

Thus there is a new technique, duplex, available alongside the older one, angiography. Because the new technique is non-invasive, it has several advantages. Since the skin remains intact, and since so far no side effects have been reported for the doses of ultrasound used, duplex has no known complications. It entails no risk to patients. They don't have to be admitted to the hospital. All they need to do is come to the vascular laboratory, take off their skirt or trousers, lie on the examination table for an hour and a half, wipe the gel of their skin, dress, and go home. This makes it worthwhile to explore to what extent duplex might take over the role of angiography in the diagnosis of patients with bad leg vessels.

Correlations

The protocol study was designed to find out whether duplex can be used in the design of therapy. It starts with the knowledge that duplex can detect disease. It states without hesitation that *detailed information about the location and extent of a lesion in the aortoiliac and femoropopliteal arteries can also be obtained non-invasively by duplex ultrasonography.* Such statements require footnotes. A lot of work has gone before them. This work established that duplex is just as informative as angiography.

In other words: it showed that duplex is capable of detecting disease at the same times and places as angiography. Their outcomes correlate. As one of the footnoted articles observes:

> 'In line with previous reports, a good agreement between Duplex scanning and angiography was found' (Rosfors *et al.* 1993).

In correlation studies that evaluate therapies the two treatments to be compared are usually given to different patients, albeit of similar populations. In correlation studies that evaluate diagnostic tools two or more such tools are used to judge the condition of the same patients.

> 'The sensitivity, specificity, positive predictive value and negative predictive value of Duplex compared to arteriography are encouraging and superior to that of segmental lower extremity pressures and pulse volume recordings . . .' (Fletcher *et al.* 1990) (Arteriography is another word for angiography).

The ability of duplex to detect disease is encouraging. But what does that mean, what is 'good agreement'? When are the sensitivities, specificities and predictive values good enough, and when are they not? Let us look at some numbers.

> 'The accuracy [of the duplex] for the following decision steps as compared to arteriography is as follows: 1. normal versus abnormal, sensitivity 96 per cent, specificity 81 per cent; 2. greater or less than 50 per cent diameter reducing stenosis, sensitivity 87 per cent, specificity 94 per cent' (Jager *et al.* 1985).

Is that a lot? Is it enough? The article continues in an interesting way. The authors presented their angiographic pictures not just to one but to two radiologists. These were asked to judge them independently. One judgement was taken as the gold standard for the other: the two radiologists were correlated with each other.

> '. . . when one radiologist is compared with a second reader: 1. normal versus abnormal, sensitivity 98 per cent, specificity 68 per cent. 2. greater or less than 50 per cent diameter reducing stenosis, sensitivity 87 per cent, specificity 94 per cent' (Jager *et al.* 1985).

Duplex comes out strong. Its correlation with angiography, the gold standard against which it is measured, 'compares favourably' with the correlation between judgements of angiography by two different radiologists. So the correlation studies show that duplex is as good as angiography in detecting disease.

But which 'disease'? What is the object to be detected? The article asks how similar duplex and angiography are when it comes to differentiating between normal and abnormal; and between greater or less than 50 per cent reduction. The choice of these distinguishing criteria is not accidental for they are linked to what the article in question calls 'decision steps'. A normal vessel needs no treatment. And if the reduction in diameter is small, less than 50 per cent, the consequent loss of pressure isn't 'significant', which again implies there is no need of treatment.

> 'From a clinical standpoint, significant disease is often defined as that which produces more than 50 per cent diameter reduction' (Jager, *et al.* 1985).

So the reduction in diameter used for comparison is clinically significant. It is a threshold above which invasive treatment may be considered. The whole point of detecting disease, then, is to find out if there is a reason for invasive intervention. Detection leads on to design.

> 'In order to select patients for either direct arterial surgery or transluminal angioplasty, it is necessary both precisely to localize the areas of involvement and define the hemodynamic significance of such lesions' (Jager *et al.* 1985).

Diagnosis is about localising and defining the hemodynamic significance of lesions. It is done in order to 'select patients for direct surgery of transluminal angioplasty'. The quantitative readings of the new technique, duplex, are intended to respond to this double requirement. There are quite a number of possible parameters to be drawn from a duplex measurement. In each of them the attribution of meaning to duplex is a matter of aligning it to the results of angiography. Duplex outcomes are therefore expressed in terms of percentages of diameter reduction (Mol 1993).

> 'A 50–99 per cent diameter reduction is characterized by the loss of reverse flow with forward flow during the entire heart cycle (monophasic wave form), a marked increase in systolic peak velocity (more than 100 per cent) and extensive spectral broadening' (Jager *et al.* 1985).

In the hospital where we did our studies another duplex parameter is used. *If invasive treatment was considered necessary, a duplex-scan of the ipsilateral aortoiliac and femoropopliteal arteries, and the contralateral aortoiliac tract, was performed to determine the location and degree of diameter reduction of the lesions. . . . The criteria outlined by Legemate et al. were used to interpret the degree of diameter reduction (Table 1) (Legemate et al. 1991 a and b).*

In their articles Legemate *et al.* tell where their criteria come from. They have linked the duplex parameter 'peak systolic velocity' (PSV) in

several ways to the quantifications of angiography. A detailed discussion explains how for some arteries a PSV ratio of 2.0 is the best cut off level, while for others it is 2.5 or 3. These complications, however, never appear on the handout in the hospital's vascular laboratory. This merely says that: a PSV ratio smaller than 2.5 equals a diameter reduction of 0–49 per cent; a PSV ratio larger than or equal to 2.5 equals a diameter reduction of 50–99 per cent; and no doppler signal means occlusion.

The handout abbreviates an extensive correlation study to a single line. But correlation studies are designed to allow such abbreviations. Even if they differ in lots of ways (focusing on wave form or PSV ratio, comparing these to angiography one way or another) they try to find out whether a duplex apparatus can be made to generate information that is clinically relevant. That is: information that may help in the design of treatment. Thus the very habits of designing treatment are incorporated in the way in which duplex is read and parameters are drawn from it. The disease a duplex apparatus detects, is a disease to be treated. In this way habits in treatment design inform what will be detected as disease in the first place.

The Protocol

Quoting a correlation study or two, makes it possible to say that duplex scanning helps to obtain *detailed information about the anatomical site and severity of lesions without angiography, in almost every vascular bed of interest to the vascular surgeon.* Duplex detects disease, it gives the information vascular surgeons are interested in. *However, most surgeons and radiologists at present still consider diagnostic angiography mandatory before therapeutic intervention and duplex scanning is therefore used only as a complementary diagnostic technique.*

Duplex is used in a complementary manner. The question is whether or not this is sensible. Whether techniques should be piled on top of one another. More and more techniques. Or whether it might not be possible to use information from duplex to replace angiography for certain purposes. What can duplex accomplish in the process of designing treatment? *Although duplex scanning has become an accepted diagnostic technique, little is known about its role in therapeutic decision making and its potential to replace angiography.*

But how should one learn about the 'role' of duplex in therapeutic decision making and its 'potential' to replace angiography? The answer of the vascular surgeons in our hospital, was to engage in a study in which duplex was assigned a role in the design of treatment. And then to monitor its usage to see whether or not it was able to fulfill that role. *The aim of the present study was to determine in which patients with arterial occlusive disease of the lower limb it is possible to formulate a therapeutic plan based on non-invasive tests and to investigate the need for angiography.*

So the difference between the detection of disease and the design of treatment is the very reason for the protocol study. If the two were identical, there would be no need for a further study. Referring to the impressive correlation between the two techniques and the fact that duplex is cheaper and safer, it might have been simply decided that from now on angiography would be obsolete. But this is not what happens. Though duplex's ability to detect disease is as good as that of angiography, its potential to replace angiography in the design of treatment has yet to be established.

All the patients entering the study were to have complaints and an ankle/arm index serious enough to warrant invasive treatment. And to be willing to undergo this if the doctors would advise it. At this point the surgeons were to order a duplex measurement, in order to distinguish the patients into three therapeutic groups: conservative treatment; PTA (percutaneous transluminal angioplasty); and surgery. If duplex didn't give the surgeons enough information to make this distinction, then they were free to fall back on their old, trusted strategy and send a patient in for angiography. *Based on the results of non-invasive tests, conservative treatment was advised for 22 patients, PTA for 36 and operation for 32. In 10 patients it was not possible to determine a treatment strategy so angiography was subsequently carried out.*

Let us go through each of these groups. First, there are those whose duplex suggested conservative treatment. *Nineteen of the patients for whom conservative treatment was advised after duplex scanning had intermittent claudication.* Some of these patients seemed too well to treat invasively. The risks outweighed their chances of improving. In fact several of them shouldn't have had a duplex in the first place, for the study protocol said that duplex would only be used on patients 'eligible for invasive treatment'. But protocols are never followed rigidly (Berg 1995).

Among the nineteen selected for conservative treatment, there were also some patients whose complaints were severe, and whose duplex showed that their arteries were diseased. But they could not be improved surgically. *Two had rest pain and one ischaemic ulceration.* These are matters that usually warrant intervention. But not always. Age, or heart disease, or too severe a stenosis over too long a period: any of these may lead to a decision not to intervene. *There was no possibility of arterial reconstruction in the patient with ischaemic ulceration; he was suffering from dry gangrene so an expectant policy was advised.* If this patient doesn't die from a heart attack or a stroke first, at some point he is likely to have an amputation. If, that is, he won't be among those who prefer death from gangrene over their ongoing and aggravating suffering. *One of the two patients with rest pain was treated by a chemical sympathectomy, the other one became pain-free with medication.* The first of these treatments opens up the downstream vessels, the second merely eases the pain.

The detection of severe disease, then, doesn't mean that the patients concerned will have invasive treatment. For the design of a therapy doesn't simply demand the presence of disease but also the possibility of intervention. Sometimes the duplex – in combination with other sources of information – suggests that intervention is out of the question. In those cases the severity of the disease cannot be countered by any therapy, however aggressive. Because the patients concerned are likely to deteriorate, however, the surgeons sometimes hesitate to trust the duplex in these cases. *Angiography was performed in four of these 22 patients [for whom conservative treatment was advised]: the two patients with rest pain, the patient with ischaemic ulceration and one patient with intermittent claudication. None of these angiograms changed the treatment policy.* The hope was that angiography would suggest alternative approaches. That unlike duplex it would help to design a therapy. But it didn't. Duplex may be trusted in future. But maybe it still won't be, for in hopeless situations it is difficult to stop searching for solutions.

Thirty of the 36 patients planned for PTA had intermittent claudication, three had rest pain and three ischaemic ulceration. No diagnostic angiographies were ordered before PTA. But the diagnosis may change during the preparations for PTA. This is because it is a treatment performed in the angiography room guided by X-rays.

> The eyes of the radiologist move between the monitor and the catheter in his hands. The white shadows on the monitor are the vessels. There, in the middle of the picture, the shadow suddenly narrows. A stenosis. The radiologist's hands slowly push the catheter further into the vessel, until its end point lies beyond the stenosis. On the monitor two dots can be seen inside the vessel. One on each side of the stenosis. 'Let's try it,' says the radiologist to the two residents and the assistant. He takes a pump which looks like a small version of the kind you find on bicycles, attaches it to the line that enters the patient's arterial tree, and slowly starts to pump. All professional eyes (those of the observer included, if not those of the patient) shift to the monitor. Between the two dots, an elongated balloon grows. It pushes the constricted vessel walls apart. It is kept inflated for a while. Then the air is allowed to escape again.

PTA is a therapy superimposed on the diagnostic technique of angiography. Which means that here, even if duplex was used to design treatment, an angiography is also made. And it may not only suggest a different treatment, but also a different diagnosis. *In 32 patients PTA was successful. In two patients angioplasty failed because the lesion could not be traversed by the catheter. In two further patients angiography performed during the PTA could not confirm the lesions found on duplex scanning.* PTA therapy depends on angiographic findings. If a stenosis cannot be

detected by angriography nobody knows where to inflate the balloon. Thus even if the duplex detected disease no therapy is performed if angiography fails to find it, and that is the end of it.

In the other patient with intermittent claudication, duplex scanning showed greater than 75 per cent stenosis of the right superficial femoral artery; this proved to be a non-recanalisable occlusion. So what has happened here? A stenosis 'proves to be' an occlusion. Perhaps this is another discrepancy between the two techniques and what they detect. One has diagnosed the disease as less severe than the other. But something else may also have happened. For when we looked at the patient's file again, it appeared that there was a three week gap between the duplex and the PTA. How fast do vessels deteriorate? Perhaps this one only needed three weeks to turn from a stenosis into an occlusion.

Duplex and angiography both detect 'atherosclerosis' at a single moment in time. They assess a stenosis on the particular day the pictures are made. The invasive therapies discussed here incorporate a similar conception of 'atherosclerosis'. They stretch or clean or bypass vessels as if getting blood to a patient's feet were a matter of clearing pipelines. The mechanisms which lead the same vessels to clog up again over the days, months, years to come, simply elude vascular surgery. This doesn't imply that vascular surgeons are not aware of haematological and biochemical processes in atherosclerotic vessels. They are. But in the diagnostic and therapeutic techniques of vascular surgery, time dimensions are not incorporated. For this reason invasive treatment is often called 'merely symptomatic'. Indeed it treats the one disease, that of closed off vessels, but not the other, the closing off of vessels. Calling this a 'symptomatic' treatment, is a way to link the two delineations of disease together and to grant greater power of definition to the latter. However, the power to define doesn't equal the power to perform. While the atherosclerotic process may be talked about as the 'real' disease, intervention and treatment are carried out on stenotic and occluded vessels. They are performed as real.

Based on non-invasive tests 32 patients were scheduled for operation (19 with intermittent claudication, five with rest pain, eight with ischaemic ulceration). If a stenotic lesion is too long, if an artery is occluded, or if the vessel wall is bad over too many centimetres, then PTA is not the treatment of choice. Operation is. But just categorising someone as 'to be operated on' is not a complete design of therapy. For there are several possible operative techniques. Should the vessel be stripped clean, or should a bypass be made (Van der Heijden *et al.* 1993)? And if a bypass is to be made, what course should it take? Where should it be attached upstream and downstream? *Twenty-four of these patients underwent angiography to determine the definitive policy; five angiograms gave additional information regarding treatment strategy. In four patients angiography was necessary to visualize the crural arteries before femorocrural*

reconstruction and in one a supragenual reconstruction was performed. This patient was scheduled for below knee femoropopliteal bypass after duplex scanning because of an occluded proximal popliteal artery; angiography, however, showed an open popliteal artery.

Treatment isn't designed at a single moment. It may develop through several stages. And if duplex can replace angiography at some stages, this doesn't necessarily imply that it can in others. Even if duplex can place patients in the 'to be operated on' category, surgeons may still want an angiography as a road map on which to trace the precise course of an operation. Where should a bypass be attached upstream: in the illical or the femoral artery? And where should it be attached downstream: above or rather blow the knee?

> One of the operation assistants covers the patient's belly, arms and left leg with sterile, green cloth. She paints the skin of the right upper leg yellowish brown with iodine. Then everyone takes their place. The leading surgeon points at the angiogram hanging on the light box. 'There', he explains to the observer, 'that's the place we're after'. And he moves his pointing hand downwards, towards the legs. 'It must be about here', he indicates. The skin is cut and drawn backwards by a forklike instrument; the connective tissue, the fat. The muscles are shifted sidewards. There's the artery. Separated from the tissue in which it was embedded. Uncovered. The surgeon's eyes move once more from the angiogram to the leg. As if there were a direct correspondence. A direct correspondence between the white shadows on the picture and the bumpy vessel in the flesh.

When the protocol was designed the idea was that in all the operation cases to be included, an angiography would be done in order to further decide about the precise operation course. But since duplex was available and performing well, exceptions started to creep in: for the patient allergic to dye; or for several patients with isolated occlusions high up in their thighs, whose duplex showed they had good outflow further down. Why bother to make angiographies in these cases? *Eight patients were operated on guided by information obtained from non-invasive tests only.* Since in these cases angiography had not confirmed the diagnosis made by duplex, the surgeons were relieved to discover that what they found inside the legs did. *During the operation, the data collected at duplex scanning were confirmed in all patients, and all operations were performed without unexpected problems and with good postoperative results.*

The protocol study departs from its design. No literature legitimating operations on leg vessels without angiography is available. To write such literature, is among the department's future projects. The design capabilities of duplex will be extended. Another of its potentialities will be explored.

In ten patients (one with intermittent claudication, six with rest pain and three with ischaemic ulceration) it was not possible to plan a therapeutic policy based solely on non-invasive tests; angiography was therefore necessary. Six of these patients had an occluded tibioperoneal trunk detected at duplex scanning. The other four had extensive lesions of the femoropopliteal tract. All ten thus needed special attention with regard to the quality of the crural arteries. A bypass is made from a place where the vessel is still reasonably healthy, to a lower point, where it is also fairly good. But how low is this? As yet it is hard to use Duplex to assess the vessels of the lower leg. So if this is needed for the design of a therapeutic strategy, an angiogram is made.

In ten patients 'it was not possible to determine treatment strategy' on the basis of non-invasive tests – including duplex – alone. For what or whom is this impossible? For duplex? For the surgeons? A study like this doesn't test a diagnostic tool in isolation, but a diagnostic tool in the local setting of a specific hospital. Thus the ability of the local technicians, radiologists and surgeons to work with duplex are also part of the study. The technology and those working with it cannot be separated. And why should they be? For what requires evaluation is whether duplex can be used here and now. For the practical design of therapy. In a hospital.

The intertwinement of an apparatus and its use, makes it easy to deflect criticism from the technique 'itself' to its users, whether these be technicians or physicians. If a study such as the one we report on here were to yield negative results, this would not necessarily be devastating for a tool like duplex. Some saviour of the technique would no doubt say: 'No wonder they have such bad results with their machine, they do it all wrong!'

Meanwhile, in the hospital where we carried out our studies, duplex does quite well. The protocol study shows that more than half the time it has the potential to replace angiography in the design of strategies for treatment. *In 62 patients the treatment strategy could be determined without diagnostic angiography. Only 38 diagnostic angiograms were made. And a third of these didn't really help to improve the design of therapy. Twenty-three of the 39 angiograms performed did not give additional information on the treatment strategy.*

Detection and design

Sociologists have often pointed to the 'interests' that drive the development of new techniques (e.g. Blume 1991). Of course there are lots of interests involved in doing angiography and duplex, too. But in this paper we let these rest in order to analyse the reasoning linked up with

putting these techniques to use – the 'legitimations' if you prefer (see Dodier 1993). Such reasoning doesn't cause activities to come about. It is interlinked with them, may, in part, follow from them. So analysing 'reasons' doesn't explain anything, but helps in understanding the direction, content, and consequences of techniques. Their interdependencies; their changes over time.

Studying the content of medical discussions and techniques instead of the interests behind them gives new insights into what is done in hospitals. It shows, for instance, that detecting disease and designing treatment differ. Different people perform these activities in different places and at different times. While radiologists judge angiographies and technicians detect disease in duplex, it is surgeons who design courses of treatment and discuss them with patients. And even if the ability of duplex to detect disease correlates well with that of angiography, the study reported on here was set up to explore its usefulness in the work-up of patients. Moreover, the protocol incorporated the idea that duplex might be as good as angiography in some stages in the design of treatment – the decision about whether to do a PTA or operate – while not so good in others. Once an operation was decided upon, angiography would still determine the course of that operation – if an operation was possible at all. For sometimes disease may be severe, but impossible to treat.

And yet detection and design also interweave in many ways. There is the very quantification of duplex. Correlation studies don't attempt an assessment of all the facts that duplex might come up with, but lead it to yield information relevant to the design of treatment. They create duplex parameters that correlate nicely with an established, therapeutically relevant measure, like that of 'more or less than 50 per cent diameter reduction'. Moreover, neither duplex, nor angiography are used for all patients who visit the outpatient clinic with complaints, or even for all the patients who appear to have problems with the blood vessels in their legs. Duplex and angiography are only used if complaints and the ankle/arm index are so bad that an invasive treatment seems required. So the fact that they are used at all is already part of the process of designing treatment.

Detecting disease and designing treatment are different and interdependent. There are gaps between them and they interweave. The boundary between them is neither simple nor solid. It is not a boundary that can be drawn in time, between this phase and the next, between the first encounter with the patient in the consulting room and the final decision to intervene. For in the first encounter the question is already 'what to do' and the final decision may hinge on the question of how severe the patient's complaints are or where exactly a stenosis is located. Instead of a difference in phase, there is a difference in accent, in relevance. In dealings with a patient and in the use of diagnostic tools, what is important shifts back and forth between searching for clues for how to react, assessing the severity, determining the site of the disease, and measuring its extent.

Mapping the many relations between the detection of disease and the design of treatment while moving from one site of investigation to another, therefore yields a complex picture. We presented such a picture here. It moves, but it does not lead to a conclusion. The image sketched cannot be summarised in a short, all-encompassing statement. Instead, it draws together vessels, surgeons, research designs, hospital organisation, patients, apparatus, general practitioners, dye, buttons, interview questions, catheters, gel, blood and many other elements. All of them interrelated. Yet each irreducible to the other.

> Note by one author to the other: Here's the material I promised and a current version of the protocol article. I also have some patient files on my desk right now. We'd better have a look at them together, for they are very thick. It seems as if vascular patients are never treated once but keep on coming again and again'.

> A patient in an interview: 'But the second time I was a lot more attentive, of course. When that little toe, when it was blue, when it showed a blue blood spot that I couldn't explain, I went to my general practitioner. I said: look, there, dammit. He said: yes. So I said: send me back to those boys, those surgeons, then. That's where I'll end up anyway.'

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Notes

1 In surgical journals many of the people whose work contributes to a paper are turned into its authors, from supervisors to (one of) the technicians. For names in this case: see our acknowledgements, where we have left out the MDs, PhDs and other such marks of academic merit that appear at the top of the surgery paper. For an analysis of writing practices in science (see Bazerman 1988). For one of narrative practices in medicine (see Hunter 1991).

2 This image recurs in the many teaching books that instruct students and doctors how to perform diagnosis where it is treated as an art distinct from that of administering therapy (see *e.g.* Bernstein 1985). It can also be found in the way the ideal of 'informed consent' is framed: when it has become clear what's wrong, the doctor explains the array of solutions to the patient who may then choose among treatments. For an analysis (see Kaufmann 1983).
3 See for a good example of this: Berg 1992. Several pragmatist philosophers of medicine take a somewhat similar direction (see *e.g.* Engelhardt 1984).
4 The ethnographer/philosopher among the present authors made notes of her observations the same or the subsequent day. She analysed written material with semiotic techniques. Patient interviews were conducted by a research assistant, Jeannette Pols. Quotes presented here are free translations of the Dutch transcripts.
5 In this example, consent with treatment isn't sought after the facts are known, but before the effort is made to get to know them. Another way in which diagnosing disease and designing treatment may intertwine. For a very different situation, that of prenatal diagnosis in the US (see Rapp 1993).
6 Several studies have analysed differences in medicine along the lines of differences between specialisms (see *e.g.* Fox 1994). Fox aptly shows tensions between anaesthetists, concerned with overall fitness, and surgeons, concerned with the elimination of specific diseases. The differences we attend to here, however, do not neatly latch onto those between *e.g.* radiologists and surgeons, or internists and surgeons. They show more erratic distributions, are never static, and even divide the so called individuals concerned.
7 There's a painful irony in the fact that this patient praises medical improvement despite the fact that the vascular surgeons were incapable, as one says, of 'saving her leg'. For an extensive analysis of the story telling about 'wonderful medicine' by patients who do not visibly profit from its wonders (see Wynne 1988).

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