ANALYSIS, DESIGN AND PRODUCTION OF PRODUCTS COMPRISING SUPERELASTIC MATERIALS

Field

The invention relates to the analysis, design and production of products using exotic materials such as superelastic materials, including for example certain nickel-titanium metal alloys.

Background

One example of such an alloy is the family of nickel-titanium alloys known conventionally as Nitinol. Nitinol is known as a material having “shape memory” behaviour and also superelasticity in tension and in compression. The superelasticity, coupled with general bio-compatibility of the metal, make it ideal for use in structural components of medical devices for implantation in the human body. Vascular stents are an example of such products, and a particular application example for the present invention is in stents used as the structural elements of so-called stent-graft devices for supporting blood vessels. Various types of stent-graft product are available from different manufacturers, all employing different forms of Nitinol stents. The superelasticity is exploited firstly to allow the stent to be compacted to high deformations in a narrow tube for delivery by minimally-invasive techniques, and then recover from the high deformation and provide radial force for sealing in the artery when deployed.

Many forms of stent are known for use as components of stent-graft devices. These, typically comprise Nitinol wire or wire-like shapes cut from Nitinol sheet forming a convoluted path around the circumference of the stent-graft. A common form is the so-called Z-stent. The convoluted shape coupled with the elasticity of the material allows the stent to be compacted to a very high degree. Another particular form of stent used in products of the applicant Vascutek Limited comprises a simpler ring structure formed of multiple turns of fine Nitinol wire. For such a safety-critical component, manufacturers and regulators want to ensure that it will not only meet its performance specification, but also to predict accurately its service lifetime. With a vascular implant deployed in a pulsatile environment, or any medical implant subject to varying stresses and strains, it is important that a product will serve predictably for a certain number of years and not fail due to cyclic fatigue. A 'design for fatigue' approach is taken in the production of such devices. Similar considerations apply to safety-critical components in non-medical applications where high numbers of service cycles are incurred, for example high pressure equipment for oil and gas service, aerospace, automotive and rail industries. In designing such products for manufacture, rigorous computer modelling of the structure and its behaviour is therefore undertaken.

Such modelling may be performed for example using a Finite Element approach to simulate the structural behaviour of rings stents or other components. A structural model is combined with a model of the material from which the component is made. In the example of the Vascutek ring stent, the accuracy of the modelling as a whole naturally depends on the ability to accurately model a strand of the thin wire in bending. The structural model of a wire ring is simple, but producing a material model that will accurately represent the superelastic tensile and compressive properties of the specific grade of Nitinol wire is not straightforward using commercially available software. One example of commercially-available software is ABAQUS (version 6.11-2) from Dassault Systèmes Corp., Providence, RI, USA, 2011.

Some commercially available software packages such as ABAQUS provide inbuilt 'constitutive models' for mathematically modelling materials that exhibit exotic behaviours such as superelasticity. In ABAQUS, 'UMAT' is the name for a 'user subroutine to define a material's mechanical behaviour'. The ABAQUS FEA system includes a material model 'UMAT for superelasticity'. This model is based on the work of Auricchio and Taylor (Auricchio, F. *et al*, "Shape-memory alloys: modelling and numerical simulations of the finite-strain superelastic behaviour", *Comput. Methods. Appl. Eng.,* 1997,**143**, p175-194, and Auricchio, F. *et al*, "Shape-memory alloys: macromodelling and numerical simulations of the superelastic behaviour", *Comput. Methods. Appl. Eng.,* 1997,**146**, p281-312). When applying such models to specific grades of Nitinol wire used in the ring stent, as an example application, experiments conducted by the present inventors have shown that the mathematical numerical model does not accurately simulate the behaviour of the real product. In particular, the inventors have found that the material has significantly unsymmetrical behaviour in tension compared to compression. While the known material model for superelastic and shape memory materials incorporates the ability for the user to specify a degree of asymmetry, but not to the extent that the inventors have observed in the mentioned Nitinol wire.

SUMMARY OF THE INVENTION

The inventors have recognised that an improved representation of the material can be achieved by treating an exotic material such as Nitinol wire material as two different materials, depending whether it is in tension or compression. This is possible in a finite element model because the object being modelled is subdivided into many small elements. Different elements in the modelled article can be treated easily as if they are made of different materials. The more appropriate material model can be assigned to each element according to whether it will be subject to tensile or compressive forces.

The invention in a first aspect provides a computer-implemented method of simulating the performance of an object made of a material. The method comprising (a) obtaining a first material model that describes the behaviour of the material under tension; (b) obtaining a second material model that describes the behaviour of the material under compression; (c) creating an object model that describes the geometry of the object in a form suitable for numerical analysis; (d) performing numerical analysis using the object model and material models together to simulate behaviour of the object under defined conditions, the object model being partitioned such that in parts of the object model subject to superelastic tension the first material model is used to simulate the material behaviour and in parts of the object model subject to superelastic compression the second material model is used to simulate the material behaviour.

The partitioning of the object model may be fixed throughout the numerical analysis.

The method may further comprise a step (e) of varying the partitioning of the object model after performance of the numerical analysis step (d) and repeating the numerical analysis with the varied partition. In step (e), the varied partitioning of the object model may be calculated automatically in response to conditions of tension and compression calculated during the numerical analysis.

In an embodiment of the present invention, the partitioning of the object model may be varied during said numerical analysis, for example between iterations of an FEA process. In the embodiment, the method may further comprise a step (f) of varying the partitioning of the object model automatically during performance of the numerical analysis step (d) in response to conditions of tension and compression calculated during the numerical analysis.

The first material model and the second material model may be arranged such that for values of tension and compression close to zero both models describe substantially identical behaviour. The first material model and the second material model may be arranged to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

The above step (a) may comprise (a1) obtaining experimentally observed stress-strain characteristics of the superelastic material under tension; (a2) creating the first material model so as to approximate the experimentally observed characteristics under tension while assuming that the stress-strain characteristics under compression and tension are symmetrical, and the above step (b) may comprise (b1) obtaining experimentally observed stress-strain characteristics of the superelastic material under compression; (b2) creating the second material model so as to approximate the experimentally observed characteristics under compression while assuming that the stress-strain characteristics under compression and tension are symmetrical.

In the above steps (a2) and (b2), the first and second material models may be constrained to describe substantially identical behaviour for values of tension and compression close to zero. Optionally, the first material model and the second material model are arranged to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

The numerical analysis may comprise finite element analysis, where the object model may be a finite element model which describes the object geometry by subdividing it into a plurality of interconnected elements, and said partitioning is performed so as to assign to each element of the object model either the first material model or the second material model.

The material may be a superelastic metal, a shape memory metal, or a nickel-titanium alloy.

According to a second aspect of the present invention, there is provided a method of designing a product made of material. The method comprises the steps of (j) receiving a design specification of the product including both dimensional and performance requirements; (k) selecting a candidate material from which the product might be made, the candidate material having asymmetric stress-strain characteristics; (l) creating a first candidate object model describing the geometry of a candidate design for the product; (m) performing numerical analysis using the candidate object model so as to simulate behaviour of a product made to the candidate design under test conditions; (n) evaluating the simulated behaviour of the product against the requirements of the design specification; (o) modifying the selected material and/or the candidate design and repeating steps (m) and (n) until the evaluation in step (n) indicates compliance with the requirements of the design specification; and (p) outputting the modified design as a final candidate design, wherein the numerical analysis in step (m) includes partitioning the object model such that in parts of the object model subject to superelastic tension a first material model is used to simulate the behaviour of the selected material and in parts of the object model subject to superelastic compression a second material model is used to simulate the behaviour of the selected material.

Said evaluating step in the second aspect may include predicting fatigue safety of a product made to the candidate design, based on a strain amplitude per cycle calculated using said numerical analysis.

The numerical analysis in the second aspect may be performed by a method according to the first aspect of the present invention, as described above.

According to a third aspect of the present invention, there is provided with a product obtained by performing a method in the above-mentioned second aspect of the present invention, to obtain final candidate design and manufacturing the product according to the final candidate design.

The method in the second aspect may further comprise a step (q) of manufacturing a product using the selected material and the final candidate design.

Said product in the second aspect may be a medical implant. Optionally, said product is an endovascular stent-graft device in which at least one stent component has been made using the selected material and the final candidate design. Optionally, said stent component is a ring stent comprising one or more turns of wire.

According to a fourth aspect of the present invention, there is provided with a method of obtaining a material model for use in simulating the behaviour of objects made from a material. The method comprises the steps: (a1) obtaining experimentally observed stress-strain characteristics of the material under tension; (a2) creating the first material model so as to approximate the experimentally observed characteristics under tension while assuming that the stress-strain characteristics under compression and tension are symmetrical, and (b1) obtaining experimentally observed stress-strain characteristics of the material under compression; (b2) creating the second material model so as to approximate the experimentally observed characteristics under compression while assuming that the stress-strain characteristics under compression and tension are symmetrical.

In steps (a2) and (b2) of the fourth aspect, the first and second material models may be constrained to describe substantially identical behaviour for values of tension and compression close to zero.

In the fourth aspect, the first material model and the second material model may be constrained to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

The method in the fourth aspect may further comprise steps of forming an object model and running a numerical analysis, where the numerical analysis comprises finite element analysis, where the object model is a finite element model that describes the object geometry by subdividing it into a plurality of interconnected elements, and where said partitioning is performed so as to assign to each element of the object model at a given time either the first material model or the second material model.

According to a fifth aspect of the present invention, there is provided with a data processing apparatus arranged for simulating the performance of an object made of a material. The apparatus comprises: storage for a first material model that describes the behaviour of the material under tension; storage for a second material model that describes the behaviour of the material under compression; storage for an object model that describes the geometry of the object in a form suitable for numerical analysis; and a processor for performing numerical analysis using the object model and material models together to simulate behaviour of the object under defined conditions using the object model, the processor being arranged to partition the object model such that in parts of the object model subject to superelastic tension the first material model is used to simulate the material behaviour and in parts of the object model subject to superelastic compression the second material model is used to simulate the material behaviour.

Said processor may be arranged to vary the partitioning of the object model after performance of the numerical analysis and to repeat the numerical analysis with the varied partition.

Said processor may be arranged to calculate said varied partitioning of the object model automatically in response to conditions of tension and compression calculated during the numerical analysis.

Said processor may be arranged to vary the partitioning of the object model during said numerical analysis.

Said processor may be arranged to vary the partitioning of the object model automatically during performance of the numerical analysis step in response to conditions of tension and compression calculated during the numerical analysis.

Said numerical analysis in the fourth aspect may comprise finite element analysis, where the object model is a finite element model which describes the object geometry by subdividing it into a plurality of interconnected elements, and where said partitioning is performed so as to assign to each element of the object model at a given time either the first material model or the second material model.

According to a sixth aspect of the present invention, there is provided with a computer-implemented method of simulating an object where an object model representing the object is partitioned such that in parts of the object model subject to superelastic tension a first material model is used to simulate the behaviour of the selected material and in parts of the object model subject to superelastic compression a second material model is used to simulate the behaviour of the selected material.

According to a seventh aspect of the present invention, there is provided with a method of manufacturing a product wherein one or more components of the product have been designed based on behaviour of the component simulated by a method in the above-mentioned sixth aspect of the present invention.

The invention in its various aspects may be implemented wholly or partly using computer hardware and suitable programming. Accordingly, the invention further provides computer program products including machine-readable instructions for causing a data processing apparatus to implement the apparatuses and methods of the invention in its various aspects.

The above and other features and advantages of the invention will be apparent from a consideration of the exemplary embodiments described below.

BRIEF DRESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 illustrates a product that may be modelled, designed and produced by methods according to the present invention, together with a more detailed view of one component of the product under compaction, and a computer-aided design system displaying a model of the same component;

Figure 2 illustrates (a) a finite element model of a wire undergoing bending and (b) a cross-section of the wire in a bent state showing zones of tension and compression;

Figure 3 illustrates a known constitutive material model for a superelastic materials such as Nitinol (nickel-titanium alloy), commercially available for use in finite element analysis of Nitinol products;

Figure 4 is the principles of a finite element model of a Nitinol wire according to an embodiment of the present invention;

Figure 5 illustrates two material models in the method of Figure 4, modelling the Nitinol material (a) in tension and (b) in compression;

Figure 6 illustrates performance of the known material model being used conventionally and the novel bi-material model against experimental results of tensile and compressive stress testing;

Figure 7 illustrates a three-point bending test used in validation of models produced according to embodiments of the invention;

Figure 8 compares results of an experimental three-point bending test against results predicted using the conventional model and the novel bi-material model;

Figure 9 compares digital image correlation test results with predictions of the conventional model and the novel bi-material model;

Figure 10 is a flowchart of an example method of creating and validating a bi-material in an embodiment of the present invention;

Figure 11 is a flowchart of an example method of creating and validating a bi-material in an another embodiment of the present invention;

Figure 12 is a flowchart for a method for designing and producing a range of products in an embodiment of the present invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Background

Before describing specific embodiments of the invention, it will be helpful to application example concerning the design and production of cardiovascular implants. At the same time, it will be understood that the invention is by no means limited to application to this particular design of implant, nor to the field of designing cardiovascular implants or medical implants in general.

In the lower part of Figure 1, an endovascular stent-graft product is shown, fitted within a blood vessel, in this case the aorta (an artery) 102 of a patient. The artery is suffering from an aneurysm 104 (a ballooning of the artery wall), and the stent-graft is being used to treat the aneurysm in a minimally invasive way. The stent-graft product, as its name implies, comprises graft material 106 supported on a framework of structural ribs or stents 108, 110, 112 and 114. The graft material 106 comprises fabric for containing the flow of blood and relieving pressure on the artery wall in the region of the aneurysm in 104. The stents 108-114 provide structural support for the graft material, and have the form of elastically expanding rings, so that they may be referred also as “ring stents”. Ring stents 108-112 have a particular function at the openings of the graft, where they should press against the walls of the artery and create a seal for guiding through the graft.

Many different designs of stent-grafts are available, all having a similar principle of construction, but differing in constructional detail, as well as in size and shape. It will be understood that the bifurcated design of stent-graft shown is specific to one particular site in one particular artery, and other designs such as single tubes will be used at other sites. Further, each design of product is made available with a range of lengths and diameters of each graft section and opening. The selection from this range must be carefully tailored to the measurements of the individual patient. An important function of all these products is the ability to be compacted into a very narrow form, for delivery by non-invasive techniques. A delivery tool (not shown) is used to insert and guide the compacted product through a catheter at a suitable entry point into the vascular system, and from there to the desired location. Guide wires 116 are provided for this purpose. Once at the desired location, the product is allowed to expand and may be anchored by hooks or barbs on the ring 108 (not shown at this scale), so as to remain in place. The guide wires 116 are removed.

The upper left part of Figure 1 shows in more detail the form of an example ring stent 108 used in the example product 100. Stent 108 is shown in its compacted state, from which by its own elasticity it will expand to form a wide ring when released at the operational location. In this example, ring stent 108 is made of a number of turns of fine wire of a superelastic metal alloy such as Nitinol. Beginning and end portions of the wires are joined together by a crimped joint at 122. The compaction is achieved simply by folding at four points around the circumference of the ring.

Those skilled in the art will appreciate that many other forms of ring stent and stent having the ability to be compressed and then expand in the desired manner are known in the art. These include various forms of “Z” stents, in which a ring of superelastic material forms a “zigzag” pattern around the circumference of the graft, so that it may be compressed for insertion, and expand when in position. The invention is not limited in application to Nitinol, but Nitinol is a particular variety of nickel titanium alloy that is well known for its superelastic properties, as well as its well-established bio-compatibility. In addition to examples formed from bent wire or joined wires, such products may also be formed by laser cutting from thin sheets or tubing of the superelastic metal. The skilled person will readily appreciate how the principles of the embodiments described below may be extended to such products. In general, any structure exhibiting bending behaviour (or just direct compression) can benefit.

As mentioned, the stent-graft product requires to be designed to have very specific dimensional and performance capabilities, and this applies to the ring stents 108, as to other components. Shown at top right in Figure 1 is a display 130 of a computer-aided design system showing a model 108' of the ring stent 108. Careful analysis and simulation of proposed designs is required in order to understand the interaction between stent rings and the artery, and the dynamic motion of the stent *in vivo.* It will be appreciated immediately that the design requires to satisfy certain geometrical and loading constraints in order to be able to compressed for insertion, and to expand and provide sufficient sealing force over a period of time. The endovascular product in use may be subjected to many thousands of cycles of pulsing and a design and testing process must take account of strain cycling over the lifetime of the product, in order to estimate its fatigue life. In addition to strain cycling due to operation in the pulsatile environment, the history of deformation and loading associated with the initial compaction (folding) and delivery may have a pronounced effect on fatigue life of the product.

The computer aided design system that provides display 130 and other outputs can take any form, and will comprise one or more data processing systems and subsystems made of processors, memory, user I/O and communications components. These are represented schematically by blocks 132 (CPU) and 134 (memory) in the drawing, with user input represented as USR. On this hardware platform, many different software products can be run to manage the investigation and design of products and components such as the ring stent 108. 3-D modelling modules will be provided by which an object model can be created and adjusted that defines the geometry of a component in mathematical terms. Various additional modules will be provided for analysing the modelled product under various conditions. A particular type of analysis widely used in engineering is Finite Element Analysis or FEA. Experimental equipment 136 may also be provides, directly or indirectly communicating with the modelling system to determine parameters of a material model by reference to the behaviour of real samples.

Figure 2 illustrates a Finite Element Model (FEM) that may be used to perform FEA on the model 108' that represent the stent 108 in the computer aided design system. As seen in Figure 2(a), the wire is modelled such that its volume is divided into many smaller sub-volumes or elements, whose behaviour can be treated individually in an iterative computational process known as Finite Element Analysis. Each new element is modelled for us to have properties dictated by the material of which the product under investigation is made. Elements 200 and 204 are shown. Boundaries between elements such as boundary 202 are defined. The behaviour of each element under the influence of its neighbours is modelled by an iterative computational process, as is well known.

The ring stent 108 comprises multiple turns of thin wire. In a simplified embodiment the modelled wire 108' of Figure 2(a) represents the bundle of wires as a single equivalent ring which has the structural stiffness of the bundle of wires, while taking stress and strain readings from wire of the real diameter. For greatest accuracy, the strands can be modelled individually. As is seen in Figure 1, the wires undergo very large deformations in use, particularly during compaction. The ring remains to some extent bent when deployed, so as exert an elastic sealing force against the artery wall. The bending varies cyclically with pulsatile variations in the local blood pressure. Different elements across the cross-section of the wire will therefore experience very different influences, ranging from a high degree of compression at the inside of a bend, the high degree of tension at the outside.

Figure 2(b) shows this effect in a cross-section of the wire model 108'. The inside of the bend is at the top of the figure, while the outside of the bend is at the bottom. As will be described in more detail below, the superelastic material exhibits several different behaviours at different levels of tension and compression. In a wire bent only slightly, the superelastic behaviour of the wire may not be exploited and the stress-strain behaviour is well represented by a "linear elastic modulus". In a wire subject to more severe bending however, superelastic compression and superelastic tension behaviours may arise, where a conventional material would undergo permanent plastic deformation. The superelastic behaviours arise from reversible phase changes that exist within these exotic materials. Figure 2(b) illustrates zones of the following different behaviours in a significantly bent wire: initial tension (TI) and initial compression (CI), superelastic compression (CS) and superelastic tension (TS). The zone boundaries are shown as straight lines in Figure 2(b), while they may have different shapes of course in practice.

Figure 3 is a diagram showing a generic stress-strain (σ-ε) relation for the material Nitinol, as represented in the "UMAT for superelasticity" model used in the ABAQUS FEA software. To the right of the vertical (stress) axis, tensile behaviour is described. The region of initial tension is labelled TI where a conventional linear modulus of elasticity is represented by a steep linear slope. At higher tension, however, superelastic behaviour is seen in the region labelled TS. The strain (deformation) increases dramatically for a relatively small increase in stress. To the left of the vertical axis, regions of initial compression and superelastic compression are labelled CI and CS, respectively. The shape of the graph, and hence the behaviour of the material in an FE model, is defined by a dozen or so parameters. While the graph exhibits a similar form of behaviour on both sides of the axis, it is not precisely symmetrical, reflecting to some extent the real behaviour of the materials covered by the model. A parameter 300 is defined in the known model, that modifies the behaviour under compression. However, the shape of the graph under compression is constrained largely by the parameters of the tensile side, and the parameter 300 effects only a different scaling of the graph in practice.

The strain variations experienced at each point in the material of the product or component during service are key to estimating its safe service lifetime. The inventors have found that for fine wires, for example, the known model cannot adequately represent the stress-strain relationship under compression. Where the strains experienced by the model in the compressive direction are significant, the real effects of fatigue may be either lesser or greater than are indicated by the conventional model. In that case, the lifetime of the component may be under- or overestimated with dire consequences. While one can compensate for safety by adding margins of uncertainty, this will generally restrict one's ability to meet other design criteria. Therefore it is always in our best interest to model the devices, and perform any fatigue testing, with the most accurate overall material model. That way, that the global structural response and interaction with the artery or other environment is as realistic as possible, and subsequently the strain variations predicted as accurately as possible. This will give us the greatest confidence in device fatigue safety.

Bi-material Modelling

Figure 4 illustrates the principle of bi-material modelling applied to improve modelling of effects of bending on a superelastic (e.g. Nitinol) wire. The object model, represented here by the cross section of the finite element model of a wire ring, can be the same as in Figure 2(b). The labelling of the zones CI, CS, TI and TS at the right hand side of Figure 4 is the same as in Figure 2(b). However, although the material in every element of the real wire is the same, in the new model, different elements are assigned different properties, as if they were made of two different materials. In the example model of Figure 4, a boundary line B is estimated between elements subject to compression during the movements to be simulated (above the line), and elements that are subject to tension (below). Elements above the model boundary B are assigned a first material model MC which is specifically designed to represent the material when under compression, while elements below the line are given a second material model MT, designed to model the material in tension. As far as the FEA system is concerned, in a simple implementation, these models might represent two completely different materials.

In the real and modelled situations, an actual zone boundary B' exists where tension and compression are exactly zero. This real boundary lies somewhat above the model boundary B which marks the boundary between the compressive and tensile material models. Accordingly, the elements through which the zone boundary B' passes, are assigned the compression model MC but in reality are subject to a mixture of tension and compression. As will be described, the models MC and MT are designed to accommodate this cross-over between tension and compression, without losing significant accuracy. It will be seen that the partitioning of the object model has been performed such that first material model MC is used in all elements that are subject to superelastic compression, and the second material model MT is used in all the elements that are subject to superelastic tension.

As will also be described in more detail, the partitioning of a product model into compressive and tensile elements can be performed either in an automated fashion or a manual fashion. Further, the partitioning may be fixed throughout the simulation of a bending movement, or the partitioning can be dynamic. In other words, if bending occurs in opposite directions at different times, or occurs about different axes, a given element may be at one time assigned first material model MC, and at another time assigned the second material model MT. The changing of the model partition may be pre-programmed to occur at certain points in a simulated movement cycle, or it may be triggered automatically. In summary, the partitioning of the product model under certain movements may be performed manually or automatically, and, separately, the decision to change partitioning dynamically as the type of movement changes may be manual (pre-programmed) or automatically.

Figure 5 illustrates schematically (a) the tensile model MT and (b) the compressive model MC, in a schematic embodiment of the bi-material model. Each model defines by suitable parameters a stress-strain curve showing features of initial formation, superelastic deformation and hysteresis. The parameters can be the same in form as the parameters of the known Nitinol model. However, unlike the conventional Nitinol model of Figure 3, no attempt is made in either model to incorporate the asymmetric behaviour that is characteristic of the true material. Rather, each model MT and MC defines a perfectly symmetrical stress-strain characteristic, but with the knowledge that it represents the behaviour of the material accurately only in the tensile domain (MT) or only the compressive domain (MC). As indicated by hatching lines, the opposite part of each model will be (substantially) used.

As already mentioned, use of the correct model is ensured by providing an appropriate partitioning of the finite element model, as shown in Figure 4. As noted above, certain elements straddle the true boundary B’ between compressive and tensile portions of the object being modelled. In the example of Figure 4, this means that the elements immediately above the model boundary B are modelled with the compressive model MC, but are, in part, subject to tensile forces. The bi-material model disclosed herein is designed to be tolerant of this. Firstly, it is noted that in both models MT and MC, the form of the modelled characteristic around the central point X is very similar, being a simple linear slope with relatively little strain (deformation). (This is a feature of the real material, whose experimental behaviour is used to program the model parameters.) Further, although certain elements lying along true boundary B' have the compressive model but are in fact exposed to tensile forces, these tensile forces are only within the initial linear gradient tension range TI and not the superelastic tension zone. Provided this remains true, the compressive model will model initial tension in the same manner as the tensile model would, had it been assigned to these parts.

Secondly, in designing the models MC and MT, the present embodiment takes care to arrange that the slope of the characteristic around the point X, that is to say the initial modulus of the material, is exactly the same in both models. That is to say, the initial modulus of the compressive material model is identical, by design, to the initial modulus of the tensile material model. Consequently, where the boundary B' varies over one or more elements such that element having the compressive material model is exposed to a slight tension, or an element having the tensile material model is exposed to a slight compression, the results of any calculation will be completely unaffected. Moreover, neighbouring elements with different material models will behave consistently so that discontinuities will not arise.

Experimental Verification

Using ABAQUS FEA software, thin wire (0.45mm) in a 'three point bend' setup has been validated firstly by load-deflection results, and secondly by comparing surface strain results from Digital Image Correlation (DIC). It was found that the specific grade of Nitinol wire used has significantly unsymmetrical behaviour in tension compared to compression. Further it was verified that simulation results such as are used in validation of product designs can be improved by modelling the approximate tensile and compressive halves of the wire with separately dedicated material models in the manner described above.

Figure 6 is a graph showing in solid lines the asymmetry observed from the empirical testing of uniaxial tensile and uniaxial compressive behaviour of the wire samples. The horizontal axis represents strain ε expressed as a percentage length increase or decrease. The vertical axis represents stress σ in pascals (Pa). Also shown in broken lines are plots of the behaviours predicted by FEA using different material models. A first curve labelled “Uni UMAT” shows the behaviour predicted using the known, single material model. The known model parameters are programmed in the usual way, using parameters taken purely from tensile uni-axial experiments, plus a value for the stress at which transformation begins in compression (parameter 300 in Figure 3). The curve labelled “Bi UMAT” is the novel bi-material model, developed using the same constitutive model, but creating separate material models with specific parameters to represent independently the tensile and compressive behaviour observed in experiments. The improved ability to replicate the empirical compressive behaviour is readily observed.

Two different sets of equipment and procedures were used to gain load-deflection and surface strain results from ‘three- point bending’ of the thin (0.45mm) NiTi wire. A low-load linear dynamic tester was used to gain load deflection results while microscopic DIC (digital image correlation) equipment was used to track surface strains.

Figure 7 shows an FEA model of the experimental setup, which involves two stationary pins 702, 704 located 20mm apart supporting wire 706, and one indenter pin 708. Indenter pin 708 which was displaced by a distance d = 10 mm (position 708’) and back to zero, deflecting wire 706 to shape 706’ and back again in the process. For the purpose of this experiment, the bi-material model was implemented in a simplified manner in which the regions of compression and tension were approximately pre-determined as shown in Figure 4 (as outer and inner halves of the bent wire) and assigned the relevant tensile or compressive model. For a more complex problem an adaptive approach would be used in which elements can switch between tensile and compressive model through the analysis.

Figure 8 shows the load-deflection results, represent the force-deflection relation of the indenter as it was displaced to 10mm and then back to 0mm. The step in force F at the change in direction was found to be due to friction, and the friction coefficient applied in the FE model was to be iteratively calibrated. (The graph would still exhibit hysteresis, even without friction.) Again, broken lines represent the conventional single material model (Uni UMAT) and the novel bi-material model (Bi UMAT). A considerable improvement in load deflection modelling is observed with the bi-material model, in the loading direction in particular.

Figure 9 shows strain measurements taken around the surface of the cross section at the apex of the wire using DIC testing, at maximum deflection (d = 10mm). The DIC testing provided strain measurements at this cross section at circumferential positions from 90˚ to -45˚, where the 90˚ is the outermost point on the bend (in tension) and -90˚ would be the most inner point (in compression). Again, experimental results (from DIC) are overlaid with single material and bi-material model results. On comparison between the DIC results and the conventional single-material FEA model, the general profile shape is well represented, but with a shift in the neutral axis (zero strain) position and an under-estimate of strain in the tensile side. These errors are consistent with the compressive stiffness being under represented in the conventional model. The bi-material FEA model shows good correlation with the available DIC data including a correct position of the neutral axis, and a strain value that lies within a 3% agreement from mean DIC measurement at 90˚.

Practical implementation

Methods will now be described that may be implemented using a computer aided design system to create and then exploit the bi-material model described above. The methods can be applied without limitation to any particular hardware or operating environment, and details of such environments need not be described herein.

Figure 10 illustrates a method of creating a bi-material model for use in the modelling and design of products using superelastic metals and other exotic materials. In step S1, material in the form to be used is tested to obtain characteristics for each of the environments which are to be separately modelled (in the examples, these are compressive and tensile environments). In the example of the wire stent 108, testing of uniaxial tension is performed on a sample of the wire to be used, and separately uniaxial compression is tested on a sample of the same wire. Particularly in the case of the stent made of thin wire, using the bulk properties of the Nitinol or other material will not provide a good representation of the wire used in the actual product. Accordingly, careful experiments with wire of the correct specification (not only gauge but also the exact manufacturing method is influential) would be performed to obtain uniaxial compression. It is important in these experiments that buckling is avoided, but that certain level of strain is attained. Also the set-up has to allow for expansion of the wire as it is compressed.

In step S2, separate stress-strain relations are calculated from the experimental results, one relating to the behaviour under compression and the other to the behaviour under tension.

In step S3, separate tensile and compressive material models are made, by fitting parameters of a a suitable constitutive model for superelastic materials. Using the ABAQUS "UMAT for superelasticity" model, for example, this would involve setting the parameters shown in Figure 3. In fitting the parameters to the constitutive model, two user defined models are obtained, each based on experimental results only from the tensile or only from the compressive regime, while the stress-strain characteristic in each case is simply assumed to be symmetrical. As described above, it may be arranged that the initial modulus for the tensile and compressive models is equal. It will be appreciated that, from the experimental results, the initial moduli in tension and compression are not necessarily equal. In a simple embodiment, the initial modulus for both models is set to be equal to the average of the moduli suggested by the tensile and compressive sets of experimental results. This may be done for example by averaging the experimental results before fitting, and/or by adjusting the model parameters after fitting.

In step S4 the (geometric) object model is created, for simulating the behaviour of an object made of the material tested and modelled in steps S1 to S3.

In step S5, the elements of the object model is partitioned according to whether they are expected to undergo compression or tension during the simulation. According to the partition, each element is assigned a material model that is either a tensile material model or the compressive material model (as seen in Figure 4). The partition may be estimated based on knowledge of the deformations to be simulated. In the case of the simple bent wire seen in Figure 4, a good partition can be estimated by a human user. Alternatively, and particularly where automatic partitioning will be required, the initial partitioning can be somewhat arbitrary, and all elements could even be assigned the tensile model MT initially, or all the compressive model MC.

In step S6, the object model incorporating the assigned compressive and tensile material models is created and at S7 a simulation is set up including boundary conditions and loading. At S8 numerical analysis is run using well-known FEA algorithms. This process may be, for example, used to simulate a product being designed, and optionally to determine modifications of the design prior to manufacturing an actual product. Such an application will be described below with reference to Figure 12. Other applications could be for example post-failure analysis, or research.

In step S8 the FEA analysis is run, using whatever bending movements or other stresses are specified in the simulation setup. to be placed upon the product. As described so far, only an initial partitioning has been made, which may or may not reflect accurately the distribution of tensile and compressive states within the simulated object. As already explained above, a key requirement is to ensure that an element having the compressive model does not experience superelastic tension, and an element having the tensile model assigned does not experience superelastic compression. Accordingly, in step S9 it is examined whether at any point in running the model, a region of super elasticity reached an element on the model boundary B. If so, in step S10 the partition is improved. This refinement of the partitioning may be performed manually or automatically, depending on the implementation. A suitable strategy might be to move the model boundary by one or more elements in a direction away from elements experiencing superelasticity. If necessary, it may also involve refining the finite element model itself, for example, by sub-dividing a larger element into multiple smaller ones, or by changing the spatial arrangement of elements without increasing their number.

The flow returns to step S6, S7 and the model is run again at step S8. The revised results are again examined at S9 to determine whether this time any superelastic behaviour reached the model boundary B. If so, the partition is improved again and the model is run again, as many times as is necessary. If the test at step S9 reveals that the superelastic behaviour did not reach the model boundary, the model is suitable for use and flow proceeds to step S6, as before. The test at step S9 does not need to be specifically a test for superelastic behaviour at the model boundary: the partitioning could be examined against a more restrictive threshold, such as a certain percentage of strain.

It is important to note that discussion here in terms of the model boundary does not mean that the model boundary B is actually expressed or considered explicitly in the implementation. Each element can simply be examined in its own right to determine whether it experienced the “wrong kind” of superelasticity for the model assigned to it. The model boundary may not be a continuous boundary separating only two zones of different behaviour. The object may experience multiple zones of compression and/or multiple zones of tension.

Once the test at step S9 is passed, the results of the numerical analysis are deemed correct and can be used for whatever purpose at step S11. Optionally additional steps S12 may be taken to validate the bi-material model using experiments on physical objects.

As will be seen, partitioning is relatively straightforward, even if several iterations may be required to get it right, and both manual and automatic methods are readily implemented and validated. Using for example a simple model of a wire, such as is shown in Figure 4 and using the simple beam bending of Figure 7, , the model boundary B is placed at the geometric centre of the wire cross-section, and the simulation is run to a desired maximum degree of bending. The calculations can be reviewed at S9 to ensure that the geometric centre (or other model boundary B) does not at any point reach the superelastic state. The model can be validated in addition by comparing the simulated behaviour with the experimental results at S12. The same method is applicable also to simulate objects having more complex shapes than the simple ring, and/or objects that are subject to more complex "three-dimensional" bending movements. One may simply expect more iterations of steps S6 to S10 in such cases.

Note that the steps S1 to S3 and step S12 do not need to be carried out for each new object model (geometry) and each new simulation. These steps, surrounded by broken lines in Figure 10, only need to be carried out once for each new material, and validated in simple representative bending tests. Once the material models are validated under a range of conditions, more complex shapes can be simulated by repeating only steps S4 to S11.

As mentioned above, it may be that there are situations where is object is subjected to bending in different directions at different times in an operating cycle, so that different partitions would be appropriate in the running of the same simulation. In a simple situation, the simulation itself can be partitioned into different time periods, and partitions can be designed specifically for each stage of the simulation, using the automated or manual methods described with reference to Figure 10.

Alternatively a completely automatic and adaptive partitioning can be adopted in that case, optionally omitting any attempt at making a good initial partition.

Figure 11 shows the proposed automatic adaptive partitioning method. Steps S1 to S12 are present and labelled as before, while emphasising that the initial partition defined and applied in steps S5 and S6 can be completely arbitrary. For example, all elements may be assigned the tensile material model initially. Then, during running of the FEA model in S8, an adaptive partitioning process S8a is performed. It will be recalled that FEA, and probably any other numerical analysis technique that may be considered, operates by simulating the behaviour of the material iteratively. Each iteration may represent a very small "slice" of the final behaviour.

At each iteration of the FEA process, or after certain stages, the iterations are interrupted to examine and optionally modify the partitioning. This examination and modification can be performed in exactly the same as the steps S9 and S10 of Figure 10, except it is performed between iterations while running the simulation, and not only when the simulation is finished. In the event that modification is necessary, an iteration may be repeated. Alternatively, it may be that the individual iterations are so small in effect that the simulation can run forward and any "wrong" portioning will be corrected before it has caused any significant error in the result. This is particularly the case if a margin of error is applied so that the assignment of the material model is corrected before the "wrong kind" of superelasticity.

Figure 12 is flowchart of a production process, that may be used in the design and production of products using the improved material model described above. The product may be of any kind, while the example of the ring stent 108 or similar stents for endovascular stent-grafts may be kept in mind. At step S20, a design specification is defined, comprising required performance criteria, dimensions and so on of the product to be manufactured. In the case of a stent for use in a stent-graft, for example, performance criteria may include: maximum strain for compaction (that is, the maximum tensile or compressive strain of the material experienced at any one point in the structure), minimum radial force for sealing, minimum radial force for fatigue resistance and maximum variation of strain (“delta strain”) for fatigue resistance.

Based on the product design requirements, a material selection is made (the selection of material may be revisited interactively during the design process, if desired). At S24, the material is tested to obtain parameters including the uniaxial tension and compression characteristics mentioned above, but also fatigue testing, corrosion testing and other tests may be performed as desired. From the uniaxial testing comes the bi-material model (MT, MC), as described above with respect to Figures 10 and 11. Of course, if the model already exists for the material being used (specific alloy, gauge of wire/sheet, etc.), then the testing phase need not be repeated for each product design task. The bi-material model, effectively a matched pair of material models, can be stored and supplied on a storage device or communication network as desired.

Assuming that a range of products are then to be manufactured meeting the performance criteria defined in step S20, then in step S26 design development is performed to produce one or more specific product (geometric) models. For the example of stents for stent-graft products, parameters may be sizes of each ring stent, determined by the size of the blood vessel for which it is destined, or the range of sizes. Parameters for an individual stent may be defined by reference to further performance specifications such as optimal ring size/oversize in the vessel, optimal wire diameter, and optimal number of wire turns. All of these parameters are determined with initial values, and then a model of each product is subjected to simulation of compaction or deployment and/or operational lifetime at step S28. This is the point at which the FEA model with the bi-material model and partitioned elements is used to simulate performance of the candidate design. Simulations for each product size are repeated as necessary, updating the design and/or performance specification as required.

An additional validation and verification of the design may be performed at step S30 to ensure the design meets the specifications. If not, the process repeats design step

S26 to refine the object model. Upon satisfactory completion of step S30, the product design is “frozen” and documented at step S32, at step S34 the design or designs are transferred to production and used to control manual and/or automated manufacturing processes yielding the manufactured product at step S36. If the design does not meet the specifications in step S30 and refinement of the object model in step S26 cannot achieve the specification after a certain number of iterations, the product design specification may be updated in step S38.

In the validation step S30, a particular characteristic of interest will be the fatigue life of the product. Fatigue life can be measured for example in numbers of cycles, corresponding to a lifetime under specified operating conditions. For a vascular implant, cardiovascular pulses are the cycles. Superelastic materials can be treated as having a fatigue life dependent on strain amplitude per cycle, whereas for conventional materials we would use stress amplitude as measure. Given the number of cycles, we calculate a “delta strain” (amplitude of strain variation per cycle) limit by performing accelerated fatigue testing on real samples. Then, when we model a Nitinol stent component in its pulsatile operating environment, in step S30 we are looking to ensure that the amplitude of strain variation at a specific location is less than our delta strain limit.

In conclusion, the reader will appreciate that the new models and methods described above enabled a production of a wide range of products, with more accurate modelling of performance and lifetime. Particularly for critical medical applications, as well as for applications in industrial, consumer, aerospace and the like, the enhanced model produces a more efficient design process, and enhanced reliability.

As mentioned already, the principle of partitioning an object model and applying a bi-material model can be applied to a wide range of products, that may be made out of exotic materials such as Nitinol and other superelastic materials. The techniques may be applied, in particular in different forms of stents for endovascular stent-graft devices, whether they be made of wire or cut-sheet or cut tubing, and whether they be made of turns of wire, zigzags, welded sections or the like.

An advantage of the described embodiments is that the bi-material model can be input to existing FEA systems such as ABAQUS and other commercially available products which have symmetrical constitutive models for superelasticity, without modification of the underlying software. The operator need only tell the software that a product is made partly of one material (tensile material model) and partly of another (compressive material model). On the other hand, in future there may be provided commercial software, including the bi-material model as a "virtual material", implementing automatic adaptive material assignment so that the operator is not so concerned with the partitioning. The modified FEA system running the model would then perform automatic adaptive partitioning as described above, in which the elements are inspected at each iteration or periodically. In this way the system can determine whether, within the "virtual material" model, a sub-model for compressive behaviour or tensile behaviour should be applied. The invention is not limited to one mode of implementation or the other.

It will be appreciated that different steps in the illustrated methods may be performed at different locations in the world and/or by different persons collaborating. Just as an example, the computer-implemented modelling steps using FEA might be performed on a data processing system physically remote from the system on which the object design is being developed. The steps of creating the bi-material model may be performed on a system physically separate from the system performing FEA. These data processing systems may further be remote from the location at which products according to the resulting design are manufactured.

The above and many other variations and modifications can be envisaged by the skilled reader, without departing from the spirit and scope of the invention.

CLAIMS

1. A computer-implemented method of simulating the performance of an object made of a material, the method comprising the steps:

(a) obtaining a first material model that describes the behaviour of the material under tension;

(b) obtaining a second material model that describes the behaviour of the material under compression;

(c) creating an object model that describes the geometry of the object in a form suitable for numerical analysis;

(d) performing numerical analysis using the object model and material models together to simulate behaviour of the object under defined conditions, the object model being partitioned such that in parts of the object model subject to superelastic tension the first material model is used to simulate the material behaviour and in parts of the object model subject to superelastic compression the second material model is used to simulate the material behaviour.

2. A method as claimed in claim 1 wherein the partitioning of the object model is fixed throughout the numerical analysis.

3. A method as claimed in claim 1 or 2 further comprising a step (e) of varying the partitioning of the object model after performance of the numerical analysis step (d) and repeating the numerical analysis with the varied partition.

4. A method as claimed in claim 3 wherein in step (e) the varied partitioning of the object model is calculated automatically in response to conditions of tension and compression calculated during the numerical analysis.

5. A method as claimed in any preceding claim wherein the partitioning of the object model is varied during said numerical analysis.

6. A method as claimed in claim 5 further comprising a step (f) of varying the partitioning of the object model automatically during performance of the numerical analysis step (d) in response to conditions of tension and compression calculated during the numerical analysis.

7. A method as claimed in any preceding claim wherein the first material model and the second material model are arranged such that for values of tension and compression close to zero both models describe substantially identical behaviour.

8. A method as claimed in claim 7 wherein the first material model and the second material model are arranged to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

9. A method as claimed in any preceding claim wherein the step (a) comprises:

(a1) obtaining experimentally observed stress-strain characteristics of the superelastic material under tension;

(a2) creating the first material model so as to approximate the experimentally observed characteristics under tension while assuming that the stress-strain characteristics under compression and tension are symmetrical,

and the step (b) comprises:

(b1) obtaining experimentally observed stress-strain characteristics of the superelastic material under compression;

(b2) creating the second material model so as to approximate the experimentally observed characteristics under compression while assuming that the stress-strain characteristics under compression and tension are symmetrical.

10. A method as claimed in claim 9 wherein in steps (a2) and (b2) the first and second material models are constrained to describe substantially identical behaviour for values of tension and compression close to zero.

11. A method as claimed in claim 10 wherein the first material model and the second material model are arranged to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

12. A method as claimed in any preceding claim wherein the numerical analysis comprises finite element analysis, wherein the object model is a finite element model which describes the object geometry by subdividing it into a plurality of interconnected elements, and wherein said partitioning is performed so as to assign to each element of the object model either the first material model or the second material model.

13. A method as claimed in any preceding claim wherein the material is a superelastic metal.

14. A method as claimed in any preceding claim wherein the material is a shape memory metal.

15. A method as claimed in any preceding claim wherein the material is a nickel-titanium alloy.

16. A method of designing a product made of material, the method comprising the steps of:

(j) receiving a design specification of the product including both dimensional and performance requirements;

(k) selecting a candidate material from which the product might be made, the candidate material having asymmetric stress-strain characteristics;

(l) creating a first candidate object model describing the geometry of a candidate design for the product;

(m) performing numerical analysis using the candidate object model so as to simulate behaviour of a product made to the candidate design under test conditions;

(n) evaluating the simulated behaviour of the product against the requirements of the design specification;

(o) modifying the selected material and/or the candidate design and repeating steps (m) and (n) until the evaluation in step (n) indicates compliance with the requirements of the design specification; and

(p) outputting the modified design as a final candidate design,

wherein the numerical analysis in step (m) includes partitioning the object model such that in parts of the object model subject to superelastic tension a first material model is used to simulate the behaviour of the selected material and in parts of the object model subject to superelastic compression a second material model is used to simulate the behaviour of the selected material.

17. A method as claimed in claim 16 wherein said evaluating step includes predicting fatigue safety of a product made to the candidate design, based on a strain amplitude per cycle calculated using said numerical analysis.

18. A method as claimed in claim 16 or 17 wherein the numerical analysis is performed by a method as claimed in any of claims 1 to 12.

19. A method as claimed in any of claims 16 to 18 further comprising a step (q) of manufacturing a product using the selected material and the final candidate design.

20. A method as claimed in claim 19 wherein said product is a medical implant.

21. A method as claimed in claim 20 wherein said product is an endovascular stent-graft device in which at least one stent component has been made using the selected material and the final candidate design.

22. A method as claimed in claim 21 wherein said stent component is a ring stent comprising one or more turns of wire.

23. A product obtained by performing a method as claimed in claim 16, 17 or 18 to obtain final candidate design and manufacturing the product according to the final candidate design.

24. A method of obtaining a material model for use in simulating the behaviour of objects made from a material, the method comprising the steps:

(a1) obtaining experimentally observed stress-strain characteristics of the material under tension;

(a2) creating the first material model so as to approximate the experimentally observed characteristics under tension while assuming that the stress-strain characteristics under compression and tension are symmetrical,

and the step

(b1) obtaining experimentally observed stress-strain characteristics of the material under compression;

(b2) creating the second material model so as to approximate the experimentally observed characteristics under compression while assuming that the stress-strain characteristics under compression and tension are symmetrical.

25. A method as claimed in claim 24 wherein in steps (a2) and (b2) the first and second material models are constrained to describe substantially identical behaviour for values of tension and compression close to zero.

26. A method as claimed in claim 25 wherein the first material model and the second material model are constrained to have the same modulus of elasticity for values of tension and compression below respective thresholds of superelasticity.

27. A method as claimed in claim 24, 25 or 26 further comprising steps of forming an object model and running a numerical analysis, wherein the numerical analysis comprises finite element analysis, wherein the object model is a finite element model that describes the object geometry by subdividing it into a plurality of interconnected elements, and wherein said partitioning is performed so as to

assign to each element of the object model at a given time either the first material model or the second material model.

28. An data processing apparatus arranged for simulating the performance of an object made of a material, the apparatus comprising:

- storage for a first material model that describes the behaviour of the material under tension;
- storage for a second material model that describes the behaviour of the material under compression;
- storage for an object model that describes the geometry of the object in a form suitable for numerical analysis;
- a processor for performing numerical analysis using the object model and material models together to simulate behaviour of the object under defined conditions using the object model, the processor being arranged to partition the object model such that in parts of the object model subject to superelastic tension the first material model is used to simulate the material behaviour and in parts of the object model subject to superelastic compression the second material model is used to simulate the material behaviour.

29. An apparatus as claimed in claim 28 wherein said processor is arranged to vary the partitioning of the object model after performance of the numerical analysis and to repeat the numerical analysis with the varied partition.

30. An apparatus as claimed in claim 29 wherein said processor is arranged to calculate said varied partitioning of the object model automatically in response to conditions of tension and compression calculated during the numerical analysis.

31. An apparatus as claimed in claim 28, 29 or 30 wherein said processor is arranged to vary the partitioning of the object model during said numerical analysis.

32. An apparatus as claimed in claim 31 wherein said processor is arranged to vary the partitioning of the object model automatically during performance of the numerical analysis step in response to conditions of tension and compression calculated during the numerical analysis.

33. An apparatus as claimed in claim 28 wherein said numerical analysis comprises finite element analysis, wherein the object model is a finite element model which describes the object geometry by subdividing it into a plurality of interconnected elements, and wherein said partitioning is performed so as to assign to each element of the object model at a given time either the first material model or the second material model.

34. A computer-implemented method of simulating an object wherein an object model representing the object is partitioned such that in parts of the object model subject to superelastic tension a first material model is used to simulate the behaviour of the selected material and in parts of the object model subject to superelastic compression a second material model is used to simulate the behaviour of the selected material.

35. A method of manufacturing a product wherein one or more components of the product have been designed based on behaviour of the component simulated by a method as claimed in claim 34.