USING HAPTIC MODELLING FOR SPINAL IMPLANT DESIGN

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ABSTRACT

The link from medical scan images through data manipulation to additive manufacturing is well established. Various types of software are used to deliver the required .STL file(s). Often, the data manipulation will require the generation of new shapes around existing geometry, e.g. an implant that will replace missing bone tissue. This paper reports exploratory work undertaken to assess the feasibility of using haptic modelling and “virtual sculpting” software to generate novel designs of vertebrae implants for correction of spinal curvature. .STL data of several vertebrae, originating from CT scans, was imported into the Freeform system from SensAble technologies. It was used to create immutable “bucks” around which the user “sculpted” three-dimensional implant geometries. It must be noted that the designs have not been medically assessed and were for demonstration purposes only. However, the process route followed did prove to be feasible and offered some particular advantages, e.g. a precise fit between the implant and the vertebra and the possibility of enabling the direct intervention of medics in the implant design process.

Keywords: Spinal deformities, spinal implants, haptic modelling, shape memory alloy

1. INTRODUCTION

In recent years, medical modelling has proven to be a growing application area for additive manufacturing (AM). Earlier applications mainly involved surgical planning and other visualisation tasks. More recently, direct implants have been generated. In every case, there is a need to translate the medical scanning data (taken from CT or MRI) into the final .STL file used for layered production of the model or implant. Although the route for this translation is now well established, using the MIMICS software from Materialise, for instance, it is nonetheless still a very skilled and time-consuming task. Prior to exporting the data to the AM system, it may first be necessary to generate new shapes, e.g. a prosthesis that matches up to remaining tissue. This can potentially be undertaken within MIMICS (e.g. by using the MedCAD module) or by exporting the geometry to a conventional CAD system. A third option is to use the .STL file as the starting point within a haptic modelling system based on voxel representation of geometry. The exploration of this third route is the topic covered by this paper. The paper begins by presenting a typical medical problem that could benefit from this approach, goes on to report the procedure that was followed and concludes by assessing the feasibility of using haptic modelling in this field.

2. SCOLIOSIS AND CURRENT TREATMENTS

Scoliosis (curvature of the spine) is a condition that involves complex lateral and rotational curvature and deformity of the spine (Figure 1). The deformity is essentially three-dimensional, but pathological curvatures may occur in the lateral plane or sagittal plane. Although the causes of scoliosis are poorly understood, the mechanical factors that contribute to its progression are now quite well defined. For reasons that can be related to congenital vertebral anomalies, an imbalance in the coronal or/and sagittal planes is created that leads to increased compressive loads across one side of a vertebral body. According to the Hueter-Volkmann law, a differential is created that causes a diminished growth in the area subject to compression (concave side). Conversely, distractive forces induce an exuberant growth on the convex side. Thus, in the setting of an established spinal asymmetry such as scoliosis, a vicious cycle of increased load asymmetry and progressive deformity is created: the greater the growth imbalance, the more severe the deformity, and this only stabilises at skeletal maturity when the growth plates fuse (Michael, 2006).

Fig. 1: X-ray showing a typical scoliosis deformity (also showing surgical implant)

Strategies for managing a case of scoliosis depend on the age of the patient, the severity of the condition and the predictable outcome. They can range from doing nothing to performing spinal surgery. Several alternatives are commonly used. For immature patients with a moderate degree of curvature, the technique known as bracing currently represents the standard method of care. Bracing involves the patient wearing a shaped "corset" that attempts to prevent further curvature occurring. However, studies have shown that 18% to 50% of these cases will worsen in spite of bracing (Betz et al., 2003).

So even though bracing is non-invasive and preserves the potential for continued patient growth and functional movement of the spine, it is only modestly successful in preventing curve progression. Moreover it must be considered that bracing for teenagers is not an easy treatment; it is uncomfortable and it may have a negative psychological impact due to compliance and aesthetic issues. For teenagers who have a high degree of curvature, surgery is usually the preferred option. Spinal deformity surgery aims to achieve a reasonable correction of the curvature that will prevent further progression as well as restoring or preserving function and the optimisation of cosmetic issues (Schlenk et al., 2003). Spinal fusion is the most widely performed surgery for scoliosis. Bone is implanted to the vertebrae so that two or more of them are combined when the bone itself heals. To keep the straightened spine in position until the bones are fused together, multiple hooks or wires are attached to the back of the individual vertebra and these are connected to one or two metal rods which have been pre-bent to the desired contour. Patients with fused spines and permanent implants are able to live relatively normal lives with unrestricted activities. However, the main drawback of spinal fusion is a loss of flexibility in the fused segments of the spine. All the associated risks that accompany major surgery also need to be taken into account.

To overcome these drawbacks, new techniques are being developed that exploit the patient's natural growth and redirect it to achieve correction (Braun et al., 2006a). Rather than restraining the spine with rods and screws, these new methods rely on vertebral bodies being stapled on the convex side of the curvature. This so-called fusionless scoliosis surgery has many potential advantages over either bracing or fusion techniques. Bracing only transmits forces indirectly by mean of the ribs, pelvis and torso whereas with stapling, the forces are directly applied where needed. Spinal stapling can also preserve motion, lessening the chance of back pain in adulthood (Braun et al., 2005). The technique requires the vertebral staples to be made from nickel-titanium, an alloy that exhibits a particular property called the shape memory effect. Before surgery, the staples are first immersed in an ice bath and the prongs, initially bent, are manually deformed to a straightened position. When finally applied to the bones, through the heat of the body the staples clamp down to a "C" position for a secure fixation (Figure 2). Studies have shown how vertebral body stapling for the treatment of adolescent idiopathic scoliosis is feasible and safe as well as having the capability of stabilising curves. Moreover, experiments carried out on animals have demonstrated bone growth modulation determined by the stapling, even though the strain provided by the implants was not able to fully reverse the Hueter-Volkmann effect. The use of shape memory alloys is relatively new and, although these results are encouraging, it is generally believed that a long term follow-up is needed as well as a better understanding of the forces acting on the vertebrae when the staples are inserted (Braun et al., 2006b).

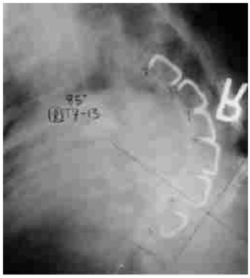

Fig. 2: Implantation of shape memory alloy staples on a goat model

3. INNOVATIVE SPINAL IMPLANT DESIGN

Vertebral stapling provides the advantages of preserving spinal flexibility and of being a less invasive procedure. However, the corrective force applied is not large enough to significantly correct the deformities since there is a limited amount of force that can be applied to the small area of contact with the vertebrae. Nevertheless, the use of shape memory effect to produce a continuous straightening force is a promising solution that requires further investigation.

An innovative implant design that aims to address the limitations of spinal stapling is one which embraces a larger surface area of a vertebral body and can therefore apply more force. However, to achieve a design that fits anatomical shapes and naturally occurring geometries is not a simple task with traditional CAD packages as these are mainly used to define regular mathematical geometries. A possible solution is the FreeForm Haptic Modelling system from SensAble Technologies which uses “virtual sculpting” techniques to manipulate complex, unconstrained three-dimensional shapes and forms. It provides tools analogous to those used in physical sculpting and works through a haptic interface (Figure 3), allowing the user to “feel” the object being worked on. The models are geometrically represented through voxels (three-dimensional pixels) and referred to as virtual 'clay' owing to the fact that they can be modified in an arbitrary way. FreeForm has already been employed successfully in the design of implants which perfectly fit naturally occurring geometries (Bibb et al., 2002).

Fig. 3: The Phantom haptic device used with the FreeForm modelling system

Working with the haptic-feedback stylus, the user is allowed to design surfaces onto already existing models, in this case a three-dimensional reconstructed geometry of an anatomical site. The models act as immutable "bucks" which are protected from accidental modification. The surface can be edited through a set of control points but still remain constrained to the bone of the vertebral body (Figure 4). This is the first step towards creating an implant that perfectly fits the bone geometry. An offset can be created if a certain clearance is required between the bone and implant. The surface can then be thickened to create a solid model which follows the size and shape of the anatomical bone. Additional features can then be added using virtual sculpting or more conventional solid modelling commands.

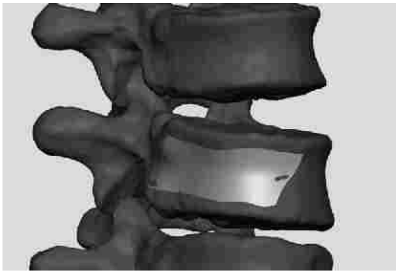

Fig. 4: An anatomical patch drawn on the vertebral body

The starting point for the new design of implant is the assumption that a curved spine can have a complex three-dimensional deformity with curvature in more than one anatomical plane and could also involve a twisting of the vertebra. The hypothesis for the work is that holding the vertebral body with a perfectly fitting custom made plate would make it possible to generate corrective forces that act on the whole bone rather than through a single point as happens with staples. Thus as well as preserving spine flexibility, the design could help more effectively to reach the goal of bone growth modulation and progressive correction of the deformity, according to the direction of the applied load. Using the haptic modelling techniques described above, a new design of implant has been created that surrounds the front and sides of the vertebral body and attaches to the transverse processes to anchor the implant at the back (Figure 5).

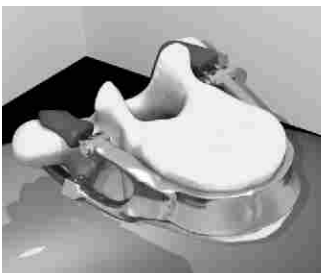

Fig. 5: The implant fits the anatomical shape of the bone

As pointed out by previous researchers (Sener et al., 2002) FreeForm excels in quickly producing organic form but is weak in the creation of engineering details. So the implant model had to be exported to an external CAD package in order to be finished. Bosses were added together with an assembly of clips and a coil spring intended to apply corrective loading (Figure 6). The placement of the coil spring would be chosen according to the plane in which the deformity occurs and any twisting that is present. It must be noted that the new implant design has not been medically assessed and was created for demonstration purposes only.

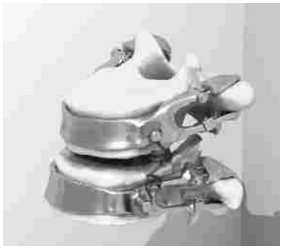

Fig. 6: Implant assembly showing positioning of corrective spring

4. MATERIAL REQUIREMENTS

Ideally, the plates shaped around the vertebral body would be connected to each other with coil springs made of a biocompatible shape memory alloy (SMA). Such springs exhibit a property known as super-elasticity due to a solid-solid reversible austenite-martensite transformation that happens when a tension is applied. Super-elasticity means that a strain range with approximately constant stress can be observed as in the stress-strain diagram of a Ni-Ti alloy shown in Figure 7. In this diagram, region A to B relates to the elastic behaviour of the austenite phase, region B to C is the “loading plateau” caused by the transformation from austenite to force-induced martensite, region C' to D represents the elasticity of the martensite phase, region D to E is the “unloading plateau” where the retransformation from martensite to austenite occurs and region E to A once again shows the elasticity of the austenite phase.

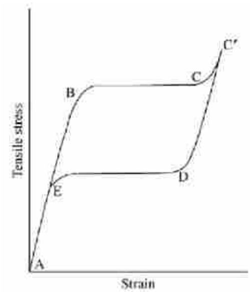

Fig. 7: Theoretical stress-strain curve of an SMA

Super-elasticity is the most important advantage afforded by an SMA material. If the extension of the spring between two points to which it is attached falls in the elongation range where constant stress is provided, then a constant force can be applied to straighten the spine, whilst still allowing the flexibility required during the patient's movements. Shape memory alloy coil springs are already commercially available for orthodontic applications. They provide orthodontists with the ability of exerting light constant spring-back force over a large range of deformations thus helping to gradually straighten the patient's teeth (Raboud et al., 2000). Obviously, higher spring rates would be required for the treatment of scoliosis.

The material properties of an SMA need to be tuned to meet the demands of a specific clinical situation through suitable thermo-mechanical treatments. Therefore, the mechanical effectiveness of a particular appliance is closely related to the specific material properties. In addition, the biocompatibility of Ni-Ti alloy is an issue that needs to be addressed. Investigations by Machado and Savi (2003) showed that although nickel is a highly poisonous element, good biocompatibility of Ni-Ti alloys can be achieved through the innocuous surface layer of TiO_2 that is produced by the oxidation of the titanium. This layer surrounds the sample, theoretically making the alloy harmless to the human body.

5. CONCLUSIONS

To shape the implants to the exact features of the anatomical bones is a promising concept to develop more effective spine device designs in the future. The forces exerted by the prosthesis can be directed more precisely. Using the CAD interface, other issues such as the accessibility of the sites during the surgery can be addressed even before the real intervention takes place. It must be pointed out that FreeForm is an easy to learn software: the interface is friendly and once a new user has become familiar with some basic concepts, it is straightforward to work with and design tasks can be carried out without experiencing many problems. It may even be feasible to have surgeons working directly on the 3D model using the haptic modelling interface. From experience, the greatest barrier here would be the time availability of the surgeons rather than the difficulty of using the system.

In the view of the authors, the design process should be thought out and configured by drawing upon experiences and skills from different working and cultural backgrounds. Due to the complexity and the specificity of the issues faced in both the medical and engineering fields, only through a collaborative project can a reliable and robust design be achieved. Indeed, future studies should focus on how the innovative implants integrate with muscles and ligaments. Moreover, depending on which is the best insertion strategy, the design should be modified and updated to meet the demand for safe medical procedures.

Although only one application area has been investigated here, haptic modelling is flexible and could potentially be applied to many regions of human anatomy. It scores particularly well where the anatomical geometry is too complex to be dealt with easily in existing CAD systems, even those tailored to medical design. Future work will investigate a range of application areas and draw measured comparisons with other process routes.

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