Orthopaedic Applications of Ferromagnetic Shape Memory Alloys

by

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Submitted to the Department of Materials Science and Engineering
in partial fulfillment of the requirements for the degree of

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Abstract

Ferromagnetic shape memory alloys (FSMAs) are a new class of magnetic field-actuated active materials with no current commercial applications. By applying a magnetic field of around 0.4 T, they can exert a stress of approximately 1.5 MPa, exhibiting a strain of up to 6%. This thesis evaluates their technical and commercial feasibility in orthopaedic applications. Remote actuation is a key advantage FSMAs have over current implant materials. Also, the human body temperature is constant, providing a stable environment for FSMAs to operate.

A number of potential orthopaedic applications are proposed and evaluated. Out of these, the most prominent application is the spinal traction device. It is a temporary implantable device, intended to perform internal spinal traction. A design has been proposed, with suggestions of suitable materials for its various components and appropriate device dimensions. Preliminary market and cost analyses have been conducted. This orthopaedic technology is currently in its infant stage. To commercialize this device, more trials are needed.

Thesis Supervisor: Samuel M. Allen
Title: POSCO Professor of Physical Metallurgy
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1. Overview of Ferromagnetic Shape Memory Alloys

1.1 Introduction

This thesis evaluates the technical and commercial feasibility of ferromagnetic shape memory alloys (FSMAs) in orthopaedic applications. A photo of a Ni-Mn-Ga single crystal (a member of the FSMA family) is shown in Figure 1. The background of the development of such alloys is provided in the following section. Their properties and capabilities are briefly discussed. Some potential orthopaedic applications of these alloys are proposed and analyzed in this thesis. During the author’s search for viable orthopaedic applications, a key application identified is the incorporation of FSMAs into spinal implants. An overview of spinal problems is given in Chapter 3, which also introduces the means by which FSMAs may be utilized to mitigate and possibly cure these disorders. Besides these, competing technologies, supply chain, and intellectual property issues are analyzed. Risks and the future direction are outlined at the end.

Figure 1. Photo of single-variant sample of Ni$_{49.4}$Mn$_{29.7}$Ga$_{20.9}$ at room temperature in zero external field [1].
1.2 Background of Ferromagnetic Shape Memory Alloys

Ferromagnetic Shape Memory Alloys (FSMAs) officially became recognized as a new class of active materials when a 0.2% magnetic-field-induced strain in a single crystal of Ni$_2$MnGa was observed in 1996 [2]. This was only a fraction of the 6 to 7% strain ultimately attainable by field-induced twin selection in such alloys [3], which can exert a stress of 1 to 2 MPa as one twin variant is completely converted to another [4,5]. This strain is reversible upon the application of a magnetic field in an orthogonal direction [5]. Comparatively, other active materials exhibit much lower strains. Piezoelectric materials show strains on the order of 0.1%, while the leading magnetostrictive material, Terfenol-D, exhibits a field-induced strain of about 0.24% [6]. FSMAs exhibit martensitic phase transformation, allowing control of large strains by magnetic field application. The field-induced strain is the result of twin boundary motion in the martensitic phase. It can be induced by either magnetic field or mechanical stress. These large strains make FSMAs suitable for actuator and sensor applications. Although other members of this family of materials, including Co$_2$MnGa, FePt, CoNi and FeNiCoTi, have been explored during the past few years [5], Ni-Mn-Ga alloys remain the best-performing room-temperature candidate.

The strain phenomenon of Ni-Mn-Ga results from twin-boundary movement in martensitic single crystals. The magnetic easy axis is in the same direction as the c-axis of the tetragonal martensitic unit cell. This axis direction is different for each of the twin variants. For martensitic crystals with large uniaxial magnetic anisotropy, applying a magnetic field parallel to the easy axis of one variant would destabilize the others present [7]. This process is shown in Figure 2. The minimum required magnetic field to initiate twin boundary motion is typically 0.4 T [8]. Any field beyond this can induce the twin boundary to move such that the volume of the variant which best aligns with the applied field is increased. The magnetic field-induced austenite to martensite transformation is illustrated in Figure 3, which shows how an increasing field or stress can induce the transformation.
Figure 2. Application of magnetic field in the same direction as the easy axis of one twin variant induces the twin boundary to move such that the volume of that variant is increased [7].

Figure 3. Top: Magnetic field-induced transformation of an austenitic sample to a single-variant martensitic structure. Bottom: The A-M phase boundary is shown below in field-stress-temperature space; the arrow indicates how an increasing field can induce the transformation (horizontal ε-H path). This process may also be assisted by the application of a suitable stress (vertical ε-σ path) [1].
In order to exhibit magnetic field-induced strain, four essential material property criteria need to coexist [4]. Firstly, a low-symmetry phase, martensite, must exist under actuation conditions for twinning deformation to occur. For tetragonal martensites, the crystallographic ratio $c/a$ determines the maximum twinning strain. Next, the twin-boundary yield stress must be sufficiently low to allow the magnetic moments of the material to maneuver the twin defect structure. Also, the material has to be ferromagnetic with a large saturation magnetization. This magnetization magnitude plays a role in generating sufficient magnetic forces within the material. Finally, the magnetocrystalline anisotropy must be sufficiently large along a particular crystallographic axis of easy magnetization, rather than in a plane.

For martensitic Ni-Mn-Ga, large magnetocrystalline anisotropy causes magnetic moment alignment with the c-axis on either side of the twin-boundary. The magnetic energy stored as a result of hard-axis magnetization exerts pressure on the twin-boundary. This occurs until the twin-boundary yield stress is reached and twin-boundary motion occurs. If twin boundaries are pinned on defects, which prevent the former from sweeping through the whole alloy, actuation stops and further energy storage occurs.

The aforementioned twin-boundary-driven strain effect has only been observed in single crystals, which are brittle and expensive to grow [9]. Under uniaxial loading, however, cyclic magnetic field actuation has demonstrated hundreds of thousands of strain cycles without fracture [4]. These factors limit their commercial usefulness. Therefore, there is current research on composites fabricated from Ni-Mn-Ga powder mixed with polymer [10]. Such composites are easier to make and are more economical. Also, they are capable of withstanding higher stresses in both compression and tension than the single-crystal form. The viability of such composites may be pivotal to the commercial success of FSMAs.

Due to the large linear deformation-induced change in magnetization, FSMAs can be implemented into stress sensors. They have been explored as possible magnetoelectric converters [11], although the conversion efficiency is currently too low to be commercially feasible. There has also been interest in the thin film technology of Ni-Mn-Ga alloys for micro- and nano-system applications [12, 13].
In the field of active flow control technology, FSMAs are being researched as actuators in synthetic jet applications [14]. To produce string synthetic jet flow at high frequency, a new membrane actuator based on an FSMA composite and hybrid mechanism was designed and constructed. Due to the large force and martensitic transformation on the FSMA composite diagram, the membrane actuator designed can produce 190 m/s synthetic jets at 220 Hz.

Although FSMAs have been widely investigated in the laboratory, little research has been conducted to apply the unique properties of FSMAs to biomedical devices. The following chapter analyzes some potential orthopaedic applications of these alloys.
2. Potential Orthopaedic Applications

2.1 Search for Applications
Since the first demonstrated magnetic-field-induced strain in 1996 at MIT [2], there has been significant interest in FSMAs from the scientific community from a materials research point of view. However, there is yet to be any large-scale commercial application. The United States Navy has experimented with them as the active material for sonar transducers, but has achieved limited success [15].

The author believes that FSMAs have great potential to be used as a medical implant material. This is because of two reasons. Firstly, the human body is a constant temperature environment, which is very stable for the operation of FSMAs. Secondly, FSMAs can be remotely actuated by a magnetic field. Such remote actuation means that the conformation of implants may be remotely altered after surgery. However, there is no current research on the orthopaedic applications of FSMAs. Thus, it has been the author’s task to identify and evaluate various potential applications since the commencement of this project.

2.2 Bone Fixation Devices
One such possible application lies in the field of bone fixation. Bone fixation devices are tools which hold fractured bones in place to enable them to heal. They include bone plates, rods and screws. An initial compression is usually applied on the fracture site by these devices because compressive stresses promote faster healing. This is referred to as compression healing, which is only suitable for simple fractures, where the cortex of the bone is still intact, with good cortical contact [16]. For convoluted fractures, where the bone has been broken into several pieces, compression cannot be used because the bones will otherwise collapse.

Simple fractures usually heal well using current bone plates and screws [16, 17]. Difficult fractures may occur for cases of high trauma, such as for high impact fractures. For such fractures, bone loss may result at the fracture site. The osteocytes at the connecting ends of the bones may die off, leaving a gap. Such cases are known as delayed unions or non unions, which
may not heal even with the aid of current bone plates. In these situations, the usual course of action taken by surgeons is to conduct another surgery and use bone grafting [16].

Figure 4. General purpose plating for a variety of midfoot and rearfoot surgical procedures [18]. Such plating is useful for isolated tarsal fusions and for Evans lengthening procedures with interpositional bone grafts.

This is a field where FSMAs can play a useful role. Figure 4 shows a conventional bone plate being implanted during a foot surgical procedure. FSMAs may be incorporated into the inner shaft of the bone plate, so that medical personnel can induce further compression externally to stimulate healing for difficult fractures, negating the need for additional surgery. Whenever surgeons identify high-impact fractures, which are likely to result in delayed or non unions, they can implant bone plates with FSMA enhancement. These can be furthered compressed after surgery for treatment of the fractures. Cost would play a large role in determining the popularity of such enhanced bone plates in hospitals. Thus, a preliminary estimate of how much more expensive such plates would be, compared to conventional ones, is important in determining their viability.

2.2.1 Cost
Since there has not been any large-scale commercial production of FSMAs, it is challenging to obtain an accurate prediction of the cost of such FSMA-enhanced bone plates. MIT obtains FSMA crystals for research purposes from the Ames Laboratory, United States Department of
Energy. A single Ni-Mn-Ga crystal, 7.5 cm in length with a diameter of 2.5 cm, costs approximately $2,000 [19]. A preliminary estimate of the cost of FSMA incorporation would be close to at least an additional $800 per device. It is reasonable to assume that this cost would drop as FSMAs are mass produced. Also, the cost of the external electromagnet has to be factored into the overall cost of treatment. However, the electromagnet can be re-used and shared among several patients. Thus, its cost can also be distributed.

2.2.2 Potential Market of Enhanced Bone Fixation Devices

The global demand for bone fixation devices is rapidly growing. Synthes, a leading global medical device company, currently holds a 50% share of the US orthopaedic implant market [20]. Specializing in fabricating bone plates, rods and screws, its global net sales was close to 2.8 billion dollars in 2007. Its growth of more than 15% from the preceding year shows that the market is rapidly expanding. A summary of its global sales is provided in Table 1. Although this market size appears promising, FSMA-enhanced bone fixation devices would take up only a niche segment of it, probably in the domain of difficult fracture treatment.

<table>
<thead>
<tr>
<th>In US$ millions</th>
<th>Full Year 2007 (January – December)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consolidated Net Sales</td>
<td>2007</td>
</tr>
<tr>
<td>North America</td>
<td>1,721.0</td>
</tr>
<tr>
<td>Europe</td>
<td>637.3</td>
</tr>
<tr>
<td>Asia Pacific</td>
<td>248.4</td>
</tr>
<tr>
<td>Rest of the World</td>
<td>153.0</td>
</tr>
<tr>
<td>Total</td>
<td>2,759.7</td>
</tr>
</tbody>
</table>

¹ Local currencies – 2007 results translated at 2006 foreign exchange rates.

Table 1. Global sales summary of Synthes in 2007. The net sales have grown by more than 15% from the previous year [20].

2.2.3 Supply Chain Analysis

In order to bring FSMA-enhanced fixation devices into the market, collaboration with existing device manufacturers is the most cost-effective route to take. AdaptaMat is a company in Finland,
specializing in the growth of FSMA crystals and actuators. One strategy is to obtain appropriate patents and license them out to companies like AdaptaMat. A better way would be to collaborate with AdaptaMat to produce specific FSMA components suitable for incorporation into bone fixation devices. Such sharing of expertise and facilities is helpful to producing top quality and low-cost FSMA products. The components could then be sold to large medical implant companies such as Synthes, which would incorporate them into some of their fixation devices. It is not cost-effective to produce entire implants solely by a new start-up. Major implant firms like Synthes run hundreds of product lines. Thus, from an economy-of-scale perspective, it is unwise for a start-up to run entire production lines just to produce a few types of products. Therefore, smooth virtual vertical integration with companies like AdaptaMat and Synthes is the best route to commercialization of the products. Such collaboration is illustrated in Figure 5.

Figure 5. Collaboration with existing manufacturing companies is a cost-effective route to bring the products into the market. Mutual exchange of expertise is helpful in improving product quality and lowering cost.

2.2.4 Competing Technologies
In the treatment of difficult fractures, the main competing technology is bone grafting. The cost of a bone graft ranges from $250 to $900 [21], excluding other hospital charges such as surgeons’ fees and equipment costs. This is relatively inexpensive, compared to FSMA-enhanced bone plates. In a study of over 1000 patients who received very large allografts after surgery for bone cancer, 85% of them were able to return to work or normal physical activities without using clutches [21]. Less severe bone defects, such as fractures, should heal completely without serious complications. This shows that bone grafting is an effective treatment for difficult fractures.
When treating difficult fractures, surgeons may prescribe the use of bone grafts directly. Thus, FSMA-enhanced bone fixation devices do not achieve a truly unique treatment purpose. Compared to its main competitor, bone grafting, FSMA bone fixation is not cheaper. Also, bone grafting is effective in treating difficult fractures. The disadvantages of FSMA bone fixation outweigh its merits. Therefore, it is not advisable to continue with the development of FSMA bone fixation.

2.3 Fracture Union Detector

Knowing exactly when a fracture has healed optimizes treatment for the patient. It provides an indication of when various rehabilitation programmes can be initiated [22]. Studies of fracture treatment often rely on radiographically defined end-points to make treatment recommendations [23]. Since union is considered the end-point of fracture healing, it must be accurately defined. Its clinical definition must be precise enough to avoid both over- and under-treatment. Currently, it is challenging to use radiographs for defining fracture union in conservatively treated fractures [24, 25]. Clinical assessment of such union is also unreliable [26].

Internal fixation of fracture affects its mechanical and biological environment. Thus, the amount of callus formation and the extent of cortical bridging may be affected. The definition of union by radiographs depends on these two factors. In a recent study of fracture union, 47 radiographic series of forearm, femoral and tibial fractures treated using internal fixation over a 3-year period were reviewed [27]. Callus formation and fracture line filling with time were measured on each radiograph. The conclusion of the study was that radiographs do not define union in internally fixated fractures with sufficient accuracy to enable their use as end-points of fracture healing. Thus, radiographic end-points are not sufficiently dependable for treatment recommendations. Therefore, there is a need for a more accurate method of fracture union detection.

This is an area where FSMA-enhanced bone fixation devices may play a part. Figure 6 shows a diagrammatic side view of a fracture fixated by a bone plate with an FSMA component as part of its shaft. As the fracture heals, callus formation at the interface of the fracture shares more of the load originally borne by the bone plate. To quantify the amount of callus formation, and thus the extent of fracture healing, an approach is to detect the stiffness of the fracture region. With the
patient at rest and hence, in the absence of external forces, apply a time-varying magnetic field on the bone plate. The strain response of the bone plate would provide an indication of how stiff the fracture region is. The stiffer the fracture region, the more the strain response of the bone plate would be impeded, indicating more callus formation and better fracture healing. Thus, the progress of fracture healing and its end-point can be determined with FSMA-enhanced bone plates. Care has to be taken such that these assessments of the progress of fracture healing do not have detrimental effects on the healing itself. The author feels that this potential application deserves further exploration.

Another promising orthopaedic application of FSMAs is in the treatment of spinal problems. This concept is attributed to Professor James Goh and his research group at the National University of Singapore. It is discussed in detail in the following chapter.

2.4 Magnetic Field Exposure Concerns

Since the actuation of FSMA devices in the body would inevitably entail human exposure to magnetic fields, it is necessary to check whether such exposure would involve any risks or cause long term effects. Some of the established effects of exposure to static magnetic fields include
vertigo, nausea and phosphenes, as a result of movement in the field [28]. The magnitude of the magnetic field required to actuate the FSMA component is up to 0.4 T. To achieve this value at the site of the FSMA component, higher field levels may be inflicted upon the regions of the body nearer to the external magnet. Thus, a safety margin is needed.

According to the International Commission on Non-Ionizing Radiation Protection, the ceiling value of static magnetic field exposure is 2 T [28]. The magnetic field level required for the actuation of FSMA devices is significantly lower than this value. Also, the exposure limit averaged for a working day is 0.2 T. This average value is not a cause for concern, since patient exposure to magnetic field is only needed for actuation to occur and hence, the exposure time is very short.
3. Traction for Spinal Disorders

3.1 Spinal Traction Overview

Since at least 1800 BC, traction has been used to treat spinal disorders [29]. By the 19th century, the traction bed was used to treat scoliosis, backache, rickets and spinal deformity [30]. During the last century, traction became a common treatment technique for chronic low back pain, although opinions differ regarding how traction should be applied [31]. Currently, it is still popular as a treatment technique for lumbar spine conditions, being used in approximately 7% of physiotherapy sessions in The Netherlands [32]. It is most commonly used for the relief of pain, normalization of neurological deficits or painfully restricted neuromeningeal tension signs [33, 34], and for improving joint mobility [35]. It has also been promoted for lumbar disc lesions, relying on the theory that it would produce negative pressure in the disc and thus reduce disc herniations [36].

Traction could improve signs and symptoms of spinal disorders by biomechanical effects, primarily the separation of the intervertebral motion segments [37]. This mechanical vertebral separation may induce neurophysiological changes which result in pain reduction. It may provide relief from radicular symptoms by removing direct pressure or contact forces from sensitized neural tissue [38].

Axial lumbar traction has been reported to increase intervertebral disk height [39, 40]. In the area of stenosis relief, it has also been shown to produce an increase in bony foraminal area, although the central canal area remains unchanged [41]. It is believed that any force or movement that causes a measurable anatomical increase in central or lateral canal size will result in physiological neural decompression at least temporarily [42]. The apparent lack of a dose-response relationship suggests that low doses may be sufficient to achieve benefit [38].

By its non-surgical nature, traction is an externally administered technique which is unable to target specific problematic regions of the spinal vertebrae. Current traction techniques are unable to limit their effects to targeted treatment regions. The applied traction forces are distributed over a large portion of the spinal column and inadvertently affect other healthy spinal regions. This
may reduce the forces acting on the targeted region, as well as the displacement experienced by it.

After discussion with Prof James Goh of the National University of Singapore, the author proposes the design of an FSMA spinal traction device which could cater to this issue. Such a device is intended to be temporarily implanted, for up to a few months, to achieve regulated and specific traction from within the body. Its purposes are to provide pain relief and promote tissue recovery. Similar to current traction protocols, the FSMA device can be actuated to provide traction for a fixed number of hours every day. The amount of force and displacement required by the treatment can be regulated by adjusting the externally applied magnetic field. This device is designed to be positioned in between two spinous processes and to exert a force to push the processes apart when actuated, resulting in separation of intervertebral segments. The following section describes this proposed device in detail.

3.2 Proposed Treatment: FSMA Spinal Traction Device

The author has undertaken the task of designing an FSMA device which can fit into the confines of the space between two spinous processes, exert sufficient traction force and exhibit the required displacement. Schematics of the proposed design are presented in Figures 7, 8 and 9.

To make an FSMA component, a piece of FSMA (4 cm x 1 cm x 1 cm) is cut into 10 equal slices for better actuation. To minimize biocompatibility issues with the body, it is encapsulated with a rigid polymer cap and a flexible polymer cover, as shown in Figure 7. The rigid cap has to possess sufficient load-bearing capability, while the flexible cover must not hinder the extension of the FSMA.
Figure 7. Encapsulated FSMA. Each FSMA component is encapsulated by rigid caps on both ends and by a flexible cover in the middle, as shown in this figure. The rigid cap can be made of poly(styrene-block-isobutylene-block-styrene) (SIBS). The flexible cover can be made of either polydimethylsiloxane (PDMS) or polyethylene terephthalate (PET). The dimensions of the FSMA component are 4 cm x 1 cm x 1 cm. It is cut into 10 equal slices for better actuation.

Figure 8. Diagram of the FSMA spinal traction device (side view). Two encapsulated FSMA components would be slotted into two titanium casings and positioned in between two spinous processes of the body. External magnetic actuation of the FSMA components would push the spinous processes further apart from each other.
Slots to insert encapsulated FSMA components

Figure 9. Top view of a titanium casing. One FSMA component would be inserted into each of the slots shown. When the FSMA components have been sandwiched in between two titanium casings, they would be prevented from falling out of the spinal traction device by the side barriers of the casings.

The proposed candidate for the rigid cap is poly(styrene-block-isobutylene-block-styrene) (SIBS). The development of SIBS for medical devices evolved from deficiencies encountered with the long-term in vivo performance of polyurethanes, such as their degradation and resulting inflammatory and fibrotic reactions [43]. These deficiencies limited the use of polyurethanes for long-term load-bearing implant applications and for applications in contact with a metal, as metal ions contribute to polyurethane degradation by oxidative pathways. SIBS has been developed to overcome these deficiencies. The inertness of SIBS has enabled some novel medical devices, including a synthetic trileaflet aortic valve to possibly replace tissue and mechanical valves. Several other medical devices made from SIBS, including spinal implants, are in their early stages of development and may be commercialized over the next few years. From the processing perspective, SIBS can be injection and compression molded, as well as extruded and solvent cast from non-polar solvents.

However, there are some drawbacks to the thermoplastic nature of SIBS [43]. Firstly, it is susceptible to stress cracking in the presence of organic solvents. Also, it has poor creep properties and therefore requires fiber reinforcement for certain load-bearing applications. The non-polar nature of SIBS does not allow sites for hydrogen bonding, unlike polyurethanes, thus limiting its ultimate tensile strength to less than that of dry polyurethane. SIBS has poor gas
permeability, which renders it more cumbersome to sterilize with ethylene oxide. All surfaces must be exposed to this gas. Furthermore, SIBS is not gamma-ray sterilizable. At the present production rate, the cost of synthesis and purification of SIBS is relatively high. Finally, due to intellectual property constraints, there is no source for implant-grade SIBS. To make use of SIBS, an agreement would have to be reached with Boston Scientific Corporation and Innovia LLC. This intellectual property issue is further discussed later in this chapter. Despite these drawbacks, the author believes SIBS is still the best candidate as the material for the rigid cap.

For the flexible cover, the author proposes the use of either polydimethylsiloxane (PDMS) or polyethylene terephthalate (PET). PDMS, commonly known as silicone rubber, has been proven to be very stable in contact with body fluids over a period of up to 2 years [44, 45]. However, PDMS heart valve failures have been reported and are believed to be caused by the absorption of blood lipids into the implant over years [46]. Although PDMS may suffer from property changes after implantation over time [47], the spinal traction device is intended to be a temporary implant of at most a few months. Hence, the author believes that lipid absorption will not be an issue here and that PDMS is still a viable candidate as the flexible cover material.

Besides PDMS, PET may also be a good material choice for the flexible cover. At present, it is the preferred material for most large-caliber textile vascular grafts [48]. Being reasonably inert, flexible, resilient, durable and resistant to biological degradation, it is one of the two materials that withstood the test of time and are still used for vascular graft applications (the other being polytetrafluoroethylene PTFE). Further research may be needed to determine the final choice of material for the flexible cover.

After discussing the material selection, it is important to perform a few basic calculations to determine whether the device dimensions are suitable for its required function. For a person lying on his or her back, the amount of force needed to distract adjacent spinous processes is approximately 15% of the body weight [22]. For a person weighing 800 N, that force would be equivalent to 120 N.

For each FSMA component, the relevant cross-sectional area is $1 \text{ cm} \times 1 \text{ cm} = 0.0001 \text{ m}^2$. 
Taking the maximum stress exerted by the FSMA component to be 1.5 MPa [4, 5], the maximum force which can be exerted by each FSMA component would be 150 N. Since each spinal traction device has two FSMA components, the maximum force which can be exerted by each device would be 300 N. This upper limit is significantly higher than the 120 N required to distract adjacent spinous processes of a patient lying down.

As shown in Figure 7, each FSMA component is 4 cm long. Taking its maximum strain to be 6%, the device is capable of achieving a displacement of 2.4 mm. With data from future research, this FSMA component length may be modified to give the required displacement values.

3.3 Competing Technologies

One obvious competitor with the FSMA spinal traction device is conventional traction treatment. The current typical cost for a session of traction therapy in the United States is between $50 and $100 [49]. A popular form of it is the vertebral axial decompression (VAX-D) system. By its very nature, it is non-invasive and does not require hospitalization, giving it a strong advantage over the FSMA spinal traction device. It claims to be successful in over 70% of patients, providing relief of acute or chronic low back pain and associated leg pain generally within a month [50]. A recent study was conducted to verify its effectiveness [51]. Its participants consisted of 296 patients with low back pain and evidence of a degenerative or herniated intervertebral disk at one or more levels of the lumbar spine. The intervention was an 8-week course of prone lumbar traction, using the VAX-D system, consisting of five 30-minute sessions a week for 4 weeks, followed by one 30-minute session a week for 4 additional weeks. The system has shown to reduce pain intensity, although the results are not fully conclusive. Since the FSMA spinal traction device is able to target specific areas of the spinal column, its performance is expected to be better.

Current surgical treatment options, such as spinal fusion and artificial disc replacement, involve passive and permanent implants. Also, spinal fusion permanently limits spinal motion. These implants cannot be actuated externally to induce tissue repair and recovery, which is the premise of the FSMA spinal traction device. The latter is intended as a temporary treatment device, and would be removed from the body after recovery.
3.4 Market Analysis

This section attempts to predict the level of market demand for the FSMA spinal traction device. It would be erroneous to make such a prediction based on the number of patients undergoing current conventional spinal traction procedures. This is because patients are likely to pursue non-invasive options first and only consider surgery after such options failed to work. One approach would be to evaluate the potential market based on the number of patients undergoing surgery for related spinal disorders.

Lumbar spinal surgery is one of the most common types of surgeries performed in the United States with over 500,000 surgeries performed for lumbar herniated disks and lumbar spinal stenosis annually [52]. Assuming that the FSMA spinal traction device gains a 5% penetration of this current market, it would be equivalent to a demand for 25,000 units per year. The actual market share of the device will depend on how effective the treatment is proven to be and the cost of the entire treatment compared to current and emerging alternatives, as well as the surgeons’ and patients’ receptivity to this new form of treatment. One factor which is likely to keep this market share low is the fact that such implants are temporary and non-bioresorbable, necessitating an additional surgery for their removal.

3.5 Cost Modeling

This section attempts to do a preliminary analysis on how much each unit of the spinal traction device would eventually cost when it is out in the market. This is important in determining its competitiveness and market penetration.

The eventual unit cost depends heavily on the supply chain pathway taken to make the device. The supply chain in this case is similar to the one discussed in Section 2.2.3, which is for the supply chain of bone fixation devices. The strategy would be to set up a company to manufacture the FSMA components used in the spinal traction device, with involvement from experienced FSMA companies like AdaptaMat. The FSMA components would then be sold to large medical implant firms, such as Synthes, which would manufacture the titanium casings and in turn introduce the final product to hospitals and medical centers. This virtual vertical integration of the supply chain is intended to keep the manufacturing costs at the minimum. The distinctive
feature in this case is that involvement of Boston Scientific Corporation is needed, because it holds the intellectual property rights to SIBS, which is the chosen material for the rigid encapsulation caps. The following is a brief analysis of the costs of the device materials.

**Poly(dimethylsiloxane)**
Although both poly(dimethylsiloxane) (PDMS) and poly(ethylene terephthalate) (PET) are being considered as candidates for the FSMA flexible cover material, PDMS will be used here for the cost modeling analysis. PDMS can be obtained from Sigma-Aldrich™ at $208.50 for 250 ml [53], which should be sufficient for encapsulating 5 FSMA sticks. Since each device comprises 2 sticks, it requires 100 ml. Thus, the cost of PDMS for each device is $83.40.

**Poly(styrene-block-isobutylene-block-styrene)**
Leonard Pinchuk of Innovia LLC patented poly(styrene-block-isobutylene-block-styrene) (SIBS) in 2003 [54]. The SIBS intellectual property is currently owned by Boston Scientific Corporation and a license is required for its use [55]. It has been mentioned that the current cost of SIBS is relatively high [43]. Therefore, for the purpose of this cost analysis exercise, the cost of SIBS is taken as $166.80, twice that of PDMS for each component.

**Ni-Mn-Ga Crystal**
As mentioned in Section 2.2.1, there is no current large-scale production of FSMAs. Thus, it is challenging to obtain an accurate prediction of the cost of such FSMA components. MIT obtains FSMA crystals for research purposes from the Ames Laboratory, United States Department of Energy. A single Ni-Mn-Ga crystal, 7.5 cm in length with a diameter of 2.5 cm, costs approximately $2,000 [19]. The usable proportion of such crystals is 50 – 75%. Taking this into consideration, each such crystal should be sufficient for making 4 FSMA components. Since each spinal traction device requires 2 FSMA components, the cost of FSMA for each device currently stands at $1,000. The author believes that with mass production and further research, economy of scale may bring the production cost of FSMA for each device down to approximately $500.
Titanium
Titanium can be obtained from Sigma-Aldrich™ at $249 for 100 g [56]. Taking into consideration the process yield, it is expected that approximately 100 g of titanium would be needed for each device.

Electromagnet
The cost of the electromagnet will not be added here for the computation of the total production cost of each device. One of the main reasons is that the electromagnet can be shared amongst several patients, and re-used for new patients. The strategy to adopt would be to license out the intellectual property to a third party company, which has the expertise of manufacturing general electromagnets, for it to make electromagnets compatible with the FSMA device. This company would then sell its electromagnets to hospitals, which would rent them out to patients. Thus, from the perspectives of patients, the electromagnet cost comes in the form of rental fees of hospital equipment. Even though the electromagnet cost is to be spread out via the aforementioned system, it is imperative to keep the final overall cost low to maintain the competitiveness of this treatment approach.

Cost Computation
Total cost of materials = $83.40 + $166.80 + $500 + $249
= $999.20

Assuming that the processing and sterilization costs add up to $500, the total cost for each device would be $1499.20.

The effect of production yield has to be taken into consideration to give a more accurate figure for the production cost. The overall yield $Y$ of all the processes can be computed by:

$Y = Y_1 \times Y_2 \times Y_3 \times \ldots \times Y_N$, where $N$ is the number of processing steps.

For simplicity of computation, the overall yield $Y$ is taken as 80%.

After accounting for yield, the actual production cost of each device is $1874. This amount can be further reduced if the production costs of FSMA and SIBS become much lower as their
manufacturing technology becomes more mature. Also, if the demand is high, economy of scale can push the cost down further.

3.6 Intellectual Property: Patents

The number of patents related to FSMAs is limited. Currently, there are no patents for orthopaedic applications of FSMAs. The most relevant patent to the application outlined in this thesis is shown in the following:

Patent Title: High-strain, magnetic field-controlled actuator materials
Patent Number: 5, 958, 154
Date of Patent: Sep 28, 1999
Inventors: Robert C. O’Handley, Kari M. Ullakko
Assignee: Massachusetts Institute of Technology, Cambridge, Massachusetts

This patent is about FSMAs being used as actuator materials. The inventors are Dr O’Handley (MIT) and Dr Ullakko (AdaptaMat, former Visiting Scientist at MIT), who were among the first researchers to demonstrate magnetic field-induced strain in FSMAs [2]. The assignee is MIT. This means that commercialization of FSMA enhanced products may be carried out by paying licensing fees to the MIT Technology Licensing Office (TLO).

There are some existing patents which document remote actuation of medical implants through the application of an external magnetic field. An example is given in the following:

Patent Title: Method and apparatus for stimulating the healing of medical implants
Patent Number: 6, 032, 677
Date of Patent: Mar 7, 2000
Inventors: Abraham M. Blechman, Jonathan J. Kaufman

This patent describes a technique to enhance the stability of dental and orthopaedic implants by inducing implant micromotion via a permanent magnet coupled to the implant which is vibrated using a cyclic magnetic force to enhance growth and apposition of the surrounding bone. The
implant temporarily holds a rigidly fixed, permanent magnet that is oscillated by an externally applied, time-varying magnetic field of controlled frequency and intensity. Movement of the internal magnet transmits movement to the implant and effects stimulation of the implant-bone interface.

Although patents such as these describe remote actuation of medical implants using an external magnetic field, their claims involve an implanted permanent magnet. The device described in this thesis involves FSMAs for actuation, and not permanent magnets. Thus, these existing patents are not directly related to it. However, these patents are an issue to be aware of during any possible future patent application.

One of the potential materials to be used to encapsulate Ni-Mn-Ga in the spinal traction device is poly(styrene-block-isobutylene-block-styrene) (SIBS). The patent describing this material is presented in the following:

Patent Title: Drug delivery compositions and medical devices containing block copolymer
Patent Number: 6, 545, 097 B2
Date of Patent: Apr 8, 2003
Inventors: Leonard Pinchuk, Sepideh Nott, Marlene Schwarz, Kalpana Kamath

Leonard Pinchuk of Innovia LLC patented poly(styrene-block-isobutylene-block-styrene) (SIBS) in 2003. The SIBS intellectual property is currently owned by Boston Scientific Corporation and a sublicense from the company is required for its use [55]. Therefore, use of SIBS in making the spinal traction device would involve negotiation, and probably collaboration, with Boston Scientific Corporation.

Another patent worthy of mention is one documenting a method for bonding silicone rubber and polyurethane:
Patent Title: Method for bonding silicone rubber and polyurethane materials and articles manufactured thereby
Patent Number: 5,147,725
Date of Patent: Sep 15, 1992
Inventor: Leonard Pinchuk

Coincidentally, the inventor of this method, Leonard Pinchuk, is also the inventor in the preceding patent. The method described in this patent may form the basis of a method used to bond SIBS with PDMS or PET, which is required in the production of the spinal traction device.

On the whole, the author expects this field to be less litigious than other more mature fields, such as the semiconductor industry.
4. Future Direction

4.1 Issues and Risks

There are several issues with using FSMAs as part of medical implants. A leading concern is the biocompatibility of FSMAs, which has not been tested before. Ni-Mn-Ga crystals have never been implanted into the human body for extended periods of time. Direct contact with body tissues may lead to cytotoxicity issues. The extent of these biocompatibility issues has to be determined. Since the spinal traction device is expected to stay in the body for up to a few months, the FSMA components would have to be properly isolated from body tissues. Suitable encapsulation materials have been suggested in the preceding chapter. These candidates have to undergo rigorous in vitro and in vivo tests to prove their suitability. Also, how the encapsulation materials are to be bonded together and used to enclose the FSMA requires further investigation. Concern needs to be placed on the cost and ease of mass production.

The effectiveness of the device in treating spinal disorders is another uncertainty. It is unknown whether the device can significantly improve spinal conditions, even if it works according to its specifications. Seeking FDA approval is another challenge, which is likely to take a long time.

At this stage of development, it is challenging to give accurate predictions of the manufacturing yield and costs. Since there has not been any large-scale production of FSMAs before, there is no reliable information about the yield and costs involved. The exact materials to be used for making various components of the device are still unconfirmed. At this point, it is unknown which material or combination of materials is the cheapest effective candidate for FSMA encapsulation. Thus, the current prediction of production costs has a large margin of error.

There are also market risks to consider. Although this new device is slated to be the most precise means to perform traction, how receptive surgeons and the general public are to this new treatment technique remains to be seen.
This FSMA orthopaedic technology is very early in the development stage. It is still quite some time away from the state desired when starting a company. As seen in Figure 10, there are likely to be several hurdles and uncertainties ahead on the road to commercialization. These include the aforementioned issues and risks. Therefore, the current strategy would be to conduct relevant research (prototype fabrication and testing) and secure appropriate patents. Constant monitoring of the patent arena is needed. Sufficient coverage in the field of intellectual property is crucial to protecting the research team’s interests, in anticipation of future litigation.

Figure 10. This FSMA orthopaedic technology is in its embryonic stage, with much development needed before concrete commercialization steps (such as company formation) should be considered.

The setup and strength of the electromagnet required to generate sufficient magnetic field at the FSMA location for device actuation have to be determined. The characteristic magnetic field-strain behavior of such a setup has to be ascertained. In vitro trials are expected to take approximately 1.5 years [22]. These include bench-top tests and measurements in cadavers. A couple of these in vitro compatibility tests are outlined in the following section. If these achieve satisfactory results, animal trials should follow. These in vivo trials may be conducted on rabbits [22]. Spinal disorders would be deliberately created in rabbits. The prototype device would then be implanted and tested for its effectiveness in treating these disorders.

4.2 In Vitro Compatibility Testing

Any metal in direct contact with biological systems will corrode, resulting in the release of ions which cause adverse physiological effects [57, 58]. These include toxicity, carcinogenicity,
genotoxicity and metal allergy. Although metal ions are naturally present in the body, concentrations beyond physiological levels can be toxic. Therefore, release of metal ions from implants remains an important concern. However, the boundary line between acceptable and toxic levels of metal ions is currently unclear [59]. The compositions of the main alloys used in orthopaedic implants outlined by the American Society of Testing and Materials (ASTM) are presented in the following table.

<table>
<thead>
<tr>
<th>Group</th>
<th>Co</th>
<th>Cr</th>
<th>Ni</th>
<th>Mo</th>
<th>W</th>
<th>Ti</th>
<th>Al</th>
<th>V</th>
<th>Cu</th>
<th>Mn</th>
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<tr>
<td>F 75 cast</td>
<td>59-60%</td>
<td>27-30%</td>
<td>&lt;1%</td>
<td>5-7%</td>
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<td>N/A</td>
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<td>1%</td>
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<tr>
<td>F 799 forged</td>
<td>~59%</td>
<td>26-30%</td>
<td>&lt;1%</td>
<td>5-7%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
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<td>19-21%</td>
<td>33-37%</td>
<td>9-10%</td>
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<tr>
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<td>13-15.5%</td>
<td>2-4%</td>
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<td>N/A</td>
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<td>0.5</td>
<td>N/A</td>
</tr>
<tr>
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<tr>
<td>ASTM F136</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>89-91%</td>
<td>5.5-6.5%</td>
<td>3.5-4.5%</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Titanium alloy</td>
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</tbody>
</table>

Table 2. Compositions of the main alloys used in orthopaedic prostheses [59].

Toxic concentrations of transition metals, especially chromium and nickel, disrupt the body’s oxidation-reduction balance, preventing normal cell signaling and gene expression, and resulting in toxicity and carcinogenicity [60]. Nickel, which is present in Ni-Mn-Ga alloys, has been identified as a human carcinogen [61]. With their participation in oxidation-reduction reactions, metal ions can also shift the pH in the body [62]. In terms of cytotoxicity, nickel from stainless steel is one of the most harmful components in alloys used as implant material [63]. It has been shown that soluble forms of nickel cause significant increases in cell transformation in fibroblasts of mice [64]. This transforming ability is directly related to the toxicity of the metal.

Compared to nickel, less is known about the effects of increased concentrations of manganese and gallium in the body. In general, more research is required to have a better understanding of the effects of metals used in implants and their resulting ion concentrations [59].
Although the FSMA components of the implant would be encapsulated, certain compatibility tests still have to be conducted to ascertain possible outcomes of improper encapsulation. The following are some in vitro corrosion tests to be conducted before animal testing. Note that they are in no way exhaustive.

4.2.1 Pitting Corrosion Test
Chloride ions in the body cause pitting corrosion of implants. Thus, a pitting corrosion test is required to evaluate how Ni-Mn-Ga responds to pitting. The cyclic pitting scan is to be conducted in saline solution of 0.9% NaCl, at 37°C with a sweep rate of 0.2 mV s\(^{-1}\). From a plot of the corrosion characteristics curve of current density against potential, the critical pitting potential and the protection potential can be obtained. The critical pitting potential is the potential above which new pits will initiate and existing pits will propagate. The protection potential is the potential below which there is zero pitting. Between these two values, existing pits will propagate with no new pit formation. Comparing these two potential values of Ni-Mn-Ga with those of implant materials in literature would show how relatively resistant to pitting Ni-Mn-Ga is. The more positive the potential values, the more resistant to pitting a material will be.

Being in the single-crystal form, Ni-Mn-Ga is expected to be relatively resistant to pitting [65], although this needs to be confirmed by experimental data. For this test, several sets of data are needed because there are usually significant variations in the test results [65]. This may be accomplished either with several samples of the same dimensions, or by polishing the sample surface after each measurement.

For a detailed guide to conducting the test, one may refer to ASTM G61, which documents the standard test method for conducting cyclic potentiodynamic polarization measurements for localized corrosion susceptibility of iron-, nickel-, or cobalt-based alloys in a chloride environment. This test method also describes an experimental procedure which can be used to check one’s experimental technique and instrumentation.

When conducting pitting corrosion tests, take note of crevice corrosion, which refers to localized corrosion of a surface, usually a metal, at or immediately adjacent to an area which is shielded from full exposure to the environment due to close proximity between the metal and the surface.
of another material. This corrosion is prominent because the solution stagnates in such crevices, and can turn more acidic and become more effective in corroding the material. This form of corrosion should be avoided during pitting corrosion tests, because it would affect the potential values obtained. In the event that crevice corrosion is detected, the pitting corrosion test results would become void.

4.2.2 Weight Loss Test and Trace Nickel Detection
This test is to be conducted on NiTi, 316L stainless steel and Ni-Mn-Ga, with one sample of each material. This juxtaposition allows comparison of Ni-Mn-Ga with materials already used for implants [66]. Obtain one sample of each material and weigh them. Completely immerse and suspend each in a separate saline solution of 0.9% NaCl. Suspend them in such a way as to minimize surface contact, reducing the chances of crevice corrosion. Leave them in solution for 1 month, before removing and weighing them again. Compute and compare the weight loss. The less the weight loss, the better Ni-Mn-Ga would perform as an implant material.

Determine the amount of nickel released into the solutions of all three samples with inductively coupled plasma (ICP), which is an analytical technique used for the detection of trace metals in solution, commonly used for environmental samples. Compared to the solutions of NiTi and 316L stainless steel, a comparable or lower concentration of nickel in that of Ni-Mn-Ga would negate the nickel toxicity issue, while a much higher concentration would raise a cause for concern.
Conclusions

The optimal strategy to take now is to perform the device fabrication and testing, and obtain relevant patents to cover the IP arena in anticipation of future litigation. In vitro trials are expected to take about 1.5 years, while in vivo trials are expected to take longer. Two of the in vitro trials have been outlined in Section 4.2. If the trials prove successful, seeking FDA approval would be the following step. After that, commercialize the product by collaborating with companies such as AdaptaMat, Synthes and Boston Scientific Corporation, through virtual vertical integration of manufacturing processes. Collaboration with AdaptaMat could mean licensing the technology to them or to form a specialized start-up with the help of their expertise in FSMA growth and fabrication. The decision between these two choices may lie in technical considerations. This orthopaedic technology is currently in its infant stage. Its technical feasibility and commercial viability remain to be seen.
References


17) K.S. Ngian, Personal communication, March 2008.
20) Synthes media release, West Chester (PA), USA, February 28, 2008.
22) C.H. Goh, Personal communication, April 2008.

31) C. Hinterbuchner (1985), Traction, In J.V. Basmajian (editor), Manipulation, traction and massage, pp. 178, Baltimore, MD, Williams and Wilkins.


65) D.J. Blackwood, Personal communication, June 2008.