Shape Memory Alloy Expandable Pedicle Screw to Enhance Fixation in Osteoporotic Bone: Primary Design and Finite Element Simulation

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The properties of shape memory alloys, specifically the equiatomic intermetallic NiTi, are unique and significant in that they offer simple and effective solutions for some of the biomechanical issues encountered in orthopedics. Pedicle screws, used as an anchoring point for the implantation of spinal instruments in the spinal fracture and deformity treatments, entail the major drawback of loosening and backing out in osteoporotic bone. The strength of the screw contact with the surrounding bone diminishes as the bone degrades due to osteoporosis. The SMArt™ pedicle screw design is developed to address the existing issue in degraded bone. It is based on the interaction of bi-stable shape memory-superaelastic elements. The bi-stable assembly acts antagonistically and consists of an external superelastic tube that expands the design protrusions when body temperature is attained; also an internal shape memory wire, inserted into the tube, retracts the assembly while locally heated to above the body temperature. This innovative bi-stable solution augments the pull-out resistance while still allowing for screw removal. The antagonistic wire-tube assembly was evaluated and parametrically analyzed as for the interaction of the superelastic tube and shape memory wire using a finite element model developed in COMSOL Multiphysics. The outcomes of the simulation suggest that shape memory NiTi inserts on the SMArt™ pedicle screw can achieve the desired antagonistic functionality of expansion and retraction. Consequently, a parametric analysis was conducted over the effect of different sizes of wires and tubes. The dimensions for the first sample of this innovative pedicle screw were determined based on the results of this analysis. [DOI: 10.1115/1.4007179]

1 Introduction

Shape memory alloys (SMAs) are a class of smart materials that undergo phase transformation from martensite to austenite and vice versa in response to a change of temperature or the application of stress. The shape memory effect and superelasticity, which occur as a result of this phase transformation, are the unique properties of these alloys. The shape memory effect is the recovery of apparently permanent deformations by raising the temperature of the material. Superelasticity is the nonlinear recoverable loading-unloading behavior of these alloys that can occur beyond the elastic limit of conventional metals [1,2].

Over the past 40 years shape memory alloys (SMAs) have been used for a variety of medical applications. These applications can be divided into two general categories: active and passive. In active applications the temperature of the material is controlled to induce phase transformation between austenite and martensite, which results in the desired thermomechanical behavior. As an example, by heating the SMA elements in an active endoscope, the device bends in the desired direction. The shape memory and superelasticity effects allow alloys such as Nickel-Titanium (NiTi; Nitinol) to undergo large mechanically induced deformations and consequently to recover the original shape. An example of passive use of SMAs is a coronary stent expanding inside the blood vessel due to body heat [3,4].

The second section of this paper reviews the orthopedic applications of the NiTi shape memory alloys. The following section deals with the shortcomings of the conventional pedicle screws in osteoporotic bone and presents the design of a novel bi-stable SMA implant, the SMArt™ pedicle screw. The implant can compensate for bone loss due to osteoporosis and can be removed easily as needed. The latter functionality is a departure from the existing solutions that tend to strengthen the bone-implant interface but at the same time make the implant removal extremely challenging. The later sections are allocated to the finite element simulation of the behavior of the pedicle screw using a modeling framework for shape memory alloys developed in COMSOL Multiphysics®. An approximated experimental evaluation of the implant-bone engagement is also presented.

2 Orthopedic Applications of NiTi Shape Memory Alloys

Due to superelasticity (SE), shape memory effect (SM), high damping capacity, corrosion resistance, and biocompatibility NiTi shape memory alloys (SMAs) have gained researchers’ attention for implementation in biomedical fields especially orthopedics. The shape memory effect can be employed to activate medical devices in an operation either through body heat or through another external heat source. Such designs could not be realized with conventional alloys. Superalasticity-based applications, in general, take advantage of either the possibility of recovering large deformations (up to 8%) or the existence of a transformation stress plateau which provides a nearly constant stress over significant strain intervals.

NiTi alloys have been implemented in various orthopedic applications such as compression staples/clamps for the treatment of bone fractures [5–17], anterior fusion of the spine [18–21], intra-medullary nails that are used to apply controlled forces to the bone [22], fixator systems for suturing tissue in minimally invasive surgery [23], as well as fixation bone plates [24,25], and rods for the treatment of scoliosis [23,26–30].

In these applications, the martensite start transformation temperature, is typically set between 4–7°C which can usually be attained in the device by immersion in a sterile ice-cold saline solution [6]. NiTi in this phase is soft and malleable and therefore the device can be easily deformed (up to 6–8%). The recovery, or austenite start temperature, above which the original shape will be restored, is normally chosen around 37°C.

3 Pedicle Screws in Osteoporotic Bone

Metabolic bone diseases such as osteoporosis, osteomalacia, and Paget’s disease are usually linked with osteoporotic bone or a soft skeleton, especially in elderly patients. Due to its wide prevalence and its associated costs, osteoporosis has received a great deal of attention over the past decades. Approximately 30% of post-menopausal Caucasian women in the United States have osteoporosis and 16% have osteoporosis of the lumbar spine. The cost of this was approximately $746 million in 1995 [31]. The surgical treatment of deformities such as kyphosis and scoliosis in the elderly can be very challenging considering the poor bone quality and likelihood of instrumentation displacement in these patients.

Several advances in instrumentation such as the use of laminar fixation, multisegment fixation, limited correction of the deformity, avoiding ending the instrumentation within the kyphotic
segments, and augmentation of the pedicle screw purchase through biologic and nonbiologic fillers have been accordingly developed [31–34].

Bone screws have been used in spinal fixation since the mid-1940s. Boucher reportedly was the first to implant pedicle screws and Roy-Camille was the first to connect pedicle screws to a posterior plate. Later bone screw pioneers include Harrington, Cotrel, and Dubousset [35]. Pedicle screws are standard in posterior fixation procedures (Fig. 1) for the treatment of spinal instability caused by deformity, degenerative disc disease, fracture, spinal stenosis, spondylolisthesis, or tumors. However, implanting pedicle screws in patients with osteoporosis presents surgeons with a challenge: the loss of purchase or the grip between the bone and screw interface leading to hardware pull-out or loosening which may occur during surgery, during manipulation of the instrumentation, or at a time after the surgery. If the screw loosening occurs late after the surgery, depending on the case, two approaches may be taken; either revision of the instrumentation or supplementation with an anterior fusion which both incur complications and high costs. Therefore, selection of appropriate instrumentation and the means to augment it is crucial in the care of osteoporotic patients [33,34,36].

The results of a historic cohort study on patients treated for either degenerative spondylolisthesis or spinal fracture showed that 1.4% had experienced a loss of screw purchase during the surgery, while 3.5% had screw loosening or pull-out after the surgery. It is worth noting that the patients in the spondylolisthesis cohort (57.8 years old) who had pedicle screw fixation were significantly older than the corresponding patients in the fracture cohort (35.7 years old). Therefore, the spondylolisthesis cohort had higher rates of intra-operative loosening (1.7% and 0.2%, respectively) and pull-out (3.8% and 2.3%, respectively) [37].

The several methods that have been investigated for addressing the screw loosening problem in osteoporotic and other patients can be summarized in the following categories:

- extending the fusion to more vertebral levels to share the loads on the pedicle with other elements [34]
- using pedicular hooks, laminar hooks, and sublaminar wires to supplement the pedicle screw [34,38–40]
- undertapping or not tapping the preparation site and using large diameter screws for purchase in the cortical part of the pedicle [41–43]
- using tapered screws for better bone compaction [44]
- using longer pedicle screws to gain support from the anterior side of the vertebrae (bicortical purchase) [45]
- augmenting the bone and/or screw using bone cement (poly-methyl methacrylate PMMA, calcium phosphate, or carbonated apatite) placed down the pedicle shaft prior to pedicle screw insertion [40,44,46–48]
- using hydroxyapatite-coated pedicle screws [40,49–51], and
- delivering bone cement using cannulated/fenestrated pedicle screws (screws designed with multiple holes in their shaft allowing for bone in-growth and/or influx of bone cement) [52,53].

The aforementioned alternative surgical options are not ideal and entail drawbacks including increasing the time of surgery, increasing the risk of screw malpositioning, increasing the risk of injury to the spinal soft tissues, and sequestration of the bone cement in the spinal canal or unintended tissues (e.g., lung) leading to complications such as neurologic or vascular injury. Furthermore, some of these methods could cause damage to the bone and spinal cord. Regardless of the aforementioned techniques, fixation in the severely osteoporotic spine still represents a challenge.

4 **SMArt™ Pedicle Screw**

The design of the **SMArt™** pedicle screw is presented in this section. This screw is intended to address the problem of pedicle screw loosening and backing out due to bone degradation. It should be noted that such a design, although developed initially to enhance pedicle screw performance, can be implemented in any procedure in which bone degradation generates fixation difficulties.

The design consists of bi-stable shape memory-superelastic elements. These elements are mated with a pedicle screw such that it extends itself when implemented in order to augment the screw purchase as the surrounding bone degrades (see Figs. 2, 3, and 4). The expandable bi-stable insert in the original (Fig. 2(b)) and deformed (Fig. 2(a)) configurations is shown in Fig. 2. The insert consists of two parts: a retractor and a protractor. The protractor activates at body temperature and tends to expand the insert. The retractor, with austenite transformation temperature (\( A_s \)) higher than body temperature, can be activated by heating the assembly. Upon heating above the body temperature, the assembly folds to a form that can be easily unscrewed.

At surgery, the whole system comprising a screw and a number of helical inserts (seven in the current design), previously kept at low temperature using an ice-cold saline solution, is inserted in the pedicle-bone (see Fig. 3). In healthy cancellous bone, the system acts as a standard screw with an insert that distributes the load on all of the threads. In the case that the bone goes through degradation and a loss of purchase with the assembly occurs, inserts that have attained a steady state body temperature unfold (see Fig. 4) to compensate for the bone loss and thus enhance the interface strength.

Should the screw need to be removed for any reason, the application of heat to the assembly will fold the protrusions back. The temperature at which the device activates can be adjusted by modifying the alloying elements and heat treatment of the implant. This allows the transformation temperatures to be set to a level that does not harm the surrounding bone and tissue. The reported unsafe temperature range for the bone tissue is 47–50°C. The maximum endurable temperature above which bone necrosis occurs is reported to be 53°C [54]. Conductive heating can be provided through a resistive component placed inside the body of the screw.

This novel implant addresses the unsettled problem of loosening and backing out in bone screws that occurs due to osteoporosis. The screw can eliminate the need for bone cement and is removable without stripping the surrounding tissue and/or damaging the bone structure.

4.1 **Concept Evaluation.** The performance of the expandable part of the insert in improving the pull-out strength of the new screw was evaluated through a pilot experiment. To this end,
standard hex head lag screws with 1/4” thread size, 3 1/2” total length and 2 3/4” threaded length were enhanced with Nitinol superelastic wires. Wires with a diameter of 0.5 mm and a length of 16 mm were attached to the screw through cross drilled holes in the minor diameter. The holes were drilled such that their beginning and end would be on different levels of the thread without damaging the thread profile (see Fig. 5(a)). The lag screw enhanced with the NiTi wires was inserted in a 43 x 43 x 90 mm foam block with the density of 15 lb/ft³ (comparable to normal bone; 5–10 lb/ft³ for osteoporotic bone). Prior to insertion, a hole was drilled and tapped into the block with a diameter of 1/4”. The size of the hole that was selected is slightly larger than the thread size of the lag screw in order to represent degraded bone. The primary objective of the bone screw enhanced with NiTi wires is to overcome this drawback by maintaining contact with the receded bone. The screw insertion depth in the foam block was 53 mm (2.08”). A control specimen was also prepared with exactly the same specifications. The specimens were evaluated on a testing machine (MTS, Bionix 858) with a tensile pull-out load applied to the head of the screws; as illustrated in Fig. 5(c). The pulling rate was set to 5 mm/min as per ASTM F543-02. The tensile load versus displacement results are depicted in Fig. 6. As it can be seen, the mode of failure was the rupture of material surrounding the screw thread. The load at the instance where the displacement equaled the screw pitch (2.85 mm) was chosen as the initial strength of each screw for the purpose of a conservative comparison. The improvement in the pull-out strength of the screw from enhancing it with superelastic NiTi wires is significant as shown in the figure.

It is worth noting that the SMARn™ screw regained purchase after the displacement of 3 mm. This may be due to the repeated reengagement of the NiTi wires within the foam; a behavior which was not present in the control specimen. Also, the fluctuation in the force-displacement response of the screws beyond the...
initial strength level is likely due to the rupturing nature of the pull-out test. This experiment demonstrated the effectiveness and merit of the proposed concept.

5 Finite Element Analysis of the SMART Pedicle Screw

The functionality of the screw in engaging with and disengaging from the bone is evaluated through a bi-stable NiTi tube-wire assembly. In this assembly, as shown in Figs. 7(a)–7(d), the tube is superelastic at body temperature. The tube is shape set to engage the assembly with the surrounding bone in response to exposure to body heat. A NiTi wire is inserted inside the tube. The wire is shape set to disengage the assembly from the surrounding bone when heated to above body temperature. Figure 7 shows the opposing curves in the plane in which the tube and wire deflect when activated. The tube and wire can be viewed as two serially connected springs with nonlinear stiffness properties. This analysis includes the following assumptions. The shear force between the wire and the tube is neglected, assuming the same curvature at every cross section.

Figure 7 also represents the functionality of the wire-tube assembly. \( \delta_{A1} \) and \( \delta_{B1} \) are the required opposing deformations of the wire and the tube from the straight form in the shape setting process. According to Fig. 7, the overall deflection of the assembly at body temperature, \( \Delta_L \), can be solved via the following equilibrium equations:

\[
\begin{align*}
\frac{F_{A2}}{C_0} - \frac{F_{B2}}{C_0} &= 0 \\
\delta_{A2} + \delta_{B2} - \delta_{B1} - \delta_{A1} &= 0 \\
\Delta_L &= \delta_{B1} - \delta_{B2} = \delta_{A2} - \delta_{A1}
\end{align*}
\]

By the same token, the overall deflection of the assembly at high temperature, \( \Delta_H \), can be found by:

\[
\begin{align*}
\frac{F_{A3}}{C_0} - \frac{F_{B3}}{C_0} &= 0 \\
\delta_{A3} + \delta_{B3} - \delta_{B1} - \delta_{A1} &= 0 \\
\Delta_H &= \delta_{B1} - \delta_{B3} = \delta_{A3} - \delta_{A1}
\end{align*}
\]

In these equations, the subscript 1 represents the shape set form, subscript 2 represents the body temperature shape, and subscript 3 corresponds to the elevated temperature form.

As Eqs. (1)–(4) and Fig. 7 indicate, the design parameters \( \Delta_L \) and \( \Delta_H \) define the functionality of the assembly. \( \Delta_L \) corresponds to the amount of engagement of the NiTi assembly with the surrounding bone while at body temperature. \( \Delta_H \) characterizes the retraction of the assembly at elevated temperature. In order to produce the desired functionality of expansion and retraction for the SMART pedicle screw, a wire and a tube with proper geometries should be shape set to the appropriate shape. In order to find these geometric properties, a finite element model developed in

![Fig. 6 Results of the axial tensile test: force versus displacement. The tensile strength is selected to be the force required to displace the screw in the block as much as the screw thread pitch.](image)

![Fig. 7 Schematic procedure representing the functionality of the antagonistic bi-stable tube-wire assembly in engaging with and disengaging from the bone. (a) and (b) Initial memorized shapes of the assembly components attained by proper shape setting. Assembly at (c) body temperature (d) elevated temperature.](image)
Table 1 Commercially available sizes of NiTi wires and tubes considered for parametric analysis

<table>
<thead>
<tr>
<th>Case no.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>OD (mm)</td>
<td>0.76</td>
<td>1.19</td>
<td>0.89</td>
<td>1.02</td>
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<tr>
<td>ID (mm)</td>
<td>0.76</td>
<td>1.19</td>
<td>0.90</td>
<td>1.02</td>
<td>1.02</td>
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<tr>
<td>B</td>
<td>OD (mm)</td>
<td>1.31</td>
<td>1.32</td>
<td>1.29</td>
<td>1.25</td>
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</tbody>
</table>

COMSOL Multiphysics® incorporating the shape memory behavior is used as explained in Sec. 5.1.

5.1 FE Modeling and Parametric Analysis. It has been shown that the desired behavior of the screw can be achieved by a wire-tube NiTi assembly. This section presents a FE-based parametric analysis regarding the wire-tube assembly. To this end, five commercially available wire and tube sets are considered as summarized in Table 1.

The modeling procedure for the first case of Table 1 is described here as an example. The wire has an OD of 0.762 mm, length of 11 mm, and is shape set along a path representing a helix (which corresponds to the wire attached to the body of the screw) with a diameter of 5.13 mm and a pitch of 3.63 mm as opened in a plane. The wire is made of NiTi shape memory alloy with an austenite finish temperature ($A_f$) of 70 °C. The deflection of the tip of the wire, in the shape set form, as shown in Fig. 9, is 2.44 mm. The tube has an OD of 1.31 mm and length of 11.74 mm with an inner diameter that fits the OD of the wire. The deformation of the tube follows a helix with a diameter of 4 mm and a pitch of 3.63 mm opened in a plane. The deflection of the tip in the shape set form for the tube is 3.26 mm. The tube is made of another composition of NiTi shape memory alloy that has an $A_f$ of 35 °C.

The properties of the NiTi alloys used for modeling of the wire and the tube are listed in Table 2.

The wire-tube assembly is modeled in COMSOL Multiphysics® and is simulated via the SMA capability developed in the framework of this software. Three application modules of the software, namely the structural mechanics, partial differential equation (PDE) solver, and heat transfer module were used to solve the problem. The structural mechanics module was responsible for solving the equations of virtual work with dependant variables of displacement components in Cartesian coordinates. The kinetics of the martensite transformation in the shape memory material was modeled through the PDE module using cosine transformation functions and an empirically derived stress-temperature phase diagram. From this module, the transformation strains were obtained and integrated into the solid mechanics equations. Also, the heat transfer module was used to solve the heat equation for heat conduction in the component and possible convection interactions with the environment. The modified SMA model is capable of capturing shape memory effect, superelasticity and hysteresis behavior, as well as partial transformation in both positive and negative directions and was validated against experimental results taken from the literature.

Table 2 Material properties for NiTi alloy A (wire) and B (tube)

<table>
<thead>
<tr>
<th>Moduli</th>
<th>Transformation temperatures (°C)</th>
<th>Transformation constants</th>
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<tbody>
<tr>
<td><strong>A</strong> NiTi: Ni 55.6%wt</td>
<td>$E_A = 67 \times 10^3$ MPa</td>
<td>$M_f = 40$</td>
</tr>
<tr>
<td></td>
<td>$E_M = 26.3 \times 10^3$ MPa</td>
<td>$C_M = 8$ MPa/°C</td>
</tr>
<tr>
<td></td>
<td>$\alpha_p = 6.7%$, $\kappa_p = 0.33$, $\tau = 1.0$</td>
<td>$C_A = 13.8$ MPa/°C</td>
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<tr>
<td></td>
<td>$A_f = 59.12$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$A_t = 70$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$M_i = 5$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$A_0 = 20.5$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$A_1 = 35$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$\sigma_r = 100$ MPa</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$\sigma_t = 170$ MPa</td>
<td></td>
</tr>
</tbody>
</table>

**B** NiTi: Ni 55.1%wt | $E_A = 67 \times 10^3$ MPa | $M_f = 40$ |
|        | $E_M = 26.3 \times 10^3$ MPa | $C_M = 8$ MPa/°C |
|        | $\alpha_p = 6.7\%$, $\kappa_p = 0.33$, $\tau = 1.0$ | $C_A = 13.8$ MPa/°C |

Figure 8 shows the meshing of the wire-tube assembly with quadratic hexahedral elements. Fifteen elements were used along the axis of both the wire and the tube. The model consists of a total of 8000 elements and 243,000 DOFs. The variation of temperature at the three stages of the operation of the assembly is shown in the inset of Fig. 8.

6 Results

In this section, the three stages of operation of the bi-stable assembly is simulated to evaluate the performance of the screw. It should be mentioned that higher $\Delta t$ results in more engagement of the smart pedicle screw with its surrounding bone and provides a higher pull-out resistance in the screw. $\Delta t$ should be as low as possible so that the screw can be removed when heated. Therefore, the goal is to find a configuration of outer diameter of the tube, $d_B$, and outer diameter of the wire, $d_A$, to achieve maximum $\Delta t$ and minimum $\Delta t$. The behavior of the assembly in terms of tip load versus tip displacement is evaluated using the FE model to determine the equilibrium condition, where equal load acts on the tube and the wire which results in a total tip displacement equal to the initial gap between the tips of the two structures ($d_A + d_B$). This procedure is repeated for the body temperature as well as at the high temperature stages of operation which take place at the temperature levels shown in the inset of Fig. 8.

As noted before, this is an approximated estimation of the behavior of the actual wire tube assembly wrapped around the pedicle screw.

The load-deflection plots for the wire and tube of size #1, as listed in Table 1, at three different temperature levels are depicted in Figs. 9 and 10, respectively. The transformation of the temperature induced martensite in the SMA to the stress induced martensite at low temperature levels is responsible for the nonlinear load.
displacement behavior of the beams. Since the austenite phase is more stable at elevated temperatures, this mechanism is replaced with the transformation from austenite to stress induced martensite for loading at temperatures above $A_f$. The wire and tube have different transformation temperatures; therefore their general loading behavior will be dissimilar when compared under identical conditions.

At the second stage, while the system is at body temperature, the tube transforms to the austenitic state which is a stiffer phase than martensite. Therefore, the behavior of the tube exhibits a closed hysteresis. The wire is still at the martensitic phase. Because both the wire and the tube are in the austenitic phase at the 3rd stage, a superelastic hysteresis is observed in their deflection behavior.

Figure 11 shows the results of the equilibrium analysis for the second stage. The state of equilibrium where the sum of displacements is equal to the initial gap $d_{A2} = 5.6$ and $d_{B2} = 0.1$.

Figure 12 Load-displacement plots for the wire-tube assembly at the third stage. The equilibrium is reached at a common level of force where the sum of displacements is equal to the initial gap $d_{A3} = 5.5$ and $d_{B3} = 0.2$.

<table>
<thead>
<tr>
<th>Case no.</th>
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<th>2</th>
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<tbody>
<tr>
<td>$\Delta_l$ (mm)</td>
<td>3.14</td>
<td>3.01</td>
<td>3.15</td>
<td>3.15</td>
<td>3.16</td>
</tr>
<tr>
<td>$\Delta_H$ (mm)</td>
<td>3.06</td>
<td>1.26</td>
<td>3.10</td>
<td>3.01</td>
<td>2.96</td>
</tr>
</tbody>
</table>

Investigation of the load-deflection behavior for different commercial wire-tube combinations in Table 1, as described above for case #1, elucidated that case #2 yields the most desirable performance. The performances of the five analyzed cases of the wire-tube assembly are summarized in Table 3.

Case #2 had the lowest ratio of tube thickness to wire diameter. The positive $\Delta_H$ indicates that the assembly does not close completely at high temperature. Decreasing the tube thickness and increasing the diameter of the wire will help to decrease $\Delta_H$. However, the manufacturing conditions and the ductility of the NiTi material limit the smallest thickness achievable for this purpose. The configuration listed for case #2 is being used in the manufacturing of the first sample of the SMArt™ pedicle screw. Another engineering point in the design of the NiTi components is the strain the material sustains. If the application entails cyclic loading, the strain should be limited to 3% in order to prevent failure.
due to fatigue. Although the current application is intended for one-time actuation only, fatigue due to external loadings may still occur. Figure 13 illustrates plots of the first principle strain in the wire and tube at the instance of maximum deformation. The 8% maximum strain, which pertains to the superelastic tube, is in the normal operating range of NiTi alloys.

7 Conclusion

Degradation of the bone, mainly as a result of osteoporosis, causes loosening in the screw-bone interface. This problem exists in pedicle screws which are widely used for certain spine-related treatments such as implanting spinal instrumentation in spinal fracture and deformity corrections. As a result of bone degradation, the pull-out strength of pedicle screws hazardously diminishes. The conventional remedies for this issue, such as using bone cements, add their own problematic issues. This paper introduced a novel pedicle screw that is intended to mitigate these unwanted effects. The design and development of the bi-stable NiTi-based SMArt pedicle screw, which utilizes the shape memory effect and superelasticity of NiTi alloy to expand itself in the case that the surrounding bone goes through osteoporosis and degrades, was described.

The functionality of the smart screw design was studied via a finite element model which incorporated the behavior of SMAs. The results of the FE simulation show that a wire-tube bi-stable assembly is capable of performing the required expansion and retraction functions. Moreover, a parametric analysis was conducted over the effect of different sizes of wires and tubes. The geometric parameters for the first sample of this innovative pedicle screw were determined based on the outcomes of this analysis.

The present FE model approximated the behavior of the helical wire-tube assembly in an opened planar fashion. This limitation will be addressed by a more detailed 3D simulation which can capture the SMA behavior. It is also necessary to take into account the bone-screw interaction by conducting a simulation capable of representing the pull-out test. Moreover, the removal of the smart pedicle screw requires activation of the retractor wires through an external heating source which may cause damage to the surrounding bone and tissue. Therefore, a finite element heat transfer simulation is necessary to evaluate the heat interaction between the screw surface and the bone tissue and to estimate the safe temperature required for activation.

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References


Fig. 13 First principle strain (plotted on the undeformed configuration for more clarity)


