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Development of Integral Spring-Loaded Orthopedic Microfasteners

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Abstract

Over the last decade, biodegradable screws and plates have received wide acceptance over metallic fasteners for orthopedic fracture fixation. A biodegradable fastener would gradually "disappear" during healing of a fractured bone or tissues, therefore, avoiding a secondary operation to remove that fastener. When using metal fastener, the current approach requires manual threading on a large bone fragment for fixation using a metal screw. This technique is difficult when it is required to attach a small bone fragment. This paper presents the design of a microfastener incorporating a spring element, which dispenses with the tapping operation while still maintaining the bone fragments under compression. The locking of the microfastener is achieved through an interference fit between the fastener and the bone block. The fastener is designed with microratchets on its surface, which deflect during insertion and subsequently stiffen to prevent being pulled out. The spring element, similar to a Belleville washer, is integrated with the head of the fastener and keeps the bone fragments under compression upon removal of the insertion load. A two dimensional finite element model has been developed to simulate the insertion, locking, and separation of the fastener and the bone fragments. The pull-out force per unit length of interference is taken to be a measure of the effectiveness of the fastener. The variation in the push-in and pull-out force with the insertion depth shows that the push-in force increases with insertion depth and a sharp increase is seen as the spring begins to deform. The pull-out force is maximal while initiating separation and significantly affected by the bone/fastener friction.

Introduction

Bone fracture occurs when the bone breaks due to stress that exceeds its strength. The nature of loading affects the response of bone. It is strongest under compression but weaker in tension and shear. Different types of fractures that are commonly encountered are namely simple, compound, comminuted fracture, etc. In a simple fracture the bone breaks into two parts. A fracture in which the bone penetrates the skin is called as compound fracture and in a comminuted fracture the bone breaks down into small fragments. Depending upon the type and severity of fracture, either the external or fixation method is used. The main purpose of these fixation methods is to realign and maintain the bone fragments in their proper position and provide interfragmental compression to aid in the consolidation of the fragments[1].

Conventional fracture fixation methods involve the use of biocompatible metals like stainless steel or titanium. Metallic internal fixation methods such as cortical screws, cancellous screws, cannulated screws, lag screws, Herbert screws or non-threaded means like Kirschner wires and staples have been widely used[2]. Cortical threads have a small pitch and low nominal to minor diameter ratio whereas cancellous threads have a higher pitch and higher nominal to minor diameter ratio. Cannulated screws have a guide wire passing through them and are self-drilling and self-tapping. Lag screws are partially threaded; they pass through one bone fragment and screw into the other fragment. Herbert screws are threaded at both the ends but not at the center, the difference in pitch of the threads at the two ends produces the compressive action across the bone fragments but prove difficult for removal[3, 4]. Difficulties are experienced while inserting threaded fasteners at a large angle with the bone surface as bending of the screw or breakage of the bone fragment due to stress concentration are observed[5]. Kirschner wires and staples are easy to use but do not produce interfragmental compression and might cause infection if protruding outside the skin[6].

These fixation methods provide secure fixation but possess disadvantages on account of the material properties. Metallic implants due to a variety of reasons are removed after the damaged bone has healed, this often requires a second surgery that is not only time consuming but also puts the patient at risk. Metals have a higher elastic modulus than bones. So during the healing process, the load is taken by the stiffer implant and the bone is not subjected to sufficient loading. This causes the bone to be resorbed inside the body. The strength of the healed bone tends to be lesser than the unfractured bone, which might cause subsequent fracture at the same site once the implant is removed[7]. Metallic implants interfere with the magnetic imaging studies causing difficulty in post operative observation. The presence of alloying materials like nickel, cobalt and chromium might cause allergies and could prove to be carcinogenic[8].

To overcome these drawbacks, biodegradable polymers have been developed. The first use of biodegradable polymers was for a resorbable suture (Dexon) in 1962. Polydioxanon (PDS), Polyglycolic acid (PGA), Polylactic acid (PLA) and their copolymers are being used for producing these polymers. In the initial stages of healing, these polymers maintain their mechanical strength and fragment fixation. As the bone healing progresses, the implant gradually decomposes (Figure 1) and the loads are transferred to the healing bone[9]. These polymers gradually undergo hydrolysis[10], the byproducts of which are eliminated through natural metabolic means. The degradation time of the polymers can be controlled by changing their chemical composition. PGA has a degradation time of 2-4 weeks whereas PLA degrades much slower, from weeks to years[11]. Though biodegradable polymers overcome the drawbacks of metallic fixation methods, they might exhibit inflammatory sinus formation[12]. Also the mechanical strength of these polymers is substantially less than that of metals[13, 14, 15].

So as to use these polymers in load bearing applications, high strength self reinforced biodegradable composites have been developed. In these the polymer matrix is reinforced with highly oriented fibers of the same material by a solid state extrusion process. As the matrix and the fibers are of the same material, their interface possesses high adhesive strength. Such self reinforced composites display substantially higher mechanical strength and toughness[9].

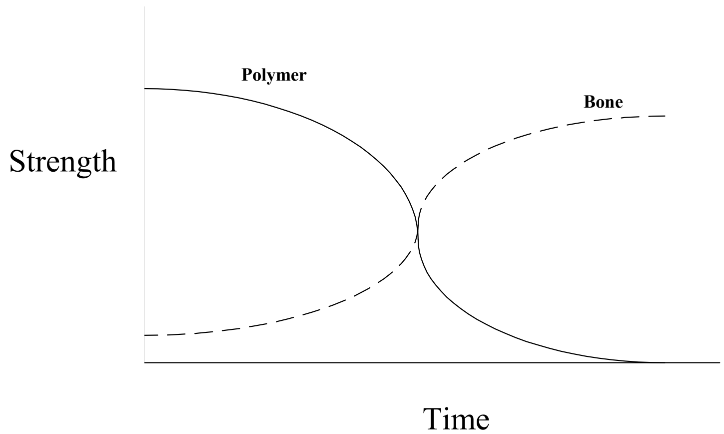


Figure 1: Variation of strength of biodegradable polymer and bone with healing time[7]

Currently available biodegradable fixation methods are mostly thread based. Commercially available biodegradable screws like Arthrex, Bioscrew, Endo-fix, Phantom, Sysorb etc. differ in their thread and head profiles[16]. The ability of fixation methods is usually measured in terms of their pull-out strength and the fastening torque. The pull-out force of the fastener is the tensile load applied along the longitudinal axis that is required to pull out the fastener from the bone block[17]. Study by Weiler etal.[18] has shown that the maximum pull-out force and stiffness of fixation for biodegradable screws is comparable to titanium screw, with the screw design having a bearing on the fixation rigidity. Tests for evaluating the torsional strength showed four different modes of failure like shearing of screw at the interface, radial screw driver failure at the screw driver hole, failure of the screw to screw-driver hole interface and failure of the screw driver shaft[16]. It has been observed that the pull-out strength of a screw is dependent on the thickness and type of the bone into which it is fixated[19, 20] and affected by the screw diameter[21].

These screws require tapping of the drilled hole prior to screwing and tightening. This is not only time consuming but also causes difficulty in fixation of small bone fragments[22]. Breakage of screw heads while tightening further worsens the problem. To overcome this drawback, thread less fasteners called as “biodegradable tacks” have been developed recently[8]. These tacks are push-in fasteners, which eliminate the tapping operation. This fixation method is based on the interference fit between the fastener and the hole drilled in the bone block. There are ratchets on the shaft of the fastener which deflect during insertion and subsequently stiffen to hold the fastener in place.

A compressive force should be applied across the bone fragments to achieve secure fixation and consolidation of the fragments. Bone screws, due to the mechanics of threaded joint are able to maintain the bone fragments under compression aiding their consolidation. Tacks are able to hold the fragments in place but are not as effective as screws in subjecting the fragments to compression. Studies have compared the pull-out force of mini screws with tacks. These studies show the efficacy of the tacks during the pull-out tests but do not illustrate whether they are capable of maintaining the fragments under compression[12, 17].

The purpose of this paper is to put forth the design of a spring loaded, threadless orthopedic microfastener which would be able to hold the bone fragments in place due to interference fit and also maintain a compressive force across them with the help of a spring element. A two-dimensional (2D) finite element model is developed to determine the pull-out force of the fastener and the stresses inside it.

Design

The integral spring-loaded fastener (Figures 2 and 3) has been modeled analogous to an interference fit between a hub and a shaft. It is assumed that the contact pressure produced due to the interference fit and the resulting frictional force will hold the fastener and bone fragments together, preventing separation. There are microratchets (A) on the shaft of the fastener that deflect while being inserted into the hole and subsequently stiffen to hold the fastener in place. The nominal diameter of the fastener is more than the hole drilled inside the bone fragment. The spring element (B) is analogous to a Belleville spring. When the fastener is being inserted into the hole, energy would be stored inside the spring causing it to deform. On removal of the push-in force, the spring would tend to regain its original configuration, thus pulling the bone fragments against each other.

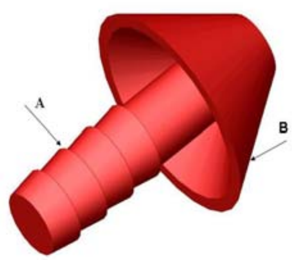
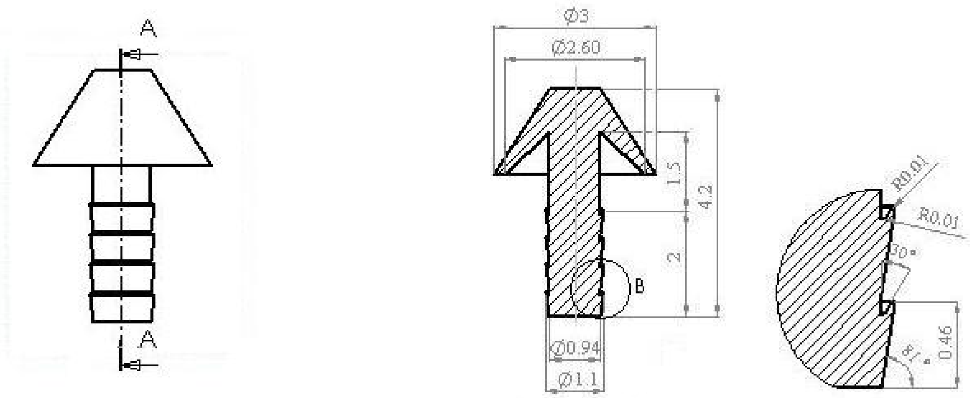


Figure 2: 3D model of the fastener with ratchets (A) and spring (B)



Section A-A Detail B

Figure 3: Details of the design. All dimensions are in millimeters.

Finite Element model

Finite element method was used to model the fastener-bone fragments assembly to evaluate the push-in and pull-out forces and the stresses in the fastener-bone assembly. Three different steps namely insertion, spring back and removal of the fastener have been simulated. The results obtained from this simulation will be compared with results from experiments that would be conducted.

The material for the fastener was taken to be high density polyethylene (HDPE), which has comparable mechanical properties to that of biodegradable polymers[13, 14, 15] but is more cost effective for design verification and testing purposes. The material was modeled as elastic-perfectly plastic with a Young's modulus of 1 GPa and yield strength of 26 MPa, the Poisson's ratio was taken to be 0.45. The properties of bovine bone instead of human bone were applied for the bone block[23]. It was modeled as a homogeneous, isotropic material with a Young's modulus of 20 GPa and Poisson's ratio of 0.3.

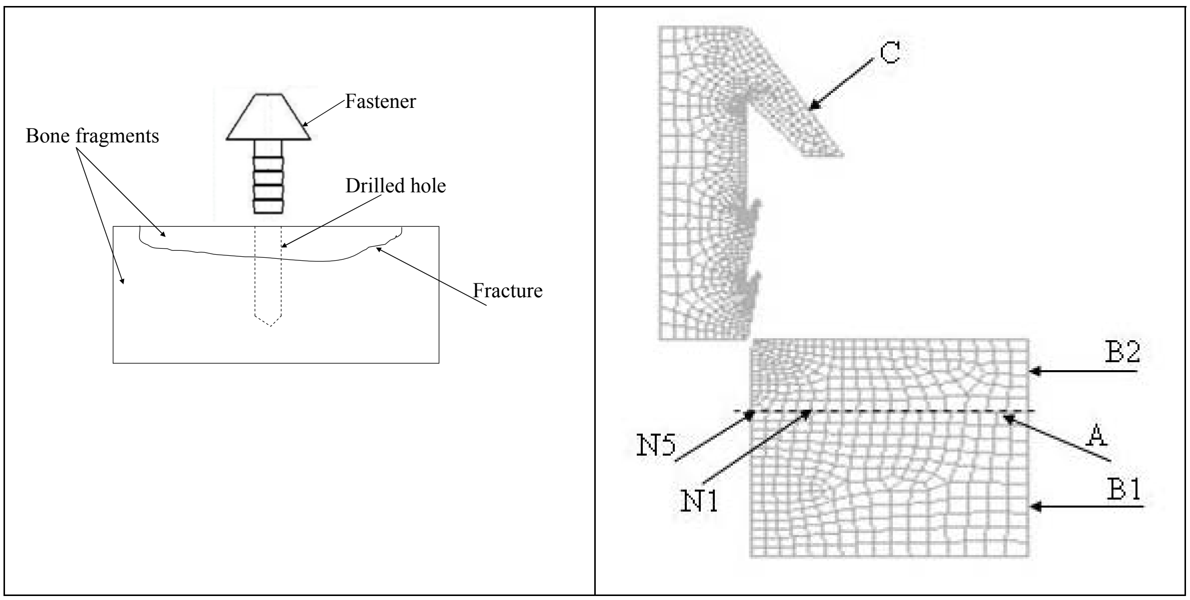


Figure 4: FE model of the fastener-bone fragments

The coefficient of friction at the fastener-bone interface has a dominant effect on the frictional reaction force. Initially the coefficient of friction was assumed to be 0.3 and subsequently it was varied between 0.2 and 0.5 to study its effect on the reaction force. The coefficient of friction for a particular level of interference would be experimentally determined later.

The nominal diameter of the fastener was taken as 1.1 mm with a diametric interference of 0.1 mm. Since the reaction force is a function of contact area, the length of interference (length occupied by ratchets) was taken as 1 mm so that the frictional force (push-in/pull-out force) per unit length could be evaluated. The model (Figure 4) consisted of two bone fragments (B1 and B2) placed on top of each other with their outer surfaces being fixed.

Thickness of the upper and lower bone fragments were taken to be 0.5 mm and 1 mm respectively. The interface between the two fragments would be the fracture plane (A). The fastener (C) was inserted perpendicular to the bone fragments for easy creation of the model. The displacements normal to the longitudinal axis of the fastener were set to zero. The mesh near the fastener-bone interface was meshed densely to effectively predict the high stress gradients in that region. The simulation was conducted in three steps in the following sequence: insertion, spring back and pull-out. A displacement boundary condition of 1.5 mm was given to the top surface of the fastener, with the appropriate direction during the insertion and pull-out step. On completion of the insertion step, the displacement boundary condition on the top surface of the fastener was removed, so that the spring element can spring back to an unloaded state.

High strains and frictional contact at the fastener-bone interface required the use of a non-linear solver. The finite element program ABAQUS™, which is capable of modeling such non-linearity was hence used for this problem.

Results and Discussion

FE analysis was conducted to determine the von Mises stresses and the pull-out force required to initiate separation of the fastener from the bone block. Starting with the fastener and bone (Figure 5a), the fastener is then pushed into the concentric holes in the two bone fragments (Figure 5b). The ratchets are observed to be highly stressed due to the interference and frictional sliding along the bone surface. The deformation of the ratchets is a function of the level of interference and the coefficient of friction. The spring element, under the application of the push-in force deforms by sliding along the top surface of the bone block. The region of the spring near the top of the fastener is stressed the most. Removal of the push-in force causes the spring element to get unloaded (Figure 5c) resulting in stress redistribution. Spring after getting unloaded, tends to regain its original configuration thus pulling up the shaft of the fastener. The lower bone fragment due to the interference fit with the fastener will also move upwards and compress against the upper fragment. Spring back of the fastener is characterized by the horizontal displacement of the tip (T) of the spring element resting on the top surface of the upper bone fragment (B2). The plot of vertical displacement versus spring back (Figure 6a), of the nodes (N1 to N5) on the fragment B1, which are on the fracture plane, shows that they move upwards against the fragment B2. Similarly, the vertical normal stress in this region becomes compressive (negative) with spring back (Figure 6b). Thus the interface between the fragments is subjected to a compressive stress of 0.5 MPa.

To evaluate the holding power of the fastener in the bone, variation of frictional (push-in/pull-out) force with the insertion depth has been plotted for coefficient of friction varying from 0.2 to 0.5 (Figure 7). No force is required till contact is established. Hence up to insertion corresponding to point (C) no force is required as there is no contact. After that, push-in force (negative) starts increasing due to frictional resistance and a sudden rise is observed as the spring begins to deflect, which requires a maximum push-in force of about 1.5 N. During the pull-out step, maximum force (positive) of 0.3 N is required to initiate separation and it gradually reduces as separation progresses. The pull-out force is less than the push-in force as no force is required for deformation of the spring in the prior case.

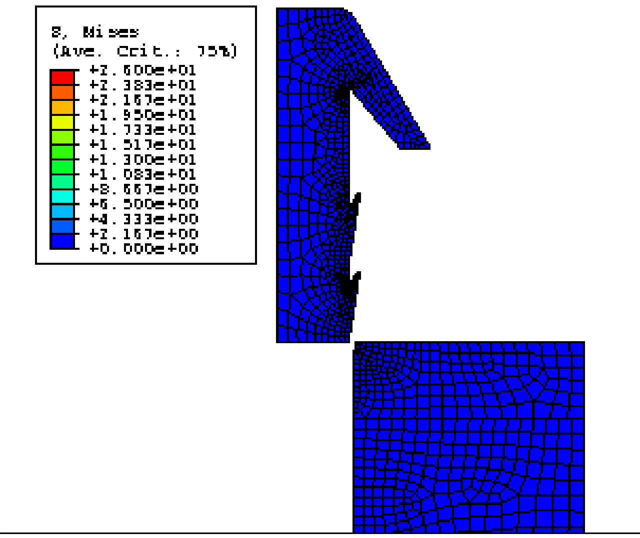


Figure 5a: FE model prior to insertion of the fastener.

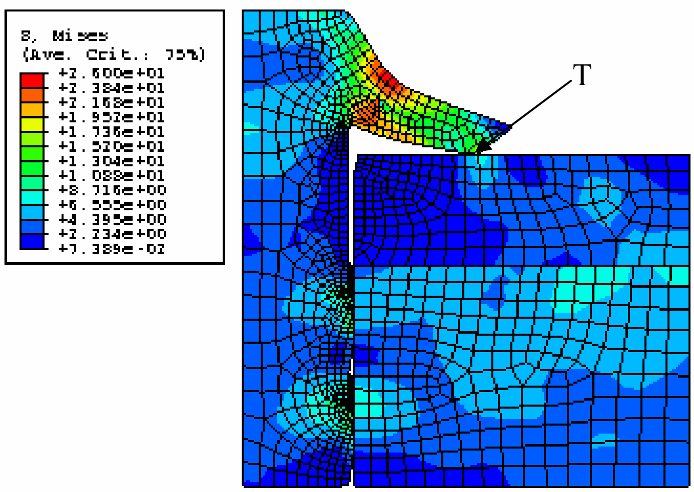


Figure 5b: Von Mises stress profile after insertion. Spring element with deflected ratchets is deformed due to insertion. Spring tip (T) pressing against top surface of B2. The top surface of spring element stresses the most but does not exceed the yield strength (26 MPa)

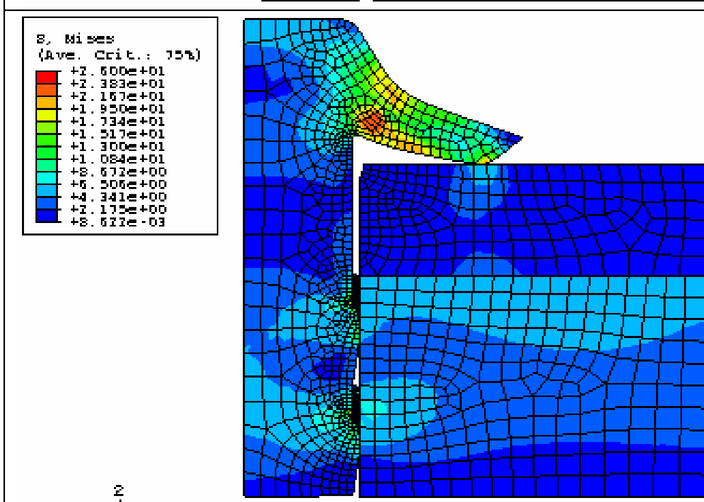


Figure 5c: Stress profile after spring back. Increased stresses along the fracture plane. Spring tip (T) slides along top surface of B2, tending to pull up the shaft of the fastener. Spring back causes stress reduction in the spring element.

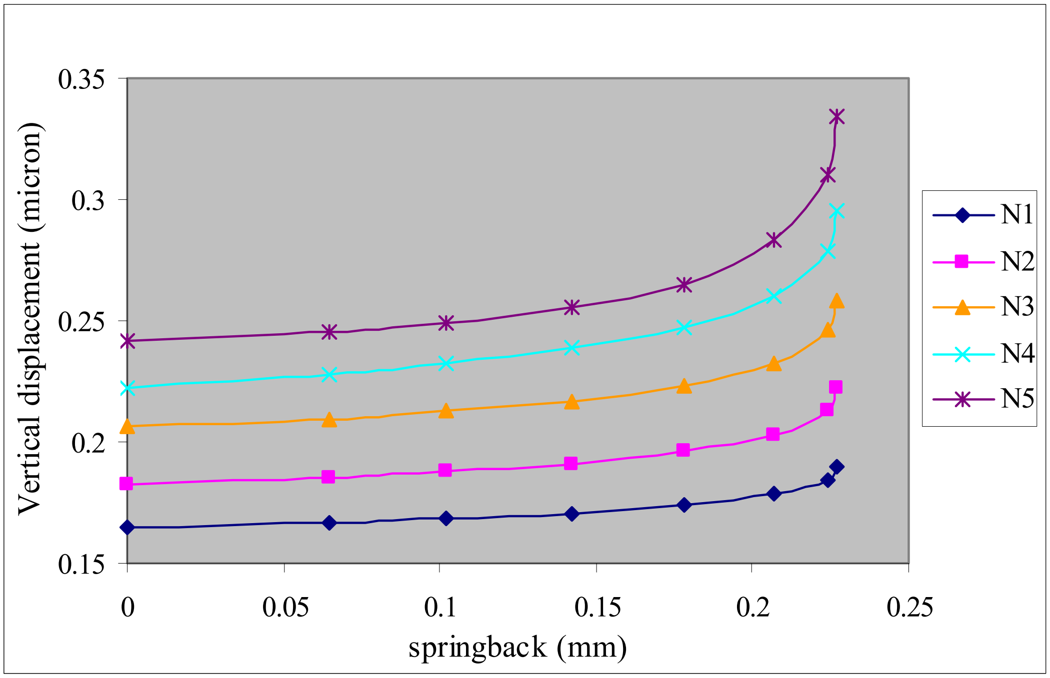


Figure 6a: Vertical displacement of nodes (N1 to N5) on fracture plane with spring back

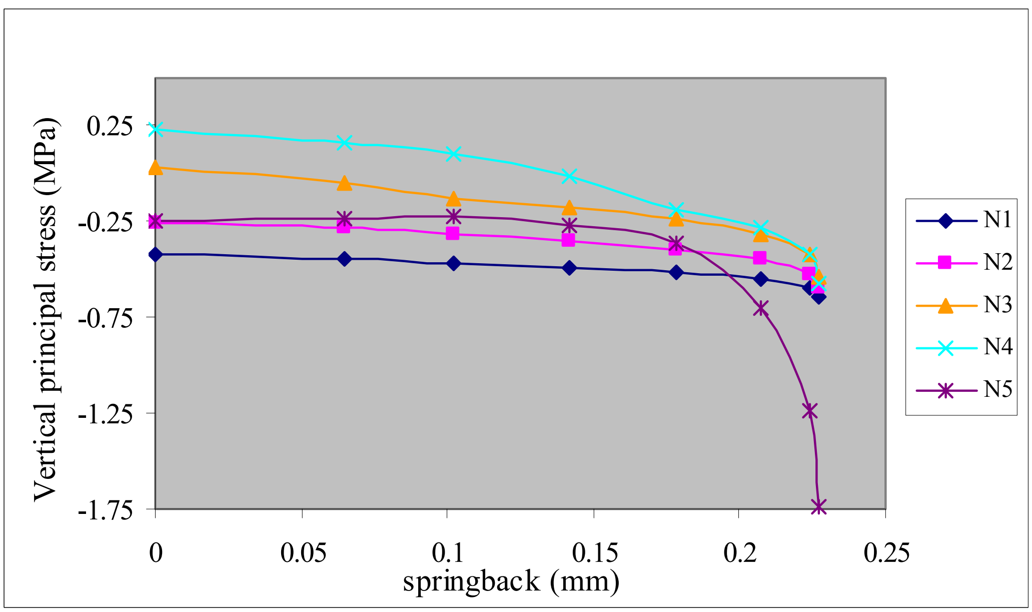


Figure 6b: Vertical principal stress at nodes (N1 to N5) on fracture plane with spring back

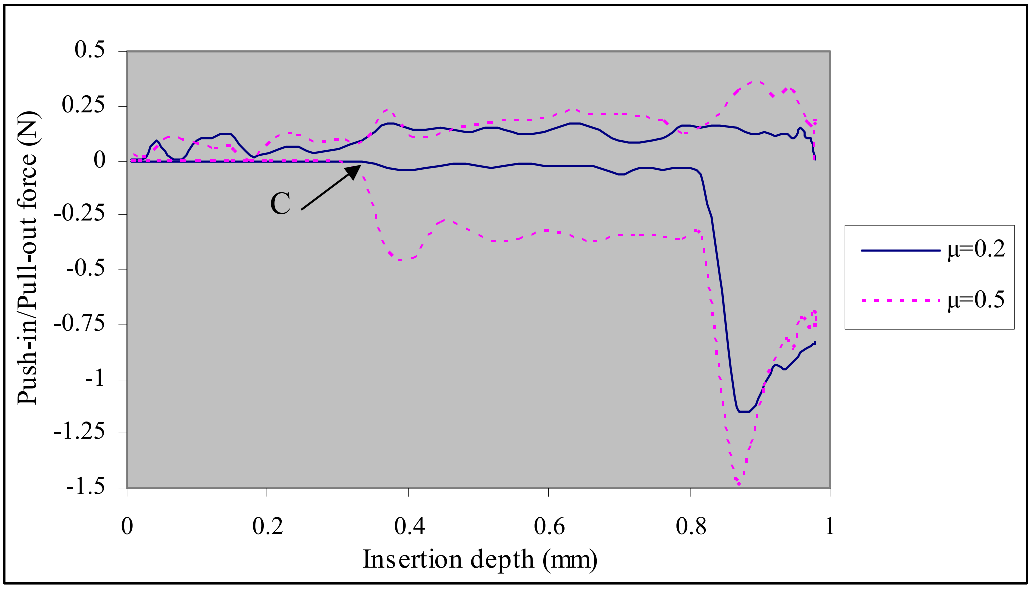


Figure 7: Simulated push-in (negative) and pull-out (positive) forces during insertion at different coefficients of friction μ. The point "C" indicates initial contact of the first micro ratchet and the bone wall.

Conclusion

A new orthopedic fixation tool has been proposed which will maintain interfragmental compression while dispensing with the tapping operation necessary with conventional thread based fasteners. Finite element modeling was able to predict the pull-out force of the fastener which gives the efficacy of the fastener and also showed that it was capable of providing interfragmental compression 0.5 MPa to facilitate bone healing.

Future Works

Future work would include the determination of coefficient of friction between HDPE and bone for varying levels of interference. Literature for testing of biodegradable fasteners mostly pertains to clinical studies where in commercially available fasteners of varying diameters and materials have been tested for their pull-out strength, thus lacking standardization. Hence the above FE results would be corroborated with the experimental values obtained after developing a prototype of the fastener.

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