Implant Design Report

Case Study 3

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Abstract

We have proposed two separate implants to solve our case study, an inflatable intramedullary nail for the femoral shaft fracture and an expanding, cementing lag screw to secure the distal fracture. Both will be manufactured from a fully bioresorbable PLA + glass phosphate composite, capable of variable resorption times. A quantitative, evidence-based approach has been used to cull early design concepts, making use of decision matrices and existing clinical trails. Both implant designs have been rigorously supported with both theory and current orthopaedic practice. Each design has been fully modelled and dimensioned, including tolerances matching existing ISO standards. We include a discussion detailing possible future development of our designs.

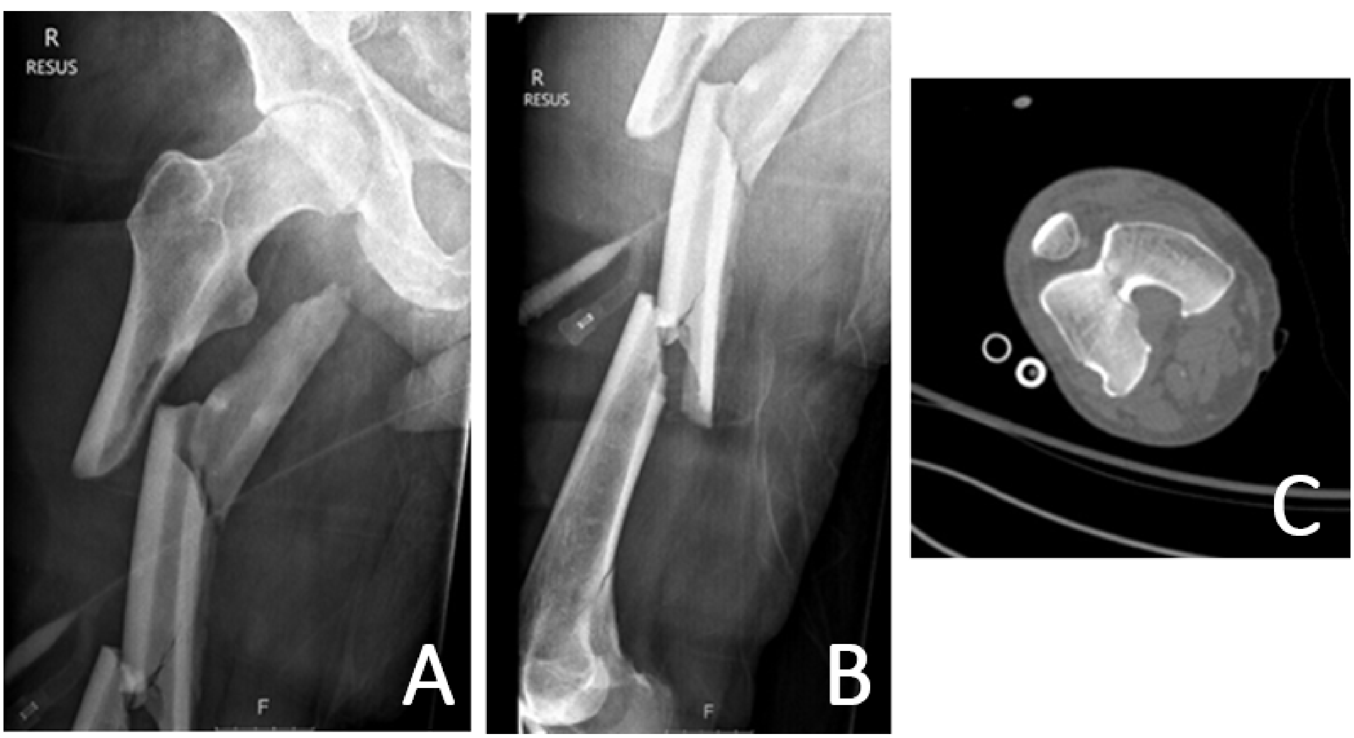

Fig. 1. An X-ray image of our fracture. Patient suffers from a pronounced compound fracture of the femoral shaft extending distally into the knee, there is a significant reduction in length and likely cartilage damage.

I. Introduction

A. Background

Osteoporosis is a condition that increase bone weakness, leading to a higher chance of fracture. Over 3 million people in the UK were diagnosed as osteoporosis and over 500,000 people receive hospital treatment per annum [1], [2]. Most common surgical implantations for femoral fractures require a metal base material, like titanium or stainless steel, necessitating an additional surgical procedure for removal. However, the reduction in bone quality due to osteoporosis in elderly patients greatly increase the risks inherent in these metalic implantations, complications such as infection and stress shielding limit the efficacy of this material [3]. Recently, the implementation of both inflatable and Flexible Axial Stimulation (FAST) intramedullary (IM) nails greatly reduce the time and complexity of surgical procedures, thereby decreasing the risk of infection (Table I) and even (in the inflatable nail's case) do not require locking screws. Expansive pedicle screws and cementation have been proven to dramatically increase pullout strength [4], [5]. These designs piqued our interest during investigation along with bioresorbable materials that reduce the number of surgical procedures for elderly patients (Table IV).

The aim of the report is to identify the problem in the case; construct a valid implant design to tackle the problem and meet the specification requirements. This is achieved via research and analysis of existing and experimental treatments that leads to the development of an original implant design, modelled with CAD, containing material and performance specifications, and the methodology of the implantation.

B. Case Presentation

A 70 year old man with osteoporosis was hit by a van whilst on his moped. The impact led to a femoral fracture, which is represented in Figure 1. No bone fragments have penetrated to the skin, therefore resulting in a closed fracture and greatly reducing the risk of infection. However, a comminuted segmental fracture with four large segments of the femoral shaft (Figure 1A/B) has been observed with the fracture extending distally into the knee joint (Figure 1C). Furthermore, a butterfly fragment (Figure 1A) was shifted upward, causing a significant reduction in the length of the knee. The fracture is hence classified as 32-C2 by the Mller AO Classification of Fractures.

C. Proposed Design

After much consideration about the limitations of existing solutions we have designed an inflatable intramedullary nail to secure the femoral shaft fracture, and an expandable, cementing lag screw to fix the distal fracture. Both fixators will be made from a fully bioresorbable material - specifically a PLA/glass fibre composite.

II. Initial Design Ideas and Concepts

A. IM Nail

For the Intramedullary Nail three main designs were considered, two of which were based on the original design of stainless steel Inflatable IM nails, the other a concept known as FAST nailing.

Our FAST nail design is a solid PLA rod reinforced by glass fibres. The nail requires minimal reaming before insertion and once inserted requires proximal and distal locking. The key difference between our FAST nail design and the classic fixed reamed IM nail is that the proximal locking system has an active element. Like the FAST nail, the proposed design will have bushing over the proximal section of the nail, that has non-circular holes for allowing 1 mm lateral micromotion. Like active plating, our proposed design has a polymer housing (in our case PLA) between the bushing and the nail to allow greater control over this micromotion.

Our two Inflatable IM nail designs are to be made of a PLA reinforced bioglass. Design 1 has three main components, the nail, the pump and the pump insertion mechanism (PIM). The design has eight ridges around the circumference that run down the length, these act as struts to aid in axial stability. The PLA membrane folds out from a complex clover-like shape. Along the centre of the implant runs a channel for guide wire insertion, at the bottom of this channel is a valve that closes after the guide wire is removed. This guide wire channel (GWC) has a second function for the PIM. Near the distal end of the implant the channel has screw threads, these match with the screw threads on the PIM. Near to this valve are openings into the inflatable section of the design, when lined up properly the pump openings match with these openings. The Implant can then be inflated using a screw pump mechanism connected to a manometer. A small hole at the top of the implant releases air within the system (a valve allows this to be closed once the implant is filled but not under pressure). Once the implant is filled, continued pumping results in its inflation. The pump is then disconnected from the pump mechanism at the neck of the implant, and this is closed off.

The Inflatable IM nail Design 2 is similar to Design 1, with the main changes being in the saline delivery system and the guide wire introduction. For Design 2 the GWC is removed, the shape of the implant when deflated shall act as a channel for the guide wire to move up. Removing this section allows for thicker implant walls, therefore a more variable rate of implant degradation.

The strengths and weaknesses of each proposed IM nail have been considered (Table I), but for a more quantifiable measurement we opted to use a decision matrix to choose which design to develop (see appedix, Tables IX and XII).

B. Lag Screw

Our proposed fixator for the distal fracture must limit mechanical strain to below the 2% [20] required for primary bone healing. Therefore we decided to design a lag screw capable of interfragmentary compression. The screw must be secured into cancellous bone, which is already weaker and more porous than cortical bone [21]. Additionally, our patient is osteoporotic, further lowering the bone mineral density [22].

We started by analysing the current screw fixation practices for cancellous bone: what properties of our screw should we maximise to resist pullout? Screw purchase in porotic bone is primarily affected by *"the major diameter of the screw, the length of engagement of the thread, the shear strength of the material into which the screw is embedded, and a thread shape factor which accounts for thread depth and pitch"* [23]. The length of engagement is dictated by fracture geometry, as such manufacturers produce screws in increments of 5mm to fit different fractures. The mathematics behind determining the thread shape factor and major diameter will be discussed during validation.

There is a way of increasing the shear strength of the surrounding bone through augmentation with bone cement. The McKoy-An cementing screw notes an increase in holding power of over 278% [5] when PMMA is injected through the cannulation into the surrounding bone. We improve upon his design by suggesting PMMA alternatives capable of isothermally hardening in moist environments. The mathematical theory behind cementation will be discussed later in the report.

Next we tried approaching the problem by looking for design analogues. Fixing a screw into porotic bone is not so dissimilar from fixing a screw into porous drywall or plaster. In such cases a rawlplug is often used. We pursued this idea but ultimately did not want to make the screw from two separate components, however we liked the novel idea of using expansion to help anchor the screw. Currently, expandable pedicle screws have been used successfully for spinal fixation [4], but they require the use of a driving pin to expand the screw. We decided to replace the metal driving pin with a viscous bone cement putty, able to force open the screw while still being completely bioresorbable.

TABLE I
EVALUATING THE FAST AND INFLATABLE INTRAMEDULLARY NAIL DESIGNS

Criteria	Flexible Axial Stimulation (FAST) Nail Design	Inflatable Nail Design
Biomechanical Stability	+ Greater torsional stability and good control over axial micromotion. - Issues of screw holding in osteoporotic bone (stress concentration at screws) [6], [7], [8]	+ Greater bending stiffness, rotational stability and less play than fixed, reamed IM nails, reduced torsional strength [9], [10].
Bioresorbability	- Nail denser and screws will take longer to degrade	- Design 1 has thin walls therefore the system will biodegrade faster, difficult to alter rate of biodegradation as not much variability in wall size. + Design 2 has greater control over thickness of wall, this won't significantly affect mechanical properties, it also allows more control over biodegredation rate + Both designs have no need for screws
Failure rate	+ As seen with fixed IM nailing the rate of failure is relatively low [11] - However screw pull-out is a significant issue with osteoporotic bone [12]	- Old designs have high failure rate with type C fractures [9], [13], [14]. + Both Design 1 & 2 attempt to reduce this with the use of a guide wire for aid in implant insertion. - Spontaneous premature deflation can occur, this can result in non-union although looking at the existing inflatable nail, this is rare (2.8%) [15].
Invasiveness	- Reaming is significantly more invasive than non-reamed nailing, it may cause thermal necrosis and can result in debris [11] - Proximal and distal screws increase number of entry wounds	+ Small entry wound and no need for reaming or screw fixation [16], [17]
Stress Concentration	- Osteoporotic bone degrades fastest at screws due to stress concentration resulting in weak point of implant fixation [6], [18]	+ Fixation along whole length of nail [17], osteoporotic bone lacks mechanical strength to act as a stable anchor for screws [18]
Infection rate	- Screws increase sites for infection - Reasonably invasive procedure, results in an increase in the risk of infection	+ The procedure is not very invasive, also reduces entry points and reduces risk of infection [17]
Micromovement	+ The bushing and PLA layer gives controlled micromovement [19]	- There is less play in the system than with fixed IM nailing, suggesting that there isnt very much micromovement [9]

III. How Our Design Works

A. IM Nail

We opted to develop Design 2 due to the results of our decision matrix (Table IX).

Before implanting the Inflatable Design 2 IMN a 3.2mm Steinmann Pin [24] is to be inserted into the femur as a guide wire. This is essential as without adequate pre-realignment the use of an inflatable nail can cause non-union at the fracture site [9], [13], [14]. Prior to nail insertion, the pump mechanism is assembled and readied. The pump is filled with sterile saline solution, the tube outlet is immersed in the saline and the pump handle is rotated. Once the pump is filled, it should be verified that there is no air within the pump [24]. After this, having determined the narrowest point of the medulla (using x-ray), an appropriate sized nail is chosen [24]. The protruding end of the guide wire is inserted into the distal end of the implant, pushing the distal flap valve open. The guide wire can be threaded through the implant, the proximal valve is to be pushed downwards to allow the guide wire through the proximal hole at the top of the implant. This process then allows the accurate positioning of the implant without affecting bone reduction. After the implant is positioned, the guide wire is removed; in doing so the proximal and distal valves close. The pump can then be put into the proximal hole, pushing the valve aside. Under fluoroscopy, the implant is inflated, all air inside is forced through a ventilation tube attached to the pump mechanism. Once saline solution is seen to leave the ventilation system, it can be closed off, ensuring that no air is within the implant and that inflation can take place. Due to the shape of the deflated implant and the positioning of the struts, the implant rotates as it is inflated. This acts to fix the implant in place more securely, but also as a safeguard to not put direct axial pressure on the already damaged cortical bone, reducing risk of further injury during expansion. Resistance should be felt within the pump when the implant is inflated (the manometer shall also indicate this [24]). Once the pump is removed, the one-way valve should close tightly under the pressure of the inflated implant, stabilising the system.

B. Lag Screw

Similar to the IMN a guide wire is first used to reduce the fracture. A preoperative DEXA scan should be used to determine the bone mineral density at the fracture site, the screw should be placed through the most dense areas to maximise pullout strength [25], while also laying complementary with the existing trabecular network of the bone [26]. A hole slightly smaller than the major diameter of the screw is drilled perpendicular across the fracture site, and after ensuring proper alignment the screw can be inserted over the guide wire. There is no need for tapping due to the presence of a positive angle self-tapping rake. Once sufficient compression of the fracture is achieved the guide wire can be removed. Now a less viscous Norian SRS calcium phosphate bone cement is prepared and injected down the cannulation, where is spreads out through the segmented screw threading and enters surrounding porous bone. Before hardening a more viscous Norian SRS putty is injected at the site of the screw thread, forcing open the wedges and expanding the screw. The bone cement sets and the fracture can be sealed.

IV. Bioresorbable Materials

Both IM nail and lag screw will be made of a bioresorbable material because this will eliminate the need of secondary surgeries to remove the implants. In addition, the mechanical properties of biodegradable polymer materials are closer to those of bone, which will reduce stress shielding and bone loosening, issues commonly seen with metal implants [27]. The precisely controlled degradation rate of the nail will ensure that the implant is very strong in the first 3 to 4 weeks after implantation as in this period the load will only be carried by the IM nail. As bone reunion is achieved, the implant will begin its degradation, thus allowing the newly formed bone to carry progressively more load and hence, prevent bone resorption. The four classes of bioresorbable materials that were considered are magnesium alloys, self-reinforced polymers, particulate reinforced polymers and fibre reinforced polymers. These were evaluated by comparing the most fundamental material properties relevant to our design in a decision matrix that can be found in the appendix, Tables X and XIII. The results reveal that the most suitable materials for our design are fibre-reinforced polymers.

Phosphate glass fibre (PGF) reinforced poly-lactic acid (PLA) will be used for the design of the implants. Both PGF and PLA have been used for biomedical applications in the past and they proved to be highly biocompatible (PGF degrades to calcium phosphate, which is a natural constituent of bone, and PLA reduces to carbon dioxide and water)[28], [29]. However, the manufacturing process must ensure that the composite exhibits suitable mechanical properties that will alter with its gradual degradation accordingly. The specific properties of the composite are presented in Table IV below.

TABLE II
ADVANTAGES, DISADVANTAGES AND LIMITATIONS OF OUR PROPOSED IM NAIL

Part	Function	Advantages	Disadvantages	Limitations
Struts	Gives the implant axial support.	Resists axial loading. During implant inflation, the strut rotation ensures space is made for the implant to expand into, reducing excessive outward pressure on the cortical bone [10].	The struts result in increased implant size when deflated, increasing size of entry wound.	Difficult to ensure micromotion within the 1mm-2mm range [30].
Inflatable membrane	IMN is implanted deflated. The inflatable membrane is then inflated, ensuring the IMN is the size of the medulla, holding it in place.	High rotational rigidity, bending stiffness and reduces implant play without use of interlocking screws [9]. Stress shared over implant. Can implant in a greater range of medulla diameters [17].	Failure due to biodegradation will be catastrophic, resulting in loss of implant fixation. Reduced torsional strength [9].	
Steinmann Pin	Implanted under x-ray to ensure accurate femur reduction. Further used as a guide wire for implant positioning.	Conventional Inflatable IMNs shouldnt be used for type C fractures due to misalignment [9], [13], [14]. Reduces and stabilises bone before insertion of implant. Steinmann Pins allow for relatively easy fracture reduction [24].		The size of the Steinmann Pin limits the diameter of the deflated implant. The Steinmann Pin also limits the size of the inflation hole.
Distal flap valve	Opens inwards to allow the guide wire through. Closes distal end of implant after the guide wire is removed.	Prevents excess blood or tissue entering the inflatable nail. Also, the positioning of the valve prevents cavity formation and bacteria growth.	Risk of valve damage when inserting guide wire or for the valve to not close properly if debris within the distal hole.	
Proximal flap valve	Opens inwards as to allow the guide wire through. Opens when pump introduced, and closes under high implant internal pressure	As pressure grows within the system, as does the force closing this valve. This not only prevents backflow but can also be felt by the surgeon as a guide to implant pressure.	Could be difficult to thread the guide wire as flap opens into the implant.	The flap valve could add another limitation to the hole size at which saline solution can be introduced.

TABLE III
ADVANTAGES, DISADVANTAGES AND LIMITATIONS OF OUR PROPOSED LAG SCREW

Part	Function	Advantages	Disadvantages	Limitations
Hollow shaft	Allows the screw to be cannulated, allowing for accurate insertion over K-wires. Also allows for bone cement to be applied while the screw is inserted	The K-wires guide the screw precisely into the bone, while still allowing for readjustments and reduction of bone fragments [31]. Cementation increases bone holding power by 278% [5].	Requires a larger minor diameter to compensate for the hollow shaft.	Shaft diameter must match existing K-wires.
Rounded screw head	Allows for even force transmission to the underlying bone even if the screw is not aligned perfectly parallel	Lag screws are frequently incorrectly positioned, even a slight misalignment can cause uneven force transferal to the bone. A rounded undersurface ensures some screw will be making contact with bone no matter the angle. The rounding also reduces stress risers [32].	Takes up more space than using a flat undersurface, causing a larger protrusion from the bone surface if not countersunk.	Screw head diameter must match the major diameter of the screw
Hexagonal head	Allows the screw to be driven into bone.	Reduced risk of cam-out. Forms a *"strong and alignment-insensitive connection with the screw"* [25].	Harder to machine, requires broaching.	Must follow existing standards for driver bits.
Reverse buttress screw thread design	Perpendicular to the direction of screw pullout to better transfer force to bone [33]. Rounded buttress resists load and reduces stress concentration.	Highest resistance in direction of screw pullout, while buttress reduces stress risers and allows for a greater thread depth.	Poor at asymmetrical loading, screw must be properly aligned. Weaker than a square thread and more difficult to manufacture than a V-thread.	The buttresses ability to resist load is ultimately what limits thread depth, which is ideally as deep as possible.
Positive angle self-tapping rake	Bone does not need to be tapped prior to screw insertion.	Tapping causes a decrease in pullout strength of almost 30% in porous bone due to the removal of material around the screw hole [23], and as such should be avoided. *"The positive raked flute is sharpest and generates the least heat with installation"* [25].	Requires more torque to drive the screw into untapped bone, would be impossible if we were dealing with cortical bone.	Testing must confirm rake angle is strong enough to cut bone without breaking. Can only be used with porous, cancellous bone
Expandable wedges	Screw thread is divided into six segments allowing	Already seen successful use in pedicle screws used for spinal fixation where the see a 50% increase of pullout force in poor quality bone [4].	Loads the surrounding bone, which may lead to crack formation.	
Norian SRS bone cement	Calcium phosphate bone cement replaces PMMA and is used for cementation and expansion of the screw.	Norian SRS is isothermic meaning there will be no heat damage as the bone cement sets. It can also be used in moist environments.	More expensive than PMMA, available as a commercial product.	

TABLE IV
EVALUATION OF BIORESORBABLE MATERIALS FOR USE IN IMPLANT DESIGN

Feature	Type/value	Reasoning/Explanation
Manufacturing process	Melt spinning and pre-form drawing method	The glass solution is melted and spun to produce PGF of diameter $\sim 25\mu$m. The fibres are annealed to remove surface stresses. Fibres are then coated with coupling agent (hydroxyethyl cellulose) to improve matrix-fibre adhesion. Finally, fibres are incorporated into the PLA matrix by film stacking and lamination process [27], [34]
Fibre orientation	Unidirectional (UD) along long axis of implant	UD fibre orientation ensures implants are strongest along their long axis, which is desirable because both of them will be primarily loaded along that axis (IMN in compression, lag screw in tension). UD fibres will also facilitate the lateral expansion of the inflatable nail.
Fibre volume fraction (Vf)	30 pm 5%	These values will produce composites of mechanical properties similar to those of cortical bone (Youngs modulus $\sim$30GPa, flexural strength $\sim$200MPa, flexural modulus $\sim$25GPa, compressive strength $\sim$300MPa and shear strength $\sim$80MPa). These values can be calculated from the rule of mixtures: $$E_c = V_f E_f + (1 - V_f) E_m$$ where Vf is the fibre volume fraction and EC, Ef and Em is the specific property of the composite, fibres and matrix respectively [35]. This composition also provides suitable material degradation and gradual loss of implant mechanical properties [27], [29].
Fibre length	10-15 mm	

V. Final Product Design Specification

TABLE V
Final Product Design Specification

Design Specification	Explaination
Aim	To develop a valid implant design that will improve patients mobility and achieve full bone reunion both at the comminuted and distal fracture sites
Components	An inflatable biodegradable intramedullary nail (IMN) used for stabilizing the 32-C2 femoral fracture. A lag screw that provides interfragmentary compression is used for fixating the distal knee fracture.
Function	The IMN is placed into the femoral intramedullary canal after reduction of the bone is achieved using a K-wire. The nail is than inflated with a non-toxic saline solution that is introduced via pump insertion mechanism. The solution is kept inside the nail with two unidirectional valves at both ends of the implant. The lag screw function is to provide sufficient compression between both segments of the distal fracture and promote bone reunion. After the fracture is reduced with a K-wire, the screw is inserted into the slightly smaller pre-drilled hole. Calcium phosphate bone cement is then injected down the cannulation to maximise pullout strength. After it sets, the fracture can be sealed.
Materials and manufacture	Both implants are made out of a composite material phosphate glass fibre reinforced poly-lactic acid. The fibre/matrix composition is manufactured so that it ensures adequate mechanical properties and degradation rate of the implants. The components are manufactured through a melt spinning and pre-form drawing process. This manufacturing method allows for highly controlled production of composite materials as it precisely controls the orientation and volume fraction of the fibres laid down onto the PLA matrix.
Safety	This implant design reduces surgery invasiveness and decreases operation time by using non-toxic fully biodegradable material. An initial validation and verification of the current design can be encountered in the next section

VI. Initial Validation and Verification

A. IM Nail

1) Critical Load: By modelling the intramedullary nail as a column we can calculate the theoretical Euler critical load [36]:

$$P_{cr} = \frac{\pi^2 EI}{(KL)^2} \tag{1}$$

where:

$$\begin{aligned} P_{cr} &= \text{Euler's critical load} \\ E &= \text{Young's modulus} \\ I &= \text{area moment of inertia} \\ L &= \text{IM nail length} \\ K &= \text{effective length factor} \end{aligned}$$

We determine the second moment of area of the intramedullary nail by breaking down the complex cross sectional geometry into six separate elements, all calculations are found in the appendix for 0° and 45°.

We calculate critical load for the PLA and glass fibres separately knowing the rule of mixtures shows the actual critical load will fall somewhere between these two values, dependent on fibre composition. The peak critical loads are found in Table VI:

TABLE VI
Maximum and Minimum Critical Loads for the IM Nail

	Maximum Critical Load [N]	Minimum Critical Load [N]
0°	1710	714
45°	1800	749

The ground reaction force while walking is 107% of an individuals bodyweight [37], although this rises up to 230% while running [38]. However both are far below the critical threshold for our IM nail, especially when you consider the reinforcing effects of the saline and surrounding bone which we have neglected.

2) Calculating Saline Flow Rate: The pressure difference needed to pump saline into the implant can be calculated using the Hagen-Poiseuille equation [39]:

$$\Delta P = \frac{8\mu LQ}{\pi R^4} \tag{2}$$

where:

$$\begin{aligned} \Delta P &= \text{the pressure difference} \\ L &= \text{pipe length} \\ \mu &= \text{the dynamic viscosity} \\ R &= \text{the pipe radius} \end{aligned}$$

Saline flow rate is important to optimise, too long and the operation takes longer than necessary, too quickly and the higher pressures increase risk.

B. Lag Screw

1) The Thread Shape Factor: The shear stress required for lag screw failure is proportional to the bone strength and thread area. The mathematical theory behind this has been formulated by Chapman et al. [23] which we state in Equation 3.

$$F_s = S \times (L \times \pi \times D_{major}) \times TSF \tag{3}$$

where:

$$\begin{aligned} F_s &= \text{predicted shear failure force } [N] \\ S &= \text{material ultimate shear stress } [MPa] \\ L &= \text{thread length } [mm] \\ D_{major} &= \text{major diameter } [mm] \\ TSF &= \text{dimensionless thread shape factor } [N] \end{aligned}$$

and the thread shape factor (TSF) has been experimentally found to be:

$$TSF = \left(\frac{1}{2} + 0.57735\frac{d}{p}\right)$$

where d is the thread depth and p is the thread pitch.

The TSF of existing lag screw solutions has been collated by Asnis and Kyle [25] (see Table VII). With a thread depth of 2mm and a pitch of 2mm our proposed design has a TSF of 1.08, noticeably higher than current competition.

TABLE VII
TSF of existing large diameter cannulated lag screws

Manufacturer	Major Diameter	Minor Diameter	Thread Depth, d	Pitch, p	TSF
Synthes	7.0	4.50	1.25	2.75	0.76
Zimmer	7.0	5.00	1.00	2.75	0.71
Ace Medical	6.5	5.25	0.63	1.85	0.75
Richards	6.5	4.70	0.90	2.12	0.75

2) Cementation Theory: Cementation increases the density, ρ, of weak porotic bone. Research by Stone et al. [26] has derived a power law relationship between density and shear stress, S:

$$S = 21.6\rho^{1.65} \tag{4}$$

For this reason we predict cementation with Norian SRS will show the greatest increase in pullout strength.

VII. Discussion

Further research must be done before manufacture of the IM nail and lag screw can begin manufacture.

A prototype fixator must be tested in a bone substitute, Chapman *et al.* have found success using unicellular polyethylene foam as a bone analogue as its density closely matches cancellous bone [23] (recall from Equation 4 density was the key predictor for the shear stress of a material). However bone is anisotropic due to a complex trabecular network [26], while polyethylene foam is not. Until a substitute has been developed we can use cadaveric tissue.

Swartz *et al.* [40] show how bovine bone can be a good substitute for human bone as its inherent anisotropy closely matches with human bone.

Within the last decade finite element modelling has been used to model both inflatable intramedullary nails [30] and expandable lag screws [41]. But it can also be used to optimise certain specific aspects of the fixators design. For example Eraslan and İnan have been using finite element analysis to optimise lag screw thread design with the goal of lowering stresses. Clever optimisations such as these can be applied to our proposed design to increase stability.

Clinical trails are a valuable (and mandatory) stage before our proposed designs can reach market. Often a fixator can work well theoretically but fail to meet surgeon's expectations. The Marchetti-Vicenzi IM nail (Figure 2) was one of the more attractive designs we first considered, however high nonunion rates from one clinical trail raised concerns [42]. They also note how *"the absence of a pin guide is a disadvantage"* [42], something we made sure to incorporate into our design.

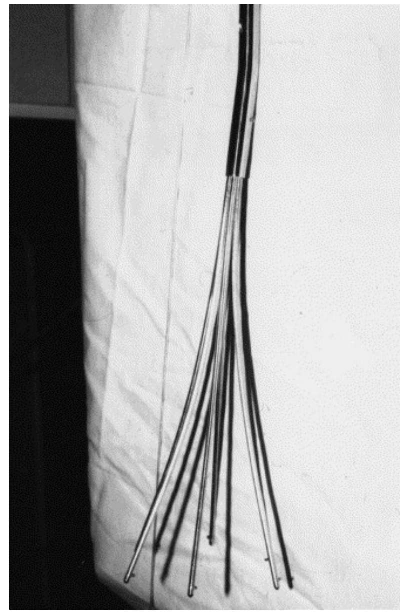

Fig. 2. The Marchetti-Vicenzi IM nail failed to live up to expectations under clinical testing [42]

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Appendix

TABLE VIII
DESIGN DECISION MATRIX RATING SCALE

Criteria Rating	Implant Rating
5 = Essential	5 = Excellent (cheap)
4 = Very Important	4 = Good (low)
3 = Important	3 = Average
2 = Not Important	2 = Bad (high)
1 = Unnecessary	1 = Terrible (expensive)

TABLE IX
DECISION MATRIX RESULTS FOR THE IM NAIL - SEE TABLE XII FOR MATRIX

IM Nail	Total
FAST nail (current)	125
FAST nail (new)	156
Inflatable Nail (current)	141
Inflatable Nail (Design 1)	169
Inflatable Nail (Design 2)	180

TABLE X
DECISION MATRIX RESULTS FOR THE BIORESORBABLE MATERIAL - SEE TABLE XIII FOR MATRIX

Material	Total
Magnesium alloy	90
Self-reinforced polymers	101
Particulate reinforced polymers	113
Phosphate-glass fibre reinforced PLA	121

TABLE XI
MANUFACTURING THE LAG SCREW

Stage	Manufacturing Process	Description
A	Cutting	Extruded round rods (diameter 12mm) of our chosen glass fibre reinforced PLA composite are cut into 80mm blanks
B	Turning	The blank is lathed into the rough geometry of the screw, establishing the minor and major diameters
C	Cutting	A 0.6mm saw blade makes three 30mm deep cuts into the screw tail, forming the six expandable wedges
D	Broaching	The hexagonal driving head is broached into the screw head to a depth of 3mm
E	Drilling	A gun drill forms a 2mm channel along the length of the blank, the screw is now cannulated
F	Milling	Thread milling can be used to form the high precision screw thread and to create the curved screw head
G	Milling	Finally the self-tapping head is formed. The screw is now complete and can receive a surface finish to control degradation

TABLE XII
DECISION MATRIX FOR THE IM NAIL

Criteria	Biomechanical Stability	Bioresorbability	Overall Cost	Failure rate	Time to union	Vascular conservation	Invasiveness	Stress Shielding	Infection rate	Reoperation Rate	Micro-movement	Oporation complexity	Tools/inventory
Criteria Rating	5	4	2	5	3	3	4	3	5	4	4	2	2
FAST nail (current)	4	0	4	4	5	3	2	2	3	0	4	1	3
Score	20	0	8	20	15	9	8	6	15	0	16	2	6
FAST nail (new)	5	3	3	4	5	3	2	2	3	3	5	1	3
Score	25	12	6	20	15	9	8	6	15	12	20	2	6
Inflatable Nail (current)	2	0	5	3	2	4	4	5	5	0	3	5	5
Score	10	0	10	15	6	12	16	15	25	0	12	10	10
Inflatable Nail (Design 1)	3	4	3	3	3	4	4	5	5	4	3	3	3
Score	15	16	6	15	9	12	16	15	25	16	12	6	6
Inflatable Nail (Design 2)	3	5	4	3	3	4	4	5	4	4	4	4	5
Score	15	20	8	15	9	12	16	15	20	16	16	8	10

TABLE XIII
DECISION MATRIX FOR THE BIORESORBABLE MATERIAL

Criteria	Biocompatibility	Young's modulus	Compressive strength	Bending modulus	Fracture toughness	Degradation rate control	Corrosion resistance	Overall cost	Ease of manufacture
Criteria Rating	5	4	4	3	2	5	3	3	3
Magnesium alloy	3	2	5	2	5	2	1	3	3
Score	15	8	20	6	10	10	3	9	9
Self-reinforced polymers	3	2	3	3	2	4	5	3	3
Score	15	8	12	9	4	20	15	9	9
Particulate reinforced polymers	4	2	4	2	2	4	5	4	4
Score	20	8	16	6	4	20	15	12	12
Fibre-reinforced polymers	4	3	4	5	4	4	5	2	3
Score	20	12	16	15	8	20	15	6	9

Critical Load Calculations - 0°

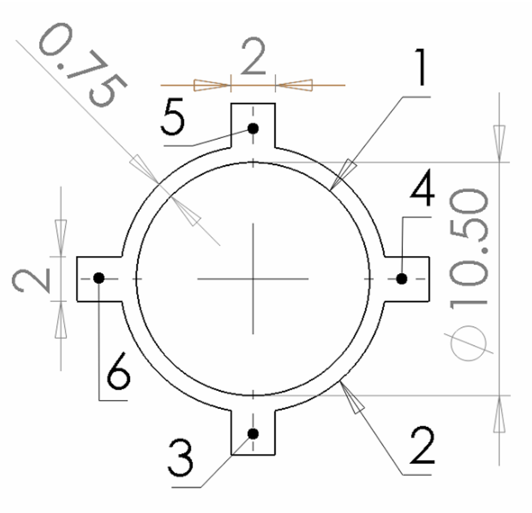

Fig. 3. Cross section of the intramedullary nail divided into six elements. Intramedullary nail is oriented at 0° ad the effect of saline has been neglected.

The second moments of inertia of a circle and square are found to be:

$$\begin{aligned} I_{z \text{ circle}} &= \frac{\pi D^4}{64} \\ I_{z \text{ rectangle}} &= \frac{1}{12} bh^3 \end{aligned} \tag{5}$$

So that the second moment of area of each component is calculated as:

$$\begin{aligned} &[1] \qquad I_z = \frac{\pi (10.4)^4}{64} = 189.9\pi \\ &[2] \qquad I_z = \frac{\pi (12)^4}{64} = 324\pi \\ &[3] \qquad I_z = \frac{1}{12} bh^3 + Ad^2 = \frac{(2)^4}{12} + 4(11 - 81) = 29.3 \\ &[4] \qquad I_z = \frac{1}{12} bh^3 = \frac{(2)^4}{12} = 1.3 \end{aligned} \tag{6}$$

So that the total second moment of area of the complex shape is found to be:

$$\begin{aligned} I &= 324\pi - 189.9\pi + 2(29.3) + 2(2.13) \\ &= 482\text{mm}^4 \end{aligned} \tag{7}$$

The Euler critical load of an intramedullary nail composed purely of PLA is found to be:

$$\begin{aligned} P_{cr \text{ (min)}} &= \frac{\pi (30)(482)}{200} \\ &= 714\text{N} \end{aligned} \tag{8}$$

And when considering just the glass fibres:

$$\begin{aligned} P_{cr \text{ (max)}} &= \frac{\pi (72)(482)}{200} \\ &= 1.71\text{kN} \end{aligned} \tag{9}$$

The rule of mixtures ensures the actual critical load falls somewhere between the maximum and minimum values, dependent on fibre composition.

Critical Load Calculations - 45°

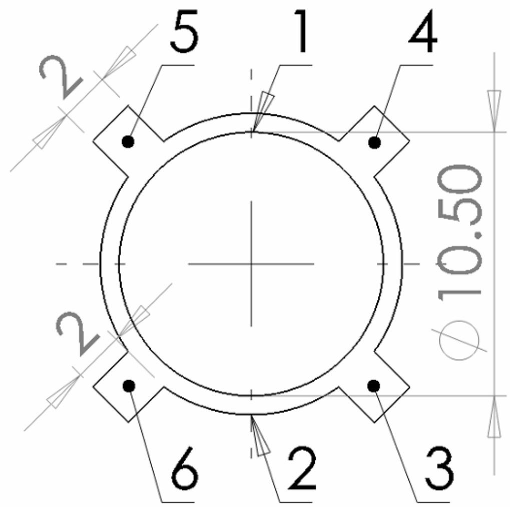

Fig. 4. Cross section of the intramedullary nail divided into six elements. Intramedullary nail is oriented at 45° ad the effect of saline has been neglected.

The second moments of inertia of a circle and square are found to be:

$$\begin{aligned} I_{z \text{ circle}} &= \frac{\pi D^4}{64} \\ I_{z \text{ rectangle}} &= \frac{1}{12} b h^3 \end{aligned} \tag{10}$$

So that the second moment of area of each component is calculated as:

$$\begin{aligned} &[1] \qquad I_z = \frac{\pi \left(10.4\right)^4}{64} = 189.9\pi \\ &[2] \qquad I_z = \frac{\pi \left(12\right)^4}{64} = 324\pi \\ &[3] \qquad I_z = \frac{1}{12} b h^3 + A d^2 = \frac{\left(2\right)^4}{12} + 4\left(\left|\sqrt{2} - \frac{9\sqrt{2}}{2}\right|\right) = 21.1 \\ &[4] \qquad I_z = \frac{1}{12} b h^3 + A d^2 = \frac{\left(2\right)^4}{12} + 4\left(\left|\left[9\sqrt{2} - \sqrt{2}\right] - \frac{9\sqrt{2}}{2}\right|\right) = 21.1 \end{aligned} \tag{11}$$

So that the total second moment of area of the complex shape is found to be:

$$\begin{aligned} I &= 324\pi - 189.9\pi + 4\left(21.1\right) \\ &= 506\text{mm}^4 \end{aligned} \tag{12}$$

The Euler critical load of an intramedullary nail composed purely of PLA is found to be:

$$\begin{aligned} P_{cr \text{ (min)}} &= \frac{\pi \left(30\right) \left(506\right)}{200} \\ &= 749\text{N} \end{aligned} \tag{13}$$

And when considering just the glass fibres:

$$\begin{aligned} P_{cr \text{ (max)}} &= \frac{\pi \left(72\right) \left(482\right)}{200} \\ &= 1.80\text{kN} \end{aligned} \tag{14}$$

The rule of mixtures ensures the actual critical load falls somewhere between the maximum and minimum values, dependent on fibre composition.