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An investigation into the intramedullary pressure rise during femoral nailing: Does the level and type of fracture determine peak pressures during the procedure?

Dr. Graham McCollum
Supervisor: Dr Nicholas Kruger

Master of Medicine in Orthopaedic Surgery
Faculty of Health Science
Department of Orthopaedics
University of Cape Town
# TABLE OF CONTENTS

DECLARATION: ................................................................. 2  
INTRODUCTION AND AIM ........................................... 3  
ETHICS APPROVAL, PROTOCOL, PRO FORMA AND CONSENT FORM... 5  
LITERATURE REVIEW ................................................. 13  
MATERIALS AND METHODS ........................................ 22  
RESULTS ........................................................................ 29  
DISCUSSION ................................................................. 40  
SUMMARY .................................................................... 45  
REFERENCES ............................................................... 46
Declaration:

I, Dr. Graham Antony McCollum state that this is my original work for the degree Master of Medicine in Orthopaedic surgery.

The study was conducted in Groote Schuur Hospital from January 2010 till July 2010.

My supervisor is Dr. Nicholas Kruger from the department of Orthopaedic Surgery Groote Schuur hospital.

Signed.  At Groote Schuur

Date: 14/11/2011
**Introduction and aim**

First introduced by Künthshner, femoral nailing has become the ‘Gold Standard’ of treatment for femur fractures. The efficacy and benefit of early osteosynthesis by this technique is well established. Some of the acute complications of intramedullary manipulation and nailing are fat embolism syndrome, pulmonary dysfunction and Adult Respiratory Distress Syndrome (ARDS). One of the causes of fat embolism is a raised intramedullary pressure. Investigators have shown the direct correlation of intramedullary pressure with fat intravasation and embolism in both animal and human studies.

Fat embolism syndrome is unpredictable and the true incidence is unknown. Mortality from fat embolism syndrome ranges from 10-35%. The incidence is increased with associated pulmonary trauma and in the multiply injured patient.

The aim of our study was to investigate the intramedullary pressure rise during reamed prograde femoral nailing and determine whether fracture level and complexity affect the peak pressures. The relevance is that certain fracture types or levels that result in the highest pressures can be identified before the operation. Measures could be taken to reduce the intramedullary pressure during the procedure, particularly in those patients at greatest risk of pulmonary complications from fat embolism.

We hypothesised that more proximal, simple fractures generate higher pressures during nailing because there is a long ‘closed tube’ distal to the fracture. Pressure proximal to the fracture does not reach the same high levels because the intra-
medullary content is able to decompress through the fracture as the reamer moves distally. With proximal fractures there is a greater volume of medullary content distal to the fracture which can enter the venous system and embolize. Fracture comminution and complexity should lead to lower intramedullary pressures because there is a greater length of the femur through which the intramedullary content can decompress. The study sought to answer the question of whether fracture level makes a difference with respect to the intramedullary pressure rise during reamed prograde nailing.

The results of this study have not been submitted for publication at the time of submission of these results for the thesis.
Ethics approval, protocol, pro forma and consent form.

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone (021) 406 6626 • Facsimile (021) 406 6611
e-mail: shureta.thomas@uct.ac.za

13 October 2009

REC REF: 399/2009

Dr G Mc Collum
Orthopaedics Surgery

Dear Dr G Mc Collum

PROJECT TITLE: AN INVESTIGATION INTO THE INTRA-MEDULLARY PRESSURE RISE DURING FEMORAL NAILING: DOES THE LEVEL AND TYPE OF FRACTURE DETERMINE PEAK PRESSURE RISES DURING THE PROCEDURE?

Thank you for addressing the queries raised by the Research Ethics Committee.

It is a pleasure to inform you that the Ethics Committee has formally approved the above-mentioned study including the following documentation:

Approval is granted for one year till the 20th October 2010.

Please submit an annual progress report if the research continues beyond the expiry date. Please submit a brief summary of findings if you complete the study within the approval period so that we can close our file.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (RB) number: IRB00001938

Thomas

5
Informed consent for the measurement of the intramedullary pressure of the femur during nailing.

I hereby confirm that I have been informed about the nature, conduct, benefits and risks of participation in this trial. There may be a risk of infection or a slightly larger scar down the leg.

I am aware that the results of the trial, including personal details regarding my age, date of birth, initials and diagnosis will be anonymously processed into a trial report.

I may, without prejudice, withdraw my consent and participation in the study at any time. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient’s name ____________________________________________

Patient’s signature ________________________ Date _____________

Witness’s name ____________________________________________

Witness’s signature ________________________ Date _____________

I Dr __________________________ hereby confirm that the above patient has been informed fully about the nature, conduct and risks of the trial.

Doctor’s name ____________________________________________

Doctor’s signature ________________________ Date _____________
**Patient information sheet**

To stabilise your fractured femur we have to place a titanium metal nail within the femur. During the procedure the pressure within the hollow part of the femur in which the nail will be seated can rise. This rise in pressure can lead to fat being dispersed through the circulation to your lungs. Sometimes this fat in the circulation can lead to the lungs not functioning properly and pneumonia-like condition. The pressure in the femoral canal is not normally monitored during the routine operation. In the study we’re asking you to partake in, we are going to assess the femoral canal pressure and see if certain fracture patterns lead to a greater or lesser pressure increase during the operation. It may benefit you in that the anaesthetist will know what the rise in pressure is and be ready for any complications thereof. Through a small incision we will drill a 4.5 mm hole and place a pressure monitoring device in the bone for the duration of the procedure. The same incision and drill hole will be used for the standard screws used to lock the nail. The perceived risk of this added procedure is small but may include infection and maybe a slightly larger scar at the bottom of the leg which we’d normally make. Other similar studies have shown no complications with this way of measuring the pressure. By partaking in this study you will help us to determine which patients are most at risk of one of the serious complications of this procedure. If you do not wish to participate in the study you will receive normal surgical treatment of your fracture and you will not jeopardise your after care. You may withdraw at any time. Should there be any research related complications or injury you will be covered by the UCT No Fault Insurance policy. This entitles you to prompt medical care and financial compensation thereof. Any concerns about your rights and welfare during the trial can be directed to Professor Marc Blockman (021 4066338), Chairperson of the Human Research Ethics Committee.
Pro forma: Femoral pressure study.

Surgeon: ________________

Patient: ________________ Date: ______

Age: ___

Sex: M [ ] F [ ]

Mechanism of injury (MVA Fall, etc) ____________________________

Date of trauma: ________________

Side:
Right [ ] Left [ ]
Bilateral [ ]

Associated injuries: ____________________________
______________________________
______________________________

Admission Vital signs:
Blood pressure
Pulse
Oxygen saturation

**Fracture pattern:**

- Simple transverse
- Spiral/oblique
- Segmental
- Comminuted
- Compound

**Level of fracture:**

- Proximal 1/3
- Middle 1/3
- Distal 1/3
**Intra-operative measurements:**

**Vital signs at induction.**
- Blood pressure
- Pulse
- Oxygen saturation

**Implant:**

**Intramedullary pressure:**
- After insertion of the manometer
  \[\text{mmHg}\]
- Awl/drilled wire entry
  \[\text{mmHg}\]
- Entry reamer
  \[\text{mmHg}\]
- First ream proximal to fracture site
- First ream distal to fracture site
  \[\text{mmHg}\]
- Passing the nail proximal
  \[\text{mmHg}\]
- Passing the nail distal
  \[\text{mmHg}\]
Vital signs at completion of nailing.
Blood pressure ______
Pulse ______
Oxygen saturation ______

Post operative course:

Complications:

Intra operative

__________________________________

__________________________________

__________________________________

_____

Postoperative

__________________________________

__________________________________

__________________________________

_____

11
Out-patient follow up:

Complications:

Union time
Literature review

Objectives:

Despite the proven efficacy of treating femur fractures with intramedullary devices, there are complications and concerns regarding the procedure. This literature review sought to outline current knowledge and some of the problems associated with intramedullary nailing. The review also looked specifically at research into the effects and contributing factors raised intramedullary pressures may have during femoral nailing. Another objective was to assess if other researchers had investigated the relationship of fracture level and comminution with intramedullary pressure rise as this formed the main theory for our research.

Review

Since Küntscher introduced femoral nailing it has become the standard of care for femur fractures with predictably good results. The popularity of intramedullary fixation grew through the 1950’s but authors, including Küntscher, noted the effect intramedullary nailing and reaming has on the intramedullary pressure and the possibility of pulmonary complications from embolization of intramedullary content. Küntscher never measured the pressures himself, but calculated the fat volume that is displaced by the reamer and nail and predicted that the pressure must rise significantly more than systolic blood pressure. This led investigators to seek the contributing factors to fat embolism and pulmonary dysfunction.
'Fat embolism' describes the presence of fat globules in the lung parenchyma or peripheral circulation following long bone fracture or other major trauma. Fat embolism syndrome (FES) and Adult Respiratory Distress Syndrome (ARDS) are serious complications. The true incidence of FES following single long bone fractures is unknown, but estimated to be 0.5-2%.

Embolization of fat and medullary content affects pulmonary function by altering pulmonary vascular tone and by initiating inflammation in lung parenchyma. Increased vascular resistance alters right heart function and the inflammation of lung parenchyma can lead to Adult respiratory distress syndrome (ARDS) and poor gas exchange. Activation of inflammatory cytokines and the coagulation system by intramedullary content and fat contributes to lung dysfunction. The amount of embolic material correlates with the serum levels of the inflammatory cytokines Interleukins 6 and 8. The emboli are structurally mixed, with a central nucleus of bone marrow and fat surrounded by thrombosed material, confirmed histologically and by trans-oesophageal echocardiography. Wenda showed that as intramedullary pressure increased to 50mmHg above starting pressure a 'snow storm flurry' of small emboli with no physiological consequences was observed, but when the intramedullary pressure reached 200mmHg, emboli ranging from 1-4cm were detected on trans-oesophageal echocardiography with associated pulmonary dysfunction. When intramedullary pressures reached 600mmHg, a dense contrast was evident in the inferior vena cava.

The majority of patients can tolerate the transient pulmonary and cardiovascular effects of fat embolism but those who have sustained pulmonary trauma, are poly-traumatised and shocked and those with poor cardio respiratory reserve may not.
Manipulation of the medullary canal leads to changes in intramedullary pressures. Subtle manoeuvres such as inserting a guide wire or manipulating a fracture may increase this pressure. Animal, cadaver and clinical studies have shown significant intramedullary pressure rises during reaming of long bones. Pape et al. showed that pressure in the fractured femur can reach 830mmHg during the first ream in a clinical study. Pressures of up to 1200mmHg have been recorded in animal studies and in intact human femora.

These studies have the following similar findings; 1. The highest pressures are achieved during the initial ream; thereafter pressures do not reach this level during subsequent reaming. 2. The maximal pressure is achieved distally after the reamer crosses the fracture site. 3. Insertion of the nail following reaming does not lead to great pressure rises in the previously reamed femur. 4. Location and type of fracture appear to affect pressure, but no clinical data exists to support this.

The femoral medullary cavity has a normal physiological positive pressure of 30-60mmHg in man. This is influenced by systemic blood pressure, respiration, and local factors. Under normal physiological conditions, there is a centripetal direction of blood flow within the canal and a pulse dependent positive pressure. The nutrient artery together with the metaphyseal and periosteal perforating vessels generate the positive pressure and blood flow. Venous channels and sinusoids pool blood and communicate with a central venous channel which has a metaphyseal outflow. Pressures of up to 65mmHg in the intact femurs of man have been measured by other authors. Rehm showed that pressures in a fractured mid shaft humerus were lower.
than in an intact humerus which indicates that a fracture may decompress or alter the medullary pressure. For intravesation and embolisation to occur, this intramedullary pressure must be surpassed by reaming or nailing. A reversal of blood flow from a centripetal to centrifugal direction occurs when the pressure increases, favouring embolization.\textsuperscript{25}

Reaming destroys the endosteal circulation affecting both the arterioles and venous sinusoids. The periosteal blood supply only reaches the outer third of the cortex and the inner two thirds are supplied by the endosteal system.\textsuperscript{26} Histological examination of the reamed cortex of rabbits revealed cortical vessels clogged with medullary fat and proximal thrombosis. Raised intramedullary pressure forces the fat into the vessels and further compromises perfusion. Bone perfusion is reduced but returns to pre-reaming levels at three months.\textsuperscript{27} This does not seem to affect time to union or fracture callus quantity and quality when comparing reamed with non reamed fractured tibias in a sheep model.\textsuperscript{28} Reaming leads to intravesation of fat and intramedullary content because of the high medullary pressures generated and because disruption of the venous sinusoids allows easier entry of medullary content into the venous system.\textsuperscript{29}

The earliest techniques of intramedullary osteosynthesis relied on an endosteal press fit to gain rotational and axial stability. Reaming, introduced in the 1950’s, allowed expansion of the canal, facilitating a better endosteal press fit and greater nail diameter for added strength. Proximal and distal locking options and the introduction of stronger materials has lead to debate over the benefits and detrimental effects of reaming the canal as it is not necessary in all cases.\textsuperscript{30} Consensus that the greatest
pressures are achieved during the first ream is universal but the timing of embolization is not. Wozasec\textsuperscript{31} in a study on sheep’s tibias showed with echocardiography and pressure monitoring that the greatest pressure increase was during the first ream, but that the greatest embolization occurred during nail insertion after the reaming. Kröpf\textsuperscript{32,33} compared reamed with unreamed nailing and showed higher intramedullary pressures in the former and increased embolization associated with these higher pressures.

The generation of intramedullary pressure follows hydraulic principles with the medullary cavity acting as a piston sleeve and the reamer as a piston. The pressure development is dependent on how much of the content can escape past the reamer or out of the closed system and the force applied to the reamer. Stürmer\textsuperscript{34} illustrated with the gap equation that the factors affecting pressure are the flow rate, diameter of reamer, gap between reamer and cortex, pressure difference, length of reamer, dynamic viscosity and eccentricity. If content can escape from the system, such as through a fracture, or past the reamer, the canal will decompress and lower the pressures.

There is a high morbidity and mortality to nailing impending fractures from pathological lesions in the femur. The risk of serious life threatening pulmonary complications occurs in up to 33% of cases receiving a prophylactic nail.\textsuperscript{26} Reaming an un-fractured femur results in very high intramedullary pressures.\textsuperscript{35} The high mortality is multi factorial and embolization is enhanced by the vascular nature of the tumours and the poor physiological reserve of these particular patients.\textsuperscript{32} Venting of the canal by drilling through the distal femoral cortex was shown to decrease the
intramedullary pressure\textsuperscript{36} in a cadaver model but not in a clinical setting. In a very proximal femur fracture, reaming distal to the fracture may have a similar effect to prophylactic nailing and reaming with a long closed tube distally.

Stürmer \textsuperscript{13} showed that the pressures increase as the reamer crosses the fracture site and that the canal acts as a closed tube distally with little escape of medullary content retrograde out of the fracture. The grooves in the first reamer fill with bone debris and it acts like a piston allowing little content to escape retrograde past it. The first ream generates the greatest pressure with reduction in pressure during subsequent reaming. Stürmer \textsuperscript{13} demonstrated decreasing pressures with subsequent reaming until the 13mm reamer is introduced. This causes another rise in intramedullary pressure but significantly less than the peak pressures of the first ream. Intramedullary content after the first ream has a different viscosity to native medullary fat. \textsuperscript{13} The fat is disrupted and becomes more blood filled and less fat filled. The gap equation explains that the pressure will be lower if the content is less viscous.

Johnston et al \textsuperscript{37} in a cadaver model looked at the correlation of applied axial load with intramedullary pressure during reaming with two different reamers. Peak pressures in the intact femora ranged from 270-1500 mmHg. Pressures were measured at two points in the femur and were found to be constantly similar indicating that pressures are uniform throughout the closed tube and follow hydraulic principles. There was no correlation of the axial force load with intramedullary pressure. This was attributed to the additional friction force of cutting or clutter of the reamer on the cortex dissipating the axial load to the cortex and not distally to the intramedullary content.
Heat generation is another effect of reaming. Friction from the reamer bone contact can generate temperatures of up to 44°C in a cadaver femur model with a baseline temperature of 37°C maintained in a water bath.\textsuperscript{38} Temperature was significantly higher with blunt reamers compared to sharp reamers and the larger the reamer, the greater the cortical temperature. This study confirmed that the greatest intramedullary pressure occurs during the first ream down the canal with a large reduction in pressure during subsequent reaming. Heat induced osteonecrosis is a product of heat exposure over time. Erikson et al.\textsuperscript{39} In a rabbit model showed morphological evidence of osteonecrosis after exposure to 47°C for one minute. In a human bone compromised by severe trauma, periosteal stripping or infection, this threshold may be lower.

For many of these reasons, investigators have sought ways of reducing the detrimental effects of reaming and nailing. Küntscher\textsuperscript{1} noted the problems of pressurising the canal and suggested that reaming and nailing be undertaken in a controlled manner with significant pressure and mallet strikes to be avoided. Danckwardt-Lillieströ\textsuperscript{40} showed in a sheep tibia model that the intramedullary pressure was lower after the medullary content had been suctioned prior to reaming and that there were no pulmonary complications after this. In the non suction group, significant pulmonary complications and four deaths from fat embolism syndrome occurred. They proposed that the canal should be evacuated and flushed before nailing. Stürmer\textsuperscript{13} introduced suction irrigation reaming in a sheep model. This study demonstrated the pressure lowering effect proximal suction and irrigation had on reaming. Less bone necrosis was observed histologically in the suction irrigation group. There was less reamer clogging with debris and cortical temperature was lowered by the intervention. Schult et al.\textsuperscript{41} developed the Rinsing-Suction-Reamer (RSR), a device to perform paracortical
irrigation and suction concomitantly. Animal studies showed lowered fat embolization and significant reduction in intramedullary pressure. These results were never confirmed in human studies but it set the principles for further reamer designs to help lower pressures. Another development was the Reamer Irrigation Aspiration system (RIA). In a single pass it provides both aspiration and irrigation. The principle is similar to the RSR but does not rely on paracortical irrigation. In a clinical trial comparing RIA to conventional reaming, RIA significantly reduced the amount of fat emboli reaching the lungs determined using Trans-oesophageal echocardiography.

Venting the canal by opening a small window in the cortex has been shown to reduce pressures and the amount of fat embolized during hip arthroplasty. There is debate that drilling a 4.5mm hole through the cortex will not be enough to decompress the contents of an entire femoral canal and the hole becomes clogged with medullary debris and prevents venting. Martin et al reduced the canal pressures by 90% using proximal and distal venting holes in a cadaver model. Although this was a cadaver study, every attempt was made to simulate the clinical setting.

To summarise the review, investigators have looked at many of the detrimental effects of intramedullary nailing and reaming. There is consensus in the literature that reaming causes the greatest pressure rise during the procedure and the embolization of intramedullary content is proportional to the pressure increase. Once the reamer has passed once, the intramedullary content viscosity is altered and the pressures do not reach the same levels as the first ream. The advantages of reaming are to ensure a better fit of the nail in the canal and the use of larger diameter nails for strength during healing. Reaming may increase the embolic shower by raising the pressure and by disrupting the venous sinusoids causing easier intravasation. The exact timing of
fat embolism is controversial with some studies showing evidence that reaming causes the greatest increase and some that show nail introduction as the cause of maximal fat embolism.

ARDS and Fat Embolism Syndrome have multifactorial aetiologies, but animal, human and post-mortem studies have shown embolic material in lung parenchyma following intramedullary manipulation. Trans-eosophageal echo has demonstrated the emboli and this seems to result in more respiratory complications. The insult in compromised or injured lung tissue is less well tolerated.

The piston like effect of reaming has been well demonstrated and nailing of impending pathological fractures confirms the results of running a piston down a closed tube: If the content cannot escape, it will embolize. This lends weight to our hypothesis that simple proximal fractures generate high pressures when the reamer passes distal to the fracture site. Although the piston model means the greater force applied, the greater the pressure, but one study mentioned that this may not be the case due to the friction of the reamer with the cortex during advancement. This helps to nullify the fact that in our study the bias of having multiple surgeons may not be that significant.

Recent research has concentrated on pressure lowering measures during reaming. Venting, canal suction and Rinsing, Irrigation Aspiration reaming has been shown to reduce the pressures as well as reduce fat embolization.

To our knowledge there have been no other clinical studies comparing fracture level and type with intramedullary pressure.
**Materials and methods**

The study was approved by the research committee at the University of Cape Town (REC 399/2009).

In this prospective, non-randomised study, patients admitted to the Groote Schuur Hospital Trauma unit with femur fractures requiring pro-grade intramedullary nails were enrolled. Consent to participate following explanation and a patient information sheet was obtained in all cases. Patients with reduced levels of consciousness, haemodynamically unstable patients, intoxicated patients and minors were not included. Fractures requiring alternative fixation such as retrograde nails or plating were not included in the study. The fractures were all immobilised in a Thomas splint, and the patients stabilized prior to operative fixation. The patients were scored according to the injury severity score and the fractures classified according to Arbeitsgemeinschaft fur Osteosynthesefragen (AO) classification system.

Comminution was defined as there being more than three fragments, a fracture extending over 4 cm or more or with proximal or distal splits longer than 4 cm. The femurs were measured from the tip of the trochanter to the intercondylar notch and divided into thirds accurately. Each fracture was grouped according to where the major part of the fracture occurred on the femur.

At operation the femur fracture was addressed first where other injuries needing operative fixation existed. The patient’s blood pressure, oxygen saturation and pulse rate were noted and measured continuously.
Prior to commencing the study we had welded T handles and connections for a fluid filled line to a Smith and Nephew™ 6.4mm cannulated screw with an inner cannulated diameter of 3mm. (Figure 4). They were used for all cases and sterilised after each use. The cannulated part of the screw was tested to be air and water tight.

Figure 1

Prior to the nailing procedure, under sterile operative conditions, a 4.5mm hole was drilled 3 cm proximal to the superior pole of the patella through the anterolateral cortex of the distal femoral metaphysis through a single stab skin incision. The screw was inserted just through the outer cortex and not into the canal, avoiding obstruction of the nailing procedure (Figure 5). The cannulated part of the screw was cleared of debris with a guide wire and flushed. A fluid filled line was connected to the connector part of the cannulated screw (Figure 6). Air bubbles were removed from the system and the fluid filled line connected to a pressure transducer (Data Tech Ohmeda, cardiocap 5. Lewisville USA 2003) and a pressurised fluid bag via a three way tap. The manometer was calibrated in the same manner as used for setting an arterial line with opening of the pressurised fluid bag to the circuit. When a base line
positive pressure was visible on the monitor, no obstruction to the circuit was confirmed and the procedure commenced.

Figure 2

Figure 3
In Group B and C fractures (middle and distal 1/3) we could measure the pressure proximal to the fracture. A cannulated screw was placed five centimetres proximal to the fracture (Figure 7) and connected to a separate fluid filled line and manometer in the same way as the distal circuit (Figure 8).

![Figure 4](image)

It was not possible to measure the pressures proximal to the fractures in Group A (Proximal 1/3 fractures). All in this group had fracture extension into or very close to the intertrochanteric region and it was not possible to insert a cannula into the canal proximal to this.
The pressure transducers measured the pressures continuously throughout the procedure. The data, together with the patient's heart rate, oxygen saturation and intermittent blood pressure recordings were transmitted from the manometer to a personal computer via USB connection. We used Datex- Ohmeda- Trendnet S/5™ software for management and storage of data enabling reference point marking at various times and easy study of the data after the procedure (Figures 9 and 10).
Pressures were continuously recorded and reference points marked:

1. Entry guide wire
2. Opening of canal with entry reamer.
3. First ream down the shaft with the 9.5mm cutting reamer.
4. Second ream down the shaft.
5. Seating of the nail.
6. Resting pressure 2 minutes after the procedure.

Four different registrars performed the procedures with one of the investigators always present at the surgery.

All femurs received a reamed long Smith and Nephew™ Trigen nail and reaming was performed with exactly the same reamer set in all cases. All Group A (Proximal 1/3) femurs received cephalomedullary proximal locking into the femoral head. Nailing was performed on a traction table with fluoroscopy. Reaming was performed in a controlled manner without much distal pressure exerted by the surgeon. Fluoroscopy identified where the reamer was in relation to the fracture. Reaming commenced with
The 9.5mm cutting reamer and continued in 0.5mm increments to 1.5mm greater than the nail used.

The cannulated pressure measuring screws were removed after the nail was seated and the last pressure reading recorded. Where possible, the same stab incision was used for one of the distal locking screws. The patients were followed up in the ward until discharge and in the out-patient department until fracture union.

The Mann-Whitney U test was used for group comparison and the student T test for independent variables with a p value of 0.05 or less being statistically significant. Results are expressed as mean, range and standard deviation of the mean. The unit for pressure used was mmHg. The peak pressure was rounded to the nearest multiple of five by the software programme.
Results

There were no fractures, infections or soft tissue complications related to or as a result of the study. The mean time to union was 11.5 weeks (8-14) as determined by cortical lines across the fracture site. There were no cases of fat embolism syndrome or Adult Respiratory Distress Syndrome in this cohort but the patients had low injury severity scores and there were no associate pulmonary injuries. The mean time to surgery from the time of fracture was 12 hrs (6-22).

There were 22 femur fractures in 21 patients. The mechanisms of injury are illustrated in figure 1.

Figure 1

Injury severity scores were low due to the fact that the patients had to be lucuent and stable to sign consent and understand the study. Mean score 12 (6-18).

Each fracture was classified according to the Arbeitsgemeinschaft fur Osteosynthesefragen (AO)\textsuperscript{47} classification system. Figure 2.
The patient with bilateral femur fractures was systemically stable and had no other injuries following a motor vehicle accident. There were no contraindications to bilateral reamed intramedullary nails and the patient was enrolled in the study.

There were 12 proximal 1/3 fractures (Group A), 6 middle 1/3 fractures (Group B) and 4 distal 1/3 fractures (Group C). Figure 3
Associated injuries included 2 multi ligamentous knee injuries, 2 tibial fractures, 1 distal radius fracture and one midshaft humerus fracture. Of the 21 patients, 14 were male and 7 female. The mean age was 28 yrs (18-77 yrs). There was one open fracture.

The mean intramedullary pressure measured distally at the start of the procedure varied from fracture level to fracture level. Of the 22 femur fractures, 10 had 11.5 mm diameter nails and 12 received 10 mm nails. Group A fractures, 52.5 mmHg (65-45) ± 5.9, Group B fractures 36.6 mmHg (35-40) ± 2.5 and Group C 27.5 mmHg (25-35) ± 7.5 (Figure 11). A pulsatile quality was noted, corresponding with heart rate and pulse pressure. The mean systolic blood pressure was 120 mmHg (145-110). The intramedullary pressure fluctuated with systolic blood pressure. The systemic blood pressures were not significantly different between the groups and there were no fluctuations greater than 15 mmHg during the procedures.
Comparing the groups, there was a significant difference in the starting pressures of group A with group B and group C combined (p<0.05) and with group A and group B and group A with group C individually (p<0.05). There was no significant difference in pressure comparing group B with group C (p=0.1).

The greatest mean intramedullary pressure was generated during the first ream down the shaft in groups A and B. This occurred distal to the fracture in all cases. In Group C, the first ream generated pressures similar to that of seating the nail but higher than the second ream (Figures 12, 13, 14).
Figure 12

Group A

0 50 100 150 200 250 300 350 400

mmHg

Start P Entry wire P Entry reamer First ream Next ream Nail seating End pressure

Group A

Figure 13

Group B

0 20 40 60 80 100 120 140 160 180 200

mmHg

Start P Entry wire P Entry reamer First ream Next ream Nail seating End pressure

Group B
Table 1, 2 and 3 illustrate the pressure recordings measured distal to the fracture in groups A, B and C respectively.

Group A pressures- distal measurement

<table>
<thead>
<tr>
<th>Pt</th>
<th>Start</th>
<th>Entry wire</th>
<th>Ream 1</th>
<th>Ream 2</th>
<th>Nail</th>
<th>End pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45</td>
<td>50</td>
<td>100</td>
<td>35</td>
<td>390</td>
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<td>2</td>
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34
Group B - distal measurement

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Group C - distal measurement

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Tables 4 and 5 illustrate the pressure recordings measured proximal to the fracture in groups B and C.

Group B. Proximal to fracture

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Group C. Proximal to fracture

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In Groups B and C combined, the pressure distal to the fracture was significantly higher than the pressure measured proximal to the fracture during the first ream: 63.8mmHg (55-75) +-9.6 vs. 142.7mmHg (95-190) +-40.4 p<0.05. (Figure 15)
Figures 15 and 16 illustrate the difference in proximal and distal pressures in Group B and C individually.

**Figure 16**

*Group B proximal and distal pressures*

**Figure 17**

*Group C proximal and distal pressures*
The peak pressures during the first ream proximal to the fracture in Group B and C were not significantly different: 51.1mmHg (45-60) ± 6.8 vs. 46.25mmHg (45-50) ± 6.4 p=0.74.

The mean peak pressure during the first ream distal to the fracture was significantly different between the groups. In group A 363.5mmHg (300-420) ± 45 in Group B 174.67mmHg (160-200) ± 15 and group C 98.75mmHg (90-100) ± 8.5. There was a statistically significant difference in pressure comparing group A with B and C combined (p<0.01) as well as Group A with B (P<0.05) and C (p<0.05) individually.

This graph illustrates the difference in mean peak pressures measured distally in groups A, B and C during the entire nailing procedure. (Figure 18)

![Distal pressure. Group A,B,C](image)

The greatest peak pressure was 420mmHg in group A. Three patients desaturated to an oxygen saturation of less than 90% on pulse oximetry. All three patients had unilateral fractures in group A. The desaturation occurred 30 sec to 1 minute after the first ream in all cases and peak pressures of 420mmHg, 400mmHg and 380mmHg were recorded in these cases. The period of desaturation was transient in all three
cases, lasting between one and two minutes. All had an associated tachycardia greater than 120 beats per minute but remained normotensive. Formal 12 lead ECG was not done at the time. None of these patients deteriorated to a Fat Embolism Syndrome or ARDS. No patient with fractures in Group B or C had periods of desaturation. The patient with bilateral femur fractures was not in group A. Both of the fractures were middle 1/3 and thus in group B.

Peak pressures during the second ream with the next sized reamer were significantly lower than the first ream. Insertion of the nail lead to pressures peaks similar to the second ream, significantly less than the first ream of the canal. (Figure 18).

Fracture site Comminution lead to lower intramedullary pressures. In Group A, 6 fractures were judged to be comminuted and 6 non-comminuted. The mean peak pressures in these groups were 398mmHg (420-370) in the non comminuted group and 329mmHg (300-350) in the comminuted group. This was a statistically significant difference, p<0.05. Comminuted fractures in Group B and Group C did not have a significantly different peak pressure to non-comminuted fractures.
Discussion

Despite the advantages of intramedullary osteosynthesis there are complications and physiological consequences to the procedure. Pape et al. 16 said that intramedullary pressure during reaming was likely to be higher in more proximal, less comminuted fractures and increase as the reamer passed the fracture site, although there was no clinical evidence for this. Manning 45 illustrated in a dog model how intramedullary content can escape through the fracture site and lead to lower pressures with less embolization. Our hypothesis was based on the venting effect of the fracture on intramedullary content and pressure. To our knowledge, no previous clinical study has compared the intramedullary pressure rise with fracture level and complexity. By undertaking a clinical study, the errors, or false comparisons of cadaver or animal models to the in vivo situation are eliminated.

Reaming rate and pressure exerted were not controlled. This is one of the major weaknesses of this study. Four different registrars performed the procedures. The investigator present at the procedure emphasised to the surgeon not to exert excessive force on the reamer and let it find its own way down the canal. This is a lack of control to the study that may have lead to errors in our results. Johnston et al. 34 found no correlation between applied axial load on the reamer and the pressure in the distal canal. This contradicts the hydraulic principles thought to be followed during canal reaming. Their explanation for the finding was that the total axial force should include the frictional or cutting force of the reamer on the endosteal surface. If there is more contact with the reamer and the cortex, more force will not necessarily convert to greater distal pressure. Having multiple surgeons perform the procedures also mirrors the clinical setting more closely.
An interesting finding was the difference in starting, or baseline intramedullary pressures. Group A pressures were significantly higher than in group B and C. Rehm noted the difference in intramedullary pressures of fractured and intact humeri. The predominant reason for a positive intramedullary pressure is the direction of blood flow and the nutrient artery. The artery enters the mid to proximal diaphysis along the linea aspera of the femur. It is likely that in proximal, less displaced fracture this artery remains undisrupted, contributing to the greater pressures in found group A. The pressures in the distal 1/3 fractures probably remain low because the endosteal communication with the nutrient artery is disrupted.

The difference in pressures proximal to and distal to the fracture in group B and C was significant. The effect of pressure release or venting through the fracture site was evident by the pressure difference. Stürmer said that medullary debris and clot can obstruct the canal at the fracture site and lead to a reduction in the venting effect of the fracture. We found this not to be the case as pressures were always higher distal to the fracture except in one case in group C where the pressures were exactly the same during first reaming.

It was not possible to measure pressure proximal to the fracture in group A. Knowing the pressure reducing effects of the fracture in group B; it can be assumed that the pressures distal to the fracture in group A was significantly higher than proximal to the fracture. The volume of medullary content to vent through very proximal fractures is much less than more distal fractures and the pressures should be significantly lower.
Johnston et al. measured the pressures proximally and distally during reaming of intact femurs and found no significant difference between them. The canal acts as a closed cavity or 'pressure vessel' with uniform pressures throughout. Therefore, measuring the pressure at the end of the 'closed tube' – distal metaphysis will equal that of the pressure proximally and throughout this 'closed tube'.

The greatest pressures were achieved during the first ream in all the cases. Group A achieving significantly higher pressures than the other groups. This confirms our hypothesis that the femur acts as a 'closed tube' and pressurisation of the canal occurs as the reamer crosses the fracture site. The pressure was noted to reach its maximum as the reamer entered the isthmus. The gap equation explains this. When the reamer has close contact with the cortex, there is little escape of medullary content retrograde and the reamer acts as a piston, pressurising the canal. The same set of reamers was used in all the cases. Muller showed that reamer bluntness was associated with increased use and that they led to higher intramedullary pressures and greater cortical temperature if blunt in a cadaver model. The reamers were used over a period of four months and other femurs were reamed between the study patients. It is conceivable that the reamers were not of the same sharpness for the last few femurs in the cohort compared to the first femurs and that falsely elevated pressures may have resulted.

3 patients desaturated to a saturation of less than 90%. All three had fractures in group A and had significantly high peak intramedullary pressures during the first ream (420mmHg, 380mmHg, 400mmHg). The respiratory decompensation occurred between one and two minutes post reaming and were transient in all cases, lasting between 30 seconds and one minute. Blood gases were not taken at the time. The
patients suffered no post operative pulmonary complications but they all had low injury severity scores, were normotensive and had no pulmonary trauma.

Significant emboli, detectable by trans-oesophageal echocardiography, occur when the intramedullary pressure reaches 200mmHg or more. \(^{48}\) Insignificant sonographic echoes begin when the canal pressure reaches 50 mmHg. The pressures achieved in Group A in particular far exceeded this threshold. Pape et al \(^{12}\) showed that polytraumatised and lung injured patients had increased pulmonary complications after femoral nailing. The majority of patients will tolerate the fat embolism that occurs during reaming with no lasting complications but predisposed patients or those with poor cardio-respiratory reserve may not.

Comminution tended to lower the peak intramedullary pressures. This could not be proven in group B and C fractures, but group A had significantly reduced pressures if the fracture was classified as comminuted. Hydraulic principles explain how pressure within the system will be lowered if more content is allowed to escape through a greater surface of the canal. Fluid will flow to the area of least resistance and thus out of a split or area of comminution.

Interest in lowering the intramedullary pressure and eliminating the negative effects of reaming has lead to various strategies to combat this. Venting the distal femur by drilling a hole through the cortex has been shown to reduce the pressure during reaming in an intact femur simulating a pathological lesion. \(^{33}\) Controversy exists as to the efficacy of this technique in a fracture invivo. Muller and Rahn \(^{49}\) felt that the venting hole gets clogged with medullary content and does not decompress the canal effectively. They found that draining the canal prior to nailing led to lower pressures.
Rinsing Suction Reamer (RSR) \(^{38}\) and Reamer Irrigation Aspiration (RIA) \(^{39}\) systems were developed to address raised pressure and cortical temperature. Both systems have shown pressure reducing capabilities, particularly the RIA system. \(^{39}\) Un-reamed nailing generates lower intramedullary pressures compared to reaming. There is controversy with regard to the clinical difference between un-reamed and reamed nailing but studies have shown increased fat embolism during reaming. \(^{29}\)
Summary

Proximal, less complex femur fractures led to high intramedullary pressures during reamed prograde nailing in this study. Comminution tended to lower pressure. Distal and mid shaft fractures had lowered pressures, possibly due to the venting of the medullary content through the fracture site. There was not a significant difference in the pressures comparing midshaft with distal 1/3 fractures. There was a pressure gradient across the fracture site explaining the venting aspect of the fracture. The greatest pressures were achieved during the first ream down the canal and when the reamer passed the fracture site and engaged the isthmus. Although we did not measure the canal content entering the right ventricle, the three patients that had transient desaturation had experienced very high pressures during their nailing procedure.
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49