A Comparison Of Pressures Created By Various Commonly Used Intramedullary Reamers

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Citation

Abstract
In this paper we present a comparison of four different reamers of different sizes from three different companies. Intramedullary nailing is used in a variety of long bone fractures and can be reamed or unreamed, locked or unlocked. This paper is used to demonstrate the difference in pressures generated by the different reamers. Higher pressures are generally believed to increase the likelihood of embolisation of intramedullary contents and therefore it is favourable to generate a low pressure during reaming. We have proved the older generation of reamers produce continually higher pressures than the newer generation reamers. The differences between the newer reamers was also found to be significant. We therefore recommend the older generation of reamers should no longer be used.

INTRODUCTION
Intramedullary nailing for acute long bone fractures of the lower limb and other long bone afflictions such as fracture non-unions and malalignment, is a very commonly performed orthopaedic procedure. Indeed, in many situations it is the treatment of choice.

Reamed, locked nails are essentially the “gold standard” for intramedullary nailing, as this method of fixation provides a strong and stable construct in all directions, including rotation, and some believe that the actual process of reaming encourages the process of union through an internal “bone grafting” effect. Reaming also allows the passage of a larger intramedullary device which provides the final construct with a more favourable biomechanical profile. Unreamed nails may also be used, but in modern practice this is only indicated in a few situations (see later).

Of course, intramedullary nailing is not without its complications. One of the most serious of which is that of embolization of intramedullary contents and subsequent pulmonary complications, most notably the development of the Fat Embolism Syndrome (FES) and Acute Respiratory Distress Syndrome (ARDS), which can be fatal. It is believed by many that the increase in intramedullary pressures associated with the process of reaming and nail insertion is crucial with regards to the development of pulmonary complications, although some question the extent to which the process of reaming is to blame compared with the insertion of the nail itself, as insertion of unreamed nails also produce a degree of embolization.

Some believe that unreamed nails probably produce fewer pulmonary complications than reamed nails and therefore suggest the use of unreamed nails in already compromised patients eg. following major trauma. Damage control orthopaedics is a relatively new idea based on the principle of damage limitation and is an attempt to minimise the magnitude of the second hit. However, this is a controversial topic beyond the scope of this paper.

Therefore, even patients with pre-existing pulmonary compromise should be able to receive the optimum treatment for their fracture – namely reamed, locked nailing – without an unacceptably high complication risk.

This ideal has not surprisingly spawned a great deal of research looking into optimum reamer design to try and minimize intramedullary pressures (and subsequent pulmonary complications). Numerous parameters have been investigated in the past including the design of reamer heads, reamer shafts, driving speed and revolution rates, and the effects of blunt instruments. These will be discussed later. Most of these studies, however, were carried out five to ten years ago and several new reamer designs have been introduced since then, presumably on the basis of what these studies revealed. The purpose of this investigation is to provide an up to date
comparison, in terms of arguably the most important parameter, namely intramedullary pressures generated, between four of the commoner reamer types in use in NHS hospitals today. This was performed in vitro, using hollow plastic tubing to simulate a long bone, and an artificial petroleum based mixture to simulate intramedullary fat. The reamers used in this study, from the author's experience, are commonly used in numerous trauma units but by no means are the only reamer types currently in use in hospitals in the UK.

MATERIALS AND METHODS
PRESSURE TESTING

Four diameters of Perspex tubing (RS Components Ltd.) of inner diameters 10, 12, 14 and 16 mm respectively were cut to length (approx. 40cm length) and bases fitted to the tubes such that they were able to stand vertically. Holes of 6mm diameter were drilled 50mm and 200mm above the base and clamps attached over the holes to allow pressure transducers to be connected so that the pressures at the holes could be recorded. The Perspex tubing could also be held rigidly fixed to the testing machine in a horizontal position with this arrangement. Two pressure transducers (Sensotech LM/2345-01, RDP Electronics Ltd.) were then attached over the pre-drilled holes in the tubes and clamps such that pressures at the top and bottom of the tubes could be recorded.

The pressures were recorded using a PC via Signal Conditioners and an analogue to digital converter (CM015s, CM002 and ADC-16, Pico Technology Ltd.).

The tubes were filled vertically up to approximately 30cm from the base with 50:50 mixture of petroleum jelly (Vaseline™) and paraffin oil to produce a mixture with similar physical characteristics as medullary marrow at body temperature as described by Muller et al.

Four different diameters of reamer were used for each tube diameter, 0.5mm less than the tube diameters ie. 9.5mm, 11.5mm, 13.5mm and 15.5mm, from three different manufacturers – AO Universal Reamer™ (Synthes®), and the newer generation reamers - Synream™ Reamer(Synthes®), Bixcut™ Reamer (Stryker®) and 5+ Reamer™ (Biomet®) (Figs. 1 and 2).

The Perspex tubes, having been vertically filled with the jelly/oil mixture, were clamped horizontally in position in a Colchester Triumph 2000™ lathe to act as the driver with the appropriate reamer secured in the driving mechanism of the lathe which delivered the reamer into the Perspex tube at a linear rate of 470mm per minute and at a fixed revolution rate of 470rpm. These set parameters are of the order used in previous studies and are a reasonable approximation to the real life situation, from the author's experience. The reamer was stopped on each occasion manually when it reached 25mm from the base.
Measurements were taken on three separate occasions for each reamer in its respective tubing to try and ensure repeatability. After each test, the tube was detached from the clamp and temporarily positioned vertically such that the jelly/oil mixture filled the tubes to the prescribed level (under the action of gravity) with minimal air gaps. This was felt by the author to be an appropriate approximation of the real life situation of a long bone with its medullary contents exposed to the air. Any spillage of mixture was replaced. The tube was then reclamped in the horizontal position in the lathe ready for the next test.

PRESSURE TESTING CALIBRATION

In order to obtain results in the form of pressures rather than voltages, the pressure transducers and data collection system required calibration. A plug was therefore made to fit a reamer shaft and be a good sliding fit in a 16mm Perspex tube as previously used. The reamer shaft was then fixed to a calibrated 500N load cell so as to record the load and hence pressure on the reamer. An electromechanical materials testing machine, EZ50 (Lloyd Instruments Ltd.), was used for the calibration tests.

To record pressure rather than force, a simple conversion can be performed from force to pressure measurement. This is achieved using the simple physical equation correlating force to pressure:

\[ \text{Pressure} = \frac{\text{Force}}{\text{Area}} \]

In this case the area is represented by a circle and is therefore equal to \( \pi r^2 \). The diameter of the tube was 16mm and therefore pressure measurement can be generated by dividing the force on the reamer by \( \frac{\pi}{4} \times (16\text{mm})^2 \).

In order to convert experimental voltages directly into pressures, an equation can be derived following the calibration experiments that will facilitate this. The equation is as follows:

\[ \text{Pressure} = \left( \frac{99\text{kPa}}{500\text{mV}} \right) \times (\text{Experimental voltage} - \text{Zero offset voltage}) \]

The zero offset voltage for the top and bottom transducers were -16.02mV and -27.5mV respectively. This equation is derived by comparing calibration graphs of voltage/time with force/time and using the simple graph equation \( y = mx + c \) to obtain values for \( m \) and \( c \) (\( m = 99\text{kPa}/500\text{mV} \) and \( c = \) zero offset voltage).

STATISTICAL ANALYSIS

Due to obvious large differences between the AO Universal reamer and the other reamers, all reamers were not included in the same analysis as all other differences would be masked by this large difference. Therefore two separate analyses were performed. Firstly, using a simple two-way analysis of variance (ANOVA), the AO Universal reamer was compared with the newer generation reamers. Then a second analysis was performed with the newer generation reamers treating each reamer size separately comparing the newer reamers in a two-way ANOVA with the “top” and “bottom” transducers as an additional variable. All data was analysed using SPSS for Windows® data processing package.

RESULTS

The following table shows the mean pressures of the three tests carried out for each reamer brand and size in its respective tubing. The ‘top’ and ‘bottom’ columns refer to the pressures measured by the transducers at the top and bottom of the tubes respectively. The data is shown in kPa with equivalent values in mmHg shown in brackets.
Table 1: Pressures generated by reamers used in the study

<table>
<thead>
<tr>
<th>Reamer type</th>
<th>Mean pressures generated – kPa(mmHg) Top</th>
<th>Bottom</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5 mm AO Universal</td>
<td>29.1(218.0)</td>
<td>36.6(274.7)</td>
</tr>
<tr>
<td>9.5mm Synream</td>
<td>6.9(51.7)</td>
<td>10.6(79.9)</td>
</tr>
<tr>
<td>9.5mm Biomet 5+</td>
<td>5.4(40.5)</td>
<td>8.5(63.8)</td>
</tr>
<tr>
<td>9.5mm Bixcut</td>
<td>5.5(41.1)</td>
<td>8.1(60.5)</td>
</tr>
<tr>
<td>11.5mm AO Universal</td>
<td>6.4(50.0)</td>
<td>9.9(74.3)</td>
</tr>
<tr>
<td>11.5mm Synream</td>
<td>4.3(32.2)</td>
<td>7.3(54.7)</td>
</tr>
<tr>
<td>11.5mm Biomet 5+</td>
<td>4.2(31.1)</td>
<td>6.9(51.4)</td>
</tr>
<tr>
<td>11.5mm Bixcut</td>
<td>5.1(38.0)</td>
<td>7.7(57.5)</td>
</tr>
<tr>
<td>13.5mm AO Universal</td>
<td>7.5(56.6)</td>
<td>10.45(78.4)</td>
</tr>
<tr>
<td>13.5mm Synream</td>
<td>3.9(29.3)</td>
<td>6.5(48.4)</td>
</tr>
<tr>
<td>13.5mm Biomet 5+</td>
<td>3.5(26.6)</td>
<td>5.8(43.8)</td>
</tr>
<tr>
<td>13.5mm Bixcut</td>
<td>4.1(31.0)</td>
<td>6.6(49.3)</td>
</tr>
<tr>
<td>15.0mm AO Universal</td>
<td>5.1(38.2)</td>
<td>7.2(54.0)</td>
</tr>
<tr>
<td>15.0mm Synream</td>
<td>3.9(29.4)</td>
<td>6.2(46.4)</td>
</tr>
<tr>
<td>15.0mm Biomet 5+</td>
<td>3.7(28.0)</td>
<td>6.0(45.2)</td>
</tr>
<tr>
<td>15.0mm Bixcut</td>
<td>3.8(28.6)</td>
<td>6.2(46.2)</td>
</tr>
</tbody>
</table>

It can be seen from Table 1 that the AO Universal reamer generated consistently higher pressures than the other reamers. This was particularly marked with the 9.5mm reamer head size, with the AO Universal reamer generating pressures in the order of four fold higher than the others with a peak pressure of 36.6kPa (274.7mmHg). It can also be seen that the Biomet 5+ reamer consistently generated the lowest pressures except for the bottom transducer reading of the test with the 9.5mm reading, the lowest value being generated by the Bixcut reamer (see figures 3 and 4).

Following statistical analysis of the data as previously described it was shown that all differences between the AO Universal reamer and the other reamers were highly statistically significant (p<0.001).

Although there were differences between the pressures generated by the newer generation reamers, not all were statistically significant. Each reamer head size was analysed separately to show which differences were significant at each head size. Table 2 shows the statistically significant differences.

At 15mm head size, there were no significant differences in values between the reamers.
DISCUSSION

It can be seen from the results that the largest difference in pressures generated is between the AO Universal reamer and the other newer generation reamers at all sizes of reamer head. This difference, however, was particularly marked at the lower values of reamer head diameters i.e. 9.5mm. The possible reasons for this will be discussed later. These differences were all highly statistically significant. The actual differences between the newer generation reamers are small, as can be seen in the graphical representation of the data (Figs 3 and 4), but some differences were statistically significant, as has already been shown. Overall, the Biomet 5+ reamer did produce consistently lower pressures (apart from one mean reading as previously described) which in some cases were statistically significant. Having said this, one must remember that the amount of data in this study is quite small and therefore any statistical analysis needs to be scrutinized in this context. Whether any differences shown, be them statistically significant or not, equate to clinically significant differences is an entirely different matter which cannot be investigated in this work.

Pressures measured at the bottom transducer were also consistently higher than the top. This is probably due to increased “intramedullary” material between the transducer and the advancing reamer head. As the testing has been performed in a standardised fashion, it is not unreasonable to suggest that the differences seen, particularly those seen between the older and newer generation reamers, are due to differences in reamer design. A description of design features that could explain these differences follows later.

It can also be seen that the actual values of pressures generated are considerably lower than in previous studies with peak pressures exceeding 1000mmHg in some cases. In this study the greatest pressure generated was 274.7mmHg by the 9.5mm AO Universal reamer. There are numerous possible explanations for this. Firstly, it is not surprising that reamers of newer designs will produce lower pressures than older systems used in previous studies, some of which were performed over ten years ago, with improved designs being employed over time. Secondly, the experiments in this study were performed in the horizontal position thus eliminating the effects of gravity on the mass of the Vaseline mixture above the transducers which could increase pressure measurements. This effect is unlikely to be particularly significant, however. A third possible explanation is that, although the composition of the experimental intramedullary contents was based on methods used in previous studies, the mixture was not bubble-free as in other studies and the temperature of the laboratory in which the testing was performed was variable. This would obviously affect the viscosity of the mixture which in turn would affect the pressure.

The actual pressures generated in this study were also not elevated sufficiently in most cases to produce “configured emboli” (core of bone marrow surrounded by thrombotic aggregate which are believed to cause most the clinically evident pulmonary complications) as described by Wenda et al. That study utilized intraoperative echocardiography to suggest that only pressure increases over 200mmHg would cause such emboli formation. The pressures generated in this study would however be sufficient to produce so-called “snow-flurry” (small amounts of bone marrow), which Wenda et al suggested occurred at pressure increases in
excess of 50mmHg. For many reasons, however, including those cited previously, it is impossible to say whether the actual pressures generated are an accurate reflection of what actually happens in vivo, but logic would dictate that lower pressures would be desirable in vivo.

It has already been established that essentially it is the insertion of intramedullary devices and raised intramedullary pressure that occurs during the reaming process that are the key factors in the production of clinically significant emboli giving rise to potentially serious pulmonary complications following surgery of this kind. As has already been mentioned, little can realistically be done to influence pressure changes caused by insertion of any device into the medullary cavity. However, Pape et al in 1994 suggested that the design and type of reamer may influence the degree of pulmonary compromise (by affecting pressures generated) in a study performed on sheep. Subsequent work then focussed on trying to establish precisely what factors were involved in the development of raised intramedullary pressures and therefore what steps could be taken to try and minimize these factors and their effects.

Much of the work on this topic has been performed by Muller et al. What was evident from their work was that several factors play a role in the development of intramedullary pressure during reaming, but the most significant one which could be altered was the dimensions and nature of the reamer shaft. Essentially what Muller et al discovered was that by using flexible shafts of as narrow a diameter as possible (such that the reamer head would be supported during the reaming process without failure), intramedullary pressures could be reduced by up to 75%.

The proposed explanation for this finding is based on an equation which has been taken from hydromechanics and modified to apply to the procedure of reaming: $\eta = \frac{21}{13+14}$

\begin{equation}
\tau_{av} = \frac{12\eta L}{h} * (1+1.5e^2) \text{ metres}^3/\text{second}
\end{equation}

Where:-

$Q_e =$ flow rate (metres$^3$/second) $d_n =$ average diameter of bore and piston (metres) $h =$ gap (centimetres) $p =$ pressure difference (newtons/metre$^2$) $L =$ length of seal (centimetres) $\eta =$ dynamic viscosity (Newton-seconds/metre$^2$) $e/h =$ relative eccentricity $e =$ eccentricity (centimetres)

In the case of intramedullary reaming, the variable $h$ represents the distance between the reamer shaft and the cortex, or in the experimental situation, the Perspex tubing. As the flow rate is directly proportional to $h^3$, small changes in $h$ will result in large changes in the flow rate. The flow rate is related to the intramedullary pressure generated by reaming by the fact that the debris produced by the reamer will flow easily in a proximal direction if the flow rates are high but this will occur with more difficulty with low flow rates. This lower flow rate is thus associated with increased intramedullary pressures. This therefore would explain the obvious difference in pressures between the older generation AO Universal reamer, with a shaft diameter of 8mm and 10mm respectively (depending on reamer head size), compared with the lower shaft diameters of the other, newer generation, reamers (Appendix).

Muller et al have also shown that reamer head design also has a role to play in the generation and optimization of intramedullary pressures. By enlarging the flutes of the reamer head and using a hollow reamer head, pressures were reduced by 37% and 58% respectively. However, previous studies have shown that larger diameter shafts produce very high pressures without any reamer head, such that it is believed that the design of the head of the reamer itself, although relevant, plays a much smaller part in pressure generation than that of shaft dimensions.

Although what have been described are the major factors affecting intramedullary pressures during reaming, they are not the only variables which can be addressed in an attempt to minimize pressures and thus complications associated with reaming.

A study by Mousavi et al showed that the lowest intramedullary pressures were generated at high revolution rates with low driving speeds and that these facts were most important during the initial stages of reaming when pressures were found to be particularly high. They also found that the use of small core diameter reamers resulted in lower pressures. They therefore recommended that reaming should be performed with reamer heads of a small core design at a continuously high revolution rate but at a low driving speed – a variable that can be adjusted by the surgeon.

Müller et al also demonstrated the effect of compression force on intramedullary pressures. It was shown that...
pressures could be reduced by up to 79% in the diaphyseal region and 68% in the metaphyseal region if compression forces were reduced. This once again is a surgeon-dependant variable and important information for all surgeons who undertake these types of procedures.

A further study from the same research team also showed the importance of the state of the cutting edge of the reamers. It was demonstrated that blunt reamer heads produced higher pressures (and higher cortical temperatures leading to thermal necrosis) than well-maintained, sharp heads. The authors therefore recommended that surgeons should treat the reaming hardware gently and replace them as and when it was deemed necessary to do so.

It is important to emphasize that this study was obviously performed in vitro, and that laboratory findings do not necessarily equate to clinical scenarios. Despite known embolic phenomena, adverse clinical events are not as predictable. This study has, however shown that modern reaming devices do generate much lower pressures than their predecessors, at least in the laboratory, and that there are small differences between reamers from different suppliers. It would therefore be logical to suggest that all reamers used in current NHS practice are of a modern design and that older generation reamers are removed from circulation.

**APPENDIX**

**REAMER DIMENSIONS**

**Figure 8**
Shaft Diameters

<table>
<thead>
<tr>
<th>HEAD DIAMETER (mm)</th>
<th>STRYKER</th>
<th>AO UNIVERSAL</th>
<th>SYNREAM</th>
<th>BIOMET</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5</td>
<td>6</td>
<td>8</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>11.5</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>13.5</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>15.5</td>
<td>8</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

All measurements made using Calibrated Absolute Digimatic measuring device (Mitutoyo UK Ltd.).

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**CONFLICT OF INTEREST**

Laboratories at Biomet UK(Swindon) were used to carry out this study but no funding was received from any party with respect to this work.

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