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A comparison of operative field space between sterile single use and re-useable pneumatic tourniquets in revision total knee arthroplasty

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Abstract
Adequate operative field space minimises potential complications during revision knee arthroplasty. The colonisation rate of pneumatic re-useable devices reported to be 68-78%, other devices should be considered in the revision knee surgery setting.
Sterile single use tourniquets devices (Heamaclear® /S-MART™, OHK Medical Devices, Haifa, Israel) have colonisation rates of 0%. This study assesses the operative field clearance between the two devices and discusses the potential benefits for reducing infection in revision knee surgery.
At the time of revision knee replacement, the operative field space was measured using both pneumatic and sterile single use tourniquets. The measurements were taken once the components had been explanted. The average operative field space increase using a sterile single use tourniquet compared to a multi-use pneumatic device was 8.98 cm [CI95% 7.1-10.8 cm], $p<0.001$ ($p=0.00034$).
It is recommended that sterile single use tourniquets are safe and are a useful tool for surgeons facilitating ease of revision knee surgery.

Keywords: Tourniquet, Revision Knee surgery, Sterile single use tourniquet, Infection, Pneumatic tourniquet, operative field.

1. Introduction
The use of tourniquets for both upper and lower limb surgery has become common practice since its introduction in 1864 by Joseph Lister, for procedures other than amputation, where the concept of bloodless surgery was first applied [1].
The use of tourniquets for surgery has been accompanied by reports of complications such as nerve damage [2, 3] and cross infection [4, 5]. Though the problems of nerve injuries has been addressed in recent years with use of wider cuffs and reducing duration and pressure of these pneumatic devices [6, 7], the issues with cross infection still remain a problem with lack of strict compliance to manufacturer cleaning protocols in most of hospitals [5].
In a climate of 'super-bug' fear, a lot of emphasis has been made by the Department of Health on preventing cross infection between patients, on the ward and in the theatre setting. This has manifested in the introduction of uniforms and 'bare below elbow' guidelines for doctors and nursing staff [9]. Studies have reported colonisation rates of 68-78% on reusable pneumatic tourniquets compared to 0% on sterile single use brands [5, 8]. It is imperative to look for and reduce obvious sources of cross infection, especially in the operative theatre setting where the risk and cost of cross infection could have disastrous consequences.
The size of the sterile operative field facilitates ease of surgery. Ease of exposure has a potential effect on the complication rate by reducing operating time. A larger sterile field minimises the risk of contamination from extensile exposures needed for revision arthroplasty when the incision can be extended near to the limit of the sterile field. This study aims to compare the length of sterile operative field in Revision Total Knee Replacement (TKR) with use of conventional pneumatic devices and a single use, non pneumatic elastic ring tourniquet.

2. Material and Methods
Between March 2011 and December 2011, twenty consecutive patients listed for single stage, first time revision knee surgery were included in the study. After consent was obtained, a pneumatic multi used tourniquet was applied by the hospital operating department practitioner, and checked by the senior author. The distal extent of the tourniquet was marked with a skin

marker pen and the tourniquet removed. The side support was applied to the operating table at the level required, but then rotated proximally out of the way for surgical preparation. The patients were then prepared for surgery with the use of a limb isolator sterile drape. The haemaclear® sterile single use tourniquet applied to the sterile field. Application consists of unrolling the device onto the leg. This has the effect of exsanguination of the limb. Once adequate surgical exposure was made to achieve explanation of the components, the proximal end of the incision was measured to the pre applied skin mark and to the single use tourniquets distal extent. The measurements were recorded in centimetre (Figs 1 and 2).

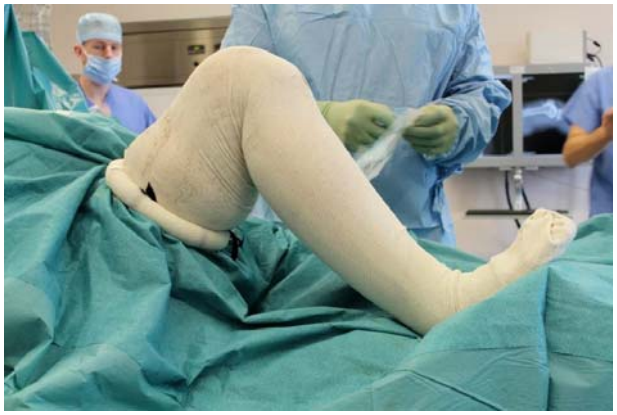

Fig 1: Haemaclear® Sterile single use tourniquet. Application following surgical preparation of the limb

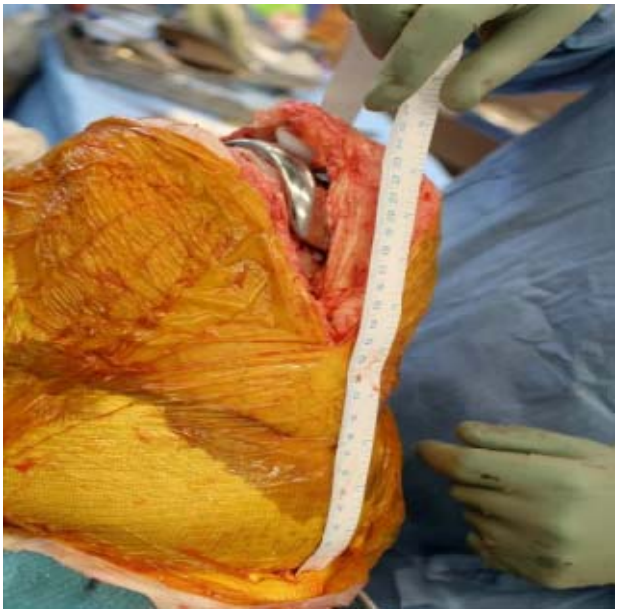

Fig 2: Measurement using sterile tape measure of the proximal extent of the wound to the distal extent of the tourniquet

3. Statistical Analysis

Statistical testing was performed using SPSS v18.0 (SPSS Inc., Chicago, Illinois) with significance defined as a p-value < 0.05. Significance testing was performed using Student's t-test when making comparisons between the operative field space available between the two devices.

4. Results

Of the 20 patients, 11 were female and 9 were male. The average age was 62 years. The average BMI was 36. The average sterile operative free space with standard pneumatic device was 5.5 cm (range 3.0-8.0 cm) while with single use non-pneumatic device was 14.4 cm (range 9.0-21.0 m). [Fig 3] The average increase in operative field space was 8.98 cm (CI95% 7.1-10.8 cm) with the sterile single use tourniquet. Using the student's t-test this difference was found to be significant. [p<0.001, p=0.00034].

There was no incidence of ischemic injury and no nerve palsies in post-operative period in any of the cases. One patient was investigated for a deep vein thrombosis but was Doppler negative. There were no postoperative wound infections an all knees were aseptic at the last follow up. In all cases the increased surgical field facilitated the operative procedure; this was especially true in obese patients.

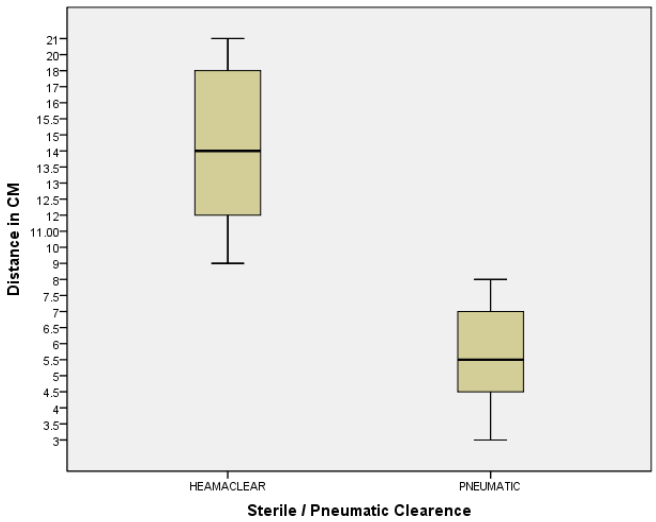

Fig 3: Box plot of the clearance of the two devices

5. Discussion

There has been a steady rise in the volume of revision Total Knee Arthroplasty (TKA) procedures in recent years and estimates suggest the number of revision TKA procedures is expected to increase. Revision knee replacement is a more technically and economically demanding procedure [12].

Improving a complicated procedure relies on the breakdown and analysis of the multiple procedural steps involved i.e. adequate pre-operative planning, adequate exposure and adherence to principles of revision arthroplasty [13, 14]. A wide exposure must be achieved to allow component removal, soft-tissue balancing, management of bone loss, reimplantation and importantly to minimise complications [13, 15].

This study adds to current literature for revision total knee replacement as there is currently no published data on operative field space associated with tourniquet type. Although a logical conclusion that if a smaller tourniquet is used operative space is increased, there is no evidence base to the statement.

Surgical factors play a role in the outcome of revision TKR. We feel that by increasing the operative field available to the surgeon during the revision, the procedure is simplified, and minimises the 'struggle' with difficult exposures. Minimising 'struggling' with an operation decreases the complications associated with exposure. It also minimises the operative time, minimises the tourniquet time and therefore and may improve outcome.

Outcome in revision TKR varies on a case by case basis and is multifactorial. Although it is not possible to singularly quantify the improvement in outcome from such a change in device, the potential gain to the operating surgeon in terms of ease of the procedure cannot be overlooked.

Recent literature has shown that infection is the single most

important predictor of outcome following revision [16, 17, 18]. Therefore every emphasis should be made on reducing the risk of infection in these patients. There are many ways that a surgeon can reduce infection including minimising operative time, minimising tissue ischemic time and giving adequate clearance from tourniquets colonised by pathogenic organisms. Hence it becomes especially significant during time of surgery to have maximum sterile operative length for adequate exposure. The sterile single use device also seals the operative field from the positive pressure from the patient warming device, where warm air could be blown into the operative field, another potential advantage.

Studies have also clearly emphasized the lack of cleaning of reusable tourniquet and hence risk of cross infection [5]. Despite all of the literature against the use of re-useable pneumatic devices they remain the most commonly used tourniquets in UK [4-6, 8].

This study is the first to compare sterile operative length of non-sterile pneumatic versus single use non pneumatic tourniquet devices. Our study clearly demonstrates the benefit of using single use non-pneumatic devices as tourniquets as it provides increased sterile operative clear space for adequate exposure as well makes operation much easier and it does not interfere with the side support. There was no post-operative complication in our study.

One limitation of the study was the small number of patients in the study group. Analysis of infection rate with newer device is therefore not possible, but it would be a logical conclusion that reducing bacterial load in close proximity to surgical site would reduce risk of infection. As far as efficacy and effect of both these devices are concerned there is enough evidence to comprehend that both have equal efficacy and safety and both have comparable effects on underlying soft tissue physiology [19, 20, 21].

6. Conclusion

It is evident from this study that that the non-pneumatic single use tourniquets provide the surgeon with much larger sterile operative field minimises potential complications with exposure and infection and therefore should be recommended for revision total knee replacement.

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