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Title: Water-Based Lubricant as an Adjunct to Wound Toilet: Validation of a Technique by Experiment.

Article Type: Full length article

Keywords: Metal debris; metalwork removal; wound contamination; novel technique

Corresponding Author: Dr. Haroon Rehman, MBChB, MRCS, MSc

Corresponding Author's Institution: Aberdeen Royal Infirmary

First Author: Haroon Rehman, MBChB, MRCS, MSc

Order of Authors: Haroon Rehman, MBChB, MRCS, MSc; Iain Rankin, MBChB, MRCS; Kimberly Ferguson , MBChB, MRCS; Bryn Jones, MBChB, MD, FRCS; Mark Frame, MBChB, FRCS

Abstract: Abstract
Introduction:
Metal debris can produce a foreign body inflammatory reaction or as third body wear in the situation of joint arthroplasty. We evaluate a simple method for reducing this debris using a sterile water-based lubricating gel.

Materials & Methods:
Eight experimental surgical models consisting of porcine muscle overlying a polyethylene tube with a titanium locking plate and screws secured were constructed. Four models had water based lubricating gel applied to the wound edges, four were left without as controls. Image were then captured before and after irrigation from which the amount of debris could be quantified.

Results:
The reduction of surface area covered by debris for models with water-based gel was greater (p=0.001). The average reduction in surface area was 27.2% for the control group and 94.1 % for the models covered with lubricating gel.

Conclusion:
We show that using a safe, inexpensive and easily available water-based lubricating gel reduces the amount of embedded debris when burring metal implants using a high-speed burr.

Suggested Reviewers:

COVER LETTER AND AUTHOR DECLARATION

We'd be grateful for your consideration for publication of this review. In this paper, we discuss using lubricating aqueous gel as a means to minimize the amount of metal debris contaminating soft tissue during implant removal. We created a study model to investigate and quantify the efficacy of aqueous lubricating gel in minimizing the degree of soft tissue contamination in burring of titanium implants. To our knowledge this technique has not previously been scientifically tested in the literature. Our work has not been published in any other journal.

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

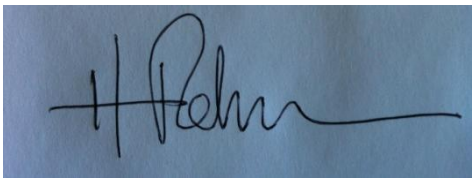
We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). He is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. We confirm that we have provided a current, correct email address which is accessible by the Corresponding Author and which has been configured to accept email from:

Haroon.rehman.06@aberdeen.ac.uk

Signed with consent and on behalf of all authors,



Haroon Rehman MBChB, MRCS, MSc

*Conflict of Interest Statement

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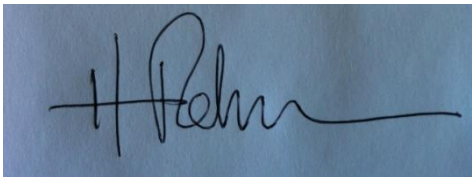
Conflict of Interests

We have no conflict of interests to declare.

Signed with consent and on behalf of all authors,



Haroon Rehman MBChB, MRCS, MSc

Table 1 Surface area covered in particulate

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Surface area (Pixels)	Group 1				Group 2			
	1a	1b	1c	1d	2a	2b	2c	2d
Before	265767	301987	299873	287649	259084	287098	276890	256787
After	216787	199878	221775	198988	18672	13996	18667	12098
Difference	48980	102109	78098	88661	240412	273102	258223	244689
%	18.43	33.81	26.04	30.82	92.79	95.13	93.26	95.29
	Group 1 average reduction = 27.2 %				Group 2 average reduction =94.12			
	P=0.0001							

Table 1: Surface area covered in particulate.

Figure 1 Surgical model

Click here to download Figure: Figure 1 Surgical model.docx

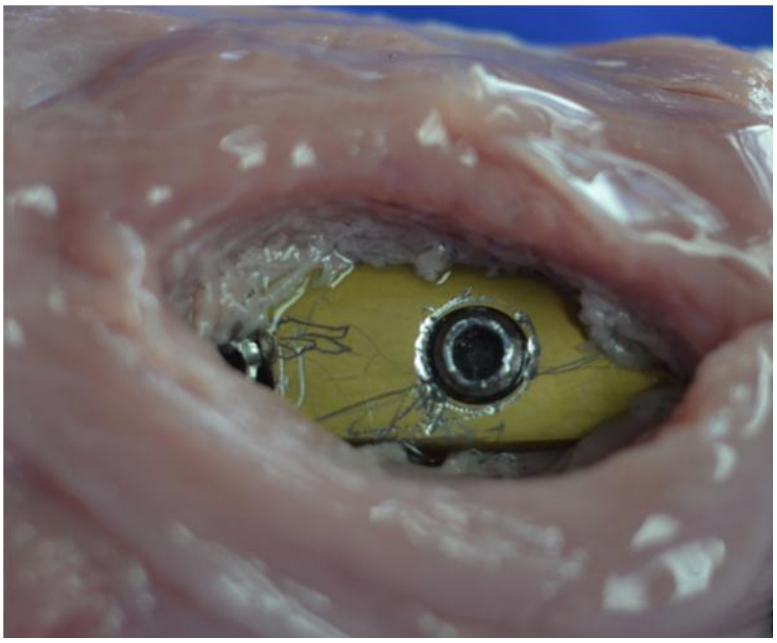

Figure 1: Surgical Model

Figure 2 mask of area

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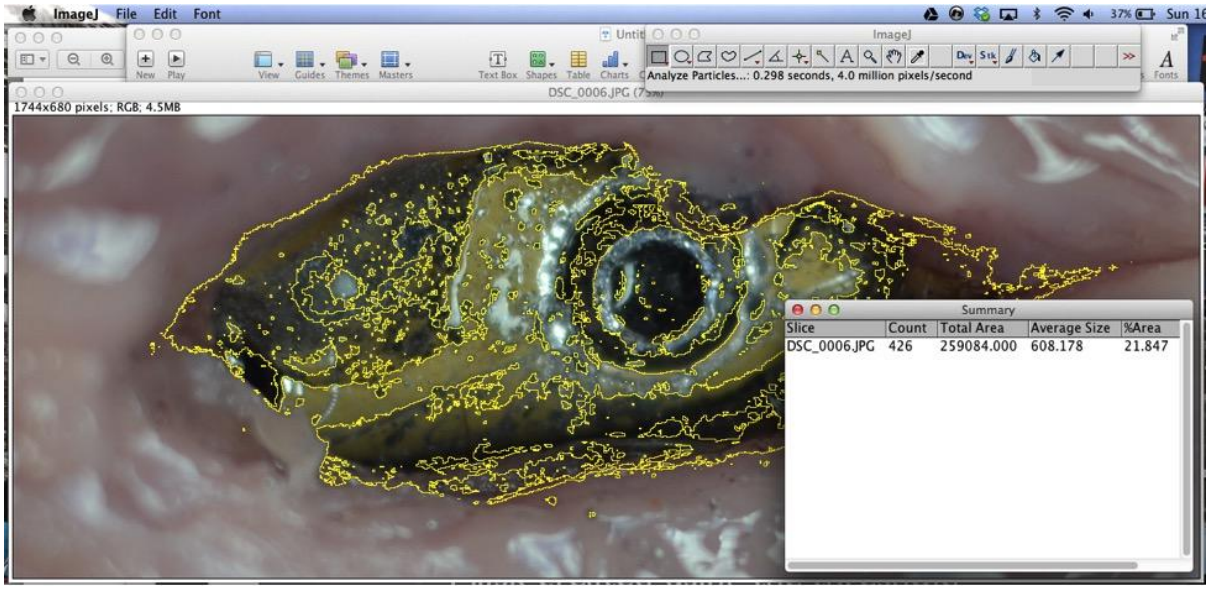

Figure 2: Computer generated mask of area covered in debris

Water-Based Lubricant as an Adjunct to Wound Toilet: Validation of a Technique by Experiment.

Haroon Rehman MBChB, MSc, MRCS[1†]

Iain Rankin MBChB, MRCS[1]

Kimberly Ferguson MBChB, MRCS[2]

Bryn Jones MBChB, MD, FRCS (Tr &Orth)[3]

Mark Frame MBChB, FRCS (Tr & Orth)[1]

[1]Aberdeen Royal Infirmary, Foresterhill, Aberdeen, AB25 2ZN

† Corresponding Author

1. Trauma & Orthopaedics Unit, Aberdeen Royal Infirmary, Foresterhill, Aberdeen, AB25 2ZN

2.Trauma and Orthopaedics Unit, Glasgow Royal Infirmary, Glasgow

3. Department of Orthopaedics, Golden Jubilee National Hospital, Agamemnon Street, Glasgow, Scotland

haroon.rehman.06@aberdeen.ac.uk

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***Revision Note (Blinded)**

Click here to download Revision Note (Blinded): Comments to reviewers.docx

Dear Dr Mauffrey,

Thank you for your suggestions. Please find below recommendations and actions taken following review of our manuscript: "Water-Based Lubricant as an Adjunct to Wound Toilet: Validation of a Technique by Experiment"

Reviewer 1

Comments	Author	
Abstract • "The reduction of debris" should be "the reduction of surface area covered by debris" • Should provide the data of how much the reduction found in this study.	Accept	• Change made • Data included
Materials & Methods • Please clarify the surgical technique for applying lubricating gel on the wound (how much of the gel thickness, single application and or multiple application) • Please clarify the group 1 and 2 (which one is the gel group / control group?)	Accept	• Information added (lines 30-36) • Groups clarified in methods (Lines 31 & 34)
Discussion • The authors should discuss about the least size of surgical field needed to apply lubricating gel (how much of the distance from the screw do needed to cover by gel?)	Accept	• Addressed lines 87 -90

Kind Regards

Water-Based Lubricant as an Adjunct to Wound Toilet: Validation of a Technique by Experiment.

Abstract

Introduction:

Metal debris can produce a foreign body inflammatory reaction or as third body wear in the situation of joint arthroplasty. We evaluate a simple method for reducing this debris using a sterile water-based lubricating gel.

Materials & Methods:

Eight experimental surgical models consisting of porcine muscle overlying a polyethylene tube with a titanium locking plate and screws secured were constructed. Four models had water based lubricating gel applied to the wound edges, four were left without as controls. Image were then captured before and after irrigation from which the amount of debris could be quantified.

Results:

The reduction of surface area covered by debris for models with water-based gel was greater ($p=0.001$). The average reduction in surface area was 27.2% for the control group and 94.1 % for the models covered with lubricating gel.

Conclusion:

We show that using a safe, inexpensive and easily available water-based lubricating gel reduces the amount of embedded debris when burring metal implants using a high-speed burr.

Introduction

Significant amounts of metal debris can be generated during attempts at metalwork removal. This is especially in cases where implants must be cut with a saw or drilled with a burr[1-3]. Implant constructs which employ locking mechanisms can 'cold weld' such that the screws become fixed to the plate; removal involves drilling the screw head with a carbide burr. In all such cases metal debris is deposited in the surrounding soft tissue and can result in foreign-body induced inflammatory reactions[4,5]. Debris around or within prosthetic joints will cause third body wear, early failure and the need for further surgery [6]. There have been case reports of metal wear debris being detected in remote bone marrow regions [7].

We performed a study to investigate the efficacy of a simple and inexpensive technique using a sterile water-based lubricating gel for the prevention and clearance of metal debris contamination.

Materials & Methods:

Eight experimental, surgical models consisting of porcine muscle overlying a polyethylene tube with a titanium locking plate and screws secured to it were prepared (Figure 1). All screws were locked within their plates. The screw heads were subjected to 90 seconds of high speed burring with a carbide burr to create metal debris. Four models were used as a

control group (Group 1) without lubricating gel on the surrounding tissue. Four models had the surrounding soft tissue coated with a water-based lubricating gel (AQUAGEL, Adams – 42g £1.98) by applying approximately 5ml to the screw head and spreading it gently with digital pressure onto the exposed tissue (Group 2). A single application was made. The gel was thickest (2-3mm) over tissue within a 20mm radius of the screw and spread more evenly beyond this. All eight models were irrigated with 500mls of sodium chloride solution using a 20mls syringe under manual digital pressure.

Images of the models were then captured before and after irrigation. Digital images were cropped and proportioned to include only the area being analysed. Adjustments were made to red, green and blue colour (RGB) thresholds to isolate the debris. ImageJ (National Institutes of Health (NIH), US) is a public domain, Java-based image processing program that we used to create a mask of surface area covered with debris and calculate amount remaining on each model after irrigation (Figure 2). The results were statistically analyzed using the student t test with Stastical Package for the Social Science SPSS v20 (SPSS Inc., Chicago, IL, USA).

Results:

There was a statistically significant difference in the reduction of surface area covered with metal debris particles before and after irrigation, favouring models in which the water-based gel was used ($p=0.001$). The average reduction in surface area was 27.2% for group 1 and 94.1 % for group 2. The greatest clearance (95.29%) was noted in a model used in group 2 and the lowest in group 1 (18.4%). The recordings are shown in Table 1.

Discussion:

Metalwork removal is performed commonly on a patient-specific basis[8]. Removal of small particle foreign material from wounds can be time consuming and difficult. Metal shaving can be particularly challenging as they can embed themselves within the surrounding soft tissues. Failure to achieve adequate clearance can resulting in significant morbidity and disability for patients[9]. In cases where neighbouring tissue is contaminated, surgical treatment conventionally involves surgical debridement of contaminated tissues. We validate by way of experimentation, a simple technique for both prevention and clearance of large amounts of metal debris contamination.

The technical application of Surgilube (Fougera, Melville, NY, USA), a sterile lubricating jelly in the management of metal debris has previously been described by Brubacher et al[10]. The authors describe a similar method in preventing contamination when removing titanium locking plates. To our knowledge the efficacy of aqueous lubricating gel in minimizing contamination has not previously been quantified by scientific methods.

Titanium and stainless steel particulate is known to elicit a macrophage- mediated inflammatory response leading to increased levels of local proinflammatory cytokine roduction, subsequent osteoclastogenesis and cellular apoptosis. This response can progress to acute or chronic infection and tissue damage locally with a potential for systemic upset.

Internal fixation and metal implants are common within current orthopaedic practice in both elective and emergency settings. This results in a significant population with metalwork in situ[11]. Removal of orthopaedic implants is common. In some countries general policy is to remove implants for fracture and in some instances surgeons are influenced by patient concern over local and systemic effects[12]. Absolute indications for implant removal include infection, peri-prosthetic fracture and soft tissue injury[13]. The rates of

symptomatic hardware vary in the literature with some authors reporting figures as high as 30% for *superficial* bones[14].

In many instances metalwork removal is performed without complication or contamination. Troubles arise in cases where the implant has fractured or cold welded requiring drilling or sawing. Meticulous clearance of debris can be achieved with the use of water based lubricating gels followed by lavage. There are no major risks associated with the use of sterile water based lubricant gels in surgical wounds provided appropriate surgical technique is used and a thorough wound toilet performed. To our knowledge there are no case reports of serious harm or adverse event using gels. The technique can be used for any type of debris despite being described for metals in this report.

It is the authors' opinion that the use of gel is most effective in cases where it is applied to tissue prior to the generation of debris such as difficult metalwork removal or revision arthroplasty surgery. We recommend coverage of all exposed deep tissue if possible, with the thickest application of gel within a radius surrounding the screw of approximately three to five centimetres. Though our experiment does not directly address particulate velocity, it is likely to be embedded with greatest force at the site closely surrounding the surgical target.

The strengths of our study are that methods and materials are reproducible in a laboratory environment; multiple models were used; a standardised approach to image analysis was performed with task specific software. A weakness of our experiment is a lack of quantification of the pressure applied in burring the metal. This could be addressed with the use of a vice and Newton meter.

Conclusion:

We demonstrate the use of water-based lubricating gel reduces the amount of embedded debris. The technique is inexpensive, safe and reproducible. It is an effective adjunct to irrigation of wounds where debris is created.

References:

[1] Bae J, Oh J, Oh C, Hur C, Technical difficulties of removal of locking screw after locking compression plating. Arch.Orthop.Trauma Surg. 2009; 129 91-5

[2] Ehlinger M, Adam P, Simon P, Bonnomet F, Technical difficulties in hardware removal in titanium compression plates with locking screws. Orthopaedics & Traumatology: Surgery & Research 2009; 95 373-6

[3] Suzuki T, Smith WR, Stahel PF et al., Technical problems and complications in the removal of the less invasive stabilization system. J.Orthop.Trauma 2010; 24 369-73

[4] Hak DJ, McElvany M, Removal of broken hardware. J.Am.Acad.Orthop.Surg. 2008; 16 113-20

[5] Georgiadis GM, Gove NK, Smith AD, Rodway IP, Removal of the less invasive stabilization system. J.Orthop.Trauma 2004; 18 562-4

[6] Davidson J, Poggie R, Mishra A, Abrasive wear of ceramic, metal, and UHMWPE bearing surfaces from third-body bone, PMMA bone cement, and titanium debris. Biomed.Mater.Eng. 1994; 4 213-29

[7] Engh CA,Jr, Moore KD, Vinh TN, Engh GA, Titanium prosthetic wear debris in remote bone marrow. A report of two cases. J.Bone Joint Surg.Am. 1997; 79 1721-5

[8] Richards R, Palmer J, Clarke N, Observations on removal of metal implants. Injury 1992; 23 25-8

[9] Case C, Langkamer V, James C et al., Widespread dissemination of metal debris from implants. JOURNAL OF BONE AND JOINT SURGERY-BRITISH VOLUME- 1994; 76 701-

[10] Brubacher JW, Owen TM, Vrahas MS, Use of Surgilube to minimize metal debris in removal of jammed titanium locking screws. Injury 2013; 44 1648-50

[11] Jamil W, Allami M, Choudhury M et al., Do orthopaedic surgeons need a policy on the removal of metalwork? A descriptive national survey of practicing surgeons in the United Kingdom. Injury 2008; 39 362-7

[12] Busam ML, Esther RJ, Obremskey WT, Hardware removal: indications and expectations. J.Am.Acad.Orthop.Surg. 2006; 14 113-20

[13] Bostman OM, Refracture after removal of a condylar plate from the distal third of the femur. J.Bone Joint Surg.Am. 1990; 72 1013-8

[14] Brown OL, Dirschl DR, Obremskey WT, Incidence of hardware-related pain and its effect on functional outcomes after open reduction and internal fixation of ankle fractures. J.Orthop.Trauma 2001; 15 271-4