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ORIGINAL ARTICLE • GENERAL ORTHOPAEDICS - BIOMECHANICS

Can the radiopaque marker in surgical swabs scratch orthopaedic implant surfaces?

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Abstract

Aims To determine whether the radiopaque marker strip, which is woven in surgical swabs, causes measureable wear on metal implants at pressures typically used to wipe off fluid from their surface.

Materials and methods Finger pressure used to wipe a surface was measured and used as a reference pressure for further testing. A tribological wear rig was then used to analyse the wear caused on polished titanium plates by a cobalt chromium pin (the control test), the pin covered by a surgical swab and the pin covered by a radiopaque marker strip.

Results It was found that the cotton part or the radiopaque marker of surgical swabs on polished medical grade titanium plates caused no significant wear. In contrast severe scratching was observed from the cobalt chromium pin on its own.

Conclusion To our knowledge, this is the first study in the literature analysing the wear caused by the surgical swabs and radiopaque strip on metal implants. The results suggest that surgical swabs are safe to use on metallic implants at pressures typical of a wiping motion.

Keywords Swab · Wear · Radiopaque marker · X-ray · Implant · Metal · Titanium

Introduction

Surgical swabs are used during surgery to absorb fluids and improve visibility of the operative field for the surgeon. The true incidence of retained swabs is unknown due to medicolegal implications, but it is thought to be between 0.02% and 1% of all laparotomies and accounts for 50% of malpractice claims for retained foreign bodies [1]. There have been reports of forgotten swabs in the peritoneal cavity, gynaecological and pelvic surgery as well as thoracic, breast and lower limb surgery [2, 3]. For this reason, radiopaque markers have been woven within the swab to aid in identification on post-operative radiographs (Fig. 1). This is particularly valuable should any swabs be unaccounted for perioperatively.

Swabs are also used mechanically to help dislocate the hip during joint surgery where they may be wound around the neck of the femoral stem. The force used to do this is greater and could potential cause wear to the neck of the stem. From an implant perspective, arguably the most important application may be wiping of the polished bearing surfaces.

In orthopaedic surgery, the most common metal alloys being used are titanium alloys (Ti-6%, Al-4%V), cobalt-chromium-molybdenum alloys and stainless steel alloys (316L being the most common). The benefits of metal alloys are their high strength, ductility, hardness, fracture toughness, corrosion resistance, formability and biocompatibility [4]. Whilst all three metal alloys are used as prosthetic implants, only stainless steel and titanium alloys are used as plates and screws. The importance of hardness and wear resistance in metal orthopaedic implants especially articulating components cannot be understated due to the deleterious effect of the wear debris on the local and distant body tissues. Furthermore, when metallic surfaces that articulate with polyethylene have been roughened then there is accelerated wear of the polyethylene due to it being a softer material ultimately leading to earlier implant failure and aseptic loosening.

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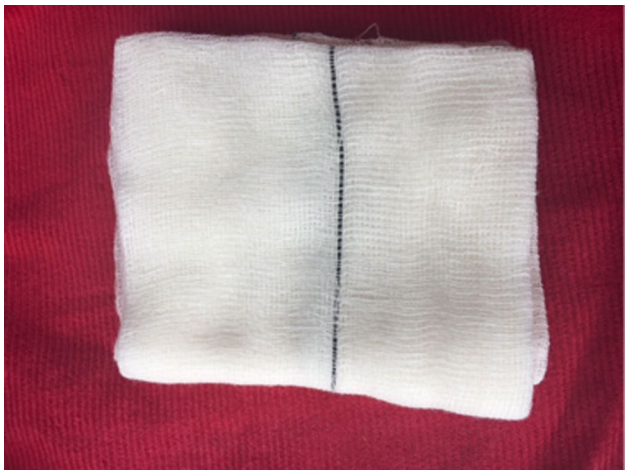

Fig. 1 Surgical swab with radiopaque marker (black line in swab) woven into it

Hardness of a material is a measure of its resistance to localized plastic deformation, most commonly by indentation or penetration. The greater the hardness of a material, the greater its resistance to plastic deformation. Wear occurs when two materials placed under load slide across each other resulting in wear debris formation. These wear particles can then cause further wear to the articulating surfaces through third body wear. The wear debris may attach to the other surfaces, remain in the space between the two articulating surfaces or disperse to distant sites via the blood vessels or lymphatic system.

In an adhesive wear model, it is assumed that wear is due to adhesion followed by fracture of asperities that come into contact from two surfaces under load. The Reye–Archard–Khruschov wear law [5] is depicted by the equation below and can be used in a simple model of sliding wear [6, 7], to calculate the wear volume, and it is based on the principle that the volume of debris created from wear is proportional to the work done by frictional forces from asperity contact.

$$Q = \frac{KWL}{H}$$

where Q is the total volume of wear debris, K is a dimensionless wear coefficient, W is the total normal load (force perpendicular to the sliding surface), L is the sliding distance, H is the hardness of the softest contacting surface.

Therefore, as can be seen from above the amount of wear produced is an interplay of the factors above. The equation also shows that increased physical activity, gain in weight, high impact activities, larger implants (due to greater contact surface area), will all contribute to production of greater volume of wear debris. Since titanium alloys are the softest compared to the other two commonly used metal alloys, it can be deduced from the equation above that for a given load and sliding distance that titanium would produce the greatest volume of wear debris [8].

The aim of the study was to investigate whether the action of wiping a surgical swab containing a radiopaque marker on the surface of a metallic implant may cause scratching and wear to the metallic implant surface.

Materials and Methods

New unused cotton swabs (DetexTM, X-ray detectable swabs, Synergy Health, Swindon, UK) incorporating a radiopaque marker were used. The radiopaque marker was subsequently removed from several swabs and analysed using a 3D non-contacting white light interferometer (Wyko, Veeko UK) to determine the surface roughness (Fig. 2). The average surface roughness (Ra) along the length of the marker was ~ 50 µm.

To simulate the force of contact in a wiping motion, contact forces (force transducer) and areas (engineering blue dye) were estimated by analysing three volunteers using a single finger contact as a worst-case scenario. The average contact pressure was then determined by dividing the average maximum force by the average contact area and found to be equal to 25 kPa (average force 2.7 N, average area 107.5 mm^2). To replicate this condition in a tribological pin-on-plate test, 12-mm-diameter pins were chosen with an applied load of 300 g to create an estimated average stress of 26 kPa. Polished medical grade titanium alloy (Ti-6Al-4V) plates were used for testing which is the softest medical grade metallic material. Three wear tests were carried out on the titanium plates (Fig. 3). The first test was a cobalt chromium pin (used as a negative control) as it is known that cobalt chromium is a harder material than titanium alloy. The cobalt chromium pin was used as a base to which

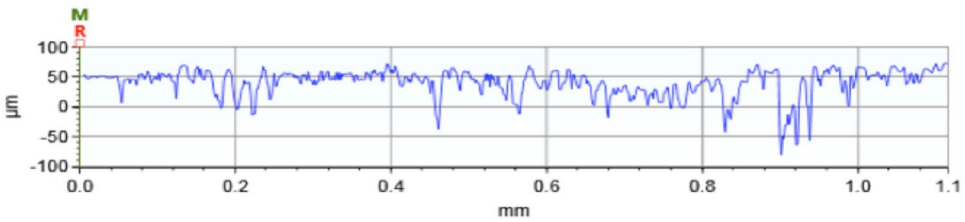

Fig. 2 Typical radiopaque marker surface profile over a 1.1 mm sample

Fig. 3 Tested pin configurations. **a** Nude polished cobalt chromium pin with its dimensions; **b** cotton part of swab secured on pin; **c**) radiopaque marker glued at the sides of pin

Table 1 Testing conditions

Test	Plate	Pin surface	Load (g)	No of samples
1	Ti	Cotton	300	3
2	Ti	Radiopaque marker	300	3
3	Ti	CoCr	300	3

to stick on the cotton part of the swab (second test) and the radiomarker strip (third test). Therefore, any differences in the wear seen in the testing of the cotton and radiomarker strip parts of a surgical swab would be solely attributable to them and not to the cobalt chromium pin.

Wear testing was completed using an in-house single station tribological pin-on-plate testing machine (Institution blinded for review purposes [9]. Testing involved articulation of the pin against the plate over a sliding distance of 33 mm at a rate of one stroke per second for 5 min over the same path for a total sliding distance of 9.9 m. Testing was performed with the pin and plate submerged in deionized water. The titanium plate and fluid were replaced after each test. Testing conditions are summarized in Table 1.

After each individual test, wear was assessed by analysing the surface profile of the titanium alloy plate in 5 different locations using a Form Talysurf 5 surface profilometer (Model 120L, Taylor Hobson UK) which has a resolution of 3 nm. The magnitude of the average plate roughness was compared to new plates using a Students t test, with a p value < 0.05 considered significant.

Results

Typical plate appearance following wear testing is shown in Fig. 4. The cobalt chromium (CoCr) pin testing on titanium plate, demonstrated a characteristic visible wear trace which was completely absent in both the cotton and radiopaque marker tests. No visible signs of wear on the titanium plates were present after the swab and radiopaque marker tests.

The mean surface roughness of new titanium plates was 0.0034 ± 0.0014 mm (standard deviation) and varied from 0.0019 to 0.0054 mm. The roughness of plates following testing with cotton-covered pins and radiopaque marker-covered pins is shown in Fig. 5. Even though the average roughness of the titanium plates post wear testing with the cotton and radiopaque marker was greater than the average surface roughness of the new titanium plates, the difference was not significant for either test (p values were 0.325 and 0.503 respectively). Additionally the accuracy of the testing machine is 3 nm (0.003 mm); hence, the differences between the test results are within the experimental measurement error.

Plates that were contacted by articulating CoCr pins increased in roughness significantly compared to new plates (p value 0.0004) by two orders of magnitude to 0.34 ± 0.07 mm (Fig. 6). This was expected as it is a metal-on-metal contact with the harder cobalt chromium pin scratching the softer titanium plate.

Discussion

Roughening of metallic articulating surfaces has been shown to accelerate wear on softer bearings such as ultra-high molecular weight polyethylene (UHMWPE) due to the raised edges of the scratched metallic surface acting to increase abrasive wear of the other surface [10, 11]. Hence the concern raised by the radiopaque marker potentially scratching the metallic surfaces and potentially increasing wear. The subsequent increased production of biologically active particles is a further cause for concern with stimulation of osteolysis and aseptic loosening of implants. The comparative linear wear rates per year (one million cycles) of the different metallic alloys on ultrahigh molecular weight

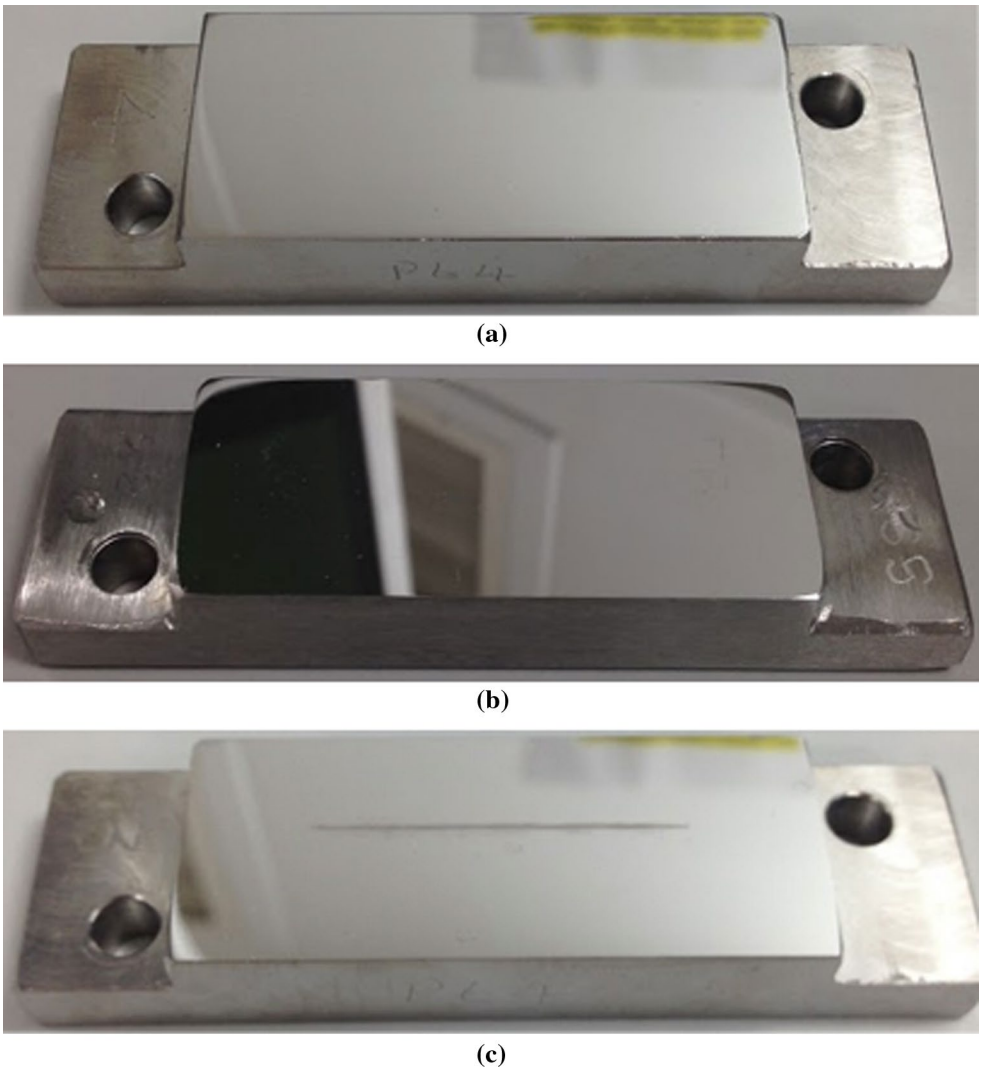

Fig. 4 Typical post wear testing titanium plates following articulation against cotton part of surgical swab (**a**), radiopaque marker (**b**) and cobalt chromium pin (**c**)

polyethylene have been shown to be approximately 0.1 µm for cobalt chromium, 0.2 µm for 316L stainless steel and 1 µm for Ti-6Al-4V [12].

Bearing surfaces in joint replacement are more commonly cobalt chromium. However, medical grade titanium alloy is a much softer material and is used in tibial trays of total and unicompartmental knee replacements and femoral stems of total hip replacements. Thus, the study utilized the softest clinical metallic alloy as a worst-case scenario. The application of wear over 9.9 m is also unlikely to occur clinically but allows for the analysis and comparison of wear under controlled conditions. The use of highly polished plates with roughness at a nanometre level further offers the best chance at capturing the potential for a surface to be scratched. In the control test, a single cycle of the nude polished cobalt chromium pins resulted in a visible scratch to the titanium plates, whereas the cotton and radiopaque marker covered pins produced no visible scratching after 300 strokes. The results clearly show that the simulated wiping action of surgical swabs produced no significant wear caused by either the cotton component or the radiopaque marker component of the surgical swab.

The clinical significance of the formation of metal debris has been well documented. Metal debris is much smaller than polyethylene debris (<50 nm compared to >0.1 µm) but is more numerous by several thousand times [13]. Even though the larger polyethylene particles are more bioactive individually, the significantly larger number of metallic debris that is produced provides a larger overall surface area for biological activity to occur per given mass [8]. Metal-on-metal hip replacements are prone to developing aseptic, lymphocyte-dominated vasculitis associated lesion (ALVAL)

Fig. 5 Mean roughness values (±SD) for new and worn plates following articulation with both swab covered pins and radiopaque marker covered pins

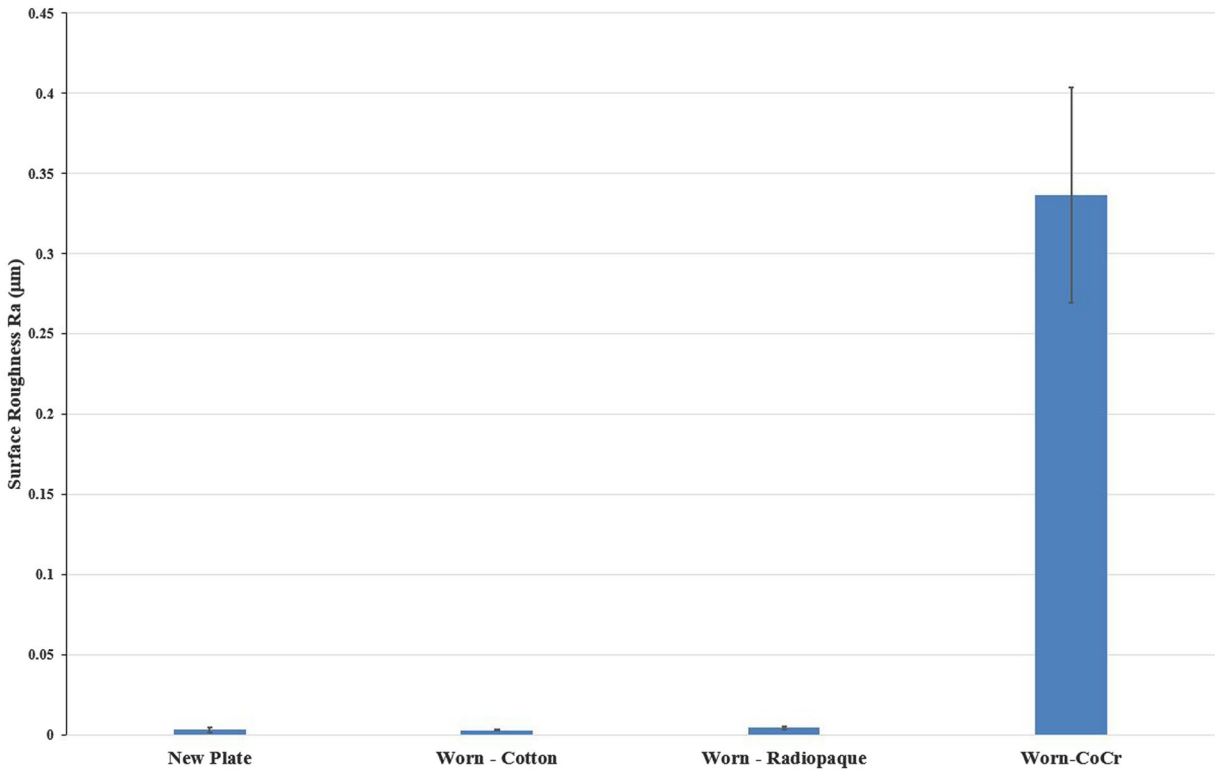

Fig. 6 Mean Ra values (±SD) of titanium plates for new and worn plates following articulation with cotton covered pins, radiopaque marker covered pins and nude CoCr pins

due to soft tissue reaction (type IV hypersensitivity) to the metal debris. The reaction can be so severe that formation of pseudotumours have been described, which are locally very aggressive and destructive [14]. This not only leads to pain and early failure of the prosthesis but makes revision surgery more difficult due to damaged surrounding tissue

and muscles which confer stability to the prosthesis. The stimulation of greater osteoclastic activity via the RANKL pathway has been demonstrated to lead directly to osteolysis and ultimate loosening of the prosthesis and increased risk of periprosthetic fractures [15, 16].

Among the limitations of the study are that only one level of pressure was used to analyse the effect of wear of theatre swabs. We are aware that the level of pressure used to wipe a surface with a swab can vary despite our initiative to use the worst-case scenario of pressures used by three volunteers. When surgical swabs are used at higher pressures such as in dislocating a femoral stem during hip arthroplasty, this could potentially damage the neck of even trunnion part of the femoral stem. Further assessment at higher pressures would help elucidate the wear profile of these swabs. Whilst the effect of wear on other metal implants which are more commonly used as bearing surfaces was not tested, the assumption was taken that if wear wasn't caused on the softer titanium alloy then it wouldn't be a concern for the harder metal alloys let alone ceramics.

Conclusion

In conclusion, no significant wear was caused on polished titanium plates by the cotton part of the swab or the radiopaque marker, suggesting that the use of these theatre swabs that have a radiopaque marker is unlikely to damage any metallic implant surface at a pressure typically used to wipe a surface.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

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