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Basic Science

Does mechanical filtration of intraoperative cell salvage effectively remove titanium debris generated during instrumented spinal surgery? An in vitro analysis

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Abstract

BACKGROUND CONTEXT: Instrumented fusion of the spine is a surgery commonly performed to stabilize vertebrae causing pain and to correct anatomic deformities. Such surgery can create substantial blood loss. Autotransfusion is a means to limit homologous blood transfusion in this setting. However, a dilemma is created when the high-speed drill used for bone removal comes in contact with implanted titanium spinal hardware. A clinician at this point is forced to decide between two options: to discontinue autotransfusion to avoid the potential transfusion of titanium fragments while risking blood loss and the need for homologous transfusion or to continue autotransfusion while risking transfusion of titanium fragments back into circulation.

PURPOSE: To conclusively identify whether titanium fragments created by a high-speed drill are able to pass through standard autotransfusion microaggregate blood filters.

STUDY DESIGN: A positive and negatively controlled experiment with blinded sample analysis.

OUTCOMES MEASURES: The presence or absence of titanium alloy on a filter with detection by energy-dispersive X-ray spectroscopy (EDX).

METHODS: A mock autotransfusion setup was devised for in vitro filtering. Six investigational and two control experiments were conducted. Titanium fragments generated by a high-speed drill were aspirated with saline and filtered with standard autotransfusion reservoirs and microaggregate blood filters. A final filter with a 1-μm pore size was placed distal to the blood filters. After filtration was complete, this final filter was analyzed using EDX.

RESULTS: The presence of titanium was confirmed by EDX on five of six investigational filters. The positive and negative control filters were analyzed by EDX and tested positive and negative, respectively, for titanium.

CONCLUSIONS: Standard 40 μm reservoir and blood microaggregate filters do not eliminate the smallest fragments of titanium generated by contact between a high-speed drill and a titanium hardware. The mass of titanium able to elude filtration is very small. The impact of transfusing blood contaminated with such a small mass of titanium is not known.

Keywords: Titanium alloy; Autotransfusion; Spinal fusion; Cell saver; Transfusion; EDX

FDA device/drug status: Pedicle screw; TSRH 3D Medtronic Spine & Biologics, Memphis, TN, USA (Approved), EL240 Cardiotomy Reservoir; Medtronic Minneapolis, MN, USA (Approved), SQ40S Blood Transfusion Filter; Pall, Port Washington, NY, USA (Approved).

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Introduction

Spinal fusion surgery for the treatment of low back pain has been performed since the early 1900s. Originally, spinal fusion procedures were performed to treat the effects of tuberculosis infection. Subsequently, it was found that the fusion procedure not only limited the deformity but also reduced the patient's low back pain [1]. Instrumented lumbar fusion surgery using metallic hardware debuted in the 1960s and 1970s [2]. Instrumentation and fusion of the spine are commonly performed worldwide to stabilize vertebrae and correct anatomic deformities such as kyphosis, spondylolisthesis, spine trauma, and scoliosis. Homologous blood transfusion occurs at a rate of approximately 30% in patients undergoing spinal surgery [3]. Blood loss can be attributed to factors such as the following: duration of surgery, arterial hypertension during the surgical procedure, the number of vertebrae fused, the site of autologous bone harvest, and increased venous pressures because of body habitus or patient positioning. The use of autotransfusion as a means to manage large blood loss was first reported by Blundell [4] in 1818 and then later intraoperatively by Duncan in 1886 [5]. Basing his method on a dairy-industry cream separator, Edwin Cohn developed the technique of component separation by centrifugation during the 1940s [6,7] But, it was not until the 1960s during the Vietnam War that autotransfusion began to progress from the simple reinfusion of shed blood to more advanced systems of centrifugation and cell washing [8]. Today, autotransfusion is commonly employed by hospitals worldwide during surgical procedures where moderate-to-large blood loss is anticipated.

An issue with autotransfusion occurs in the setting of instrumented spinal surgery when the high-speed drill for bone removal inadvertently contacts implanted spinal hardware. Although somewhat rare in occurrence, this subject has not been studied. A clinician is thus forced to ignore any such incident and autotransfuse blood potentially contaminated with metal ions. Alternatively, the clinician could abandon autotransfusion and accept the risk of blood loss and homologous blood transfusion in favor of avoiding metal ions.

The purpose of this study was to conclusively identify whether titanium fragments created by a high-speed drill were small enough to pass through standard autotransfusion blood filters. The study was designed in vitro to remove variables such as blood that might add complexity to the experiment. Energy-dispersive X-ray spectroscopy was selected as the method of identifying titanium based on its ability to distinguish individual elements and its ability to identify particles of very small size. We did not attempt to add to the extensive volume of published work already documenting the negative effects of metal ions resultant from orthopedic hardware [9]. Rather, our sole purpose was to evaluate the effectiveness of blood filters in vitro when challenged by titanium alloy debris created by a high-speed drill. A physician with this knowledge is better suited to make an evidence-based decision when confronted with a scenario of titanium debris clinically.

Methods

A total of eight filters were analyzed for titanium. The eight filters analyzed included six repetitions of the experiment, one positive control, and one negative control sample. Titanium alloy debris was generated using a Midas Rex Legend drill (Medtronic Powered Surgical Solutions, Ft Worth, TX, USA) rotating at 60,000 RPM with a 5-mm fluted ball bur (10BA50; Medtronic Powered Surgical Solutions). Intentional abrasion of the bur on a titanium-alloy (Ti-6Al-4V) pedicle screw (TSRH 3D Medtronic Spine & Biologics, Memphis, TN, USA) resulted in titanium debris. The debris was collected and weighed on an analytical balance (AE160; Mettler-Toledo, Columbus, OH, USA). The total mass recovered was 230 mg. The debris was divided into six groups of relatively equal mass (Table 1). One sample of titanium debris was used for each of the six investigational filters. All groups were aspirated with 1 L of 0.9% NaCl at a vacuum of −300 mmHg into individual cardiotomy reservoirs (EL240; Medtronic, Minneapolis, MN, USA) each containing an integral 40-μm screen. After removing the vacuum, the fluid was then drawn by syringe out of the reservoir, through a 40-μm microaggregate blood filter (SQ40S; Pall, Port Washington, NY, USA) and finally through a 1-μm life science disc filter (Omnipore PTFE, 1.0 μ, 13 mm; Millipore, Billerica, MA, USA). This path through the blood filters did not include a standard autotransfusion set or centrifuge in an effort to present the maximum mass of titanium debris to the filters. Additional tubing and or a centrifuge could possibly trap titanium debris. Trapping titanium would be clinically desirable but for the purposes of this study would lessen the credibility of our findings.

The disc filters were then removed from their holders and dried. The negative control sample consisted of an unused 1-μm disc filter. The positive control sample consisted of a 1-μm disc filter wetted with 0.9% NaCl and swabbed in unused titanium debris. All filters were sent off-site for microscopy as blinded samples.

Filters were mounted on carbon tape and imaged without coating on an FEI Quanta 3D FEG scanning electron microscope (FEI Company, Hillsboro, OR, USA). Energy-dispersive X-ray spectroscopy was performed using

Table 1
Titanium debris group

Sample	Debris weight (mg)
1	29
2	39
3	36
4	35
5	33
6	37
7	+ (control)
8	− (control)