ULTRABLOX® X-Ray Attenuating Cream

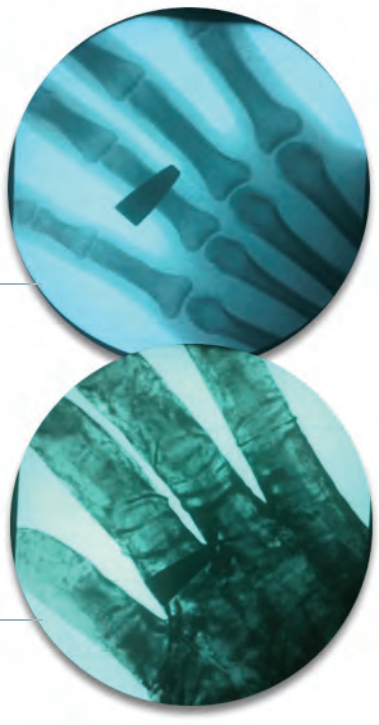
ULTRA BLOX®

Protect the hands from scatter radiation and reduce dose exposure without the loss of tactile feel. Clinical studies have shown up to 85% dose reduction. The cream can be applied directly to skin or encapsulated between two pair of surgeon's gloves.

- Patented formula.
- Easily incorporates into physician's prep procedure -- a practical and efficient alternative to leaded gloves.
- Contains no lead, lead by-products or other toxic materials. Biocompatible.
- Eliminates the need to inventory multiple sizes of lead gloves.

ULTRABLOX® X-Ray Attenuating Hand Cream
50 Gram tube, sterile, packaged in a peel pouch

PN	Quantity
100036	15/box



Unprotected hand

Hand protected with ULTRABLOX Attenuating Cream

BLOXR®

BLOXR Solutions, LLC, P.O. Box 5148, North Branch, NJ 08876 USA
801-590-9880 . Toll Free 855-256-9729 . Fax 877-254-4888
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U.S. Patent Number 9,114,121

 79021B

REF 100036

QTY 50g net/Tube
(15 Tubes/Box)

ULTRABLOX® X-Ray Attenuating Cream
Instructions for Use

STERILE R
Single Use
Sterile Unless Package is Damaged or Opened

Description

- ULTRABLOX® X-Ray Attenuating Cream is a sterile, single use attenuating cream that provides increased clinician safety through effective radiation dose reduction to hands without affecting dexterity or tactile feel.
- Contains no lead, lead by-products or other toxic materials. Biocompatible.
- Manufactured in conformance with ASTM F 2547-06, Test Method for Determining the Attenuation Properties in a Primary X-Ray Beam of Materials Used to Protect Against Radiation Generated During the Use of X-Ray Equipment.

Indications for Use

- ULTRABLOX® X-Ray Attenuating Cream is intended for use as a radiation shield from radiation, x-rays and ionizing radiation during medical procedures.
- It is intended to be applied to the user's hands before donning gloves, or applied on a gloved hand, followed by the donning of a second glove.
- **For use with natural rubber latex gloves or latex-free poly-isoprene Surgeon's Gloves only.**
- It is intended to offer some degree of protection from radiation exposure during medical procedures where it is necessary for hands to be exposed to radiation. This may include surgical procedures that require the use of fluoroscopy or radiography.

> **Warning:** This device is not intended to be used in or adjacent to the primary x-ray beam or the transmitted beam and should not be used in lieu of a Radiographic Procedure Glove which is used in radiography for those studies requiring the physician's hand or forearm to be in the direct path of the primary x-ray beam.

Caution

- Federal law restricts this device to sale by or on the order of a health care professional.
- Once applied on the hand or glove, the cream can be used for a maximum period of three hours.

To Apply

We recommend kneading or shaking the tube for 30 seconds prior to opening.

- SINGLE GLOVE: Open tube and squeeze out cream into one hand. Spread on desired parts of the hands, making sure to apply an even and thorough coat, including between each finger. Use enough cream so desired areas are completely covered with a paper-thin layer of cream. Apply surgical glove over cream on each hand making sure to encapsulate the cream between the glove and the hand.
- DOUBLE GLOVE: Put on first pair of gloves. Open tube and squeeze out cream into gloved hands. Spread cream on desired parts of gloved hands, making sure to apply an even and thorough coat, including between each finger. Use enough cream so desired areas are completely covered with a paper-thin layer of cream. Apply the second surgical glove over the cream making sure to encapsulate the cream between the two gloves.

Technical Data

The effect of cream thickness on the attenuation characteristics of the cream was determined in accordance with ASTM F 2547-06 protocol by exposing sterile films of controlled thickness of 0.005", 0.010" and 0.015" using a C-arm fluoroscope at 60, 95 and 110 kVp. A 0.010" thick sterile latex radiation attenuating glove (Radion-X, Medline) was used as a control. Transmitted dose was measured using nanoDot™ dosimeters (Landauer, IL) placed under the films or radiation glove specimens. Incident dose was measured separately. Five replicate measurements were made. Attenuation was calculated as a ratio of blocked dose to incident dose expressed as % (**Table 1**).

In practice, cream thickness varies depending on the user. To determine the effect of user-to-user variation in cream application on attenuation, a study was conducted using a modified ASTM F 2547-06 protocol. An X-ray cabinet (Faxitron, IL) and a 0.6 cc ion chamber detector (Radcal, CA) were used. Due to the size limitations of the x-ray cabinet, the ion chamber was placed proximally below the attenuating specimen. Data from two sterile attenuating surgical gloves, Radion-X (Medline Industries, IL) and International Biomedical (Austin, TX) were used for comparison. Cream was applied onto a glove donned on an anthropomorphic anatomic phantom hand (Radiology Support Devices, CA) modified to accommodate the ion chamber. Three different operators applied a calibrated amount of cream on the gloved hand phantom to achieve a 0.010" thick cream layer to duplicate realistic clinical conditions. Five replicate measurements were made and the results tabulated (**Table 2**).

An evaluation of the cream was conducted with a low-risk IRB approved protocol by clinicians at a Level 1 trauma center. Three fellowship-trained orthopaedic trauma surgeons monitored radiation exposure to their dominant hand during 60 individual trauma cases (20 per surgeon) and 75 cumulative trauma cases (25 per surgeon) requiring the use of large C-arm fluoroscopy. Each surgeon wore two dosimeters side-by-side on the dorsum of their dominant hand for each case, one dosimeter covered with a thin layer (0.2mm) of the cream and the other adjacent dosimeter without any protection. Both dosimeters were placed within a sterile package and affixed to the surgeon's hand under his or her surgical gloves prior to each case. During cumulative exposure over 25 cases, the surgeons' hand was exposed to an average of 100 mRem (range 81-128) with the cream demonstrating the ability to attenuate ≥50% of this radiation exposure (Surgeon A – 58%, Surgeon B – 52%, Surgeon C – 50%). Average attenuation among all cumulative cases was 53.5% (**Table 3**) demonstrating that the cream reduces radiation exposure to the hand by at least 50%.

TABLE 1 **Mean % Attenuation of Controlled Thickness Creams and Radion-X Glove**

Summary: At equivalent 0.010" thickness the cream blocked between 48% to 93% more radiation than the gloves.

	60 kVp	95 kVp	110 kVp
0.005" thick cream	37.4 ±3.9	36.6 ±3.3	36.1 ±2.0
0.010" thick cream	62.6 ±3.1	58.1 ±2.9	49.9 ±2.1
0.015" thick cream	76.6 ±2.0	63.0 ±1.2	63.2 ±2.7
Radion-X Glove	42.4 ±1.4	30.1 ±2.0	26.5 ±1.8

TABLE 2 **Mean % Attenuation of X-Ray Attenuating Cream**

		Attenuation of X-Ray Cream			Attenuation of Gloves (from manufacturer's claims)	
		User 1	User 2	User 3	Int. Biomed.	Radion-X
60 kVp	Mean	81.1	83.5	85.3	56.5	55
	Std Dev	8.4	9.1	7.7	-	-
80 kVp	Mean	72	74.5	77.2	47.1	43
	Std Dev	8.6	11	9.6	-	-
100 kVp	Mean	62.6	67.2	69.9	41.6	34
	Std Dev	8.2	11.1	9.9	-	-
120 kVp	Mean	58.3	57.5	64.4	37.7	26
	Std Dev	8.4	17.2	11.5	-	-

TABLE 3 **Dominant Hand Exposure and % Attenuation During Cumulative Case Series at a Level 1 Trauma Center**

Summary: The cream reduced dose exposure by at least 50% without impairing tactile feel.

Surgeon	Dosimeter	Cumulative Unshielded Dose (mRem)	Cumulative Shielded Dose (mRem)	Attenuation %
A	A5	128	53	58.6
B	A1	92	46	50.0
C	A2	81	39	51.9
	MEAN	100	46	53.3
	Std Dev	25	7	4.5

Handling and Storage

- Product is delivered sterile in an outer peel pouch. Remove product from peel pouch and peel off seal from tube in accordance with your facility's protocol.
- Over time separation may occur. We recommend kneading or shaking the tube for 30 seconds prior to use.
- Store in a cool, dry, well-ventilated place. Handle in accordance with good safety practice. Avoid exposure to temperatures in excess of 40 degrees C (104 degrees F).

Cleaning and Disposal

- To remove cream, wash hands using a mild abrasive soap or a scrubby bar utilizing your normal post-surgical scrub technique.
- Dispose of as with other surgical products.

Manufactured for:
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U.S. Patent No. 9,114,121
ISO 13485

CE

X-ray Attenuating Lotion: A Supplement to Shielding

Richard Bass, AAS, R.T.(R)
Ben D Wood, MSRS, R.T.(R)

Time, distance, and shielding have held as the gold standard in radiation protection practices. Radiologic technologists understand that anatomical structures vary in their degree of radiosensitivity and that the hands of personnel who work in fluoroscopy are inevitably exposed to higher occupational doses than other health care providers. However, only moderate attention has been given to exposure or overexposure to regions of the hands and forearms.

People who work in interventional radiology, as well as orthopaedic, cardiovascular, and vascular surgeons, often have their hands and forearms in the path of the primary beam. Other personnel in close proximity of the primary beam also are vulnerable to overexposure to their extremities. A 4-decade study produced by the National Institutes of Health found "high exposure rates to clinicians' hands, which demonstrated a need to reduce occupational radiation doses."[1] The National Council on Radiation Protection & Measurements maximum annual exposure to occupational workers for the skin and extremities is 50 rem, and this amount of radiation can be absorbed by an operator's hands within the first 30 minutes of an imaging procedure.[2]

Proximity to the primary beam dictates occupational dose to the hands and forearms.[3] Individuals who are not properly shielded working 24 inches (70 cm) or fewer from a fluoroscopic beam receive significant amounts of radiation. People working 36 inches (91.4 cm) or more from the beam receive an extremely low amount of radiation. Although distance is the best method of radiation protection for individuals, it often is not feasible with fluoroscopic procedures. Radiation protection gloves currently in use are bulky and do not allow the dexterity and tactile sensation needed to perform operations.[1]

Possible Solution

Researchers have developed a topical lotion that provides radiation protection to operators' hands and forearms during fluoroscopic procedures. UltraBLOX x-ray attenuating cream is manufactured by the BLOXR corporation, which is based in Salt Lake City, Utah.[4] Radiation protection lotion is a relatively new product, and only a few articles have been written about this innovation.[1,5] In May 2013 the U.S. Department of Health & Human Services published its stance, which included the U.S. Food and Drug Administration (FDA) approving this new advancement in radiation protection for health care personnel.[6]

The nontoxic lotion consists of aqueous organic carrier and 75% weight of bismuth oxide ceramic powder (99.99% purity). The bismuth oxide has the same effectiveness as traditional lead-based radiation protective materials.[1] The organic carrier includes lubricants, humectants, surfactants, glycol, and polyethylene, which makes the creamy mixture similar to traditional hand lotion. It is applied like sunblock and can be removed easily with ordinary soap and water.

The manufacturer suggests 2 methods of use for the lotion.[4] The first method is to have the operator apply the lotion directly to his or her hands, rub it in, and put on sterile latex gloves. The other method is to put on the latex gloves first, apply the lotion, and then encapsulate the lotion with another sterile glove.

The new product offers surgeons radiation protection for their hands and forearms without losing any required dexterity.[1] Although designed for physicians, the lotion could prove beneficial for any personnel involved with performing fluoroscopic procedures.

Assessing Effectiveness

Biocompatibility International Standards Organization ISO-10993 are protocols required for evaluating materials used in manufacturing medical devices. Biocompatibility of this lotion and the ceramic powder ingredients were assessed using these FDA protocols.[1,5] Because the lotion comprises bismuth oxide and ingredients found in ordinary lotions, it was tested for "safety, biocompatibility, skin irritation, skin sensitization, cytotoxicity, and acute and chronic systemic toxicities using well-established FDA recognized standard ISO 10993 protocols."[1] While the lotion was under review by the FDA, the American Academy of Orthopaedic Surgeons received permission to conduct a study using cadaver hands to determine the effectiveness of the lotion.[1]

The researchers used a standard C-arm to image cadaver hands to simulate an operative field.[1] The kilovolt setting the researchers used was derived from an average of the settings used for 5 cadaver hands with the C-arm on an automatic setting. Dosimeters measured direct radiation and scatter radiation for 300 seconds at 53 kV. Five dosimeters were implanted subcutaneously in the cadaver hands, and 5 dosimeters were placed superficially. Control dosimeters were provided for each configuration to measure scatter radiation. The radiation protection lotion was applied to the cadaver hands (see **Table**). Interestingly, no significant difference was found in scatter radiation between subcutaneous and superficial configurations ($P = .09$ and .07, respectively), which was a concern with previous lead-embedded sterile glove designs.[7]

Table

X-ray Attenuating Lotion Study Results[1]

Dosimeter Placement	% Attenuation[a]	*P* Value
Subcutaneous	81.5	.0000006
Superficial	63.7	.00002

[a] *Compared to bare cadaver hands.*

Researchers also evaluated the lotion's texture and consistency and found no dexterity impairment or lack of tactile sensation.[1] Thus, an argument could be made that radiation protection was the goal, but retention of dexterity is an additional benefit.

Possible limitations of the product include operators' cognizance of the lotion's expiration date, loss of the sterile field due to glove failure, and personnel radiation exposure due to inconsistent application. The lotion is contained in sterile single-use packages and should be discarded after 9 months. The FDA notes these limitations in its decision summary, including the fact that sterile glove weakening or failure presents a chance for infection to the patient. Other potential limitations include the user not fully applying the lotion over the entire surfaces of the hands, wrists, and forearms. In addition, the effectiveness of the lotion decreases when technical settings exceed 130 kVp.[6]

Conclusion

The FDA has approved radiation protection lotion for health care personnel.[6] The lotion provides some protection for up to 130 kVp; however, it is not intended for use with direct contact of the primary beam. In the study, 81.5% attenuation with subcutaneous dosimeter placement and 63.7% attenuation with superficial dosimeter placement were recorded after the radiation protection lotion was applied.[1] Because there is no loss of dexterity or tactile sensation when the lotion is applied to surgeons' hands and it is easily removed with soap and water, this lotion could greatly reduce the occupational dose received by personnel during fluoroscopy procedures.

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References

1. Shah S, Chen K, Mejia A. Radiation protection to surgeons' hands with a novel radiation attenuating lotion. Scientific exhibit abstract presented at: American Academy of Orthopaedic Surgeons annual meeting; February 7, 2012; San Francisco, CA. http://bloxr.com/img/cms/The%20Science/The%20Science%20-%20Clinical%20Papers/AAOS%20Cream%20Abstract.pdf. Accessed May 15, 2014.
2. National Council on Radiation Protection & Measurements. NCRP Report No. 116, limitation of exposure to ionizing radiation. http://www.ncrponline.org/Publications/Press_Releases/116press.html. Accessed May 15, 2014.
3. Bontrager KL, Lampignano JP. Trauma, mobile, and surgical radiography. In: *Textbook of Radiographic Positioning and Related Anatomy*. 7th ed. St Louis, MO: Mosby; 2010:594.
4. UltraBLOX x-ray attenuating cream. BLOXR Web site. http://bloxr.com/ultrablox/ultrablox.html. Accessed September 4, 2014.
5. Dougherty E, Summers H, Stover M, Hintz A, Mitchell E. Fluoroscopic radiation to the orthopedic traumatologist's hand & efficacy of a novel radiation attenuation product. Scientific exhibit abstract presented at: American Academy of Orthopaedic Surgeons Annual Meeting; March 19, 2013; Chicago, IL. http://aaos.scientificposters.com/epsAbstractAAOS.cfm?id=1. Accessed May 15, 2014.
6. X-ray attenuating cream decision summary. U.S. Food and Drug Administration. U.S. Department of Health and Human Services Web site. http://www.accessdata.fda.gov/cdrh_docs/reviews/K123422.pdf. Accessed May 15, 2014.
7. Wagner LK, Mulhern OR. Radiation-attenuating surgical gloves: effects of scatter and secondary electron production. *Radiology*. 1996;200(1):45-48.

Technical Summary

Fluoroscopic Radiation to the Orthopedic Traumatologist's Hand & Efficacy of a Novel Radiation Attenuation Product

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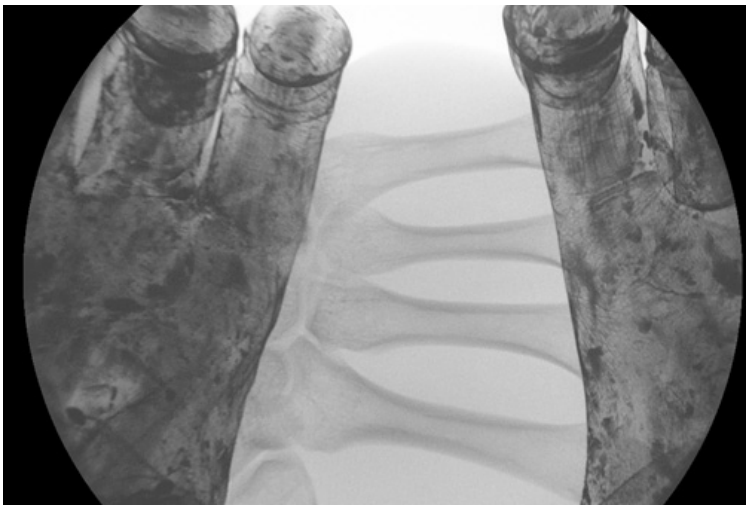
Clinical Relevance

The utilization of intraoperative fluoroscopy is vital in many specialties to minimize operative time, optimize implant placement, and improve patient outcomes. These advantages for the patient however come at a cost for the clinician, with greater radiation exposure to the surgeon's hands. UltraBLOX is a novel radioprotective cream that provides significant dose reduction without changing tactile feel or limiting dexterity during surgery. This cream allows the clinician to use fluoroscopy while performing within the operative field without compromising the safety of the surgeon.

Background

The utilization of fluoroscopy has aided the orthopaedic traumatologist by reducing operative times and soft tissue devitalization. However, these advantages must be weighed against the potential threat that fluoroscopic radiation poses to the surgeon's hands. Although surgeons can avoid direct irradiation by keeping hands out of the fluoroscopic field, working intimately around the field still exposes the hand to scatter radiation. Previous studies attempting to elucidate the amount of radiation exposure to the orthopaedic surgeon's hands during use of a large C-arm fluoroscope have lacked power and have been contradictory. Furthermore, attempting to limit this exposure through use of radiation-attenuating gloves can decrease the surgeon's tactile abilities, thus driving the surgeon to forego their use. The purpose of this study was to determine the amount of radiation that the hands of orthopaedic traumatologists experience during routine clinical practice and to evaluate the ability of a novel radiation attenuating product, only 0.2mm thick, to decrease this radiation.



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Materials and Methods

Three fellowship-trained orthopaedic trauma surgeons at a level I trauma center monitored radiation exposure to the dominant hand during 60 individual trauma cases (20 per surgeon) and 75 cumulative trauma cases (25 per surgeon) requiring the use of large C-arm fluoroscopy. Each surgeon wore two side-by-side dosimeters on the dorsum of their dominant hand for each case, one dosimeter covered with a thin layer (0.2mm) of a novel

radiation attenuating product and the other adjacent dosimeter without any protection. Both dosimeters were placed within a sterile package and affixed to the surgeon's hand under his or her surgical gloves prior to each case. The dosimeters, which were controlled for environmental exposure, had a minimum radiation detection of 5mrem. All dosimeters were returned to the manufacturer to determine overall radiation exposure (uncovered) and attenuated radiation exposure (covered).

Results

During cumulative exposure over 25 cases, the surgeons' hand was exposed to an average of 100 mrem (range 81-128), with the novel radiation attenuation product demonstrating the ability to attenuate ≥50% of this radiation exposure (Surgeon A – 58%, Surgeon B – 52%, Surgeon C – 50%). For individual cases, 77% of all dosimeters showed detectable levels of radiation (≥5mrem) to the dominant hand, ranging from 5-69 mrem (average of 16.8 mrem). Average attenuation amongst all individual cases was 33%. Of the cases that registered undetectable amounts of radiation (<5mrem) to the hand, >50% consisted of ORIF ankle, syndesmosis and distal fibula. All other case types routinely registered detectable radiation to the hand. Greatest exposure was noted with ORIF/IMN cases of the proximal femur and femoral shaft, which registered an average of 25mrem to the hand, and ORIF of distal femur and tibial plateau, which registered an average of 12mrem.

Conclusions

The orthopaedic surgeon's hand is frequently at risk to radiation when utilizing C-arm fluoroscopy. Though surgeons can easily reduce direct irradiation by keeping their hands out of the fluoroscopic field, scatter radiation still poses a danger. Hands are at greatest risk during femoral ORIF and IMN procedures. The novel radiation-attenuating product tested shows the ability to decrease the hand's exposure to scatter radiation by 33-58%. The orthopaedic traumatologist's hand is routinely exposed to fluoroscopic radiation scatter. This study outlines that risk and introduces a novel product that reduces radiation exposure to the hand.

Image is for illustration only.

Radiation Protection to Surgeons' Hands with a Novel Radiation Attenuating Lotion

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Kevin Chen, M.D.
Alfonso Mejia, M.D.

Control/Summary Number : 12-SE-2596-AAOS
Activity: Scientific Exhibit Abstract

Clinical Relevance

Orthopaedic surgeons are frequently at risk to excessive radiation exposure when performing fluoroscopy guided procedures. They choose not to use radiation protective gloves because of reduced dexterity and tactile sensation. This radiation attenuating cream may provide a new and better option for reducing their dose exposure by as much as 80%.

Introduction

Orthopaedic surgeons frequently exposing their hands and fingers to radiation with the use of fluoroscopy during procedures. An NIH study on fluoroscopically guided procedures spanning the past four decades revealed high exposure to clinicians' hands and underscored the need to reduce occupational radiation doses. The maximum annual limit to hands is 50 rem. This can be reached in 30 minutes of exposure to direct C-arm radiation, depending on X-ray intensity. Current radiation attenuating gloves lower the surgeon's dexterity and tactile sensation. This paper is the first report of the attenuation characteristics of a novel radiation attenuating lotion, that can be applied in a manner similar to sun-block lotion. The results indicate that this lotion effectively reduces radiation exposure and does not affect dexterity and sensation.

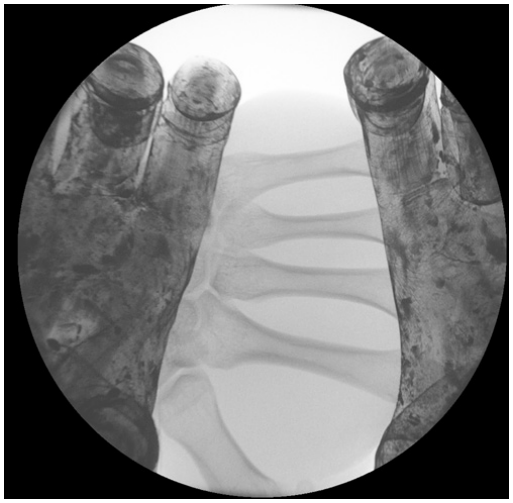
Image is for illustration only.

Methods

The lotion consists of an aqueous organic carrier and 75 weight % of bismuth oxide (Bi_2O_3) ceramic powder (Alfa Aesar, 99.99%). The organic carrier comprises lubricants, humectants and surfactants such as glycerin, glycol sterate and polyethylene glycol sterate, and emulsifiers such as glyceryl sterate. The ceramic powder was blended to make a lotion with a creamy texture qualitatively similar to hand lotions. Biocompatibility of the lotion and its constituent ceramic powder ingredient was assessed using ISO 10993 protocols.

Technical Summary

A standard C-arm fluoroscope was used to image cadaveric hands on a hand table, simulating an operative field configuration. Dosimeters measured direct radiation and scatter for 300 seconds at 53 kilovolts. The specific kilovolts used were calculated from the average of five cadaveric hands with the fluoroscope on an automatic setting. Dosimeters were implanted subcutaneously on the ipsilateral side or superficially on the contralateral side of each hand. Each configuration had five controls and five specimens with the attenuating lotion placed topically on the side nearest the source of radiation.



Results

Measured radiation exposure at the subcutaneous level and the contralateral side of the hand demonstrated that the lotion provided 81.5% and 63.7% attenuation (p-values of 0.00000006 and 0.0002) compared to bare cadaver hands. Measured scatter indicated no significant difference in radiation levels (p-values of 0.09 and 0.07).

Conclusion

This novel topical radiation attenuating lotion showed significant reduction in radiation exposure to hands. There was also no significant scatter, which is a key difference from previous glove designs for radiation protection. Use of this lotion may allow up to 5 times more radiation exposure before safety thresholds are reached.

Orthopaedic surgeons from the study group evaluated the texture and consistency of the product and concluded there was no impairment in tactile sensation. The lotion consists of a radio-contrast agent bismuth oxide and common ingredients found in hand lotions all of which were tested for safety, biocompatibility, skin irritation, skin sensitization, cytotoxicity, and acute and chronic systemic toxicities using well-established US FDA recognized standard ISO 10993 protocols. This lotion provides surgeons with a new and better option for radiation protection for their hands that can be applied in a sterile fashion prior to wearing surgical gloves and easily be washed off with soap and water.

Information provided by AAOS. Formatting and images provided by BLOXR.

For additional info, contact info@bloxr.com.