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Research

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Evaluation of platinum-catalyzed silicones for fabrication of biocompatible patient-specific elastic bolus

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Abstract

Purpose

We investigated the properties of platinum-catalyzed silicones with suitable characteristics for a biocompatible patient-specific elastic bolus.

Materials & Methods

We applied a platinum-catalyzed silicone (Ecoflex™ 0030) and a platinum cure liquid silicone (Dragon Skin™ 10 MEDIUM) to fabricate a biocompatible bolus using a mold and casting method with a 3D printer. We conducted physical evaluations including the shore hardness, cure time, transparency, and mixed viscosity. The dosimetric characteristics were basically investigated with surface dose and beam quality. For dosimetric evaluations using humanoid phantom, the dose differences between calculated dose and measured dose were compared with those of Dragon skin. To evaluate which boluses fit best, the volume of unwanted air gaps between the bolus and phantom was obtained from CT images. Biological evaluations were conducted on the skin sensitization, skin irritation, and cytotoxicity to ensure safe patient application.

Results

Ecoflex were biologically evaluated as safety materials. In addition, Ecoflex shows excellent physical properties with respect to a low shore hardness (00-30), short curing time (4 h), and low mixed viscosity (3,000). For the dosimetric properties using humanoid phantom, the average dose difference between the calculated dose and measured dose for Ecoflex is about 0.5% better than that of Dragon skin. In addition, a relatively smaller volume of unwanted air gaps for Ecoflex also showed than for Dragon skin, which these results tended to be the same

as the dosimetric results.

Conclusion

The physical properties of Ecoflex including excellent adhesive strength, lower shore hardness reduces unwanted air gaps and ensures an accurate dose distribution. Therefore, it is a suitable material for fabricating biocompatible patient-specific elastic bolus. It would be an alternative to other materials of bolus and thus improve the efficiency for clinical use.

Keywords

Bolus, Biocompatible, Patient specific, Ecoflex

Introduction

High-energy megavoltage (MV) photon beams are most widely used in external radiation therapy for tumor treatment because they can penetrate deeply into a site [1–3]. These high-energy MV photon beams have a build-up region at a certain depth below the surface where the maximum dose is delivered. Because a higher dose is deposited into the deeper tissues of this region than those of the surface, a skin-sparing effect occurs owing to the longitudinal disequilibria of the secondary electrons emitted by high-energy MV photon beams [4–6]. This effect is useful in that the dose delivered to the surface can be reduced when a deep tumor is treated. However, when a shallow tumor near the surface is treated, such a characteristic becomes a disadvantage. Accordingly, the bolus that builds up is directly applied to the surface of the patient to increase the surface dose [7–9]. In addition, the bolus improves the dose uniformity by compensating for missing tissues. Commercial bolus products are made of soft and rubbery tissue-equivalent materials and are sold as sheets. However, sheet boluses cause unwanted air gaps between the bolus and irregular skin. Butson *et al.* reported that for a 6-MV photon beam, 4 and 10 mm air gaps reduce the dose by 4% and 10%, respectively [10]. Anderson *et al.* investigated a customized bolus using paraffin wax to decrease unwanted air gaps in a standard bolus sheet [11]. Although a customized bolus was reported to show significantly lower complications than a standard sheet bolus, the use of paraffin wax may result in an irregular thickness. Next, the latest 3D printers have also been used in bolus fabrication. Park *et al.* developed the method for directly fabricating a customized bolus using a 3D printer instead of paraffin wax [12]. They reported that it fabricated with a 3D printer can replace an unwanted bolus and improve the dose distribution. However, because a bolus fabricated using a 3D printer comprises rigid materials, it is difficult to apply it to parts requiring flexibility. To overcome this problem, Park *et al.* recently developed a bolus using a mold and casting (M&C) method with a 3D printer, which

successfully overcomes the disadvantages of boluses developed through conventional methods. Among the various materials available, Dragon Skin™ 10 MEDIUM (Smooth-On, Easton, PA, USA) is the most useful for bolus using M&C method. Because Dragon Skin, a platinum cure liquid silicone, has a lower shore hardness and is thus more flexible than other materials, it causes fewer unwanted air gaps, requiring a shorter fabrication time, and achieves excellent biological characteristics. However, because this material has a high viscosity, it is extremely difficult to inject it into a mold and thus requires a long curing time. Consequently, it has a lengthy fabrication time overall. This disadvantage can be overcome using Ecoflex™ 0030 (Smooth-On, Easton, PA, USA), a recently commercialized material. Ecoflex, a platinum-catalyzed silicone, has a shore hardness of 30 (extra soft), which is considerably lower than 50A (Dragon Skin™ 10 MEDIUM). Moreover, the curing time is shorter, and thus the overall fabrication time can be reduced. Considering these advantages, in this study, the suitability of Ecoflex for the fabrication of boluses using the M&C method is evaluated. The physical, dosimetric and biological characteristics for Ecoflex were analyzed and compared with those of Dragon Skin, which is a good material for fabricating biocompatible patient-specific elastic (BPE) bolus.

Materials and methods

Fabrication of BPE bolus

This study compares the various properties of Ecoflex with those of Dragon Skin both of which are used as biocompatible materials. The BPE boluses were fabricated using the M&C method using 3D printer. Using computerized tomography (CT) images, the mold was designed after exportation using 3D Slicer software 4.10.2 (<https://www.slicer.org/>), an open-

source software package that converts a structure file into stereolithography. The material used for the bolus mold was Z-high-impact polystyrene (Z-HIPS, Zortrax, Olsztyn, Poland), with a thickness of 1 mm. Once the mold fabrication was completed, the casting materials were poured into the mold. Dragon Skin and Ecoflex were used as the casting materials. Both materials were composed of an essential material (Part A) and a hardening agent (Part B). Parts A and B were mixed at a 1:1 ratio and poured into the mold. The fabricated BPE boluses were then cured at room temperature (approximately 23°C) for the required curing time in a vacuum chamber of under 60 psi (4.1 atm) to remove air bubbles. The fabricated BPE boluses are shown in Figure 1.

Physical evaluations

Both Ecoflex and Dragon Skin are liquid silicone compounds. We designed $15 \times 15 \times 2 \text{ cm}^3$ cubic phantoms and determined the CT number through CT scanning. To evaluate the physical properties, the elongation at break, shore hardness, curing time, and tensile strength provided by the manufacturers were used. In addition, we prepared boluses of 3, 5 and 10 mm in thickness to measure the transparency for each bolus material. The transparency of each material was investigated through the measured absorbance within the visible region (400–800 nm) using the Eppendorf BioSpectrometer (Eppendorf, NY, USA). For each material, the effective atomic numbers (Z_{eff}) were obtained from the elemental analysis results using x-ray fluorescence (XRF). Elements can be identified using their characteristic XRF emissions (voltage, 60 kV; current, 170 mA), and the intensity of x-ray fluorescence is proportional to the concentrations of elements in the samples. Moreover, the effective ratios of the atomic number and atomic mass (Z/A), as well as the mass density for each material, were calculated under the depth scaling factor of the BPE.

Biological evaluations

As medical devices, materials using a bolus material must comply with the ISO standards to ensure the patient safety. We conducted cytotoxicity tests for Ecoflex and Dragon Skin in accordance with ISO 10993-5, Part 5 (testing for *in vitro* cytotoxicity). All experiments were approved by the Institutional Animal Care and Use Committee in Seoul National University Hospital (SNUH-IACUC) and animals were maintained in the facility accredited AAALAC International in accordance with Guide for the Care and Use of Laboratory Animals 8th edition, NRC (2010). The tetrazolium-based colorimetric assay (MTT method) [12] was used for the experimental evaluations. According to ISO 10993-10 (test for irritation and skin sensitization), skin irritation and sensitization tests are also necessary biological examinations for evaluating medical devices. The results of these tests, provided in the material safety data sheets published by each manufacturer, were used as references in this study.

Dosimetric evaluations

To apply the evaluation of dosimetric properties, we measured the CT numbers for each bolus. The surface dose and beam quality were obtained from a treatment planning system (TPS) (Eclipse TM, Varian Medical Systems, Palo Alto, USA) to evaluate the dosimetric effect of bolus. In the same way as described by Park et al., we evaluated cases with/without bolus depth scaling, in which the bolus thickness applied was 1 cm. The depth scaling factor was calculated through the following equation:

$$\frac{d_{bolus}}{d_{water}} = \frac{\rho_{bolus} \left(\frac{Z}{A} \right)_{bolus}}{\rho_{water} \left(\frac{Z}{A} \right)_{water}}$$

Here, ρ = mass density and $\left(\frac{Z}{A} \right) = f_1 \left(\frac{Z}{A} \right)_1 + f_2 \left(\frac{Z}{A} \right)_2 \cdots$, where f_i is the fractional weight of each element (denoted in subscript), and $\left(\frac{Z}{A} \right)_i$ represents the atomic number and atomic

mass. Next, the surface dose was also compared under a bolus. A high-energy MV photon beam (6, 10, and 15 MV) was used with a $10 \times 10 \text{ cm}^2$ open field and with a source surface distance (SSD) of 100 cm from the surface of water phantom in the TPS. Dose distributions for 100 monitor units (MU) with a grid size of 1 mm were calculated. Each beam was calibrated to deliver 1.0 cGy/MU at the maximum dose depth according to the American Association of Physicists in Medicine (AAPM) task group (TG) -51 protocol. Using the virtual bolus structure of TPS, the treatment for each area (i.e., nose, neck, and breast) was simulated. VMAT planning for each treatment was generated using 6 MV photon beams. The surface dose was calculated with a grid size of 1 mm using Acuros XB (v. 13.7, Varian Medical Systems). The differences between doses calculated under a virtual bolus in TPS and those measured on humanoid phantom surfaces with a fabricated bolus were investigated the effects of unwanted air gaps under the bolus. A humanoid phantom with fabricated all boluses scanned CT images to evaluate the volume of unwanted air gaps between the bolus and surface of phantom.

Results

Physical properties

Table 1 summarizes the physical properties of Ecoflex and Dragon Skin. Based on measurement, the average Hounsfield units (HU) for both materials were acquired as 120 and 161, respectively. Ecoflex shows a lower tensile strength and elongation at break than Dragon Skin. The shore hardness of Ecoflex, indicating the rigidity of the material, is lower than that of Dragon Skin. Therefore, Ecoflex is more flexible. This result means that Ecoflex can be better attached to irregular skin surfaces than Dragon Skin. Moreover, the mixed viscosity of

Ecoflex is approximately 1/7th that of Dragon Skin. In addition, Ecoflex showed approximately a 1 h shorter curing time, i.e., the time required for the material to harden, than that of Dragon Skin. The transparency of the boluses with different depth was obtained from measured absorbance. Figure 2 shows the picture of boluses with different thickness for average absorbance from 400 to 800 nm under normal room lighting conditions. Both materials tend to increase average absorbance as thickness increases. However, Ecoflex is more transparent, because it is lower in absorbance than the Dragon skin for the same thickness. With a thickness of 5 mm, Dragon skin is especially difficult to distinguish the surface.

The elemental compositions of these materials were obtained through XRF measurements. The compositions of both the materials were almost the same. Si accounted for the largest percentage (58.8%), followed by C (28.9%), H (7.3%), O (4.65%), Na (0.18%), K (0.06%), S (0.04%), Ca (0.02%), Al (0.03%), Fe (0.01%), Cu (0.01%), and Zn (<0.01%).

Biological properties

Table 2 shows the results of the MTT test on an extract of Ecoflex during a quantitative evaluation of the cytotoxicity. Here, 100%, 75%, 50%, 25%, and 12.5% extracts were applied in comparison with the blank test group. There was no cytotoxicity when considering the criterion of cytotoxicity (70%).

For Ecoflex, the manufacturer carried out a different test and showed no effect in terms of delayed dermal contact sensitization (details available at www.smooth-on.com). Consequently, like Dragon Skin, Ecoflex proved to be a biologically stable material suitable for fabricating boluses according to the skin sensitization, skin irritation, and cytotoxicity test results.

Dosimetric properties

Table 3 shows the relative water equivalence thickness by calculating the Dragon Skin and Ecoflex depth scaling factor. For the calculation of the depth scaling factor, the mass density and $\left(\frac{Z}{A}\right)$ of Ecoflex are 1.105 and 0.535, respectively. Dragon Skin and Ecoflex use a water equivalent at 0.921 cm and 0.940 cm per 1 cm, respectively. However, the thickness of the bolus was set to 0.9 cm for both materials. This is because the thickness can only be set to one decimal place in the TPS. Table 3 shows the calculated surface dose and the beam quality at the water phantom with/without depth scaling factors for 6, 10 and 15 MV. The surface doses under Dragon Skin and Ecoflex were 98.8 and 98.6 cGy for the 6 MV photon beam, respectively. In addition, the beam qualities ($D_{10\text{ cm}}$) were 66.0% and 66.1% for Dragon Skin and Ecoflex, respectively. Even when calculating the surface dose with the depth scaling factor applied, the difference in the surface dose and beam quality between the materials under the bolus was not significantly different independent on energies. These results indicate that the two materials have mostly similar dosimetric properties.

The effect of the unwanted air gap under the bolus was investigated by measuring the surface dose of the humanoid phantom with a fabricated bolus. Figure 3 (a) shows the percentage of difference between the calculated and measured doses for the fabricated bolus. For the Dragon Skin bolus, the differences in the nose, neck and breast areas were not significant at $-2.55 \pm 1.15\%$, $-2.93 \pm 0.18\%$, and $-2.81 \pm 0.37\%$, respectively. Ecoflex showed differences in the nose, neck, and breast areas of $-2.43 \pm 1.08\%$, $-1.95 \pm 0.14\%$ and $-2.46 \pm 0.37\%$, respectively. Negative values with respect to the differences in dose indicate that unwanted air gaps underestimate the dose measurements. As shown in Figure 3 (b), the volume of unwanted air gaps between the bolus and surface of phantom was calculated based on CT images. The smallest air volume was observed in Ecoflex for all areas owing to the low shore hardness.

This means that Ecoflex adhered closer to the surface of phantom as compared to the Dragon Skin bolus, as shown in Figure 4. In nose, neck and breast, the volume of unwanted airgap for Ecoflex and Dragon Skin were 10.9, 9.1, 49.7 cm³ and 11.5, 14.9, 70.1 cm³, respectively. These results tended to be the same as the dosimetric results.

Discussions

In this study, we evaluated the physical, biological, and dosimetric characteristics of boluses fabricated using Ecoflex and Dragon Skin. Both types of BPE bolus samples showed nontoxicity, good flexibility, and good durability, and could be easily fabricated. The M&C method using only a 3D printer is no longer the latest approach for fabricating BPE boluses. Canters et al. fabricated a bolus using a 3D printed mold and filled it with silicone rubber [13]. The researchers designed a fabricated bolus using a 3D printer based on the M&C method to treat non-melanoma skin cancer with an electron beam and investigated a new clinical workflow. They concluded that the workflow implemented using this technique achieves an enhanced efficiency. Furthermore, this technique also improves the dose coverage compared to fabricating a bolus manually. However, the study by Canters et al. lacked information on the physical, biological, and dosimetric stability of the silicone rubber used. A bolus is usually attached to the surface, and the duration of the bolus attachment is not long because it is used only during treatment. Therefore, it is applied without consideration of the biological parameters such as the cytotoxicity. In addition, no studies have reported a skin toxicity attributable to the application of a bolus. Nevertheless, only biologically stable bolus materials should be considered for patients with sensitive skin or skin wounds, or for internal installations. In this respect, Park *et al.* successfully developed a BPE bolus using Dragon

Skin, which is a biologically stable material [12]. In addition to biological stability, Dragon Skin has desirable physical properties such as a low shore hardness and short curing time, which are beneficial for bolus fabrication. Dragon Skin was therefore proposed as a suitable bolus material. However, Dragon Skin has a relatively high mixed viscosity, which is a more significant disadvantage in the M&C method. When a bolus material with a high viscosity is cast in a thin mold (less than 5 mm in thickness), it becomes difficult to inject the material into deep parts of a mold. Ecoflex is a perfect solution to this problem. Because Ecoflex has a low viscosity, it can easily fill in curved parts of a mold, leaving no empty spaces. Furthermore, compared to Dragon Skin, Ecoflex has a lower shore hardness and higher flexibility and is thus more suitable for attachment to irregular skin surfaces. The short curing time of Ecoflex also improves the efficiency of the bolus fabrication in terms of time. The results obtained thus far reveal that an Ecoflex BPE bolus material is a reasonable alternative to Dragon Skin and its physical properties alone can improve the efficiency of radiation therapy and BPE bolus fabrication; however, Ecoflex is not significantly more advantageous than Dragon Skin in terms of its biological and dosimetric properties. If a more suitable material for bolus fabrication is developed in the future, further studies will be necessary to evaluate the properties of this developed material as a replacement for Ecoflex.

Finally, a clinical quality assurance (QA) program needs to be considered as an essential step in fabricating 3D-printed BPE boluses, and such a QA program is necessary to ensure confidence when using such materials. Robar *et al.* recently reported a method of inserting dosimeters at multiple points on the skin-side surface of a bolus as a QA dose measure for evaluating 3D printed boluses [14]. In addition, Leng *et al.* proposed a comprehensive QA program for medical 3D printing applications [15]. In addition, an efficient QA program based on the geometrical accuracy was developed for ensuring accurate clinical usage of BPE

boluses. An *et al.* reported that the developed QA method was evaluated by the average distance between the fabricated BPE bolus and the planned bolus structure from TPS [16]. The average difference in distance is less than 1 mm, the absolute difference is less than ± 2 mm. As dosimetric characteristics still require additional verification, therefore, it will be performed in further studies.

Conclusion

We evaluated the physical, biological, and dosimetric properties of Ecoflex, a platinum-catalyzed silicone that can replace Dragon Skin. Because Ecoflex has a lower shore hardness and shorter curing time than Dragon Skin, it can improve the efficiency of both radiation therapy and bolus fabrication. In addition, clinical applicability of Ecoflex was verified by passing all biological tests. As a result, the bolus fabricated using Ecoflex was found to be the most effective and suitable from a clinical perspective. Furthermore, the excellent adhesive strength of Ecoflex reduces unwanted air gaps and ensures an accurate dose distribution.

List of abbreviations

BPE, biocompatible patient-specific elastic; MV, megavoltage; CT, computerized tomography; Z-HIPS, Z-high-impact polystyrene; XRF, x-ray fluorescence; TPS, treatment planning system; SSD, source surface distance; MU, monitor units; AAPM, American Association of Physicists in medicine; HU, Hounsfield units; QA, quality assurance

Declarations

Acknowledgment

Not applicable

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Availability of the data and materials

All data generated or analyzed during the current study are available from the corresponding author upon reasonable request.

Author contributions

JK conceived of the concept of the study and participated in all aspects of its design and coordination. HGW participated in the design of the study from a clinical perspective and oversaw its completion. SJ and JMP analyzed the physical and dosimetric data. JS drafted the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

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Figures

Figure 1. BPE boluses fabricated using (a) Dragon skin and (b) Ecoflex.

Figure 2. (a) Average absorbance with difference thickness for both boluses, (b) Actual images of 3, 5, and 10 mm boluses in thickness to show the transparency for each material.

Figure 3. (a) The results of percentage difference between calculated and measured under each bolus, (b) The volume of unwanted air gap between the BPE bolus and humanoid phantom calculated with CT images.

Figure 4. Volume of unwanted air gap with CT images for three regions: (a) nose, (b) neck, and (c) breast.

Table 1. Physical characteristics of Dragon Skin and Ecoflex.

Physical properties	Dragon Skin	Ecoflex
Mass density (g cc⁻¹)	1.131	1.105
Effective atomic number (Z_{eff})	12.03	11.66
Effective ratio of atomic number to atomic mass (Z/A)	0.533	0.535
Tensile strength (psi)	475	200
Elongation at break (%)	1000	900
Shore hardness	10 A (Soft)	00-30 (Extra soft)
Mixed viscosity (CPS)	23,000	3,000
Curing time	5 h	4 h

Table 2. Cytotoxicity results from MTT test on Ecoflex extract.

Group	Treated Time (h)	Test item	Concentration (% (v/v), in media)	Survival Rate (%)
Blank	24	MEM*	0.593 ± 0.011	100.00
Negative	24	HDPE*	0.495 ± 0.007	83.46
Treatment	24	Ecoflex 0030	0.585 ± 0.015	98.65
			0.600 ± 0.015	101.31
			0.595 ± 0.019	100.38
			0.604 ± 0.017	101.94
			0.618 ± 0.025	104.22
Positive Control	24	0.25% ZDBC*	0.058 ± 0.009	9.83
			0.297 ± 0.028	50.08

* MEM (*Minimum Essential Medium*): 5 mL

* HDPE (*High-density polyethylene*)

* ZDBC (*Zinc Dibuthyldithiocarbamate*)

Table 3. Surface dose and beam quality at the water phantom with/without depth scaling factor.

Depth scaling	Bolus	Depth scaling factor	Dose (cGy) at water surface					
			6 MV		10 MV		15 MV	
			Surface	D _{10 cm}	Surface	D _{10 cm}	Surface	D _{10 cm}
			dose (cGy)	(%)	dose (cGy)	(%)	dose (cGy)	(%)
No	Water	-	98.4	66.6	88.8	73.8	84.6	76.9
	Dragon Skin	-	98.8	66.0	89.5	73.4	85.4	76.5
	Ecoflex	-	98.6	66.1	89.0	73.5	84.8	76.6
Yes	Dragon Skin	0.921	97.9	66.5	87.6	73.8	83.2	76.9
	Ecoflex	0.940	97.6	66.6	87.1	73.9	82.6	77.0

Figures

(a) **Dragon Skin**

(b) **Ecoflex**

Figure 1

BPE boluses fabricated using (a) Dragon skin and (b) Ecoflex.

(a)

(b)

Figure 2

(a) Average absorbance with difference thickness for both boluses, (b) Actual images of 3, 5, and 10 mm boluses in thickness to show the transparency for each material.

(a)

(b)

Figure 3

(a) The results of percentage difference between calculated and measured under each bolus, (b) The volume of unwanted air gap between the BPE bolus and humanoid phantom calculated with CT images.

Dragon
Skin

Ecoflex

(a) Nose

(b) Neck

(c) Breast

Figure 4

Volume of unwanted air gap with CT images for three regions: (a) nose, (b) neck, and (c) breast.