DRUG AUTHENTICATION USING HIGH CAPACITY AND ERROR-CORRECTABLE ENCODED MICROTAGGANTS

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ABSTRACT

We describe an encoded polymer microtaggant patterned with Quick Response (QR) code that provides high capacity and error-correctable encoding for drug authentication. The QR-coded microtaggant is lithographically fabricated with a single exposure to patterned UV light in a microfluidic channel. Its advanced functions capable of high capacity and error correction enables not only authentication of the drug but also tracking its information such as manufacturer and expiry date, which are included in individual unit-of-dose form of drugs. A complete process of drug authentication from the formulation of the QR-coded microtaggant-equipped capsule to the decoding step using a QR code reader application on a smartphone is successfully demonstrated.

KEYWORDS

Anti-counterfeiting, Microtaggant, QR code, High capacity encoding, Error-correctable encoding.

INTRODUCTION

A microtaggant is a microscopic and traceable particle added to materials or products for authentication. The use of microtaggant is a powerful authentication method because the microscale physical identifiers in materials or unit product cannot be easily copied and replaced with counterfeits, while current packaging-oriented authentication such as printed marks and optical tags are suffering from imitations. The incorporation of microtaggants in an individual unit-of-dose drug has been introduced as a superior on-dose authentication (ODA) technology for the anti-counterfeiting of drugs.[1] By including in an individual tablet or capsule during the drug formulation process, they can be used for the authentication and identification of the drug.

Storing information or data on the microtaggant is a crucial factor in providing the multi-functionality needed for the identification and track-and-trace monitoring of drugs as well as authentication. Recently, polymer microbeads and microfibers have been utilized as microtaggants with a conventional graphical code in the form of an one-dimensional (1D) barcode or letters to specify certain drug information.[2,3] However, the conventional code scheme on the microtaggant can only provide limited features for drug authentication. The data capacity may be insufficient for supporting a large amount of drug information related to the product (ingredients, expiration date), manufacture (date, batch and lot number), and distribution (distributors, wholesalers) because only short text strings or a simple barcode can be printed on the microtaggant surface. In addition, restoring data from damaged code by physical compression during the formulation process of drug tablet or capsule is impossible because the simple graphical encoding scheme of 1D barcode has no corresponding error correction algorithm.

QR code is a 2D matrix code that contains information in vertical and horizontal directions, can hold greater volume of information than that of 1D barcode. In addition, it provides error correction feature that can restore data from a partially damaged code. These features of QR code are suitable for the encoding scheme on the microtaggant with a high-level authentication capability.

In this paper, we propose a QR-coded microtaggant which can provide high capacity and error correction capability for drug authentication. (Fig. 1) QR-coded microtaggant is lithographically fabricated with a single exposure to patterned UV light in a microfluidic channel. Additionally, we investigate UV propagation characteristics in the fabrication process of the QR-coded microtaggant. High capacity, error correction feature and a complete process of drug authentication with the QR-coded microtaggant are successfully demonstrated.

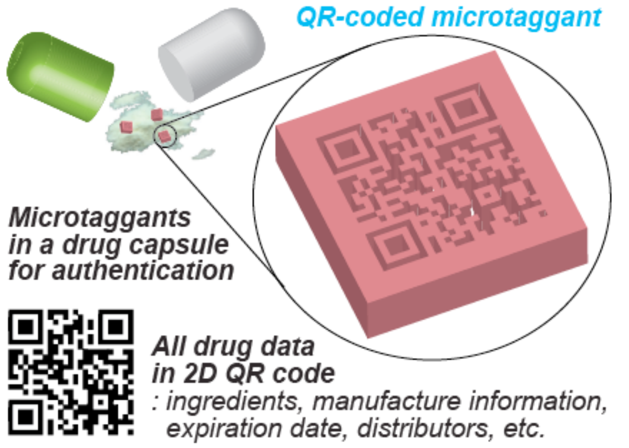

Figure 1. *A conceptual illustration of QR-coded microtaggant in a drug capsule for authentication. High capacity and error-correctable 2D matrix QR code can store and restore a large amount of drug information.*

EXPERIMENT

In order to produce QR-coded polymer microtaggant, we used optofluidic maskless lithography system (OFML) [4] composed of a microfluidic device and an a phtotolithography system. In the microfluidic channel, QR-coded microtaggants were fabricated by photopolymerization of polymer solution (poly(ethylene glycol) diacrylate, PEG-DA) through the single exposure of patterned UV light. Fluorescent acrylic monomer (methacryloxyethyl

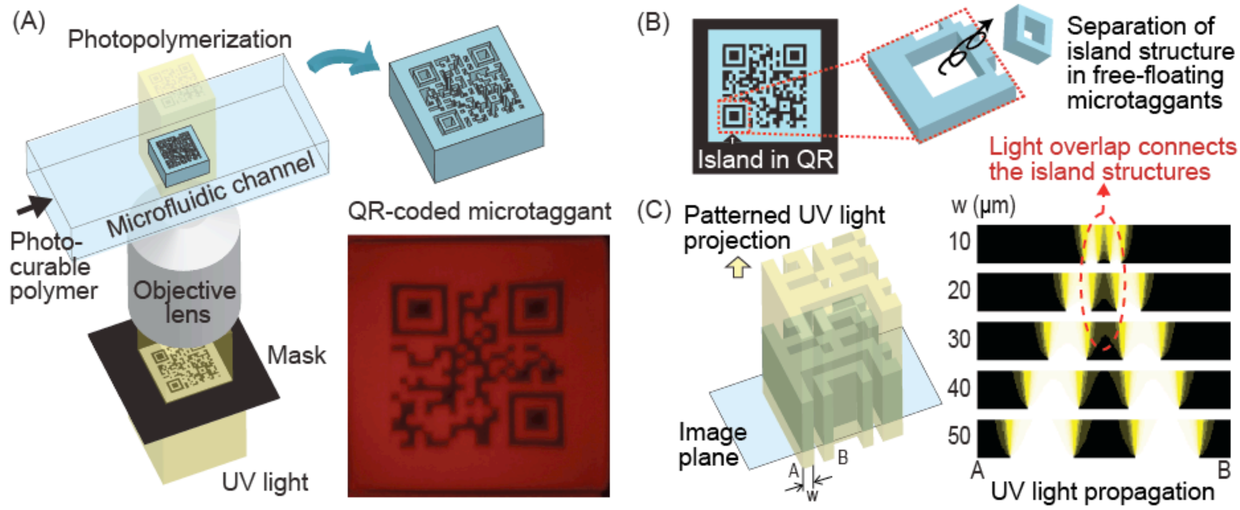

Figure 2. *(A) Fabrication of QR-coded microtaggants using OFML system based on projection lithography. (B) Island separation in free-floating form of microtaggant. (C) Simulation of patterned UV light propagation in a microfluidic channel. Light overlap between neighboring patterns connects the island structures.*

thiocarbamoyl rhodamine B) was mixed with polymer solution to give vivid color clearly distinguished from background to the QR code pattern. (Fig. 2A) Intrinsically, QR code has island patterns to be separated from the body part when it is fabricated lithographically as free-floating form. (Fig. 2B) In our projection lithography system, the projected UV light pattern propagates along the vertical direction and spreads horizontally when the image plane is focused on the bottom of the channel. (Fig. 2C) This phenomenon results in a light overlap area far from the image plane.[5] The characteristic of UV light propagation inside a microfluidic channel was investigated with respect to the unit pattern width under the assumption of the objective lens that has a magnification of 10× and a numerical aperture of 0.3. Based on this investigation, we fabricated a microtaggant without the undesired escape of the island structure by adjusting the width of unit pattern and the height of the microfluidic channel.

RESULTS AND DISCUSSION

The data encoding capacity of QR code is essentially determined by its version, error correction level. Versions of QR code are available from 1 to 40 and a greater number implies a higher encoding capacity. The error correction level is selected with reference to the degree of data recovery required, because raising the error correction level decreases the data encoding capacity. Two different versions (7, 10) of QR-coded microtaggants were fabricated with the maximum error correction level. (Fig. 3A) Each version contains 93 and 174 characters respectively. We assumed that a data capacity greater than 93 characters (version 7) would be sufficient to store approximately 5 items of drug information, such as the product name, manufacturer, date of production and expiration, and webpage links.

Four types of error correction levels (L, M, Q, H) were available in the QR code. Each level could restore errors of up to 7%, 15%, 20%, and 30% in the data area, respectively. In order to investigate how the error correction capability of QR code provides damage resistance to the microtaggant, we intentionally damaged QR-coded

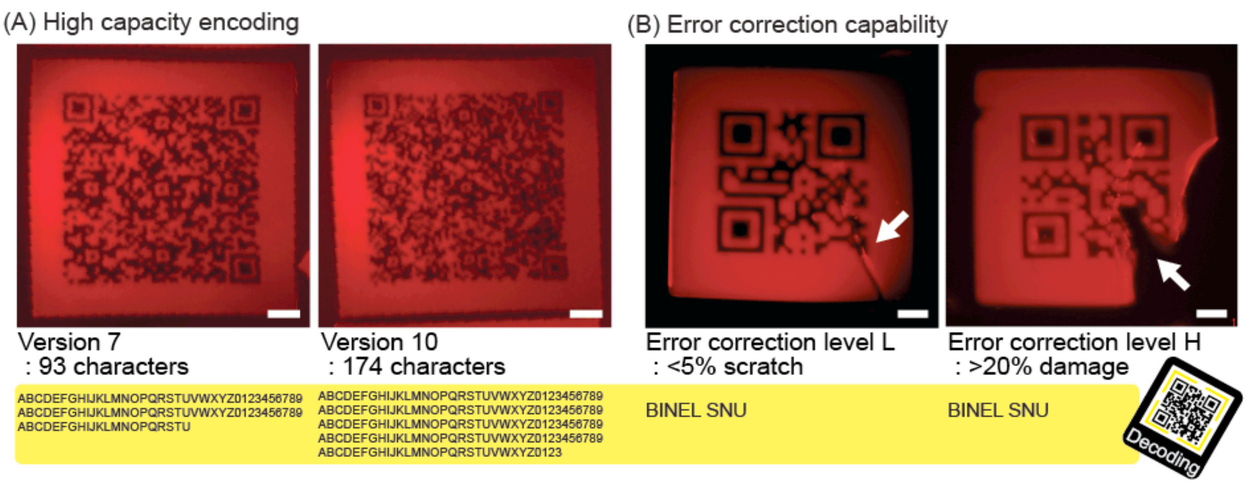

Figure 3. *The advanced features of QR-coded microtaggant. (A) High capacity encoding on the QR-coded microtaggant. For QR code version 7 and 10, 93 and 174 characters are stored respectively. (B) Error correction capability. About 5% and 20% damage are restored without data loss in error correction level L and H respectively. (Scale bar: 50 μm)*

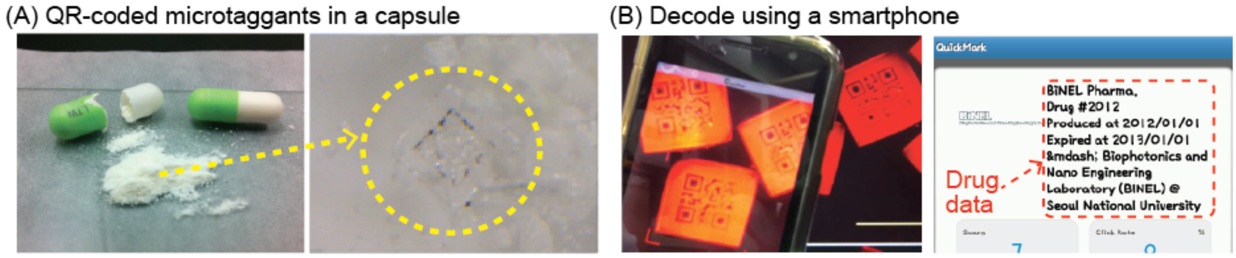

Figure 4. The complete drug authentication process. (A) The microtaggants in the capsule is founded by opening the capsule. After dissolving drug powder in water, (B) the code is read by a QR code reader application on a smartphone. The drug information such as product name, manufacturer and expiry date is retrieved for the code. (Scale bar: 50 μm)

microtaggants and read them. (Fig. 3B) At level L, code having less than 5% of the data area scratched was decoded, and approximately 20% damage to the data area was successfully restored at level H. The feature of data restorability following physical damage to the code could give microtaggants a powerful advantage, because of the high possibility of physical damage when they are incorporated in the capsule formulation process.

To verify the applicability of QR-coded microtaggants to anti-counterfeiting of drug, we formulated a drug capsule with microtaggants encoding some drug information and demonstrated the authentication process. First, we opened the capsule and found the microtaggants using a microscope. (Fig. 4A) Then, we dissolved the drug powder in pure water, because it disturbed the recognition of the code. The washed microtaggant was observed under a fluorescence microscope and was decoded successfully by reading the microscope image using the QR code reader application of a smartphone. (Fig. 4B) The drug capsule was authenticated and the information about the drug was retrieved from the QR code on the microtaggant. Furthermore, because QR code is read by a smartphone, it is possible to retrieve more information by directly connecting to the webpages linked in QR code.

CONCLUSION

In conclusion, we proposed a functionally advanced microtaggant suitable for anti-counterfeiting of drugs by lithographically patterning 2D type QR code. QR-coded polymer microtaggant would expand functionality of microtaggants for advanced ODA method and could be widely used in as a highly powerful ODA method.

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