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Designing innovative medical packaging to improve medication adherence

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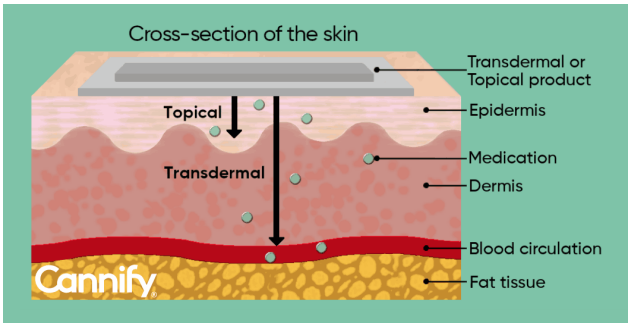
Abstract

Over the past 70 years, innovative medical packaging has led to the creation of various functional medical packaging based on effective drug administration and patient comfort from transdermals to injectors. In another progression for medical packages and in an effort to help seniors, children and those challenged by cognitive, physical or functional impairment to take their medication promptly and safely, compliance prompting packaging such as calendar packs was introduced with great success. However, addictive drugs such as opioids have proven to be a challenge as evidenced by the opioid crisis and government regulatory bodies such as the FDA have encouraged parties involved in pharmaceutical packaging to come up with innovative medical packaging designs to combat drug abuse and addiction. These have led to various innovative packages. Amongst them, blister packs have proven to be the most conducive to innovation and they are an important part of the market as they help patients follow drug regimens, protect drugs over a long shelf life and are portable. This has led to intelligent blister packs that can store the time and date of dosage removal from the package. This paper aims to look at the various medical packaging products that are in the market, give an overview of how blister packs are manufactured and why they have become the main form of medical packaging to be improved upon in recent years and offer further improvements that can be explored. Such packaging would ensure the patient is taking the right medication at the right time and complying with the medication regimen. In addition to the research value of this work, students working on this project would be inspired by the applicability of STEM to different aspects of life and it would fortify the skills of the participating students. Some of the work carried out to date and the applicability of elements of the work for lecture and lab material in various courses in the Mechanical Engineering Technology program at Farmingdale State College will be outlined.

Introduction

One of the main topics of discussion and concern currently in the healthcare and pharmaceutical industries as well as government regulatory bodies such as the FDA is to advance the use of compliance-prompting packaging to improve medication adherence, patient safety and patient health outcomes. The healthcare compliance packaging council (HCPO) [1] lists a variety of functional medical packaging innovations such as transdermals (used for nicotine, fentanyl, morphine, birth control, etc.), auto-injector and injector pens (used for insulin), inhalers (used for bronchitis or asthma).

(a)



(b)

(c)

Figure 1: Functional Medical Packaging (a) Transdermals (b) Auto-injectors (c) Inhalers

Compliance prompting packaging has offered patients and caregivers the visual confirmation of daily dosage that has been taken, a reminder of the disease being treated and a reminder of why the drug is important. While all of these are passive features, they are critical communication. Data collected by the HCPO shows that such packaging leads to greater compliance amongst patients.

Figure 2: Compliance Prompting Medical Packaging: Blister pack with calendarized dosing format

However, addictive drugs such as opioids have proven to be a challenge and the opioid epidemic has taken millions of lives and cost billions of dollars. As a result, the FDA has requested parties involved in the manufacture and distribution of controlled medications to "use, repurpose or enhance existing options and develop new options to prevent/deter, detect/track, or monitor/manage the targeted behavior(s)" [2]. The FDA has recommended parties involved in the manufacture and distribution of controlled medications look into extending or combining the following technologies to accomplish their goals [2]: Calendar/blister packaging, limited supply packaging, controlled access systems, tamper detecting/resistant packaging, deactivation/disposal options, medication adherence support systems, using abuse deterrent formulations of controlled medications, recording and reporting devices and automatic pill dispensers.

Current Products and Innovations

Amongst the most active companies in medication adherence is Information Mediary Corp. (IMC) [3]. The company has come up with both medication adherence hardware as well as software. Chief amongst these products is the Med-ic Intelligent Blister Package. The patented Electronic Compliance Monitor (ECM) incorporated into the blister package stores the date and time each unit dose is removed. The package also has on-board thermal sensing and tracking for temperature sensitive medication.

Figure 3: Med-ic Intelligent Blister Package

The blister package format allows for the space required to include graphics as well as the onboard electronics. The sophisticated packaging surrounds the blister and is covered with cardboard, which is very suitable for the printed electronics to detect each does being taken from the package while hiding the sophisticated circuitry inside the structure. The patented onboard Electronic Compliance Monitor (ECM) has a CPU and is attached to a printed sensor grid. The data is stored for later display and analysis. IMC also has the CertiScan Medication Adherence Platform. When refilling the prescription at a pharmacy or at the next doctor visit, the patient compliance data can be downloaded using the CertiScan RFID reader or any NFC-enabled smart-phone or tablet.

The company also has smart bottle caps, called eCap, which implements the novel concept of tracking and storing each bottle opening onboard the ECM which can then be accessed through the CertiScan platform.

IMC has also developed the med-ic syringe pack which tracks the real time usage and temperature history of pre-filled syringes for self-injection. The device records the date, time and syringe dose location.

As can be seen, the main form of packaging that has been innovated and improved upon has been the blister pack. Therefore, it would be worthwhile to look further into the fabrication of this form of medical packaging.

Blister Pack Fabrication

Blister packs were given a great boost in the mid-1960s as pharmaceutical companies realized its value as it offered patients a clearly marked individual dosage, protected the remaining doses in the original packaging against external conditions, were tamper-evident. Blister packs also meant no broken glass bottles on the production line, reduced cost and higher packaging rate [4].

As [4] indicates, the four basic components of a pharmaceutical blister package are the forming film, the lidding material, the heat-seal coating and the printing ink. In this conventional blister pack (Figure 4), the pill can just be pushed through the lidding material.

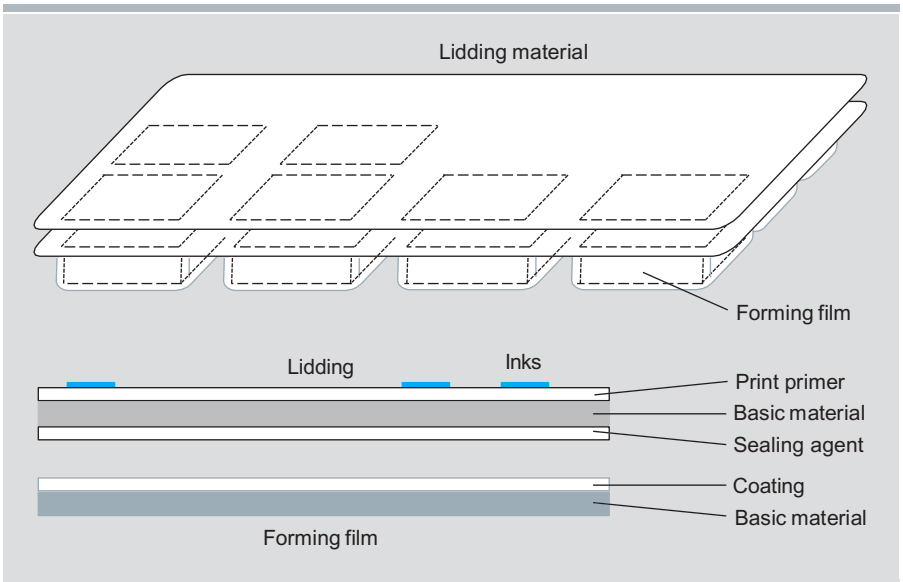


Figure 4: Basic components of blister packaging

In peel off-push through blister packs such as the one shown in Figure 5, access to medicine is restricted by requiring both actions. The main difference between Figure 4 and 5 is the modified lidding with additional layers mainly another adhesive and a new foil layer. The added adhesive

in this configuration means that the top layer can be peeled-off which then reveals the foil that can be pushed through to access the pill. This is classified as tamper-resistant.

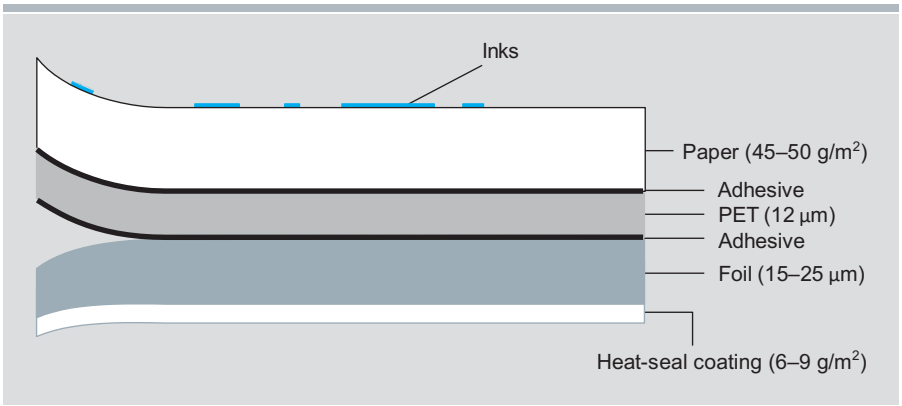


Figure 5: Cross section of a peel off-push through lidding material

As [5] mentions, the general assembly of the blister package (Figure 6) involves heating the plastic, thermoforming it into blister cavities, loading the blister with the product, placing the lidding material over the blister and finally heat sealing the package.

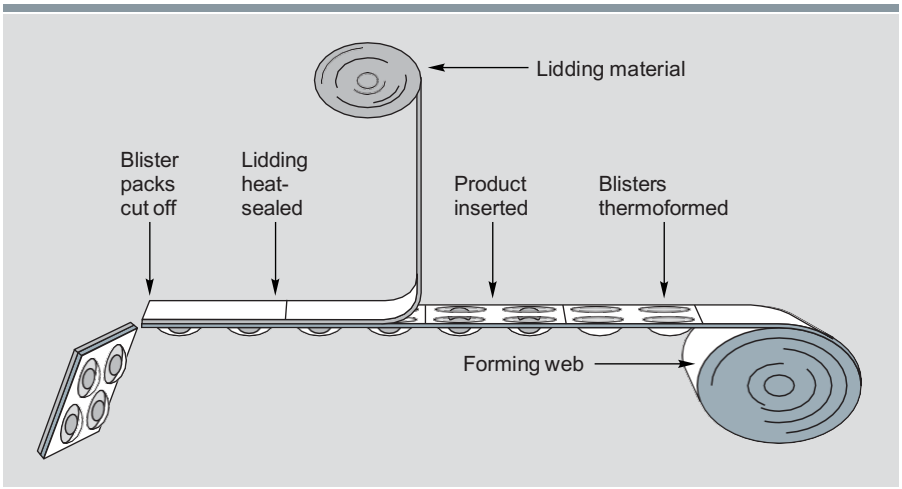


Figure 6: A typical procedure for blister packaging assembly

Possible Improvements

The main area where access can be restricted is in the lidding sandwich which is open to further exploration and research. This could involve circuitry that does not merely record date and

time each unit dose is removed as with the Med-ic Intelligent Blister Package, but one that actually electronically opens each initially locked blister pack cell at a set time and date for the number of days the medicine is prescribed. The system could involve feedback to the pharmacist/doctor as to the state of the blister package if the patient tries to tamper with it and tries to gain unauthorized access to the medicine.

Project Progress to Date and Relevance to Engineering Education

1. **Electronics**

In terms of electronics this project is to be carried out in two parts. First to create a functional circuit for the remote opening and closing of the blister pack cell and second to miniaturize the system to the blister pack level.

At the current stage, the students are using their knowledge from electronics and computer application courses to complete the circuitry and coding needed to open/close a gate mimicking that of a blister pack cell. This is a lab that is being considered for addition to a new Mechatronics course being introduced in the Mechanical Engineering Technology program at Farmingdale State College once we can successfully complete it in our research. An Arduino microcontroller in conjunction with a CNC shield is being programmed to run stepper motors that drive the gate function.

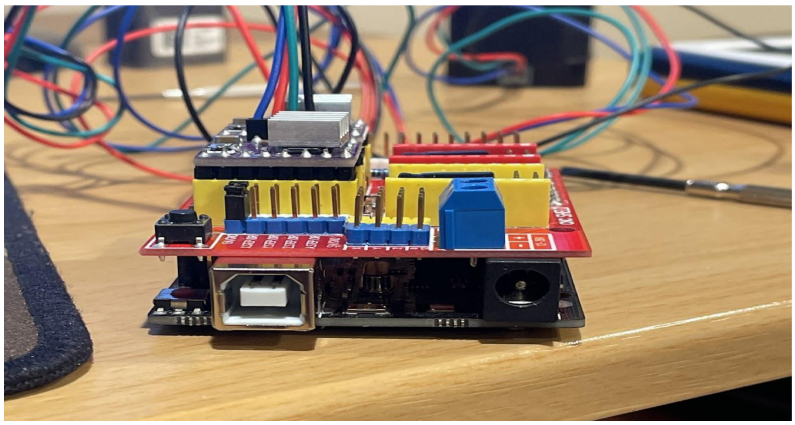


Figure 7: CNC shield mated to Arduino Microcontroller

Another element of the project is how to remotely signal the Arduino to open/close the gate. The current focus is to use an inexpensive IR sensor connected to the Arduino operated with a remote control. This would be another lab in the Mechatronics course.

Miniaturizing onto a blister pack would require Printed Circuit Board (PCB) design. Our students have the option of passing a course in Electronic Packaging although currently software such as Altium that is used for PCB design is not covered in that course. This project would be a trial run of how effectively we can integrate Altium into our Electronic Packaging course and what type of reception it would get from the students. It is not anticipated that the PCB design for a simple gate function would be particularly complex and as such I anticipate that the work done in this project could be added as a series of labs using Altium to our Electronic Packaging course.

2. Material Testing

Material testing particularly as it relates to Pressure-Sensitive Adhesives (PSAs) is another focus of this project. Pressure sensitive adhesives are a key peeling component in current blister packs. The circuitry sandwiched in the lidding material will have to deal with the peel-off of PSAs without the actual electronic gates breaking in the process. Therefore, Peel adhesion testing of PSAs with and without the circuitry is required. Instron, [6], describes ASTM D3330 as such "The ASTM D3330 is a major peel testing standard used to determine the peel adhesion properties of PSAs. It includes 6 different test methods encompassing many different specimen types." We are currently in the process of acquiring the testing setup outlined in Figure 8.

Our current Quality Control and Material Testing courses do not incorporate any lecture or lab content relating to adhesives in general. It is anticipated that acquiring this system and testing PSAs as part of this project will allow us to explore the feasibility of adding content relating to these materials to our courses and design labs which use the Instron setup for adhesion testing.

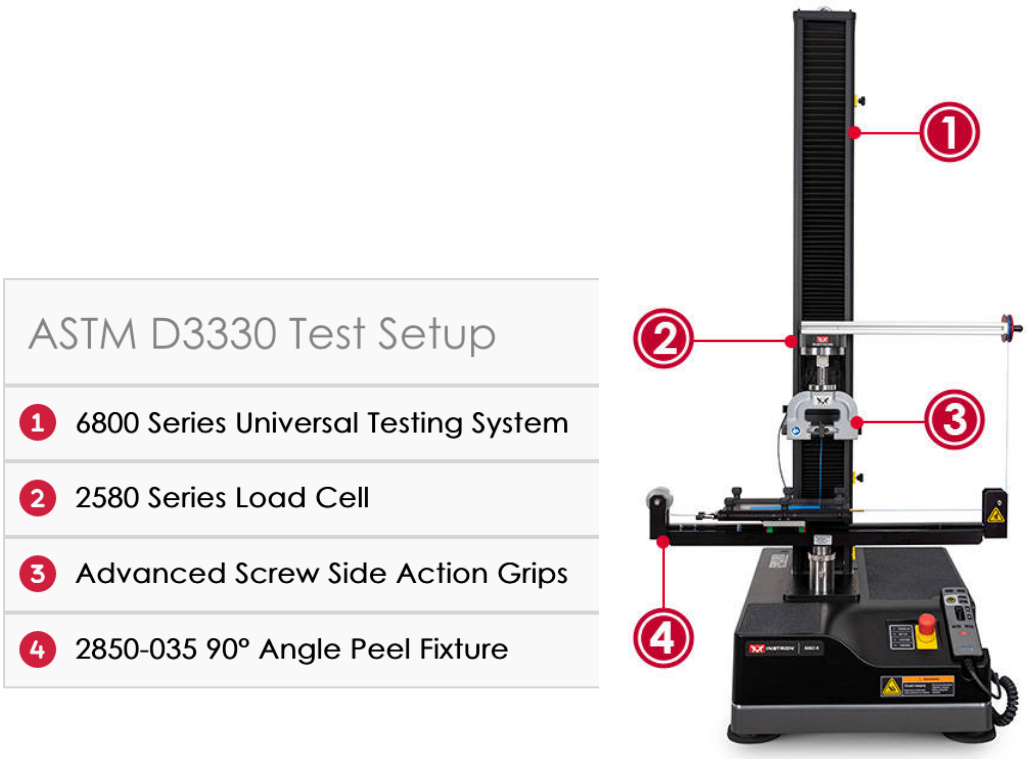


Figure 8: ASTM D3330 Test Setup [6]

Conclusion

The medical packaging industry has undergone transformational change over the past 70 years. The industry has tried to innovate new packaging formats in order to reduce costs, increase patient convenience and compliance as well as follow government regulations. This has become more acute with the advent of the opioid crisis. Blister packs have become one of the main formats of out-patient drug delivery and thus courted the attention of companies to improve upon. At the forefront of this transformation has been the Information Mediary Corp. with its Med-ic Intelligent Blister Package. While innovative, the device only records date and time of each dosage removal. STEM principles especially electronics can be utilized to further restrict access to the medicine by designing circuitry that controls the opening of each blister pack cell individually using a preset coding of time and date fed to the microcontroller onboard at the time of medicine prescription.

In addition to the research value of this project, the educational value is immense. This project allows us to trial new labs and software for use in various courses from electronic packaging to quality control and material testing within the Mechanical Engineering Technology program at Farmingdale State College.

References

[1] https://www.hcpconline.org/

[2] https://www.fda.gov/media/109526/download

[3] https://www.informationmediary.com/medication-adherence-ai-big-data/

[4] Pilchik, R. Pharmaceutical blister packaging, Part I. *Pharm. Technol.* **24**, 68 (2000)

[5] Pilchik, R. Pharmaceutical blister packaging, part II: Machinery and assembly. *Pharm. Technol.* **24**, 56–60 (2000).

[6] https://www.instron.com/en-us/testing-solutions/astm-standards/astm-d3330?utm_source=yt