Innovation for Biomedical Waste Disposal by Using Inner Ostomy Bag as a Case Study

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ABSTRACT

This new product, made from biodegradable materials, was developed as a liquid container to be used as an inner ostomy bag. Because it is biodegradable it can be flushed down a toilet after use and decomposes naturally. This invention can therefore reduce inefficient disposal steps for biomedical waste, control the spread of germs, and reduce operating costs. A solution with pH in the range of 4-8 was prepared for 1000 mL in distilled water and the desired pH was adjusted by using HCl and NaOH. This solution was then poured into the inner ostomy bag and hung at room temperature for ten days to monitor its capacity and check for any leakage of water. Results of this test showed that the bag began leaking on the sixth day as the solution gradually seeped out. Later in the test, colored spots of mold and an odor began to occur on the eighth day. The bag became soft, but was still sturdy and able to withstand scratches or movement without tearing. The material was able to withstand various pH levels during actual usage for a long period of time. It did not leak during the test and could degrade, indicating that this material could be suitable for the production of other biomedical supplies. It could contribute directly and effectively to the quality of life of patients around the world and reduce environmental problems that are currently at issue.

Keywords: Ostomy, biomedical waste, disposal, ostomy bag.

1. INTRODUCTION

Management of biomedical supplies has become a major issue and is gaining world-wide attention. Inefficient management of biomedical supplies has become one of the world's biggest environmental problems; surpassing the danger caused by nuclear weapons and radiation. It affects all life on Earth.

We are in an aging society where cancer treatment requires radiation therapy. It is estimated that there are probably more than 23 million cancer patients world-wide each year (Repić and Ivanović, 2014), with colon cancer being 1 of the 5 most common

cancer cases in Thailand (Office, 2018a) with an estimated 3,000 - 5,000 people per year. Approximately 3,000 people die from colon cancer each year, which has been attributed to cancer-causing foods such as those containing high-sodium or foods high in trans fats.

We make use of biomedical materials to ease the lives of patients and the elderly. Waste absorbent diapers, devices for catheter feeding, and implant bags are just a few. These biomedical supplies must be clean to ensure there are no issues with hygiene. These materials are usually disposable and eventually become waste. This accumulated waste, inevitably has an environmental impact. Therefore we require an environmentally friendly method of disposal. Datta et al. (2018)

The management of biomedical supplies faces many challenges. If we take the use of an artificial fistula device as a case study, a large number of patients use an implant bag around the world. In the United States, the number of prosthetics is over 1 million (Ostomy, 2020) and increases annually by over 100,000 people. In Thailand there are more than 54,000 prosthetics patients (Office, 2018c). In the year 2019 (Office, 2018a) the Board of the National Health Security Office added the Colostomy Bag as a device and prosthesis. This is necessary and gives patients more access to essential services.

This high number of patients inevitably leads to a large amount of medical consumable waste Patients with an ostomy bag must use it all the time and some people will need it for the rest of their lives because they do not have a sphincter at the end of the intestine like normal people. Therefore, they are unable to control the system of excretion of waste and gas and it is expelled all the time. In this case, it is necessary to use a ostomy bag to collect the waste and prevent it coming into contact with the skin which could cause infection.

Another reason for choosing the ostomy bag as a case study is that the ostomy bag is a medical consumable that is used and disposed of in the household. They are used more than other medical consumable, such as saline lines, syringes, blood bags, etc. Although hospitals usually have a good management system for disposal of these types of biomedical supplies, most households do not. Therefore, inefficient management of biomedical supplies in the household is a major cause of the spread of pathogens into the environment and natural water sources.

By the current method of using and eliminating the implant bags, the steps are as follows:

Table 1.1 Patterns for use and removal of an ostomy bag in hospitals.

1. The patient uses an ostomy bag
2. Clean the ostomy bag before throwing it away.
3. Throw the ostomy bag into the trash.
4. Move the trash bags to a waste collection point.
5. Store the trash bags until the infectious waste disposal company picks them up.
6. Infectious waste collection vehicle arrives
7. Dispose of waste

System for disposal of biomedical supplies in hospitals.

The advantages are:

1. It is moved and destroyed by a specialized infectious waste disposal company. With personnel who have been trained and have expertise.
2. It does not cause contact or spread of germs.

The disadvantages are:

1. High cost.
2. Not suitable for disposing infectious waste in households.
3. If the personnel of the hospital moving the waste lack knowledge and understanding they may be infected by touching the infectious waste.

Table 1.2 Patterns for use and disposal of an ostomy bag in urban areas.

1. The patient uses an ostomy bag
2. Clean the ostomy bag before throwing it away.
3. Throw the ostomy bag into the trash.
4. Throw the trash bag into the bin in front of the house and wait for the garbage collector to pick it up.
5. Garbage truck picks it up.
6. Bury any unsold waste.
7. Buried waste spreads germs.

System for disposal of biomedical supplies in urban areas.

The disadvantages are:

1. During the storage and collection of garbage there may be a foul odor and spread of pathogens. In some areas, garbage cars will only come to collect garbage once a week.
2. General garbage collectors lack knowledge and are not prepared for infectious waste collection. They may come into contact with the waste and become infected.

3. In urban areas, most homes do not have the capability to burn or bury waste and therefore rely on garbage collection. The infectious waste is then transported out of the area and buried in the ground, spreading germs into the natural environment.

Table 1.3 Patterns for use and disposal of an ostomy bag in rural or urban areas.

1. The patient uses an ostomy bag.
2. Clean the ostomy bag before throwing it away.
3. Throw the ostomy bag into the trash.
4. The trash is collected for incineration or landfill.
5. The waste is buried or incinerated, spreading germs.

System for disposing biomedical supplies in rural or urban areas.

The main advantage is that the garbage collector does not have to touch the waste products from the ostomy bags and as a result, there is no danger of infection.

The main disadvantage is the process of spreading pathogens from waste is faster because you don't have to wait for collection and the garbage can be buried or burned immediately.

By comparing the patterns for use and removal of the 3 types, you will find that the hospital's management model provides the best protection against spreading infection. However, in all 3 models there is still one step they have in common, which is that the artificial fistula must be cleaned before throwing it away. This is the point of greatest exposure to the waste and possible danger of infection, as well as the exposure to an unpleasant smell caused by the waste.

If possible, a change to the management mode, cutting contact with the waste when cleaning the prosthesis and not having to throw it into the trash, would be preferential. This would cut the cycle of contact and the spread of the disease.

The new types of removal of an inner ostomy bag, or medical waste are as follows:

Table 1.4 New methods for use and removal of an inner ostomy bag.

1. The patient uses an inner ostomy bag.
2. Flush the ostomy bag into the toilet, or cesspool, to decompose naturally

The advantages are:

1. It simplifies the process of disposing of biomedical waste material.
2. It prevents exposure to biomedical waste by patients, carers, and waste collectors, making it impossible to get infected.
3. It limits the spread of pathogens into the environment by storing all of the

excreted waste in the same sewage pond.

4. It lowers disposal costs as there is no need to use a specialized infectious waste disposal company.
5. It reduces the amount of non-degradable waste.

Research objectives.

1. Develop technology for the production of biodegradable materials to be used as biomedical consumables.
2. Develop biomedical supplies that can be disposed of in the household.
3. Develop a process for the disposal of biomedical wastes for households by enabling flushing into a toilet or cesspool to achieve an environmentally friendly natural degradation.

Research scope.

Technology

1. Find relevant information from various sources, such as academic articles, patent books, as well as information on the Internet. Study the products and technology related to prosthesis and management patterns and disposal of biomedical wastes in households.
2. Select suitable biological materials for development by looking at materials that can be degradable.
3. Develop a biodegradable film material by considering the best film based on mechanical properties and degradability.
4. Study the time of degradation. The material must be durable in dry and working conditions and decompose in water in not less than 24 hours, to prevent leakage during use.

Innovation

5. Design products that can be used as a replacement for the prosthesis which are convenient and have good hygiene, with the following considerations:
   5.1 It should have a low price to make access to the innovation easier.
   5.2 It must prevent splashing or staining from the waste when it is removed for hygiene purposes.
   5.3 It is universal in that it can be used in conjunction with a wide variety of brands. Currently products are unable to use devices of different brands.
   5.4 It can prevent leakage with a high strength and seamless material.
   5.5 It reduces noise while using.

6. This research is to produce a replacement bag for an artificial rectal bag; therefore, it must be tested in comparison to at least 2 brands of artificial rectal bags currently sold in Thailand.

7. Test the procedure for the removal of an anal implant by inserting waste into the artificial rectal bag and throwing it down the toilet.

8. Test the function of an artificial rectal bag by experimenting with using an artificial rectal bag with real sanitary ware.

9. Evaluate and measure satisfaction with questionnaires in case of questions that cannot be measured in numbers.

Management

10. Learn how to develop suitable products innovation diffusion. Manage biomedical waste uses through a process of meeting with innovators and early adopters to describe their features and suggest ways to use sample products. This includes people who directly influence the decision to use the product, such as nurses (this assumes that if a nurse introduces a new patient to a recommended innovation diffusion, there should be no obstacles), the Ostomy Clinic, Rajavithi Hospital, and artificial anal groups in various hospitals, or through the association of artificial anal patients.

11. Build a model for sustainable biomedical waste management. The subjects are then be then tested to determine suitability.

12. Test for commercial viability, distribution, and public relations channels.

Studied variables

1. Material Technology Development
   The independent variables are the different types of films that are tested.
   The dependent variable is the desired mechanical properties.

2. Development of the design of the ventricular cyst.
   The independent variables are gender, age, education, income, region of residence.
   The following variables are satisfaction with the innovation of the implant sacs.

3. Development of the management of the inner ostomy bag.

Independent variables include price and distribution channels.

The dependent variables are the possibility of discharge in the inner ostomy bag.

Research hypothesis

By analyzing the problems related to the use of artificial anal bags where the contents are poured into a toilet, they must be thoroughly washed before disposal. This causes inconvenience to the user and may bring them into contact with infectious waste. Standardized disposal is costly because the infectious waste requires special handling and must be collected frequently. This research shows that an alternative biodegradable product can eliminate smells and the spread of germs because the patient does not need to clean the artificial fistula and can throw it directly into the toilet for natural degradation.

Hypothesis testing

With the requirements for consideration as follows:

1. Sanitary management.
   There is no longer a need to clean the prosthesis before removal.
2. Reduce management costs.
   It is not necessary to transport and dispose of the waste by a dedicated infectious waste disposal company.
3. Environmental management.
   It reduces the transmission of infection. There is no need for it to be transported by staff, or to a landfill site where buried waste can cause the spread of bacteria.

Research limitations

The limitation of this research is that it will not be tested directly on human skin In order to avoid ethical issues.

Definition of Research Terms

1. An ostomy bag refers to a material that attaches to and receives waste from the digestive system through the abdomen.
2. An inner ostomy bag refers to the inner bag of ostomy bag.
3. Patient refers to a person who has an artificial fistula and excretes waste through the abdomen.
4. Biomedical waste refers to a single use medical waste.
5. Device refers to something which prevents infections, such as diapers that absorb waste, a device for endotracheal feeding, a urine bag, a prosthetic bag, etc.
6. Reduce the amount of waste means the amount of waste reduced by the weight of

the garbage.

7. Two-piece prosthesis refers to the ostomy bag and the abdominal pad which are separated.

Benefits expected from this research

1. Become an innovative model for the management of more efficient biomedical consumables for the development of other biomedical supplies in the future.
2. Reduce the amount of biomedical waste exposure from the patient, patient care person, maid, and garbage collector. Only the patient is left to touch and get rid of it by themselves.
3. Reduce the spread of pathogens from transportation and storage which accumulates until garbage collection for both household and hospital disposal.
4. Reduce the cost of disposing of biomedical waste material. From the need for storage and destruction with a special infectious waste removal company to self-degradation with free natural degradation methods.
5. Reduce the procedure for disposal of medical consumables. From having to be cleaned before throwing in the trash to putting in the toilet immediately and flushing. This helps patients have a better quality of life.
6. Help patients reduce household expenses for the purchase of self-implant bags.
7. Reduce reuse of implant bags in low income groups.
8. Help the government save money on the cost of implant bags distributed to patients making it possible to distribute implant bags to even greater number of patients.

2. LITERATURE REVIEW

The problems, condition, and situation of patients with ostomy. Based on the results of a survey conducted by the United Ostomy Association of America, Inc. (UOAA) (Ostomy, 2020) an organization for those with artificial fistulas, with branches throughout the United States, around 725,000-1,000,000 people have prosthetic fistulas in the United States with an annual average rate of 100,000 (Ostomy, 2020) cases and 50,000 deaths per year.

Research in the United States has also shown that ten percent of cancer patients who need artificial fistula surgery have had suicidal thoughts when using an artificial anal plug, and research into despair and suicidal ideation in Tehran, Iran (Sarabi, 2020) found that three months after surgery 97% of patients, had had some thoughts of suicide, and even after six months 84% still said they had thoughts of suicide and were classed at a high risk level.

In Thailand, a survey of the number of people who have prostheses was conducted by the Thai Association of Artificial Analysts. Of those who had the 30-baht gold card,

supplied by the National Health Security Office or NHSO, it was found that in 2018 there were more than 54,000 people with prostheses (Office, 2018b) who received an average of 5-6 sets of equipment per month. This means that patients with prosthetic fistulas need an average of 272,465 sets per year. The NHSO charge the rate according to the Comptroller General's Department, which is 500 baht per set (excluding bags that need to be changed, 50 baht per set). There is a general increase of approximately 10,000 new cases each year and 5,000 deaths. It is currently a major issue and is gaining global attention.

The quality of life after surgery and the use of artificial fistulas was studied in all regions of the world. According to the World Health Organization (WHO) the standard that sets the quality of life (QOL) is measured in 5 dimensions: 1. Physical health 2. Psychological health 3. level of independence 4. Social relationship 5. Environment

Knowledge of ostomy

There are many reasons for using an artificial fistula. Some patients have intestinal diseases or disorders of the reproductive organs and urinary tract. Artificial fistulas can be used for temporary relief of intestinal obstruction or treatment of ulcerative colitis. They are also used by people with colon cancer who have had bowel surgery and are unable to move body waste through normal channels. Or people who have cervical cancer, or other cancer nearby which requires radiation therapy which has made it impossible to excrete feces or urine and abdominal surgery to drain waste through the abdomen is necessary.

A prosthetic fistula is a surgical removal of the bowel through the abdomen to drain or expel urine (United Ostomy Associations of America, 2020d) or feces from the body using the abdominal bowel. The intestines that open through the abdomen will not feel or hurt when touched. Surgery is both temporary and permanent. It depends on the disease and symptoms of each person. This is when patients often have stress and anxiety due to the change in their physical condition.

From being able to excrete through normal channels, after surgery, the bowel will have to be excreted through the abdomen and a device must be attached to the stomach at all times. This affects the mental state of the patient and their social adaptation.

An artificial fistula is needed because the small intestine, or the intestine after abdominal surgery, does not have a sphincter. Therefore, it is unable to control the excretion of waste and gas, making it necessary to have a set of equipment that can collect the waste that comes out all the time. Some people will need to use this equipment for the rest of their lives. If the excreta touch the patient's skin, the enzymes that are accompanied by the waste that are not absorbed as expected from the colon will burn the skin, causing irritation. And if it touches the skin often, it will cause wounds

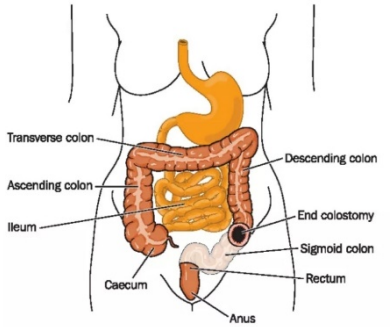
and infections. In addition to this, there is the smell and the effect on hygiene for the people around you.

Artificial fistula is divided into 2 main types:

1. Ostomy from the digestive system.
2. Ostomy from the urinary system.

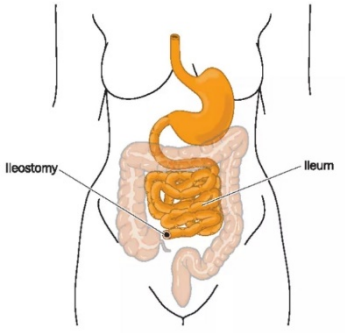
Ostomy from the digestive system can be subdivided into 2 types.

The first type is a problem with the colon called colostomy.



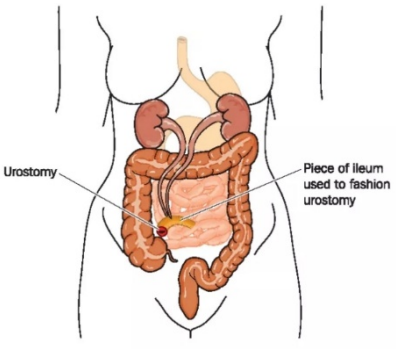
Colon colostomy (United Ostomy Associations of America, 2020a)

The second type is a common problem with the small intestine called an ileostomy.



Ileostomy of the small intestine (United Ostomy Associations of America, 2020a)

An artificial fistula from the urinary tract is called a urostomy.



Urostomy of the urinary tract (United Ostomy Associations of America, 2020) is the term used when a patient has an artificial fistula, including ostomy. The word ostomy comes from the Greek word “stoma” which means mouth or open channel, and is an artificial fistula for the digestive system. It starts from the mouth, through the esophagus, into the stomach, and the small intestine that is about 20 feet long, until it reaches the colon that is another 5 feet long. The term urinary system includes the kidneys, ureters, bladder and the urethra.

The quality of life of those who have an artificial fistula can still be negatively affected, even if the person using the prosthesis is in relatively good health. Most patients find they have to separate themselves from society. Even though their body is healthy and their brain is functioning well, the unavoidable smell of waste or excretions causes them to feel shame and makes them afraid to be close to others.

And then there is the waste disposal. Although the users of the implant bag can buy multiple sets for use each day, when they have left the house, it cannot be discarded without emptying the rectum which makes the hand come into contact with feces or urine. When washing, the toilet sprayer will be injected into the wash bag before throwing it away. If thrown into the toilet it would immediately be clogged. If thrown into the trash without washing the trash would have a very bad smell and the people who collect the garbage would be exposed to bacteria.

When going out from home, most patients would generally wash the prosthetic pouch and use it repeatedly because the prosthetic pouch is quite expensive. In this case, they must wash and rub the tip of the bag thoroughly with their hands after dropping the waste into the toilet, so that it does not emit a bad smell when being used. Unfortunately, most public toilets in Thailand lack a spray hose. This means people must carry a water bottle, so they can pour water into one hand while washing the other. This is quite difficult to do.

And finally, we have the price. One set of implant bags is the equivalent of the minimum wage for 1 day. This is very high for those with low income. Even though the government does distribute some bags to users of the gold card, it is still not enough, at only 4-5 sets per month. This is the equivalent of 1 set per week. Some people may only get 1-2 sets, or none at all. In other provinces, traveling to the provincial hospital for people with low income is a very high expense because they do not own a private vehicle. To receive 2-5 sets of implant bags worth 1,500 baht, it may not be worth the travel expense. Patients with artificial anal fistula are very anxious when taking a bus in the heat because it produces a particularly strong smell.

A study found that many patients who do not have money to buy an implant bag, cut plastic bags and modify them for themselves. Most of them have problems with

infection or leakage due to the wrong equipment being used.

Types of ostomy bag.

Nowadays, there are two broad types of prosthetic cysts: One-piece cyst and two-piece cyst. They are available in both clear and solid forms. The transparent model is used by new users, so it is easy for the doctor to see the waste from the intestines which will indicate if it is normal or abnormal. When used for a while, patients will switch to a solid form which covers up the view of the waste inside the prosthetic pouch.

What is the difference between a one piece and a two-piece model?

One-piece ostomy bag

The one-piece style, is where the bag body and the backboard are attached as one piece. There are two types of adhesives to the skin. 1. A type of glue. This is a strip of paper or plastic with glue for sticking to the skin. But often this peels off easily when the skin is moist or sweaty. 2. A Key-stick pattern which adheres to the skin better when sweaty or moist. The advantages of a one-piece bag is the convenience of use. Just cut a hole in the middle of the key to fit the intestines. Then peel off the adhesive tab and it is ready to use immediately. There is no need to assemble another part of the bag. It is uncomplicated. Hygiene is better because it is used only once, and there is no need to be afraid that the bag body and the key will fall apart while use. However, a disadvantage is that after use, when you want to discard it, you must dispose of both the backboard and the bag at the same time and the keys are the parts that are quite expensive. Single use and then throwing away can be a serious problem for low income earners if more than one item is changed per day. This type cannot be used in conjunction with an inner ostomy bag.

Two-piece ostomy bag

The two-piece, ostomy bag, can be used in conjunction with the inner ostomy bag. In this style there is a key for the belly which is separate from the ostomy bag. The advantage of a two-piece bag is that during the day, waste can be drained down the toilet or cesspool. Usually the waste is drained when it is ⅓ to ½ of the area of the prosthetic sac for easy cleaning and so it does not spill out when removed from the pad. If the waste is heavy it could cause the key to fail.

After removing the bag from the back of the key, a water hose or a water bottle can be used to clean the inside of the bag. Without having to remove the keys from the abdomen in general, patients tend to stick to the same keys for about 7 days or more or until waste flows into the edge of the keyboard while the bag will be removed and cleaned. If washing with water alone there may still be a sticky substance. It is preferable to wash with liquid soap, or dish soap. Using a small toothbrush, rub the inside of the bag so that it can cleaned thoroughly and not cause bad smells. This will help remove the sticky residue as well which stops the bags from sticking together.

Then the ostomy bag is left to air dry in the shade, and not in the sun because this may cause the bag to deteriorate quickly. If the bags still stick together, put baby powder inside and rub gently. Some people use it until the implant bag leaks. You should gradually change to a new one over time.

The figure includes each type of ostomy bag.

In addition to dividing the characteristics of the artificial fistula into two main types, there are also has 3 types of bag end.

1. The closed-end type for use with a large intestine prosthesis called Colostomy. A closed-ended prosthetic bag is quite difficult to clean and is not popular with people in low income countries because it can only be used for a short period of time. You can only pick up waste once and then have to throw it away. If there is a lot of urination on a particular day, many items must be replaced. But rest assured that there will be no leaks at the bottom of the bag, at the mouth of the bag, below or in the cork lid area.
2. The open-ended type for use with a small intestine prosthesis called an Ileostomy. It is popular in Thailand because it can be used in conjunction with an artificial colon and can be cleaned before being discarded or easily reused during the day. It has a large open end below and you can use a sprayer or a bottle of water to rinse from the top of the bag.
3. The cap-end type is for use with a urinary implant called a Urostomy, for urine drainage. During the day, as needed, most users will have more frequent urinary excretion compared to normal toilet visits. The cork cap will only be used to drain urine and cannot be used together with feces, for cleaning and reuse.

All 3 types of cyst can be used in conjunction with the two-piece implant bag of the prosthetic rectum.

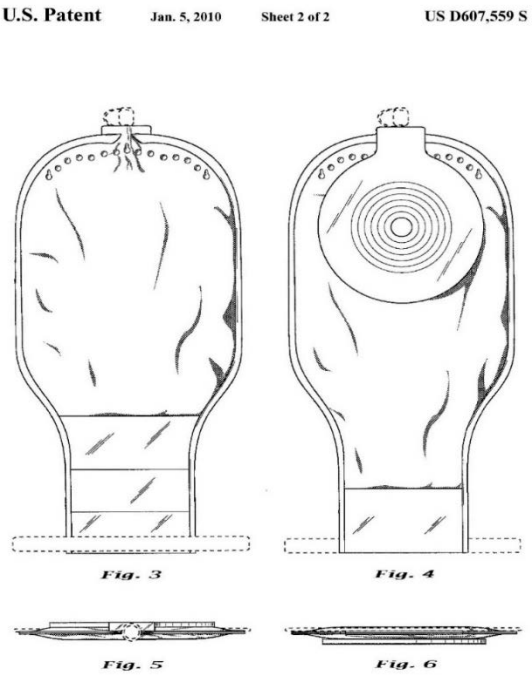
2.2 Related research

The results of studies on biomedical supplies technology found that the technology used in an artificial fistula has been virtually unchanged since 1959, namely, it is still a prosthetic anesthesia, made from polyethylene plastic, with both one-sided and two-sided open ends. There is a waste disposal section at the bottom open end. And there is

still a need to wash the bag thoroughly before throwing it away to get rid of odors and prevent germs from infecting patients and caregivers. Because it must be washed for repeated use, or before throwing into the trash, this may cause the exposure to the waste and by hands could spread infectious diseases.

Currently, the National Health Security Office provides support to eligible patients of only five to six pieces per month. Some public hospitals only allow patients to use only three pieces per month, if they need more, they have to pay themselves. Patients with low income inevitably need repeated use.

According to the results of a study of innovative design for biomedical supplies such as artificial rectal bags, most innovations were found to address the problem of odor and cleaning for reuse, or cleaning bags before throwing them into the trash. In 2011 a prosthesis was patented with a 14-head cleaning water inlet (Schena and Schena, 2010, Schena and Schena, 2006, Schena, 2011)



In 2014, another patent pertained to the development of a new film (Pham et al., 2014) And in 2015, a patent was filed for an artificial fistula with a large flushing hole on the top (Ben-Arie, 2018) that requires more water, but can be rinsed faster. However, most innovations have not improved a patient's quality of life since the 1986 prosthesis (Benzies, 1986) which also had to be rinsed with water for reuse or cleaning before throwing away.

Based on the results of a 2016 study on the management of biomedical supplies in Mangalore, India. It was found that waste separation in most hospitals was unsatisfactory and there was no suitable medical waste disposal facility. Medical personnel and staff who were involved with those medical materials were not aware of

the dangers and side effects of those exposures (Pullishery et al., 2016). The disposal of medical materials should be performed by a person who has a thorough understanding of the dangers that the operator is exposed to, including the 2019 study at Ayurveda Hospital, India which showed consistent results. The correct disposal of biomedical materials is the ethical and social responsibility of healthcare professionals. There should be training provided by the healthcare facility for staff and the training should be conducted continuously; not a single training session (Rajan et al., 2019).

In Thailand, a study of the ostomy bag by Prince of Songkla University Research and Development Office (Asst. Prof. Worawit Wanich Suwan, 2016) led by Asst. Prof. Worawit M.D. Wanichsuwan Colorectal surgeon Department of Surgery Faculty of Medicine Prince of Songkla University, together with various units, led to the successful design and manufacture of a latex-based urethral support kit. The ostomy bag has two pieces. There is a body on the pad and a waste bag, as is common and popular in commercially available kits. But the original material has been changed to be mainly rubber instead of polyethylene plastic.

The two-piece bag at Prince of Songkla University (Asst. Prof. Worawit Wanich Suwan, 2016) is a design that can be used in inner ostomy bags. But the purpose of the artificial anal bag made from rubber focuses on the use of rubber, a material widely available in Thailand. This mainly substitutes polyethylene plastic and promotes the use of rubber. It does not focus on post-use elimination processes to reduce exposure and the spread of disease. It is more important to focus on this to improve the quality of life of users when used in conjunction with an artificial rectal bag.

Research Gap

From studies of technology, innovation and management of biomedical supplies in the past, it can be seen that some of the problems have not yet been addressed or solved. As a result, the management of biomedical waste is still inefficient. For example, in the case of ostomy bags, most of the technological advances focus on improving the efficiency of rinsing for reuse or pre-emptying. This does not solve the problem that the user group faces which is that the post-operative removal should be easy, quick, convenient, and bags should be at a reduced cost. This new innovation addresses all of these points, making it easy and quick to throw away. It is possible to just flush it down the toilet without having to prepare tools for cleaning and there is no need to prepare a plastic bag for disposal after use. This reduces disposal costs and saves time. It also helps to improve the patient group's quality of life.

Compliance with Management of Innovative Technology (TIM)

Technology

1. Develop biodegradable materials that are easy to dispose of, do not cause blockages to the toilet system, and reduce negative environmental impact.

Innovation

1. Introduce a new innovative waste management system where biomedical supplies do not need to be disposed of by infectious waste disposal companies which are costly, but can be flushed down the toilet causing natural degradation which is environmentally friendly.

Management

1. Hygiene management. There is no need to clean the prosthesis before throwing it away. This reduces the unpleasantness associated with use and reduces the chance of infection. It also helps improve the patient group's quality of life.

2. Operation cost reduction. There is no need to dispose of it in a dedicated infectious trash storage unit, or transport it using a disposal company where contact with the waste could cause infection to the handlers. This instantly reduces disposal costs.

3. Environment management. This helps reduce the spread of pathogens into the environment. There is no need to dispose of the waste in a landfill thus preventing the spread of pathogens into bodies of water and nearby communities.

4. Household management. It reduces the need for storage space for waste and biomedical supplies, and also eradicates the problem of foul odors and the spread of germs.

3. METHODOLOGY

Research guidelines.

This research will be divided into 3 parts of the experiment according to the following conceptual framework:

1. Material Technology Development.
2. Development of the design of the ventricular cyst.
3. Development of the management of the implant.

3.1.1 Material technology development. This is experimental research. The materials used in the experiment were selected films with biodegradable mechanical properties.

To perform the required qualification tests materials must have:

1. Durability in preservation before use from air, light and moisture.
2. Durability while using.
3. The ability to degrade in the presence of microorganisms and bacteria (Compost)

3.1.2 Development of the design of the inner ostomy bag.

This research was conducted to test the satisfaction of the inner ostomy bag by grouping the samples in a chain (Snowball Sampling), which will be tested before and after use (Pretest-Posttest). Testing before (Pretest) was carried out on the satisfaction of the current product by analyzing issues with current products and their expected demand. After this, a demonstration of the use of the gut bag in the prosthesis was made by members of the sample group And finally, the sample group were asked to answer a questionnaire after the test (Posttest) to record satisfaction and any problems found during the test. All results from the sample group were compared.

3.1.3 Development of the management of the ostomy bag.

Once the design of the implant cyst was deemed to be satisfactory to the group, quantitative research was conducted to test the commercial viability. A questionnaire was used to find out the distribution channels favored by the sample group and how much they are willing to pay for an inner ostomy bag.

3.2 Population and sample.

The population used in this study was patients who received the gold card registered with the National Health Coverage Office consisting of approximately 40,375 people in the sample. The minimum sample size was calculated using the Chong Yamane formula with a 5% sampling error as follows:

$$n = \frac{N}{1 + N(e)^2}$$

Where

n = desired sample size

N = Number of population members (40,375 people)

e = random error, 5% (0.05)

Substitute the values in the formula to get

$$n = \frac{40{,}375}{1 + 40{,}375(0.05)2}$$

$$n = 396$$

Therefore, in this research, 400 patients were used as a sample.

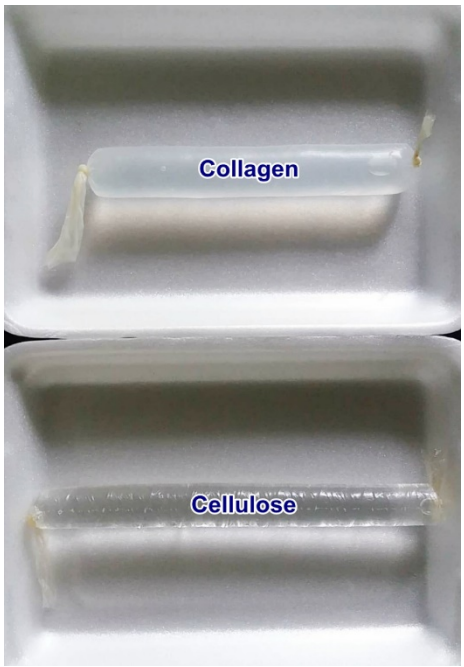
3.3 Research Tools and Experiment Materials.

3.3.1 Materials and equipment used in the material technology development experiment.

For the experiment

The experiment will be divided into two parts:

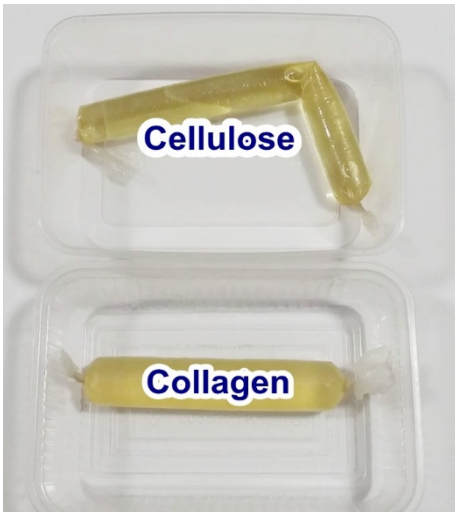
1. Testing the durability of the material before use.
2. Durability of the material during operation and disposal.



Picture of the testing of material durability before use.

For materials used to test the durability before use. Several films with biodegradable mechanical properties were selected. In preliminary testing, it was found that the films made from collagen and cellulose (Cellulose) were suitable and resistant to storage before use to a satisfactory level since there was no degradation even after

being exposed to sweat stains on the palms of hands, or moisture when left for more than 1 week.



Picture of material used to study the durability during operation and disposal.

For materials to study the durability during use and removal with microbial and bacterial degradation from waste. As needed, the process of natural degradation begins and does not use chemicals. The decomposition was slow after the exposure to the waste, and was still durable. It did not degrade for for up to 48 hours in actual use, and patients will generally use it for not more than 6 hours because the waste is expelled through the intestines at the front of the stomach all the time and the end of the intestine does not have a sphincter. As patients are not able to control or hold urine, they need to remove the implant from the outer bag once ⅓ of the area has been filled, for convenience and it must be degraded in less than 1 week to prevent being stuck in the toilet.

Findings for the film made from cellulose.

It was found that this material is too durable. It can endure microbial and bacterial degradation for more than 2 weeks and was therefore not degraded by microorganisms and bacteria in the required time. On the other hand, the film made from collagen (Collagen) yielded much more suitable properties Like a balloon, when touched by waste, it was softer and more flexible than when it was dry before use. However, it still maintained protection against seepage, and after use could be easily pressed into the toilet or cesspool, as it was soft and able to fit different sizes of sewer pipes. The cellulose film (Cellulose) had the same strength, but not the same elasticity which the collagen film provides. Using the cellulose film felt like adding more plastic and had the same stiffness as a hot PP bag. (Polypropylene). Also, some noise was caused by

the film. In contrast, the collagen (Collagen) film provided softness, and was quiet, with no noise. In terms of degradation, the collagen film results were more satisfactory. Degradation took between 48 hours and not more than 1 week, depending on the concentration of microbes and bacteria in the sewage pond.

3.4 Data Collection Tools.

3.4.1 Development of the design of the implant.

A research design used to study the development of the design of an implant cyst.

Use 3 types of tools:

1. Questionnaire.

A structured questionnaire was used [25] to study the satisfaction of the inner ostomy bag innovation. For the list of surveys and assessments according to the educational objectives for evaluation, it was divided into 3 levels as follows:

Level 1

- Preparation of questionnaire content before testing and checklists after review of literature.

Level 2

- Pre-test questionnaires and observation checklists.
- When the questionnaire is completed before the test is completed.

Level 3

- Comparison of pre-test and post-test scores and analysis of collected data

Divide the scores obtained from the comparison into 4 levels as follows:

Very satisfied	80-100%
Satisfied	60-79%
Moderately satisfied	40-59%
Unsatisfied	less than 40%.

The questionnaire will divide the data into 4 parts:

Part 1. General information.

Ask for general information about gender, age, education, income, region of residence. Number of years of use of ostomy bag.

Part 2. Experience with ostomy bag.

Ask about problems from the current use of the ostomy bags.

Part 3. Expectations from the innovative ostomy bag.

Inquire about what an innovative ostomy bag should have.

Part 4. Satisfaction.

Ask about satisfaction after watching a trial demonstration and any suggestions.

2. Field survey.

The prototype product and usage demonstration are prepared for the sample group to view. Observe the satisfaction of use. How satisfied are they with using it?

3. In-depth interviews.

With an open-ended question set allowing the sample group to express their opinions, feelings, and suggestions for improvement.

3.5 Development of the management of the inner ostomy bag

3.5.1 Use questionnaires.

A structured questionnaire was used [25] to study the satisfaction with the improvement of the management of the inner ostomy bag. To see if the inner ostomy bag can be sold or not, and at what price. Which channels should be used for distribution and public relations?

Divide the scores obtained from the comparison into 4 levels as follows:

Strongly agree	80-100%
Agree	60-79%
Moderately agree	40-59%
Disagree	less than 40%

The questionnaire will divide the data into 3 parts:

Part 1 General information

Ask about general information of the sample: gender, age, education, income, region of residence. Number of years of use of ostomy bag.

Part 2 Experience with the ostomy bag.

Ask about the perceptions of satisfaction and the price for which inner ostomy bag should be supplied.

Part 3 Public Relations

Ask about the distribution and public relations channels used by the sample group regularly.

4. DATA ANALYSIS

Experiment report.

Experimental method.

1. Prepare a 1000 mL volumetric solution at pH levels 4, 5, 6, 7, and 8 with distilled water and adjust the pH with HCl and NaOH.
2. Pour the solution into the bag and hang it to see the water holding capacity of the sample bag.
3. Measure the volume of water leaking or seeping out. Total period of 10 working days, total test 3 reps per sample.

Experimental results

From the experiment it was found that the water began to leak out of the bag on the 6th day and began to have colored spots from mold and smell on the 8th day. The sample bag, when packed with solution, was soft, but still tough and able to withstand scratches. It could be moved without breaking the bag.

Table 1 shows the volume (mL) of the solution leaked during storage of the sample bag.

pH / Day	0	2	4	6	8	10
pH 4	0	0	0	0	10.68±0.62	61.44±3.52
pH 5	0	0	0	0	5.33±0.62	31.03±2.02
pH 6	0	0	0	0	6.28±0.62	20.96±1.29
pH 7	0	0	0	0	2.54±0.62	2.97±0.37
pH 8	0	0	0	2.09±3.63	5.82±0.68	29.41±1.92

Comparison of one, two-piece ostomy bag and inner ostomy bags			
Subject	1-piece ostomy bag	2-piece ostomy bag	Inner ostomy bag
Price of bag	55 - 250 Baht	43 – 100 Baht	35 Baht
Price of pad	-	125 – 220 baht	-
Time use	1 time	More than 1 time	1 time
Clean before you leave	Yes	Yes	No
Reduce disposal costs	No	No	Yes
Reduce exposure from the user	No	No	Yes
Reduce the transmission of infection into nature.	No	No	Yes
Increased comfort of disposal	No	No	Yes
better quality of life.	No	No	Yes

A study of one-piece ostomy bags found that there were both closed-end and open-ended types for waste disposal. Because it is difficult to remove the keys that are stuck on the abdomen they are removed only when wanting to discard, or replace with a new one. In particular, the closed-end models that cannot open the waste drain, can be used only for a short time and are not suitable for collecting urine that may come out a lot during the day and cannot be drained. It is not popular in Thailand, even though it has the advantage of being easy to clean because the price is high.

Other studies show that even if it is open-ended it still needs to be cleaned before throwing away to reduce odors and germs. This means the users might be exposed to the bacteria that come with the waste. This also attracts mosquitoes and gives poor quality of life for users. Getting rid of it is problematic because the backboard attached to the abdomen and the condom is rubber which makes removal difficult. If burned, it produces toxic fumes; if buried, it will spread bacteria into the water source; and if hiring a removal company, it is expensive. Therefore, this type is not popular with users; especially in Thailand and low-income countries.

Two studies of implant cysts found there are both closed end and open end. The selling price of 43-100 baht per bag, depending on the brand, material used, and whether they are closed-ended or open-ended, used in conjunction with the belly button which is sold at a price of 125-220 baht, depending on the brand. When using the implant bag

together with the belly button, it costs 167-320 baht per set. In Thailand, it is preferable to use a 2 piece, because the keys stick on the body for about 1 week and you only need to change the outer bag. It is convenient because the keys do not have to be changed frequently and the keys are not wasted. If you want to save even more money, you can clean the bag and dry it to be used over and over again.

When adhering to hygiene principles this is considered incorrect, but for countries with low income populations and patients who use a prosthesis, there is not much choice, so it is popular. In terms of the difficulty of removal, it is hardly different from the one-piece prosthetic pouch that it needs to be washed to get rid of dirt and smell before throwing away and during the wash the user may come into contact with waste, causing a bacterial infection. When it comes into contact with something else, it can spread disease. When disposed of by incineration, it causes pollution. If the implant is buried in a landfill, it can spread germs into the soil and water table. If there is a removal system, like in a hospital or clinic that hires a private company for garbage disposal, it is expensive making this an unpopular option.

A study of the biodegradable inner ostomy bag found that if a two-piece ostomy bag was used in conjunction with the ostomy bag it could help save 8-65 baht or 18.60 - 65%. Even if you can use it only once it contributes to a better quality of life for the users because it reduces the exposure to waste, saves time cleaning, and helps to eliminate unpleasant odors and can also prevent the spread of pathogens into nature by controlling them in the sewage pond. It also increases the convenience of disposal by allowing it to naturally degrade in the sewage pond by using microorganisms and bacteria to aid degradation.

Sample study results

Characteristics of the sample. Most of them were female (55.25%), aged between 51-60 years (44.75%), followed by over 60 years old (28.5%), and had a bachelor's degree (63%). Followed by those having a bachelor's degree (31.5%), most of them engaged in trade (24.5%). Followed by business owners (22.25 percent), most of them experienced in using an artificial rectal bag for more than 5 years (29.75 percent), followed by 4 - 5 years (24.5 percent) experience in using an artificial rectal bag. From hospitals the most (43.5%), followed by receiving information from the website (30.5%) faced the least leakage problem (92.5%), followed by less leakage problem (6.5%), moderate smell problem (49.5%), followed by a problem of emitting a mild odor (33 percent) Most of them faced the problem of moderate ostomy (42%), followed by the problem with the low level of prosthesis (35.25%), had a low level of the implantation problem (45%). Followed by those experiencing moderate problems with the removal of the prosthesis (44.5%), at a low level (45%) Followed by a moderate problem of

cleaning of the prosthesis (44.5%), with a low level of noise from the prosthesis (60.5%), followed by a low level of noise from the prosthesis. The highest (29.5%) had a low level of need for solving the leakage problem (62%) Followed by the need to solve the problem of leakage at the lowest level (29.5%), there was a need to solve the problem of the anal bag emitting a bad smell while using at a moderate level (59.75%), followed by a need to solve the problem. Regarding the implant bag emitting a low level of bad smell (31.75%), there was a need to solve the problem of the price of the implant at a high level (50.75%) Followed by a demand for moderately priced solutions for the dystocia (34.75%), there was a high level of demand for the removal of the implantation device after use (48%). Solved the problem of removal of the implantation device after use at a moderate level (35.5%).

5. CONCLUSION

This study is a quasi-experimental research. The objective of this study is to develop technology for the production of biodegradable materials for use of inner ostomy bags that can be disposed of in the household by flushing it down a toilet or into cesspool to achieve an environmentally friendly natural degradation and reduce the cost of disposal of biomedical wastes. This research is divided into experiments and testing according to the concept of material technology development and the development of the management of the implant cyst using experiments in the lab to select materials. This includes studying leakage and degradation times according to different PH values. While the design of the inner ostomy bag was being developed, questionnaires were used to test the satisfaction of 400 prosthetic users. The study results can be summarized as follows.

The selected material for testing was collagen which was tested for leakage and degradation for 10 days, repeated 3 times. In the sample, the experimental results showed that collagen would start to soften when exposed to water or liquid, but retained its toughness, was able to withstand scratches, and could be moved without the bag being torn apart. The inner ostomy bag made from collagen could receive both feces and urine without tearing during use. The water began to leak out on the 6th day and there appeared stained spots from the mold and a smell on the 8th day. The collagen inner ostomy bag could be used during the day without leaking, even when handling highly acidic excretory waste. During the day, there are usually many excretions making the normal use of an inner ostomy bag only a short time; therefore, leakage is not a problem.

In conclusion, the inner ostomy bag can be used during the day without tearing or leaking. It can be flushed down a toilet or cesspool because the artificial gut pouch becomes soft when exposed to liquids. The results of the experiment were very

satisfactory.

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