BBMS4011

Biomedical Sciences Innovation Project

Final Report

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1. Executive Summary

1.1 About Nociflex
Nociflex is a student-led technology-based start-up founded in 2020, striving to counter the age-old issues of chronic somatic nociceptive pain. Whilst traditional analgesics and pain relief regimens only provide short-term solutions to pain symptoms, our company aims to alleviate chronic pain by promoting physical activity. We develop products that encourage patient mobility and exercise rehabilitation to stimulate the body’s natural recovery. Our first product - Nociflex patches (NPs) - is currently still under development.

1.2 Our Team
Nociflex was founded by two Year 3 Biomedical Sciences students from the University of Hong Kong: Ernest Tsoi and Candice Tse. Both co-founders are aspiring physiotherapists who successfully applied for an articulation programme with the University of Sydney for a Masters in Physiotherapy. We believe in developing drug-free health solutions to reduce the public’s unhealthy reliance on drugs.

Both co-founders have signed a Founder’s agreement to establish basic ownership, tax and management rights for Nociflex, with Ernest being the primary point-of-contact for tax matters. The distribution of work during this project course is detailed in the appendix¹. Ernest being primarily responsible for product design, video production and prototype development; and Candice is in charge of market surveys, competitor analysis and research development.

¹ Table indicating work distribution attached in Appendix Image 1
2. Company Name and Logo

2.1 Company Name

The name “Nociflex” is a play on words (“nociceptors” and “flexing”) meant to bring out our company’s pain management ideology. Nociceptors are the scientific term for pain receptors, this is symbolic of our project as it is founded entirely on the concept of relieving pain. Consequently, “flexing” represents the active recovery ideology of our company. The action of “flexing” directly refers to the muscle contractions necessary for exercise rehabilitation. The word “flex” also has a connotation of power and strength, implying that we would not allow pain to dictate our lifestyle.

2.2 Company Logo

**Version 1:**
Initially our patches included a mechanical aspect that mobilized the thorns to create a massaging effect. We wanted to reflect this technology in our logo hence we included a computer chip with wires spreading in the shape of a brain. We obtained this image from Getty Images as reference for our design. Afterwards we changed our patch design to a more simplistic one, hence we scrapped the idea.

**Version 2:**
After conversion to the sleeker simpler design, we only kept the colour of the background as dark blue. The dark blue hue keeps the vibe relaxed and chill, the feeling we hope to achieve within consumers upon application of the patch. This design was created by overlaying two images:

1.) Two black hands cupping the air;  
   *Represent the soft-touch mechanostimulation when applying NPs.*
2.) Coral-like nerve endings.  
   *Represents the stimulation of nerve signals, the light blue is a depiction of the healing aspect of these “soft-touch” sensations.*

Overall, the effect we wanted to create with this logo design is to have the rounded, soft shapes blend together forming a coherent image representing our product mechanism. The logo is also designed to appear very natural: nerve endings in the shape of coral; hands in the shape of tree branches. This brings out our ideology of encouraging active recovery, a completely natural and chemical-free healing process.

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2 Image obtained from Getty Images  
3 Design created on Canva by Ernest Tsoi
3. Our Product

3.1 Product Ideation

3.1.1 Issue Discovery

**Pain and physical inactivity:**

Pain is strikingly prevalent worldwide. Nearly one person in every family encounters it, and over 10% of all adults have suffered from chronic pain that lasts for more than 3 months. Arthritic pain is common amongst the middle-aged and the elderly, whilst joint and muscle sprains from sports injuries are frequent in athletes. Pain causes patients to be constrained and reluctant to perform normal physical activities. This inactivity is termed “disuse syndrome” and is a key variable perpetuating pain symptoms (Deardorff, 2015). Consequently, exercise is often prescribed for chronic pain rehabilitation. This emphasizes the need for an analgesic that complements active pain management.

**Adverse effects of medication:**

Of the countless analgesics in the current market, drug-based analgesics are still predominant choices amongst clinicians and patients. This is likely due to the quick-acting analgesic effects of medication. However, pain medication also wears off within hours hence requires frequent consumption. With growing concerns in overdosing and its adverse effects, many look towards a drug-free alternative.

3.1.2 Current Analgesic Alternatives and Scientific Backing

Current drug-free alternatives for pain management - such as dry needling and transcutaneous electrical nerve stimulation (TENS) - are mostly based on Melzack's gate theory of pain. This theory suggests that stimulating myofascial trigger points at the origins of pain could modulate nerve signalling and reduce noxious stimuli. By “closing the gate”, pain signal transmission to the brain is inhibited, thus achieving an analgesic effect. Inspired by this theory and the convenience of pain-relief patches, we tried linking them together: creating a patch that reduces pain by physically modulating pain sensation whilst also enabling patient mobility.

We came across a novel research on adhesive pyramidal thorn (PT) patches that mimicked tactile stimulation to induce analgesia (Saito et al., 2019). Their positive findings encouraged us to go through with our ideation.

3.1.3 Conceptualization and Product Design

Based on the scientific data from the paper above, we confirmed our primary product design, Nociflex patches (NP). NPs are a lightweight adhesive patch layered with thorns that simulate gentle-touches. To minimize the hindrance of the patch on movement, the patch would be flexible and comfortable. We envision NPs as a product complementing existing pain-relievers, helping patients cut their medication and enjoy an active painless life, anywhere at any time.
3.2 Technology

3.2.1 Research Background
NPs draw largely upon a research paper written by a group of Japanese scientists. Their team developed a device termed a “pyramidal thorn (PT) patch” as an alternate non-invasive analgesic pathway. PT patches are designed to stimulate gentle-touch signals upon application. The activation of these gentle-touch signaling pathways delivers an analgesic effect, this phenomenon is briefly explained below:

“It has been shown repeatedly that low intensity stimulation of cutaneous somatosensory nerves, particularly through stroking touch, warmth and light pressure, induces the release of endogenous peptides such as OT and opioids which promote relaxation and well-being.” (McGlone, Cerritelli, Walker, & Esteves, 2017)

Although gentle touch signals are known to be an effective form of pain relief, the application of this knowledge into therapeutic products is limited. The PT patch is one of the first theoretical models that apply gentle-touch analgesia as a potential therapeutic device.

The PT patch is a circular adhesive skin patch composed of synthetic resin. The diameter of the patch is 3cm wide, with a thickness of 0.1mm. The center of the circular patch is made of a single low-density polyethylene pyramid with a square base occupying a 7mm² area and a height of 3mm.

The PT patch is intended to be applied directly onto the skin. The ‘pyramidal thorns’ refer to synthetic polyethylene protrusions. When pressed against the skin, these ‘pyramidal thorns’ apply mechanical pressure recapitulating gentle-touch pathways.

The pain region is first determined by an operator who palpates the patient’s pain region using strong thumb pressure. After identification of the pain site, several PT patches are placed in a marked boundary encapsulating the pain area. Around 3 - 5 PT patches are placed covering the marked area based on the size of the pain region, placement of the patches were slightly overlapped. The patches remained on the skin of subjects until they naturally peeled off, which took approximately 4 - 5 days per treatment.

After 4 treatments with the PT patch, nearly all subjects experienced complete pain relief. The efficacy varied between pain types. Knee pain was completely eliminated post-treatment. Joint and muscle pains
were significantly alleviated. Whilst deep subcutaneous pain (ie. as neck pain, low back pain, and rump pain) required more than 4 treatments.

3.2.2 Pain Relief Mechanism

**Introduction to pain signalling pathways:**
Pain systems involve a complex combination of keratinocytes and nerve endings in the pain site. Upon tissue trauma, the damaged cells transmit pain signals to the dorsal root ganglion (DRG) and the dorsal horn (DH), two nervous system structures that house cultures of neurons and glial cells. The DRG and DH are responsible for modifying the initial pain impulse through interactions with surrounding microglia, astrocytes and neurons before transmittance to the central nervous system (CNS) for processing. The CNS relays the information and transmits a nerve impulse that stimulates the sensation of pain.

**Soft-touch analgesic mechanism:**
The modification process within the DRG and DH plays a key role in the analgesic effect of PT patches. By applying PT patches directly onto the pain site, the soft-touch signals of the PT patch and the sensory signals from the pain area act on the same DRG and DH. The effects of this interaction lead to modification and reduction of the initial pain signal, leading to analgesia.

The mechanism of modification is largely due to the release of oxytocin (Oxt) and nitric oxide (NO) in nerve fibers conducting soft-touch signals. Oxt and NO are released from soft-touch fibers into the DRG and DH, where they interact and modify pain-signalling fibers.

The anti-nociceptive effects of Oxt are especially pronounced. Oxt-receptors in the neurons of the DRG and DH are activated when Oxt is bound. The activation of Oxt-receptors triggers the release of inositol trisphosphate (IP3) and diacylglycerol (DG). IP3 and DG triggers the activation of Ca\(^{2+}\) channels in neurons, there is an influx of Ca\(^{2+}\) resulting in an increase in intracellular Ca\(^{2+}\). When intracellular Ca\(^{2+}\) reaches a certain threshold, voltage-gated channels in the neuron are activated resulting in the neuron membrane hyperpolarization. The effects of the DRG and DH hyperpolarization result in the reduction of intensity of incoming pain-signals.

**Specificity of pain relief mechanism:**

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4 PT patch treatment results attached in Appendix Image 1
5 PT patch mechanism diagram drawn on Google Drawings by Ernest Tsoi
6 Diagram indicating soft-touch analgesic pathways attached in Appendix Image 2
PT patches are most effective against chronic musculoskeletal pain, which is classified as dysfunctional pathological pain. This specificity is largely due to the type-specific nerve fibers involved in the transmission of chronic pathological pain.

The effects of PT patch-induced analgesia are also more pronounced in subjects with hairier skin, as the activation of Merkell cell-neurite complexes near the hair follicles produce a more pronounced soft-touch effect.

2.2.3 Adapting Our Ideology

Encouraging exercise rehabilitation:
The participants involved in the research described above are all athletes. There is a proven advantage in terms of the speed and efficacy of pain recovery in a more athletic patient compared to that of an average person.

Nociflex focused on enhancing the recovery aspect of the PT patches to better adapt the technology above for general consumer usage. It is widely understood that increased amounts of physical activity have a significant effect on pain recovery. Exercise induces the brain to release endogenous endorphins - our body’s natural opioids that play a role in relieving stress and pain. Muscle activity also enhances the release of anti-inflammatory myokines. Myokines suppress the effects of pro-inflammatory cytokines, which play a role in sustaining pain symptoms in chronic pain patients.

“Large population studies show that individuals who are more physically active have a lower risk for development of chronic pain. It is also well recognized that exercise is an effective clinical treatment to reduce pain and improve function in a variety of pain conditions.” (Law & Sluka, 2016)

Understanding the benefits of an active lifestyle on chronic pain recovery, our company strives to increase activity of the consumer by designing NPs to be as comfortable, mobile and lightweight as possible. We believe that these qualities encourage the patient to undergo exercise rehabilitation. We will later describe how we implement these qualities into our product in the Materials and Prototypes segment.

Improving product viability:
We also identified issues in the use case of PT patches. Patients in the study had their pain area identified by a registered operator - the need for professional advice is unsuitable and inefficient for mass consumption. Additionally, multiple patches had to be applied in an overlapping manner in larger pain regions for sufficient skin coverage. These specificities in the application process further dissuade consumer usage. These two issues are targeted and resolved in the development of NPs, which are also detailed in the Materials and Prototypes segment.
4. Business Model

4.1 Value Propositions

Nociflex patches relieve chronic musculoskeletal pain, this refers to pathological dysfunctional pain affecting muscles and joints. According to the World Health Organization (WHO), approximately 1 in people worldwide suffer from some form of chronic musculoskeletal pain, this translates to a population estimate of 1.75 billion people. The need for an effective pain management product targeting musculoskeletal pain is becoming increasingly evident, and currently many of such products are available worldwide. So what makes NPs different from all the others?

1.) A mechanosensory-based analgesic;
   NPs work based off of a novel gentle-touch approach to pain medicine. This mechanism offers a drug-free, non-invasive approach to pain medicine. A purely mechano-stimulatory approach has no side effects nor poses any risk to the body.

2.) Offers patient mobility and comfort during wear;
   NPs are designed to be breathable, comfortable, stretchy and lightweight. Unlike traditional pain management products, NPs are completely non-inhibitory. These qualities aim to promote the patient’s active exercise rehabilitation to achieve full recovery from chronic pain.

3.) Affordable and easy-to-use;
   NPs are composed of inexpensive silicone, resin and polyethylene. The specific design and layering of these components provide a deceptively simple pain management solution that is also consumer-friendly. One patch is applicable to practically all pain regions, and a single application can last for hours on end. Removing the patch is also completely non-traumatic, effectively allowing users complete freedom throughout the consumption process.

Previously, the Value Propositions differed vastly even though the mechanism of analgesia remained the same. The following elements were initially part of the design of NPs but were eventually scrapped:

Mobile unit for Nociflex thorn movement:
Initial NP designs included a mechanical function that stimulated movement of the thorns similar to a massaging device. The mobile unit would be rechargeable offering some degree of reusability. This idea was taken down due to the overtly complex nature of the mechanism. The addition of such an element would warrant major increases in weight and cost of the product.

Cost-effective and reusable:
The element of reusability was targeted as a weakness in other market competitors. Most analgesic products either could not be reused or were extremely costly. We initially believed that if we were able to find a silicone adhesive that could be reused, we could essentially produce a simple analgesic patch that is both cheap and effective. Eventually our efforts to find this material halted as we realized that a reusable patch would not be a profitable business model. Currently, we are adopting NPs as single-use products.

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7 Business model canvas reiterations attached in Appendix Image 3
Conversion to our current values:
The conversion from a complex patch to the simple one we are developing now also came about due to a change in company ideology. We originally planned on creating a patch solely to relieve pain without further plans to actually resolve pain. After repeated brainstorming as well as kinesiology lectures from a particularly passionate professor (Prof. Parco Siu), we ended up converting our product to a consumer-centric model that encourages exercise to resolve pain. This new ideology also meant that our patch had to be lightweight to encourage mobility, hence we went for a simple but more effective patch design.

4.2 Key Activities

4.2.1 Technology-based
We are currently still in the process of research and development of NPs. We have just completed and tested the first prototype. Further consolidation and validation of product efficacy will be needed - the mechanism of NPs as of right now is purely extrapolated from existing research. We will focus on contacting mechanosensory experts to assist in product refinement.

4.2.2 Market-based
We are concurrently conducting market analysis through questionnaires and interviews. This process is essential in identifying consumer interest in the product, and whether our Value Propositions need modification. Product testers will also be randomly selected to review NPs, the results of which will be taken into consideration for optimization of user experience (UX).

4.2.3 Production-based
Each step of NP production will undergo thorough quality control (QC) to keep track of product efficacy and fulfillment of Value Propositions.

4.3 Key Resources

<table>
<thead>
<tr>
<th>Physical resources</th>
<th>1. Raw materials for development and packaging of NPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human resources</td>
<td>2. Mechanosensory experts to assist in the R&amp;D process</td>
</tr>
<tr>
<td></td>
<td>3. Workers hired to regulate the manufacturing process</td>
</tr>
<tr>
<td></td>
<td>4. Market analysts to extrapolate and identify business opportunities</td>
</tr>
</tbody>
</table>

4.4 Customer Segment and Channels

4.4.1 B2B2C
Also known as a Business-to-Buyer-to-Consumer (B2B2C) approach. We plan to sell NPs in bulk to private physiotherapy clinics in specific. Consumers suffering from chronic musculoskeletal pain often seek physiotherapy, and those who are willing to pay a higher price for better services are also more likely to purchase our product. We also plans to sell NPs to other institutes such as elderly care centers and sports institutes to target the elderly and athlete populations respectively. We have identified that these two population subgroups have a higher prevalence of chronic musculoskeletal pain, which are at 25%
and 14% respectively (Ozcan & Tu, 2012) (Legault, Descarreaux, & Cantin, 2015). A B2B2C approach is going to be the main channel of product delivery initially, since it is key to spreading knowledge of NPs to potential consumers. To facilitate this process, Nociflex aims to form Key Partnerships with these institutions.

4.4.2 B2C

After the successful launch of a B2B2C delivery, we will consider adopting a direct Business-to-Consumer (B2C) approach. An online platform would be set up for direct purchase and delivery of NPs to buyers: patients suffering from chronic pain or their family members. An online platform mainly targets the consumptive patterns of athletes, who are often younger and more adept to social media.

The online platform will offer both a subscription based model and one-off options for NPs. For effective alleviation of pain symptoms, consumers have to undergo multiple NP treatments. Since NPs are a single-use product, a discounted subscription-based offer is attractive to consumers who believe in the rehabilitation process. Of course, one-off offers will also be available for dubious customers who would like to try the product out.

4.4.3 Reiterations

Previous iterations of the business model canvas adopted a purely B2C approach and neglected a B2B2C approach. We failed to consider the overwhelming costs of advertising and marketing of NPs to raise sufficient demand to breakeven on online transactions. It is simpler to first reach out to major institutions specializing in dealing with our target consumers and increasing reputation and demand for NPs.

4.4.4 Market Evaluation:

<table>
<thead>
<tr>
<th>Total Available Market (TAM)</th>
<th>Chronic musculoskeletal pain patients globally:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Accounts for 13.5 - 45% of total population (Cimmino et al, 2011)</td>
</tr>
<tr>
<td></td>
<td>- 3.79 billion USD on musculoskeletal pain in 2019 (Markets, 2019)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serviceable Available Market (SAM)</th>
<th>Chronic musculoskeletal pain patients in Hong Kong:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- No direct statistics on HK prevalence or market size</td>
</tr>
<tr>
<td></td>
<td>- 10.8% HK adults suffer chronic pain (Ng et al., 2002)</td>
</tr>
<tr>
<td></td>
<td>- Estimated around 5 - 6% of HK population</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serviceable Obtainable Market (SOM)</th>
<th>10% of chronic musculoskeletal pain market in Hong Kong:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Large market portion dominated by competitors</td>
</tr>
<tr>
<td></td>
<td>- Salonpas, NSAIDs, neurostimulants etc.</td>
</tr>
</tbody>
</table>
4.5 Cost Structure

<table>
<thead>
<tr>
<th>Fixed Costs:</th>
<th>Variable Costs:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary of full-time employees</td>
<td>Utilities</td>
</tr>
<tr>
<td>Royalties</td>
<td>Wages of part-time employees</td>
</tr>
<tr>
<td>Patenting costs</td>
<td>Raw materials</td>
</tr>
<tr>
<td>QC handling fee</td>
<td>Logistical costs</td>
</tr>
<tr>
<td></td>
<td>Costs of free samples</td>
</tr>
<tr>
<td></td>
<td>Supplying and incentivising testees</td>
</tr>
<tr>
<td></td>
<td>Advertisement expenses</td>
</tr>
</tbody>
</table>

4.6 Revenue Streams

4.6.1 Product Sales

Nociflex will likely be attaining revenue purely off of product sales. This includes the bulk selling to healthcare and sports institutions, as well as the subscription-based and one-off purchases on our online platform. This stream is dependent on product demand, hence requires high initial investment in marketing and advertising strategies.

4.6.2 Licensing

We are also considering the option of selling the technology off via licensing. We will be patenting the usage of a mechanostimulation patch on inducing analgesia. Given the benefits of a natural, drug-free approach to pain medicine, it is highly likely that the costs of licensing will pay off. The benefits of licensing this technology is that all costs associated with marketing and advertising are eliminated once R&D is completed.

4.6.3 Reiterations

We did not consider licensing as an alternative revenue stream until much later, it originally seemed much more profitable to simply sell NPs directly. However, we realized that a proper patent for the technology offers the opportunity to earn passive income aside from product sales. The initial patenting cost is insignificant in comparison to the potential revenue from selling the technology introduced in NPs.

4.7 Customer Relationship

The establishment of a good, loyal customer base can largely improve the recognition and demand for NPs. Consumers prioritize the recommendations from family members and friends when it comes to products regarding healthcare. Hence, we proposed several measures to improve customer satisfaction and increase brand loyalty. Do note that the measures below have yet to be confirmed, and only serve as an initial guideline on potential pathways to improve customer relationships.

1. Providing clear, customer-friendly post-sales services;
   
   Offering full refunds for initial one-off purchases. Provide real-time online support on the online platform to advise customers on possible rehabilitative measures. Help desk and technical
support services to modulate online transactions and misdeliveries.

2. Encourage customer feedback on consumption experience and product outcome;
   Online platform offering options to rate and review products after consumption. Providing initiatives by offering discounts off purchases after positive reviews. Establishing a consumer-centric business model that strives to continually fulfill consumer expectations and improve product experience.

3. Running social media campaigns and posting short articles relating to active pain management;
   Establishing an active recovery mindset is a value that goes side-by-side with the design of NPs. Formation of an active social media platform for hosting and promoting exercise rehabilitation campaigns or charities. Informative updates on active pain management and its benefits. A social media platform facilitates consumer-producer collaboration, hence improving brand loyalty.

The consumer relationship segment has been left untouched for the majority of the course of NP development. We struggled to identify the importance of a positive consumer relationship on product sales. Only after lectures from several notable startup founders did we finally understand and integrate this concept into our business model.

4.8 Key Partners

4.8.1 Research and Development

NPs are currently still in the development stage, hence it is our intention to establish working partnerships with the researchers involved in the PT paper, alternatively with general mechanosensory experts. Establishing a long-term trusted relationship with NP component manufacturers will be our next priority:

Researchers: scientists involved in PT patch studies; mechanosensory experts; physiotherapists

*Elkem*: supplier of silicone skin adhesives; reduce costs of raw materials

*3M*: supplier of other NP components; reduce costs of raw materials

Thorn producer: to be supplier of Nociflex thorns; reduce costs of raw materials; TBC

4.8.2 Market

Nociflex will also work towards forming key partnerships with product redistributors, which are mainly healthcare and elderly institutions. The promotion of NPs and the ideology of active recovery from chronic pain is largely dependent on these institutions:

Distributors: *APS Orthopaedic*

*Joint Dynamics*

*PhysioMotion*

*HK Sports Clinic*
5. Materials and Prototypes

5.1 Product Design Goals

The design of NPs aims to achieve three main objectives:
1.) Effective simulation of soft-touches to alleviate pain intensity in chronic pain patients;
2.) Guaranteed ease-of-consumption and convenience for mass consumer usage;
3.) Encouraging patient mobility and exercise rehabilitation to recover from chronic pain.

The successful simulation of soft touches is the backbone of our product. Given the effectiveness of pyramidal thorns in stimulating soft-touch pathways, NPs do not stray too far from PT patches in terms of overall design. Certain optimizations were made to the size and height of pyramidal thorns.

The ease-of-consumption is crucial for enhancing the attractiveness of NPs to consumers. Analysis of PT patches revealed certain qualities that dissuade consumer usage, such as the need for expert advice on patch placement, and the need for multiple patches on the same area. A single NP can be applied to virtually all chronic pain regions regardless of size. This avoids the issues of having to purchase and apply multiple patches based on specific guidelines.

NPs are designed to be as lightweight, breathable and flexible as possible. These qualities allow the consumers to engage in all forms of physical activity without having to feel limited by the patch. Oftentimes analgesic products have side effects that generally dissuade consumers from being too active. For instance, painkillers have physiological side effects such as nausea and drowsiness, whilst pain patches lack sufficient adhesion and flexibility for exercise purposes. NPs offer nearly no limitations to the wearer, promoting the wearer’s active recovery.

5.2 Initial Design

5.2.1 Patch Composition

NPs are one of the first products to implement mechanosensory stimulation in the form of a patch. As such, there is a lack of research and market data on patch composition. PT patches are composed of a singular synthetic resin thorn and a simple skin adhesive. This composition is not applicable to NPs as they do not take into account the storage and protection of the patch components before application.

We drew inspiration from transdermal patches, which are traditional medical patches for topical drug delivery. Transdermal patches designs are applicable to NPs as both require prolonged skin contact for the successful delivery of therapeutic action. Our company looked into the composition of traditional transdermal patches and extracted concepts applicable to NPs:
**Transdermal Patch Composition:**

<table>
<thead>
<tr>
<th>Materials</th>
<th>Function</th>
<th>Applicability to NPs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Backing Layer</strong></td>
<td>Outermost layer of the patch that protects formulation during wear period</td>
<td>Applicable: NPs require protection during long wear times</td>
</tr>
<tr>
<td><strong>Drug</strong></td>
<td>Drug is contained within membrane or in adhesive and delivered topically</td>
<td>Not applicable: Therapeutic mechanism of NPs is drug-free</td>
</tr>
<tr>
<td><strong>Membrane</strong></td>
<td>Film that controls rate of drug diffusion out of the patch and into the skin</td>
<td>Not applicable: NPs do not need a rate-limiting membrane for safe delivery</td>
</tr>
<tr>
<td><strong>Adhesive</strong></td>
<td>Skin-contacting layer that adheres the patch to the skin</td>
<td>Applicable: Skin adhesion is important so as to maintain mechanical pressure of thorns onto skin</td>
</tr>
<tr>
<td><strong>Release Liner</strong></td>
<td>Protects skin-contacting adhesive during storage and removed prior to application of patch</td>
<td>Applicable: NPs require a strong skin adhesive, protection of the adhesive layer before application is crucial</td>
</tr>
</tbody>
</table>

Based on the inapplicable materials, we adjusted the general design for NPs and added some general guidelines we would like to follow for each layer:

**NP Patch Composition:**

<table>
<thead>
<tr>
<th>Layer</th>
<th>Characteristics</th>
</tr>
</thead>
</table>
| **Backing Layer** | - Protects adhesive during wear  
- Thin to limit patch thickness  
- Breathable and comfortable  
- Smooth and aesthetically appealing |
| **Thorns** | - Protrudes from adhesive layer and presses against skin  
- Simulates soft touches effectively  
- Durable and lightweight |
| **Adhesive** | - Strongly adheres patch to skin  
- High resistance to shear stress  
- Breathable and non-inhibitory |
| **Release Liner** | - Protects adhesive during storage |

Given the compositional requirements above, we developed our first cross-section NP design:

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8 Diagram indicating common patch types made by 3M attached in Appendix Image 3
The design above does fulfill the general outline on the distribution of each layer and their functions, however the problem lies in the functionality:

1.) The adhesive layer should be applied last (before release liner) to maintain adhesive strength. Attaching thorns to adhesive layer leads to exposure of adhesive and a reduction in adhesion.
2.) The adhesive layer is comparatively fragile, attaching solid substances onto it can be damaging.
3.) A more logistically appropriate design should be revised to maintain adhesive layer integrity.

To resolve the issues described above, we came up with the following design:

This modified cross-section diagram attaches the thorns directly to the backing membrane. The backing membrane is generally composed of tougher and more resistant materials, providing ample support for Nociflex thorns.

5.2.2 Thorn Placement
Our Nociflex thorn design, placement and spacing is largely inspired by PT patches. This is to ensure our patch maintains the same level of soft-touch simulation and analgesia as traditional PT patches.

9 2D model drawn on Google Drawings by Ernest Tsoi
10 2D model drawn on Google Drawings by Ernest Tsoi
According to the PT research, the number of thorn numbers are arbitrary, evenly-spaced thorns and sufficient coverage of the pain region is enough to induce pain relief. PT patch placements mention a 1 - 1.5cm spacing between individual patches. This translates to approximately 1 - 1.5 cm spacing between individual thorns. To reduce the hassle of purchasing and applying multiple patches per application, NPs increase the number of thorns to 25 thorns per patch. The thorns are each spaced exactly 1.5cm from the previous thorn, ultimately forming a 5 x 5 grid. We settled on a 10cm x 10cm patch as a suitable size for coverage of a majority of pain regions. Plans for customization of patch sizes are being considered.

5.2.3 Thorn Design:

Nociflex thorns have a 6.00 x 6.00mm base with a height of 4.00mm, this is significantly different from the 8.36 x 8.36mm base and 3.00mm height of pyramidal thorns. The increased height is to make up for 1mm of the thorn embedded in the adhesive. The smaller 6.00 x 6.00mm thorn base is the result of optimizing the patch to accommodate 25 thorns. An increase in thorn number also means a proportionally reduced area of adhesive contact on the skin. This reduction in adhesive area can drastically reduce the application strength and duration of the patch, which are both characteristics that we do not wish to compromise. As a result, we decided on reducing the base area of the patches from 7.0mm$^2$ to 3.6mm$^2$, approximately halving the initial base area.

The result of an increased height and reduced base size is an increased thorn gradient, and hence a more pronounced indentation on the skin. These proportions were adjusted according to our personal perception of the effects of the thorn on our skin. After testing out multiple 3D printed models, we concluded that the overall comfort of the thorns is enhanced with our new design. The efficacy of the thorns should not be impacted as it still produces low-threshold mechanical stimulation, hence activating the same analgesic signalling pathways.

11 Image obtained directly from PT Patch paper
12 3D model generated on Tinkercad by Ernest Tsoi
Given the increase in thorn slope, the shape of Nociflex thorns are slightly modified to ensure patient comfort. We rounded off the tops of each of our Nociflex thorns to reduce the prickly sensation induced with sharper tips.

5.3 Material Comparison and Analysis

Given the objectives described in table above the next step would be to choose the appropriate material.

5.3.1 Thorns

<table>
<thead>
<tr>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Protrudes from adhesive layer and presses against skin</td>
</tr>
<tr>
<td>- Simulates soft touches effectively</td>
</tr>
<tr>
<td>- Durable and lightweight</td>
</tr>
</tbody>
</table>

We decided to construct Nociflex thorns using synthetic resin due to its cheap cost of production, high durability and resistance to abrasion. Other alternatives such as plain polyethylene and synthetic rubber were considered but dismissed due to their “cheap” feel. Synthetic resin has a more polished appearance for the same price.

---

13 3D model generated on Tinkercad by Ernest Tsoi
14 3D model generated on Tinkercad by Ernest Tsoi
5.3.2 Adhesive Layer

Requirements:
- Strongly adheres the patch to skin
- High resistance to shear stress
- Breathable and non-inhibitory

3M Adhesives and Elkem Silicone Adhesives were chosen and compared as potential adhesives for NPs. Their respective products and their characteristics are listed below:

<table>
<thead>
<tr>
<th>Material</th>
<th>Functionality</th>
</tr>
</thead>
</table>
| Elkem (silicone skin adhesives: sold as incomplete gel products) RT Gel 4743 | - 2.7N peel adhesion  
- High shear resistance  
- High wear time  
- Atraumatic removal  
- Used for non-woven based dressing |
| RT Gel 4642 | - 2.5N peel adhesion  
- Medium shear resistance  
- Movement resistant  
- Used for OTC bandages |
| RT Gel 4717 | - 2.0N peel adhesion  
- High shear resistance  
- Comfortable wear  
- Multi-purposed |
| 3M (complete skin adhesives: with liner and backing) 2475P Single-coated Medical Silicone Adhesive Tape on Liner | - 0.8N peel adhesion  
- Thin, flexible, and comfortable  
- Excellent initial skin adhesion  
- Hypoallergenic  
- Premium clear polypropylene liner |
<table>
<thead>
<tr>
<th>2476P</th>
<th><strong>Single-coated Non-woven Medical Silicone Adhesive Tape on Premium Liner</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- 1.25N peel adhesion</td>
</tr>
<tr>
<td></td>
<td>- Flexible and comfortable</td>
</tr>
<tr>
<td></td>
<td>- Excellent initial skin adhesion</td>
</tr>
<tr>
<td></td>
<td>- Gentle on skin</td>
</tr>
<tr>
<td></td>
<td>- Premium clear polypropylene liner</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2477P</th>
<th><strong>Double-coated “2-in-one” Medical Silicone/Acrylic Tape</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Silicone side: 1.1N peel adhesion</td>
</tr>
<tr>
<td></td>
<td>- Acrylic side: 6.0N peel adhesion</td>
</tr>
<tr>
<td></td>
<td>- Good for short term wear</td>
</tr>
<tr>
<td></td>
<td>- 2 adhesive systems with 2 liners</td>
</tr>
</tbody>
</table>

Upon comparison it was immediately apparent that 3M adhesive products were not applicable to the production of NPs. 3M adhesives were not available to be purchased as purely adhesive layers, instead are delivered as fully functioning skin adhesives for medical wound management. The backing membrane, adhesive and liner layer were sold in a complete set, hence modification of the product to accommodate Nociflex thorns is inefficient.

Alternatively, Elkem silicone adhesives are sold in the form of untreated gel products. We decided to obtain RT gel 4717 due to its comfort during wear, high shear resistance, and multi-purpose design. 4717’s peel adhesion is the lowest out of the three Elkem gels. Alternatively, it has the highest peel adhesion compared to all of the completed 3M silicone skin adhesives. Given that the 3M products chosen are all medically-used wound management products, we believe that the 2.0N peel adhesion in RT gel 4717 was sufficient for NP application.

**RT Gel 4717 Trial:**
Free samples of RT gel 4717A and RT gel 4717B were obtained for testing. Combination of the two silicone polymers forms the solidified gel product. The two components are first mixed thoroughly, this process can be done by hand or via a pneumatic mixer to reduce introduction of air bubbles. Afterwards, a degassing process is performed to eliminate entrapped air. During this process the mixture should expand significantly and bubbles would rise to the surface. A vacuum is flashed to burst all the surface bubbles.
The polyaddition reaction occurs after degassing at room temperature (23°C), and is reportedly fully polymerised in 30 minutes. The polymerised product forms the solidified adhesive gel (Elkem, 2018).

<table>
<thead>
<tr>
<th>RT Gel 4717A</th>
<th>RT Gel 4717B</th>
<th>Mixed Product</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
<td><img src="image3" alt="Image" /></td>
</tr>
</tbody>
</table>

Elkem offered free samples of the RT gel 4717 A/B. We attempted the polyaddition process with our limited resources. The silicones were hand-mixed and poured onto a plastic lid mold, we excluded the degassing process and left the mixture to set. The resulting silicone adhesive was highly adhesive, adhesion to skin was good and is likely to last for a couple of hours. The silicone remained highly adhesive even after peeling, which offers potential for repositioning. We were unable to fully detach the adhesive from the mold in one piece, which raises the issue of structural integrity. We found that the issue lies in the lack of a proper silicone adhesive mold and lack of degassing. Air bubbles trapped in the silicone disrupts the structural uniformity of the adhesive, and lack of a proper mold meant that detachment was difficult. Overall, with the proper technology and equipment, RT gel 4717 is a good choice for the adhesive layer of NPs.

### 5.3.3 Backing Membrane

| Requirements: | - Protects adhesive during wear  
| | - Thin to limit patch thickness  
| | - Breathable and comfortable  
| | - Smooth and aesthetically appealing |

For backing membranes we looked mainly into the options available on 3M (Chu, 2011). We selected CoTran™ Backings in particular as they specialize in being translucent and flexible, whilst also addressing skin health and comfort through breathable or moisture-retaining characteristics:

<table>
<thead>
<tr>
<th>Material</th>
<th>Functionality</th>
</tr>
</thead>
</table>
| 3M™ CoTran™ Backings 9720 | - 0.076mm thick  
| | - Breathable  
| | - Smooth and comfortable |
Both backing options are thin and aesthetically appealing. 3M™ CoTran™ Backings 9733 focuses on customizability and preventing moisture loss, whilst 3M™ CoTran™ Backings 9720 focuses on user comfort and breathability. We decided on 9720 as our patient’s comfort is top priority. Retainment of skin moisture in 9733 is not ideal for the promotion of exercise, as sweat accumulation under the patch is simply uncomfortable and unhygienic.

5.3.4 Release Liner

<table>
<thead>
<tr>
<th>Requirements</th>
<th>- Protects adhesive during storage</th>
</tr>
</thead>
</table>

Polyethylene liners were selected as this material is commonly used as silicone release liners for pharmaceutical wound care (Zucker, 2017). Exact material yet to be confirmed.

5.4 Initial Prototype:

With the compositional requirements and selected materials mentioned above, we generated a digital representation of the final product:

15 3D model generated on Tinkercad by Ernest Tsoi
We proceeded to develop an enlarged working prototype from scratch, using the following materials:

1. Free samples of RT Gel 4717 A/B offered by Elkem;
2. Polyethylene Nociflex thorns 3D-printed in HKU;
3. Aluminium foil as the basement membrane;
4. Liner was excluded.
<table>
<thead>
<tr>
<th>Nociflex Thorns (3D-printed) ¹⁶</th>
<th><img src="image1.jpg" alt="Image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium Foil as Silicone Mold and Basement Membrane ¹⁷</td>
<td><img src="image2.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Application and Setting of RT Gel 4717 A/B ¹⁸</td>
<td><img src="image3.jpg" alt="Image" /></td>
</tr>
</tbody>
</table>

¹⁶ Modelled and 3D-printed in HKU Library by Ernest Tsoi
¹⁷ Aluminium foil mold folded by Ernest Tsoi
¹⁸ Silicone polyaddition and setting by Ernest Tsoi
5.4.1 Prototype Review

**Adhesion:**
The adhesion of the patch was sufficient in lasting the majority of the day. Testing of the patch only lasted 2 hours due to the inconvenience of having the patch on. The patch felt cool and breathable throughout the entire duration of wear, and removal of the patch was completely atraumatic. However, removal of the patch resulted in some remnants of silicone on the skin, which we hypothesized was due to the lack of degassing prior to silicone solidification, compromising adhesive layer integrity.

**Thorns:**
The indents on the skin after application are due to the 3D-printed thorns, which were unsanded hence callous. The red marks highlight the importance of attaining a polished substance for the thorns, smooth synthetic resin would be a lot less traumatic to the skin. Additionally, the 3D design of the thorns could be further modified to round off the tips of the thorns in a more gradual manner. Current thorn designs were constructed by overlaying a compressed sphere shape onto a pyramid shape. Alternatively, removing pyramid tips and rounding it off directly could offer substantial improvement.
Despite the appearance of redness on the skin, application of the thorns did not produce any pain or discomfort, instead the sensation was slightly ticklish and tingly on the skin. We hypothesize that these sensations are proof that the thorns are activating the intended low-threshold mechanoreceptors. The thorn-induced sensations had no impact on muscle mobility, which is essential for achieving our ideology of active recovery.

**Prospects:**
For development and production of a finalized product, we plan to partner with 3M as they offer patch production services. The prototype revealed the necessary standardized environment for production, hence collaboration with a well-known and licensed manufacturer such as 3M is crucial. 3M also provides both backing membranes and release liners, so Nociflex would only need to supply material components for the gel adhesive and the thorns themselves.

### 5.5 Estimated Cost and RSP

<table>
<thead>
<tr>
<th>Material/Production:</th>
<th>Approx. Cost per Patch (HKD):</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Backing membrane:</strong></td>
<td>$1 - 1.5 (TBD; overestimation)</td>
</tr>
<tr>
<td>3M™ CoTran™ Backings 9720</td>
<td></td>
</tr>
<tr>
<td><strong>NP thorns:</strong></td>
<td>$0.40 - 0.80 ($11.65 - 19.42/kg)</td>
</tr>
<tr>
<td>Synthetic resin</td>
<td></td>
</tr>
<tr>
<td><strong>Adhesive:</strong></td>
<td>$1.2 - 1.3 ($38.84 - 42.72/kg)</td>
</tr>
<tr>
<td>RT gel 4717 A/B</td>
<td></td>
</tr>
<tr>
<td><strong>Release liner:</strong></td>
<td>$0.001 - 0.008 ($1.63 - 14.37/m²)</td>
</tr>
<tr>
<td>Polyethylene liner</td>
<td></td>
</tr>
<tr>
<td><strong>Production cost</strong></td>
<td>$1 - 2 (TBD, predicted decrease over time when manufacturing process matures)</td>
</tr>
<tr>
<td><strong>Total cost:</strong></td>
<td>$3.60 - 5.6</td>
</tr>
</tbody>
</table>

Given the many materials that do not disclose exact cost, our estimations in the table above is likely an overestimation, pricing each patch at around 4 - 6 HKD. Our retail selling price (RSP) is likely to be at least double the price, which prices each patch at 8 - 12 HKD. Selling in sets of 5 patches per box sets the price to around 30 - 60 HKD per box. This price is low in comparison to the alternatives available in the market, which is detailed in the *Competitor Analysis* section.
6. Market Survey\textsuperscript{19}

The views of our potential users and customers on pain management methods offer validation and refinement of our business model. To understand their needs and expectations, a local survey was conducted in March 2021 via online questionnaire and personal interviews.

6.1 Findings

Of the 13 respondents, 10 of them (76.9\%) suffered from chronic nociceptive pain (Fig. A). Amongst these 10 people, two-thirds were currently still suffering from chronic pain. Pain was prevalent across generations, with half of the 10 experiencing chronic pain during early adulthood (during their 20s).

![Figure A](image1.png)

There were several culprits of chronic pain, with poor lifestyle habits (e.g. sedentary life and incorrect postures), being the top cause (Fig. B). It was followed by arthritis and unknown causes. Some reported previous sports injury, joint sprains and muscle strains, and degeneration as well.

![Figure B](image2.png)

\textsuperscript{19} Figures in this section are all created by Candice Tse
Most respondents with chronic pain have adopted more than one intervention. Expectedly, drug-based methods (painkillers and topical analgesics) were applied most frequently (Fig. C) and were the most well-known. Some applied heat and icing, whilst neurostimulation methods were uncommon. Only 3 of 13 heard of non-conventional neuromodulative regimens like dry needling and TENs.

People held different views towards drug-based treatments. Two of them were satisfied with medications due to the fast achievement of pain relief and the ease of administration. Those who were dissatisfied reported the drug-based regimens failing to consistently relieve pain, and inducing notable side effects (e.g. skin irritation upon applying patches).

From the survey, 12 out of 13 respondents expressed their willingness to try new pain relief products when they encountered somatic nociceptive pain. Three quarters of the respondents are willing to spend ≤$1000hkd monthly on pain management. The main features of new analgesic products they preferred include: achieving fast and longer-lasting pain relief, having minimal adverse effects and invasiveness, being affordable, comfortable and easy to use (Fig. E).

6.2 Implications
Despite the small study size, that chronic pain affects people from various age groups is notable, affirming the big market for analgesics. The drawbacks of medication-based regimens and the urge for drug-free alternatives also support our concept of developing Nociflex patches.

Importance of affordability, convenience and comfort:
The concerns on minimizing invasiveness and increasing comfort encouraged us to design short, non-penetrating thorns with rounder tips. Since some patch users reported skin irritation upon prolonged patch application, sourcing non-irritant materials for both thorns and adhesive, as well as testing the optimal time for a single continuous NP application is needed. To make our product affordable for most potential users, appealing pricing by controlling the manufacturing costs and launching subscription
models will allow for us to sell at both an attractive and profitable price range. Prices similar to the conventional pain patches might help boost the competitiveness of our product.

**Lack of knowledge on neuromodulatory analgesics:**
Potential challenges in launching the product were also revealed, one of them is the lack of popularity of neural modulation in the local community. The dominance of conventional drugs remains fierce, hence promoting scientific rationales of Nociflex patches is essential for marketing, particularly through social media.

**Problems with referred pain:**
Some respondents reported experiencing referred pain, a condition that describes the pain being sensed in a site away from the origin. It is hard to be identified by patients themselves hence consultation by medical doctors or physiotherapists is needed. Without noticing referred pain, the analgesic effect of NP might be reduced. To address this, we could mention this condition in the user manual, and recommend users to seek advice from clinicians before using our patches.

![Figure D](image1.png)  ![Figure E](image2.png)
7. Competitor Analysis

In view of the escalating prevalence of pain, the global market of pain management has an anticipated revenue generation of around USD151.7 billion in 2030, and a compound annual growth rate of 6.5% this decade (Wood, 2020). Conventional drug-based analgesics have been dominating the market for years.

To target somatic nociceptive pain, non-steroidal anti-inflammatory drugs (NSAIDS), N-acetyl-para-aminophenol (APAP), and acetyl salicylic acid (ASA) are applied, with NSAIDS being most common (Kim et al., 2020). More alternatives are being recognized by the public, including neurostimulation and vibration devices. Physically-based interventions such as thermotherapy and dry needling are offered in some rehabilitation clinics as well. Hoping to differentiate our business from other candidates, the main competitors are segmented by product type and analysed as follows:

7.1 Analgesic Drugs – Oral

<table>
<thead>
<tr>
<th>Products</th>
<th>Painkillers: NSAIDs, APAP and ASA, paracetamol e.g. ibuprofen, acetaminophen, naproxen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key players</td>
<td>GlaxoSmithKline plc, Pfizer Inc, Novartis AG, Abbott Laboratories, Medtronic, Johnson &amp; Johnson, Eli Lilly and Company, etc.</td>
</tr>
<tr>
<td>Mechanism of action</td>
<td>NSAIDs: Inhibits cyclo-oxygenase (COX) pathway to suppress inflammation; reduces inflammation-induced pain. APAPs: Positive effects on serotonergic descending inhibitory pain pathway; interacts with opioid and eicosanoid systems. ASAs: Irreversibly inactivates COX-1 pathway promoting inflammation; reduces inflammation-induced pain.</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Fast-acting: Requires &lt;1 hour to reach the peak drug concentration in circulation. Therapeutic-ceiling effect: Incapable of breaking through pain; higher dose does not result in better efficacy.</td>
</tr>
<tr>
<td>Estimated Price</td>
<td>Over-the-counter: (Mannings, 2000) Panadol: HKD 58.9 (24 pills, standard); HKD 94.2 (30 pills, extra advance) Prescription drugs: (GoodPx, 2000) Tramadol: HKD 92.4 (60 tablets, 50mg) Oxycodone: HKD 127.8 (90 tablets, 5mg)</td>
</tr>
<tr>
<td>Strengths</td>
<td>- Fast effect induction</td>
</tr>
</tbody>
</table>

20 Diagram indicating Analgesic Product Market Size attached in Appendix Image 4
### 7.2 Analgesic Drugs – Topical

<table>
<thead>
<tr>
<th>Products</th>
<th>Analgesic gel, patch, spray, and cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key players</td>
<td>Salonpas (Hisamitsu Pharmaceutical), Counterpain (Taisho Pharmaceutical Holdings)</td>
</tr>
<tr>
<td>Mechanism of action</td>
<td>Constituents and working mechanisms are generally the same as the orally-administered drugs. Some topical drugs contain counterirritants like menthol to give off a “cooling sensation” by desensitizing nociceptors (Pergolizzi, 2018)</td>
</tr>
<tr>
<td>Application of topical medications to the epidermis at the pain sites allows gradual diffusion of the drug into the circulation.</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>8-hour application provided significant pain relief: Comparison of pain reported by placebo and test group reported significant differences in intensity of mild-to-moderate muscle pain (Higashi et al., 2010).</td>
</tr>
<tr>
<td>Estimated Price</td>
<td>HKD 52 - 71.8 (Baim, 2000)</td>
</tr>
<tr>
<td>Distribution channels</td>
<td>B2C: Pharmacies, drug stores, e-commerce platforms, retailers</td>
</tr>
</tbody>
</table>
| Strengths         | - Various patch sizes available  
                  - Little hinderance to movement  
                  - Cooling sensation  
                  - Relatively inexpensive |
| Weaknesses        | - Presence of milder side effects compared to oral drugs (Zeng et al., 2018)  
                  - Skin irritation more prominent  
                  - Some products are odorous  
                  - One-off hence non-reusable |
## 7.3 Neurostimulation Devices

<table>
<thead>
<tr>
<th>Products</th>
<th>Transcutaneous electrical nerve stimulation (TENS) devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key players</td>
<td>Conventional pharmaceutical MNCs: Abbott Inc., Chattanooga, etc. Innovative health gadget companies: Oska Wellness, Healthmate International, etc.</td>
</tr>
<tr>
<td>Mechanism of action</td>
<td>Mild electrical stimulation with high or low frequencies. Reduces pain by suppressing sensitization of DH neurons to noxious signals, and activating the descending inhibitory systems in the CNS (Vance et al., 2014)</td>
</tr>
</tbody>
</table>
| Efficacy | Various results reported in different randomized controlled trials:  
Positive results:  
*Pain relief observed in 8 out of 10 people; on average around 81% of pain is reduced within 1 year.*  
Negative results:  
*Study of 9 Cochrane reviews revealed low evidence quality in affirming better efficacy of TENs over sham TENs in chronic pain relief (Gibson et al., 2019).* |
| Estimated Price | HKD150-3000 (Pellek, 2000) |
| Distribution channels | B2C: health equipment stores, e-commerce platforms  
B2B2C: physiotherapist clinics, hospitals |
| Strengths | - Customizable to specific body parts (including knee, hips, feet and groin)  
- Customizable stimulation intensity and intervals  
- Long-lasting (reusable upon recharging)  
- Some are compact and suitable for domestic use or during movement  
- Money-back satisfaction-guarantee are applied to attract new users  
- Chemical-free |
| Weaknesses | - Varying analgesic effect among individuals  
- Fast diminishing of analgesic effect upon removal of stimulation  
- Regulation of actual pain-relieving effect  
- Some are pricey with added “smart-tech” functions |

## 7.4 Dry Needling

| Mechanism of action | Needle insertion into skin and muscles at the targeted myofascial trigger points (MTrPs) produces specific mechanical stimulation. This causes a local twitch response to lower the concentration of nociceptive substances surrounding the MTrPs and hence reduce nociceptive pain. |
| Efficacy | Various results reported in different randomized controlled trials:  
Positive results: |
Meta-analysis concluded that dry needling is effective for treating chronic pain from short to medium term (Liu et al., 2015).

Negative results:
*Mechanism of action only provides short term release of anti-nociceptive substances; no evidence of lasting effect. Evidence suggests exercise is more effective than dry needling for long-term pain reduction.* (Matsel et al., 2021)

<table>
<thead>
<tr>
<th>Estimated Price</th>
<th>Around HKD1,000 per session (private clinics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution channel</td>
<td>Rehabilitation clinics, Chinese medicine clinics</td>
</tr>
</tbody>
</table>
| Strengths | - Customizable treatment to the needs and conditions of the patients  
- Accompanied with consultation (therapists can accurately spot pain origin)  
- Precise nerve stimulation on pain site  
- Chemical-free |
| Weaknesses | - Must be performed by qualified practitioners  
- Risky due to penetration through skin  
- Treatment can potentially induce pain  
- Patients are immobile during treatment |
7.5 Summarised Comparison of Analgesic Therapies:\(^{21}\):

<table>
<thead>
<tr>
<th>Analgesic Therapy + Mechanism of Action:</th>
<th>Strengths:</th>
<th>Weaknesses:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nociflex Patch:</strong></td>
<td>Inexpensive</td>
<td>Limited pain type</td>
</tr>
<tr>
<td></td>
<td>Long-lasting</td>
<td>Single-use</td>
</tr>
<tr>
<td></td>
<td>Drug-free</td>
<td>Efficacy TBD</td>
</tr>
<tr>
<td></td>
<td>Non-invasive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Convenient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Enables mobility</td>
<td></td>
</tr>
<tr>
<td><strong>Oral Drugs:</strong></td>
<td>Inexpensive</td>
<td>Therapeutic ceiling</td>
</tr>
<tr>
<td></td>
<td>Fast-acting</td>
<td>Short-lasting</td>
</tr>
<tr>
<td></td>
<td>Non-invasive</td>
<td>Adverse effects</td>
</tr>
<tr>
<td></td>
<td>Convenient</td>
<td>Potential reliance</td>
</tr>
<tr>
<td></td>
<td>Enables mobility</td>
<td></td>
</tr>
</tbody>
</table>

\(^{21}\) Mechanism diagrams in this section made on Google Drawings by Ernest Tsoi
### Topical Drugs:

<table>
<thead>
<tr>
<th>Inexpensive</th>
<th>Adverse effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooling sensation</td>
<td>Short-lasting</td>
</tr>
<tr>
<td>Convenient</td>
<td>Mostly single-use</td>
</tr>
<tr>
<td>Enables mobility</td>
<td>Can be odorous</td>
</tr>
<tr>
<td></td>
<td>Potential reliance</td>
</tr>
</tbody>
</table>

### Neurostimulation Devices:

<table>
<thead>
<tr>
<th>Long-lasting</th>
<th>Expensive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customizable</td>
<td>Can be painful</td>
</tr>
<tr>
<td>Reusable</td>
<td>Varying efficacy</td>
</tr>
<tr>
<td>Drug-free</td>
<td>Limits mobility</td>
</tr>
<tr>
<td></td>
<td>Inconvenient</td>
</tr>
</tbody>
</table>

### Dry Needling:

<table>
<thead>
<tr>
<th>Customizable</th>
<th>Very expensive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precise pain target</td>
<td>License needed</td>
</tr>
<tr>
<td>Drug-free</td>
<td>Invasive</td>
</tr>
<tr>
<td></td>
<td>Can be painful</td>
</tr>
<tr>
<td></td>
<td>Patient is immobile</td>
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<tr>
<td></td>
<td>Inconvenient</td>
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Like many existing pain management products, Nociflex aims to restore the normal lives of patients by reducing pain burden. However, rather than eradicating pain, most interventions (including Nociflex patches) are only able to suppress pain sensations temporarily.

Alternatively, Nociflex attempts to be a pain-relieving complement that advocates going drug-free and staying physically active during recovery. Although the market remains dominated by conventional medications, the estimated three-fold growth in neurostimulation devices by 2027 favours our SAM growth. Setting NPs at a price similar or lower than drug-based patches also help boost our competitiveness amidst these market leaders.

Among the non-drug choices, NPs are by far the most alike to portable TENS products in terms of application. With bluetooth connection, TENS patches could be applied and controlled remotely during normal activities of the users. Yet, our patches differ mainly by inducing mechanical tactile stimulation, rather than direct electrical stimulation. The latter is riskier due to potential electric burns, and the efficacy reports on it are variable. Compared to our current design, TENS devices are advanced by enabling users to customize stimulation intensity and interval. Adding this feature to our patches is being considered. Moreover, the battery-powered TENS could be recharged and have a longer shelf life. Given our

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22 SWOT Analysis diagram created by Candice Tse
immature testing on the reusability of NP adhesives, current NP prototypes are disposable and require continuous subscriptions from chronic pain users, which helps sustain the SAM.

Meanwhile, NPs share the same nature of stimulation with dry needling by mechanically exciting myofascial trigger points. NPs performs better by being non-invasive whilst simultaneously allowing user mobility. However, NPs are only able to stimulate low-threshold mechanoreceptors in the superficial tissues, and hence are inferior to dry needling when targeting deep-seated somatic pain.

Boosting product exposure to the potential market is crucial for brand-building. When NPs are ready for sales, we will promote NPs via social media channels. We will also consider inviting KOLs specialized in sports to introduce NPs to their audience, this is a common practice adopted by many recent start-up projects.
8. Product Validity

Validation of our business model is essential in making sure our project’s development stays grounded, as well as to highlight issues to resolve in the future for a successful business launch. Validity of NPs in terms of its market and technology were checked and predicted through:

1.) Research studies;
2.) Product prototyping;
3.) Collected opinions from potential users and professionals.

<table>
<thead>
<tr>
<th>Concerns/Issues</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Size</td>
<td><strong>TAM:</strong> Chronic musculoskeletal pain affects around 10% of the world’s population, accounting for a market size USD$3.79 billion in 2019.</td>
</tr>
<tr>
<td></td>
<td><strong>SAM:</strong> 10.8% of HK adults suffer chronic pain (2002). Given the aging population and the growing prevalence of pain-induced morbidities, the SAM for NPs is anticipated to expand.</td>
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<tr>
<td></td>
<td><strong>SOM:</strong> The dominance of conventional drug-based analgesics (around % of the market) is likely to remain in the coming decade, in both domestic and clinical settings. Nociflex predicts an SOM of 10% of the current Hong Kong chronic musculoskeletal pain market.</td>
</tr>
<tr>
<td>Market Sustainability</td>
<td><strong>Stable and sustainable demand for analgesics:</strong> Growing prevalence of pain and morbidities resulting in pain - such as sports injuries and aging-associated illnesses. Around 1 in 10 Hong Kongers develop chronic pain annually.</td>
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<td></td>
<td><strong>Demand for drug-free solutions:</strong> The fashion of cutting drug-use is an emerging phenomenon in the healthcare industry.</td>
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<td></td>
<td><strong>NPs as a single-use product:</strong> The NP prototype used a non-reusable adhesive component. Chronic pain consumers would require continuous timely purchases for long-term use.</td>
</tr>
<tr>
<td>Target Consumers</td>
<td><strong>Consumers are open to alternatives to traditional analgesics:</strong> Most potential users expressed their preference in trying innovative analgesic products in the survey.</td>
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<td></td>
<td><strong>Awareness of drug-induced side effects in chronic pain patients:</strong> Growing concern on medication-oriented pain management and its side effects amidst chronic pain patients and clinicians.</td>
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<tr>
<td>Technology</td>
<td></td>
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<tr>
<td>Skin-friendly Components</td>
<td>Adhesive: <em>Medical-grade silicone adhesives cause no skin irritation, as reflected in our prototype and in manuals from the suppliers (3M and Elkem). Some adhesives specially cater to the delicate skins of children and elderly.</em></td>
</tr>
<tr>
<td></td>
<td>Thorns: <em>Plain synthetic resin is completely non-allergenic and non-traumatic given proper structural design. Prototype indicated issues with the initial design in causing mild irritation and redness, which are taken into consideration.</em></td>
</tr>
<tr>
<td>Structurally-secure Patch Composition</td>
<td>Product design modifications: <em>Continuous modifications of NP composition have been made to counteract possible structural weakness. Initial designs placed Nociflex thorns on top of the adhesive membrane, a structurally fragile design. Current designs embed thorns onto the basement membrane.</em></td>
</tr>
<tr>
<td></td>
<td>3M manufacturing offers: <em>We are considering a potential partnership with 3M, a licensed medical product manufacturer. They offer customers the option to combine their selected patch components (basement membrane, adhesive, release liner, drug) into a functional patch. Given the uniqueness of integrating thorns into a patch design, we will verify whether the offer applies to NPs.</em></td>
</tr>
<tr>
<td>Analgesic Mechanism</td>
<td>Mechanism based on Melzack’s gate theory of pain: <em>Melzack’s gain theory of pain (1965) illustrates how non-painful stimulation near a pain site induces analgesia. This theory is widely recognized and adapted in clinical settings. In the research paper ‘Adhesive pyramidal thorn (PT) patches provide pain relief to athletes’ (Saito et al., 2019), significant knee pain reduction (p&lt;0.01) upon continuous application of PT patches was observed.</em></td>
</tr>
<tr>
<td></td>
<td>Validation from prototype: <em>Prototype testee verified the 3D-printed thorns produced low-threshold mechanical stimulation when pressed against the skin. Although redness of the skin was reported upon removal, no pain was detected during the application duration. Experiments on pain-reduction have yet to be initiated.</em></td>
</tr>
<tr>
<td>Enabling Patient Mobility</td>
<td>Basement membrane: <em>3M basement membrane options offer flexibility and high shear resistance. 3M™ CoTran™ Backings in particular are particularly appealing due to the additional breathable option to increase skin comfort. The combination of durable, flexible and comfortable characteristics allows patients to undergo exercise completely uninhibited.</em></td>
</tr>
<tr>
<td></td>
<td>Adhesive: <em>El kem silicone skin adhesive options offer flexibility, comfort, and high shear resistance. Although mainly used for scar or wound management, the</em></td>
</tr>
</tbody>
</table>
silicone components themselves do not provide any resistance to muscle motion. RT gel 4717 in particular is reported to be multi-purposed, and prototypes illustrated that it has no impact on patient movement.

Prototype validation:
Prototype testees reported that the effects of the thorns also had no inhibitory effect on muscle contraction of the target area. This test simulates muscle contractions during physical activity.

| Safety Requirements | Classification as medical device:  
According to Classification Rules of Medical Devices issued by the Hong Kong Department of Health: NPs are a type of Class I medical device. NPs are a non-invasive device that comes into contact with injured skin, functioning only as a mechanical barrier for compression against the skin. According to Rule 1, this type of medical device is low-risk hence is also under the least regulations (Dept. of Health, 2010).

Regulations of a Class I medical device:  
Currently registration of Class I and II medical devices are not mandatory in Hong Kong, however Hospital Authorities will always prioritize a registered product over an unregistered one. Nociflex will likely push for a registered product to confirm product safety and efficacy, this comes with the potential need for local clinical trials (Emergo, 2020). Exact regulations regarding Class I medical devices are uncertain, and vary for the type of medical device. Since NPs are still early in development, consultation for regulatory requirements have yet to be conducted. |
9. Advice from Experts

In the past few months, we attended workshops delivered by experts from biotech start-ups, business, intellectual property law, and regulatory affairs, etc. In order to validate our ideation, gain comprehensive advice on product R&D, and understand valuable concepts before launching our start-up, we gave a brief pitch on Nociflex patches in each session. Immediate feedback was collected from our supervisors and colleagues. In general, the audience expressed interest in our idea and perceived a large, sustainable market for our patches. Further field-specific suggestions are shown as follows:

9.1 Technology and R&D

**Collaboration with experts:**
Inviting neurologists and clinicians specialized in pain management during R&D could facilitate outcome validation of the product.

**Randomized controlled trials:**
Conducting randomized controlled trials minimizes allocation and selection bias, interference from confounding factors, and is more statistically reliable to test NP efficacy.

**Offer customizability:**
Potentially making stimulation intensity and duration adjustable to cater the potential risk of patient desensitization to thorn stimulation.

**Optimizing design efficacy:**
Test variations of tactile stimulation and efficacy of inducing analgesia when the thorns: are made of different materials; have different conformation (e.g. rounder or sharp tips); are arranged in different patterns and densities.

9.2 Intellectual Property (IP)

**Rights to technology:**
Keep track of patent filing status of similar products (e.g. pyramidal thorn patches), to ensure we do not have to pay for rights to sell the technology by the time of IP registration.

**Reduce risk of copies:**
Ensure uniqueness of design through trademark features to reduce the risk of being counterfeited or copied in other products.

**Patenting our product:**
Starting patent filing during early product development phases to secure intellectual property (i.e. provisional patent). The long period for patent approval accompanies the similarly long process of R&D.
9.3 Marketing

**Social media advertising:**
Inviting key opinion leaders (KOLs) to promote NPs during its early-launch in order to boost social media presence of both our company and NPs.

**Partnership opportunities:**
Partnering with rehabilitation clinics and insurance companies whose clients have a high potential of trying out our NPs.

**Offering samples:**
Giving out free samples and inviting potential users as volunteers for efficacy and UX testing.

9.4 Business

**Sustain consumer base:**
Establishing a “community group” in which members could share their experience using NPs compared with other forms of pain management.

**Customer feedback:**
Collecting feedback from customers and users timely and actively through social media for better UX.
10. Business Roadmap

Nociflex Business Roadmap

- **EVT**: Engineering verification test
- **DVT**: Design verification test
- **PVT**: Product verification test
- **RCT**: Randomized controlled trial
11. Personal Reflection

11.1 Candice

Initiating and visualizing our novel drug-free analgesic was an interesting process. Yet, I will not continue with it in the short future. Pain management is currently a huge market where the dominance of drugs seems to last for the coming decades. Expectation from patients and healthcare practitioners on a fast and long-lasting analgesic effect has been growing. Without adequate intellectual and financial capitals, commercialising Nociflex patches with well-recognised efficacy is less likely. Not until I acquire more concrete expertise in pain management and tech-based requisites can I convince myself to keep running this health tech start-up.

Nonetheless, the concept of going drug-free in health management is trendy nowadays. It would be great to see further development on these mechanically based pain-relievers.

11.2 Ernest

Personally, I believe that continuation of a project with this immense ambition of revolutionizing the pain market would be very time-consuming and not very feasible. Given our team’s limited resources, the likelihood of successful marketing - not to mention R&D - is very slight.

The backbone of our project relies on the technology suggested by a single group of scientists from Japan. Despite many attempts to contact them, we have yet to receive any replies. Their team has also made no substantial updates since the release of their paper, which makes the future of NPs very bleak. I personally do believe that a drug-free mechanosensory product will likely dominate the market in the future, however the lack of existing research in this area means that we might not have the technology or the knowledge to properly implement this idea.
10. References


11. Appendix

Contribution Table:

<table>
<thead>
<tr>
<th>Roles</th>
<th>Candice</th>
<th>Ernest</th>
</tr>
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Image 1
(from PT patch paper)
**Image 2**
(from PT patch paper)

**Figure 3**
Proposal mechanism for physical analgesia by soft touch involving oxytocin in the DRG. As shown in Figure 2, the pain sensation can be recorded at the frontal cortex by near-infrared spectroscopy (NIRS).

**Image 3**
(from 3M)

Graphic courtesy of 3M
Business Model Canvas Iterations:

Version 1: 10/4/2020

<table>
<thead>
<tr>
<th>Key Partners</th>
<th>Key Activities: Optimization and production of a highly effective, non-invasive analgesic.</th>
<th>Value Propositions: Revolutionary High quality High customizability Reusable Rechargeable Find out which areas current products are lacking in (TENs machine, Salonpas etc.)</th>
<th>Customer Relationship</th>
<th>Customer Segments: Public health clinics Orthopaedic clinics Fitness centers</th>
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<tbody>
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<td>Key Resources: Financial resources</td>
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<tr>
<td>Channels: Web purchases</td>
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<tr>
<td>Revenue Streams: Finding alternative income sources</td>
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### Version 2: 11/8/2020

<table>
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<th>Key Activities:</th>
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<tbody>
<tr>
<td></td>
<td>Optimization and production of a highly effective, non-invasive analgesic.</td>
<td>Reducing reliance on painkillers Revolutionary High quality Highly customizable Reusable Rechargeable</td>
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<td>[Buyers]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Find out which areas current products are lacking in (TENs machine, Salonpas etc.) TENs machine; pads have to be changed, pads dry out, allergies, discomfort Salonpas: bad smell, latex, can cause severe burns</td>
<td></td>
<td>Public health clinics Orthopaedic clinics Fitness centers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[End users] Patients with chronic pain</td>
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| Key Resources: |                          |                      |                      |                          |
|                | Financial resources |                      |                      |                          |

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<tr>
<td>Most likely a cost-driven business model</td>
<td>Finding alternative income sources Subscription-based business model (patches are not completely reusable)</td>
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### Version 3: 26/1/2021

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<tr>
<td>APS Orthopaedic Joint Dynamics PhysioMotion HK Sports Clinic Elkath (silicone adhesive)</td>
<td>Optimization and production of a highly effective, non-invasive analgesic.</td>
<td>X Painkillers Revolutionary High quality Reusable Price: $80 - $100</td>
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<td>[Buyers] Private health clinics (consumers willing to pay the extra price for higher quality services are more likely to purchase our product, likely to form key partnerships to promote product) Fitness centers</td>
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<td></td>
<td>[End users] Patients with chronic pain (product mainly targets athletes as they are more likely to purchase; other patients or elderly suffering from chronic pain are also possible customers) B2B2C Potential B2C</td>
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<td>Financial resources</td>
<td>1. Redistributed by rehab centres, ortho clinics, fitness centres 2. Web purchases</td>
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<th>Revenue Streams:</th>
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<td>Finding alternative income sources Subscription-based business model (patches are not completely reusable)</td>
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