

# Analysis and Redesign Challenge

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# Product Overview

The DonJoy X-ROM™ is a post-op knee brace that prevent excess range of motion (ROM) and stability to the patient.



# Product Stakeholders Analysis

## Direct Stakeholders:

- Patient/User
- Healthcare Professional (Orthopedic Surgeon, Physical therapist, Orthotist)

## Indirect Stakeholders:

- Insurance Companies
- Manufacturer/ Distributor ( Enovis & DonJoy)
- Family Members
- Employer of the patient
- FDA

# Product Stakeholder Analysis

## Direct Stakeholders:

- **Patient/User** directly use the knee brace post-op to control ROM, pain relief, support, and stability. They use and experience this brace everyday for months for daily activities and their experience directly relates to their comfort, mobility, and recovery process. As a user myself, if the brace is not worn in all daily activities swelling and pain occur as well as loss of ROM. When the brace is worn my stamina for standing increases significantly. Failure to do so can cause major complications of the knees integrity, discomfort, and a prolonged recovery are at stake.
- **Healthcare Professional (Orthopedic Surgeon, Physical therapist, Orthotist)** directly prescribe the knee brace to aid the patients recovery, injury prevention, and rehabilitation and they are incharge of unlocking the brace when they see the patient is fit to have more ROM. The current experience according to both my PT's is that they make adjustments after assessing my own ROM. They use a goniometer to measure my ROM and then unlock the brace accordingly. At stake is the patients recovery and the satisfaction as well as their own credibility if the brace is ineffective. The surgeons have statistics of the retear rate and if the brace is ineffective this can lead to the rates increasing which will lead to less patients choosing them.

## Indirect Stakeholders:

- **Insurance Companies** motivation is to have a cost-effective solution and reduced recovery times because at stake is cost implications if the brace impacts the rehab duration which can lead to a need of additional treatments.
- **Manufacturer/ Distributor ( Enovis & DonJoy)** motivation is developing effective knee braces that meet the users need. At stake is the reduced demand if the braces are inefficient or uncomfortable.
- **Family Members** motivation is supporting the patients well-being and at stake is the well-being of the patient and a burden to the caregivers if the brace is ineffective.
- **Employer of the patient** motivation is to support the patient in a quick recovery so they can return to work. At stake is the additional benefits they are obligated to supply to the patient if the rehab process is longer due to an ineffective brace.
- **FDA** motivation is to regulate the brace for the well-being of the patient. At stake is the reputation of the agency decreasing as well as the global ranking of the best countries health agency going down on a global scale if the braces are more less effective than other countries braces.

# Design Critique

This is the inside of the knee brace which shows that there are buckles and straps that fasten around the leg but that is the only way they will stay up.



An up close look at the pieces that are in contact with the leg show that they are only foam pieces with no other grip to stay up especially if the user is wearing no skin tight clothes like jeans or sweatpants because they will just slide down.



This is the top strap that I always pull on which have altered the way it lays because of how many times the brace has fallen down

The issue for the knee brace is that there is nothing preventing the brace from falling down when walking or moving. There are buckles attached to the straps to tighten the brace around the mid quad to the lower calf. However these do not prohibit the brace from moving down because of movement when wearing clothes that are not skin tight. I have worn this brace three years in a row always in the fall or winter which means I can't get away with only wearing shorts because it will be too cold and sweats don't fit over the brace so I have to just wear the brace over the looser pants. Because of the lack of grip the brace always slides down to the point where the top strap that I always grab to hike it up altered and does not lay flat because of how often I have to tug at it. As the user and patient this has caused me discomfort and pain as well as increased swelling because the brace is not doing the intended job.



# Design Critique

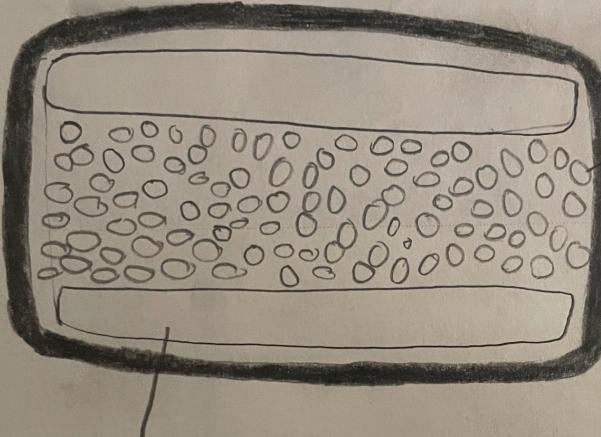
This is an image (and zoomed in) of the last strap that goes around the lower calf. Because this is the only part of the leg that has something under it (the foot) the grey plastic that runs parallel on both the inside and outside of the knee that holds the buckles in places rubs against the skin between the ankle and lower calf.



These are the outcomes of the brace sliding down and the sharp plastic not being protected which has lead to breaking my skin and causing scarring in the left photo that has lasted over 4 years. On the right is that happened when I wore my brace to the oregon vs UW gameday 2 weeks ago.

This hard plastic not only causes discomfort it also in my case has impacted my rehabilitation journey. My pt exercises include split squats but because of the exact location of the trauma to my skin it hurt too much and opens the wound if I try and do the pt exercise. Know not only am I in pain I also have to modify my routine. I have to pick out the correct shoes because if they are too high they irritate the wound. The brace slips down because the the first design critique but now it also causes damage to the skin. This affects PT because they now are modifying my schedule which can add time which hurts the insurance company because now they have to pay more for my additional pt appointments.

# Redesign Sketch #1



the dot grip  
is inspired  
by pilates socks  
because they have  
grip but also  
are not stiff  
and allow your  
feet to move

the line of  
silicone - anit slip grip  
is specifically at the top  
and bottom because the  
brace slips down not  
side-to-side

# Redesign Proposal #1

## Solution:

This solution utilizes the velcro that attaches the pads to the brace by creating another set of pads that have non slip grip which will prevents the brace from falling down when wearing clothes while not having to tighten the brace so much that it cuts off circulation.

## Stakeholders:

- **Patient/User** benefit from this proposed solution because if they are no longer having to keep pulling up the brace because it is ineffective, instead the brace is at the location where it originally should be which helps alleviate pain, swelling, and discomfort.
- **Healthcare Professional (Orthopedic Surgeon, Physical therapist, Orthotist)** benefit from the brace being in the intended position so that the patient can properly receive the benefits that the brace provides instead of an ineffective brace leading to a longer recovery and less complication.
- **Insurance Companies** will benefit by not having to costs of a longer recovery if the brace ineffective because it keeps falling down.
- **Manufacturer/ Distributor ( Enovis & DonJoy)** will have to create another product but they are meeting users needs which is their main motivation.

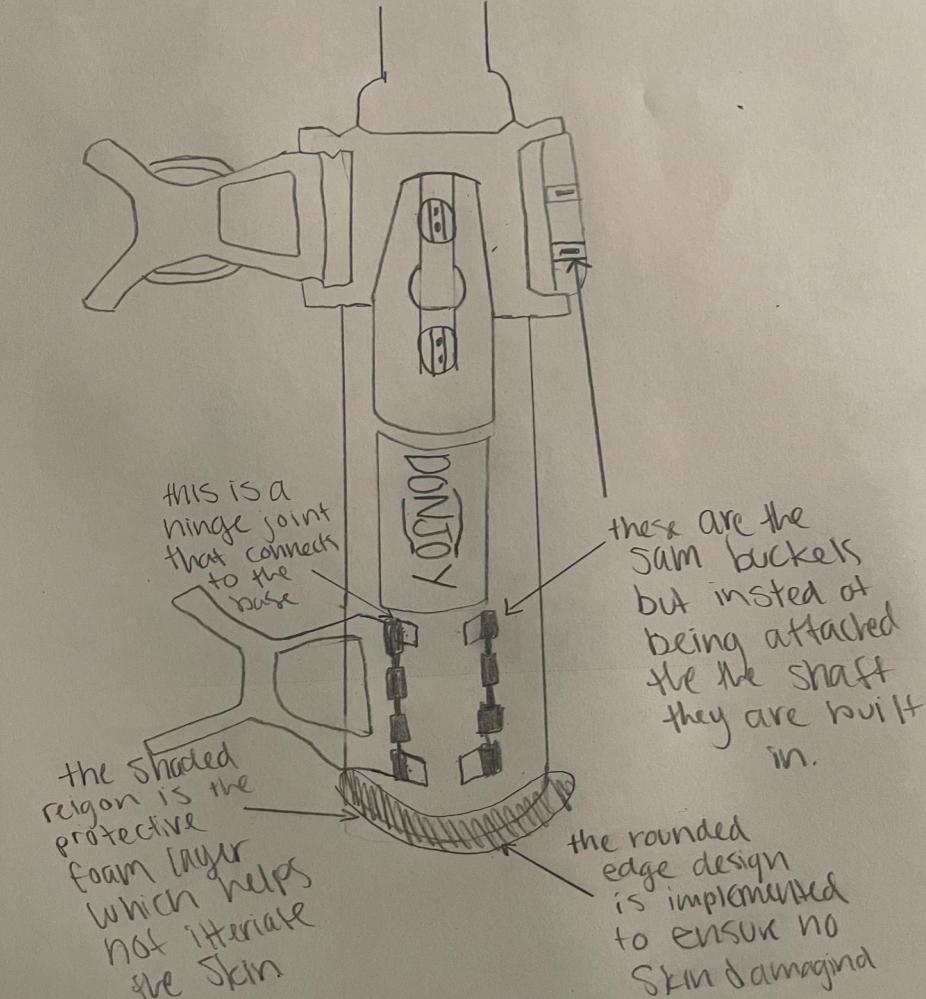
## Assumptions:

- That that user is willing to switch out the different non-slip grip pads when they are putting on their brace
- Swelling is not a factor that affect the brace falling down because of the knees movement reducing swelling

## Limitations:

- I don't have the cost breakdown of the materials and production so I don't know the effects this will have on the stakeholders who sell this and the ones that purchase it when the cost increases.
- New technology like 3D printing grip exists? I don't know what the company is currently developing and who has patents or trademarks on certain materials or uses of materials in the brace industry.

# Redesign Sketch #2



# Redesign Proposal #2

## Solution:

The solution to the sharp edge that digs into the skin is to round out the edge as well relocating the buckle attachment to the gray plastic part which eliminates anything touching the skin.

## Direct Stakeholders:

- **Patient/User** benefit from not being in pain and they have more willingness to wear the brace out which helps aid the recovery time and prevents pain, swelling and discomfort.
- **Healthcare Professional (Orthopedic Surgeon, Physical therapist, Orthotist)** benefit from not having to change their exercises because of the new injury caused by the brace which helps them stay on track in the recovery timeline.

## Indirect Stakeholders:

- **Insurance Companies** benefit from the shorter recovery time if there is no hindrance then the pt schedule stays the same as what they expected which saves them money
- **Manufacturer/ Distributor ( Enovis & DonJoy)** benefit from the user satisfaction of the redesign which helps the economics of the company if the brand image is positive and seen as beneficial not hurtful and annoying.

## Assumptions:

- My body proportions normal enough that this solution is helping more people than just myself because the brace is adjusted to wear it should be on the leg and maybe my leg dimensions are not as normal so this problem doesn't effect a lot of people
- It would be easy to add the buckle to the grey part in the manufacturing process and would not cost a lot to change.

## Limitations:

- Knowing how they manufacturer the brace to see how much of the process I am changing and how much that will affect cost
- Understanding if the stakeholders other than the direct stakeholders care if there is a little damage to the skin which is nothing in terms of the knee surgery required to use the brace

# Conclusion

As an experienced DonJoy X-ROM™ brace user I have the experience to understand what changes need to be made. Specifically the non-slip pads as well as a curved foam design for the last buckle. I not only have been impacted by it but I have talked to so many others in the community and we share the same issues that now have solutions that should be implemented for all the stakeholders involved because these redesigns benefit everyone.

# References

Casablanca, M., & Jawanda, N. (2023, October 27). Knee Brace Information from a PT. personal.

Malone, E., & Jawanda, N. (2023, October 24). Knee Brace Information from a PT. personal.

X-ROM. DJO Global. (n.d.). <https://www.djoglobal.com/products/donjoy/x-rom>