ABSTRACT

Hospitals treating Covid19 patients around the world are using the prone-positioning of patients with Acute Respiratory Distress Syndrome (ARDS) as an effective therapy to increase blood oxygenation and reduce mortality. Turning anaesthetized patients safely requires at least 3-5 medical nurses and can be tedious to do with current methods. This project proposes a simple mechanical solution to facilitate the proning procedure and reduce the amount of personnel needed. The Proning Taco consists of two parts which are wrapped around the patient before turning, the bottom of which remains under the patient during the “parking” period. A functional model was created for preliminary testing by the University Hospital of Zurich (USZ). The tests concluded that while the system has potential to facilitate rotation, particularly for heavier patients, issues with axial stability during rotation need to be overcome to present a safe and viable product. The blueprints for the design along with detailed test results are entered to the public domain for independent future development.

A Volunteering Project of HelpfulETH
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01. BACKGROUND AND MOTIVATIONS

1.1 BACKGROUND

HelpfulETH is an emergency research-initiative, which aims to provide short-term engineering solutions for needs in the healthcare sector caused by the current Covid19 epidemic situation. The initiative is backed by the product development lab (PDZ) of the federal technical university ETH Zurich. As a task mandated by the University Hospital of Zurich (USZ), the proning procedure was analyzed and multiple improvements, including the Proning Taco were proposed, a functional model developed and tested by medical staff in the time-span of two weeks.

At the time of publication in May 2020, the situation in Switzerland is stabilizing. After one of the most rapid increases in infections globally, closely resembling the spread observed in Italy, intensive care units are below capacity and the statistics show a decreasing rate of infections. Nevertheless, the risk of secondary waves of infections remains high and hospitals must take precautions and adapt their workflow to care for higher volumes of critically-ill patients. In addition, infections in North and South America as well as Africa are expected to continue rising dramatically, putting pressure on the local hospital infrastructure and staff.

Due to the emergency relief objective of this project, timing was critical. From the problem statement definition to functional prototype at the University Hospital only 14 days later, the entire engineering team worked hard to implement a viable solution in such a short period of time.

1.2 PROBLEM STATEMENT

While hospitals and ICU wards globally brace for surges in critically-ill Covid19 patients, one of the few effective therapies to alleviate the effects of acute respiratory distress syndrome (ARDS) is the prone positioning of ventilated patients. In the prone position the patient is rotated to lay on their stomach for up to 16 hours a day. The method has been shown by multiple studies to improve blood oxygenation and reduce mortality and is in use by a majority of Hospitals to treat ARDS in Covid19 patients. Prolonged immobility and pressure on soft tissue can cause complications such as pressure ulcers (decubitus) and tendinitis, it is thus important that patients are turned regularly. Correct procedure is critical to the patients safety and thus, proning a patient requires at least 3 trained medical personnel to perform safely as outlined in table 2.

In an effort to alleviate the workload of medical personnel the problem statement for this project is to develop a product or process which facilitates the prone positioning of ARDS patients in intensive care.

<table>
<thead>
<tr>
<th>Date</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 5th 2020</td>
<td>First confirmed death in Switzerland due to Covid 19</td>
</tr>
<tr>
<td>March 26th</td>
<td>Zühlke Report, Interviews with University Hospital and analysis of processes that should be optimized</td>
</tr>
<tr>
<td>April 3rd</td>
<td>HelpfulETH Problem definition and team building</td>
</tr>
<tr>
<td>April 15th</td>
<td>Engineering freeze before proof of concept test at USZ</td>
</tr>
<tr>
<td>April 17th</td>
<td>Successful test by staff at USZ</td>
</tr>
<tr>
<td>May 5th</td>
<td>Meeting with industrial partners for prototype production.</td>
</tr>
</tbody>
</table>

Table 1: Project timeline

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<td>March 5th 2020</td>
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</tbody>
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Table 2: USZ Proning process

1.3 USER REQUIREMENTS

During interviews with ICU Nurses, doctors and Physiotherapists from the University Hospital of Zurich and throughout testing, the following requirements were defined for a viable product.
### Function

**Reduction of required staff for turning.** (Reference is the turning procedure using two sheets to wrap the patient)

**Reduced required forces to pull patient to the side of the bed** (e.g. reduction of friction / reduced sinking into soft bed mattress)

**Reduced required forces to turn the patient** (e.g. stiffening the patients body or giving him a rounder shape)

**Reduction of timely effort for the overall processing time** (Reference is the turning procedure using two sheets wrapping the patient)

**Preparation of the patient** (fixation of patient in the taco)

**Turning the patient**

- "Parking" of patient/lims after turning (e.g. cutouts for breasts).

### Application

- The Taco must only be implemented once and remain in use for one patient during the whole treatment. The initial installation should still be possible while the patient is intubated.

### Environment

- Adaptation of prone position for less-than-suitable (=normal) hospital mattresses
- Patient is naked, a replaceable linen sheet is mandatory
- The Taco must not be breathable
- Infusions and connections to the patient =15
- Catheter access must be ensured

### Usability

- Enhanced ergonomy for the turning staff (e.g. handles with cushions to grab the taco which can be stored)
- Ease of use. The system must be self-explanatory widely respect Poka Yooke design rules
- Additional cushioning solutions are inadequate

### Geometry

- Dimensions must fit to hospital beds (~1100mmx2000mm)
- Dimensions must suit different body shapes and sizes (e.g. various size classes, adjustability, etc.) The focus is on heavy patients as they require most effort for the turning)

### Kinematics

- 2 Persons to lift and turn
- Patient weight 135-80kg
- Allow separate control of head positioning (the turning movement must be smooth)

### Safety

- System must not cause pressure pressure marks (e.g. patient must not lay on sharp edges of foam, buckles pressing through cushion, folds of linen etc).
- Respect safety factor for patients weight

### Maintenance / Hygienic Design

- All elements must be disinfectable
- Surfaces in contact with the patient must be wipeable
- Foam elements must be completely sealed.

### Lifecycle

- Lifetime: 4 weeks
- One time use
- No Recycling

### Quality

- Medical Class 1

### Cost

- Maximum sales price <1000CHF (initial estimation)

## 1.4 CURRENT METHOD

The current standard employed at USZ involves using bedsheets and pillows to facilitate proning is documented as follows:

### Patient in Supine Position

**Material needed:** Bedsheet, Pillows

1. Positioning catheters so that there are no pressure points after turning it
2. Ventilation hose adaption
3. Direct the catheter to the side over which it is turned (central venous catheter on the left or right neck)
4. Check catheters are long enough to turn
5. Covering with additional linen sheet
6. Ask doctor and other personal to come into the room
7. All patients have 5 adhesives on their chest or back for the ECG, these are removed
8. Physiotherapist gives the commands for all steps, the doctor tells the rhythm, nurses stand around the bed
9. Left arm placed under shoulder
10. Two nurses on the left side turn the patient by 90 degrees
11. Doctor ensures ventilation, checks oxygen at all time
12. Fourth person looks at the hoses
13. Cushion tower on the left side is being built. Patient is wrapped with sheets and normal pillows under the sternum and hip.
14. The pillows are to relieve the abdomen so that the intestinal function is not disturbed.
15. Lowering the patient by a further 90 degrees.
16. Doctor leaves the patient.
17. Straightening the catheter.
18. Attach ECG (can also be done in the lateral position).
19. The values are monitored during the entire process.
20. Check that there are no pressure points.

### 1.5 MARKET ANALYSIS

Various products exist which are designed to move patients with limited mobility. Some, like the Arjo RotoProne are designed specifically with the proning of ARDS patients in mind. An analysis of existing products and patents found that while many solutions can be used or modified to support patients with ARDS, they lack the scalability or functional simplicity to be used in Intensive Care Units on a larger scale.

<table>
<thead>
<tr>
<th>Function</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arjo RotoProne</td>
<td>Link</td>
</tr>
<tr>
<td>ICU bed with proning functionality</td>
<td>Availability and cost don’t allow nationwide application</td>
</tr>
<tr>
<td>Dräger and Guldman’s Sling</td>
<td>Link</td>
</tr>
<tr>
<td>Sling on mechanical arm with drive Attached to ceiling Application for moving handicapped person from the bed in a wheelchair</td>
<td>Not suitable for turning patients Ceiling installation not suitable Would be valuable only for extraordinary heavy patients</td>
</tr>
<tr>
<td>Rainer Glück Sling</td>
<td>Link</td>
</tr>
<tr>
<td>Sling on mechanical arm Application for proning heavy patients.</td>
<td>No market readiness (lack of certifications) Required space and handling effort rather not suitable for ICU Would be valuable only for extraordinary heavy patients</td>
</tr>
<tr>
<td>Q2Roller lateral turning device</td>
<td>Link</td>
</tr>
<tr>
<td>Inflatable supporting cushion positioning patients from one side to the other</td>
<td>Not meant to turn patients from supine in prone position</td>
</tr>
</tbody>
</table>

*Table 3: Market Analysis and feedback from USZ*
02. PRONING TACO

2.1 THE PRODUCT

The Proning Taco can quickly and easily be wrapped around an ARDS patient, securing them in place for the proning maneuver. The Taco is then rotated 180 degrees using the integrated straps. The sliding mat remains under the patient after proning, saving time in preparation and allowing for more frequent repositioning to relieve pressure points.

![Figures 1, 2: Functionality of Taco for proning and stabilization of patient.](image)

Figure 1 shows the 6 steps of proning, including wrapping and securing the patient and parking the patient in the prone position. Because a component of the Taco always remains underneath the patient, the preparation time needed is reduced. Additionally, sheets can be changed before step 2, without requiring the Nurses to move the patient.

Figure 2 shows the different mechanisms for stabilization of the patient before turning. This point is critical to ensuring safety during rotation and avoiding injury to the spine or dislodgement of any tubing or wiring. The issue of stabilization will be discussed further in section 2.4 Safety and feedback.

2.2 SAFETY AND HUMAN FACTORS

As a product intended for human use an analysis of safety concerns and human factors must be conducted. The primary issues revolve around fixing the position of the patient and any tubing or wiring attached to the patient. Secondary concerns arise when the patient is “parked” where measures must be taken to avoid the formation of pressure ulcers common to stationary patients.

Particular attention must be given to the positioning of the head and feet when parked to alleviate joint pressure and prevent decubitus formation on the soft tissue of the face.

During the turning procedure, the patient should remain rigid and axial rotation as well as slippage inside the taco must be avoided. To help with these issues, foam padding was used to fix the position of the legs which are particularly prone to displacement as can be seen in figure 2. While the middle foam block proved effective, the lateral supports were deemed ineffective by the medical personnel who conducted the test described in section 2.4. Cutouts in the foam padding are necessary to allow the use of various catheters and electrodes.

A strong advantage of the proning taco is the ability to design the ergonomics of the mattress specifically for the prone positioning. Current practice relies heavily on strategically placed pillows under the patient and is ineffective at preventing decubitus formation and compression of unprotected areas such as the groin, breasts or face. Some specialized equipment can be used for facial positioning but poses problems with intubation and hides the patients face. Footrests are little more than foam cutouts and can cause pressure on the knee in some patients. With the taco solution, a more integrated approach can be chosen, combining cutouts and support structures to reduce joint stress, ensure the correct positioning of the spine and crucially, avoid pressure points and decubitus formation. While this aspect of the Proning Taco was not tested in the scope of the proof of concept, ergonomics is a critical component of the industrialized product and has been central to the design process.

2.3 PROOF OF CONCEPT

To evaluate the viability of the proposed solution, a functional model was created using off-the-shelf foams, straps and buckles. The model was delivered to USZ where it was tested by a team of ICU nurses.

The model was designed with the core functionality in mind and the materials and geometries used were not optimized for prolonged “parking” of the patient.

The first functional model has been produced with available off shelf material. All necessary material is summarized in table 5.

From a production perspective, the biggest challenge is the connection of the foam with the belts. To reduce the force
transmission of belts to foam, the belts are continuous in the circumference of the taco. In this way the circumferential forces while tightening the taco are transmitted directly over the belts, without introducing forces in the foam. However, since the taco must be rotated, the shear forces introduced at the handles while turning the patient must be transmitted via the foam to the patient’s inertia. Both superglue and contact adhesive glue (pattex) only showed poor performance. Finally the belts were attached by sewing with zip ties at a spacing of 5cm and reinforcing the belts with hollow rivets. In this way maximum force transmission could be achieved with forfeit in comfort, since the zip ties are hard and cross the inner taco side. The higher forces at the handles are compensated by applying 3 parallel zip ties.

The buckles are capable of transmitting 15kg each at 25mm belt width and the belt length is adjustable only on the male side. As the test in chapter 2.4 shows, the buckles must be dual adjustable.

The spray glue is used to connect the side elements to one block and to boost the self-adhesive glue of the pvc gliding surface. The velcro strap is applied on both long edges on the outer side of the taco to connect the linen sheet with the foam.
### 2.4 TESTING AND FEEDBACK

Following testing strategy was done during the project:
- Feasibility test by project team: **successful**
- Feasibility test by USZ: **partially successful**

The model was tested by USZ staff on a hospital bed. The test consisted of one test subject (non-patient) wrapped in the Proning Taco handled by 3 Nurses.

The general feedback was it is in general feasible but still some details need to be solved. The tested functional model is very close to the current solution. The handles are very useful and the usage is intuitive enough.

**Recommendations:**
- Stability to be improved
- Base mattress should also cover the head
- Handles to have different colours

### 2.5 FUTURE STEPS & OUTLOOK

A central priority is to improve the parking and cushioning of the patients for long term “parking”.

Improve flexibility and toughness of the gliding surface. The high variance in flexibility of foam and pvc coating lead to the egg-shell effect. While the foam is easily compressed, the less flexible pvc coating is exposed to high forces and any sharp edge easily penetrates and damages the coating. Therefore the coating must be more flexible at higher toughness.

The application of the 4cm thick foam sheets lead to a more or less hard case shell of packing the patient. In order to provide a high variance in body sizes the gap between patient and the taco requires a high variety of cushioning. Therefore, it might be considered to reduce the stiffness of the taco, in order that the taco more easily adheres to the patient’s body. For example the foam could be replaced by a textile to which the belts and handles are sown.

To reduce the volume of parts the taco halves or the base mat could be replaced by a low friction textile.

### 2.6 DISCLAIMER

The Proning Taco is not a certified or tested medical device and should not be recreated as such.

The information provided is for general informational purposes only. All information is provided in good faith,
However the authors make no representation or warranty of any kind, express or implied, regarding the accuracy, adequacy, validity, reliability, availability or completeness of any information published.

Under no circumstance shall the Authors, HelpfulETH, ETH Zurich, University Hospital of Zurich or any affiliated partners have any liability to you for any loss or damage of any kind incurred as a result of the use of or reliance on any information provided.

2.7 AUTHORSHIP

Many thanks to all the team of contributors who worked on this project by HelpfulETH on a voluntary basis.

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2.8 COLLABORATORS

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