Disposable Surgical Torque Wrench

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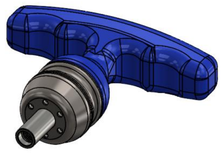
Introduction and Motivation

Torque wrenches are used in surgical applications for spinal correction of tightening bolts for bone fractures. Torque wrenches currently on the market are costly to make and require re-sterilization after each use in surgery. Many current torque wrenches are also inefficient when applying torque leading to complications such as partial ischemia and bone microfractures [1].



Precision Medical Industries (PMI) has requested that we create a disposable torque wrench composed of injection molded plastics to decrease the manufacturing costs, improve patient safety, and target a lower range of torque values. In order to accomplish this, the group went performed multiple design iterations using SolidWorks and creating three primary testing protocols. To aid in PMIs manufacturing, the group also created a manufacturing plan with all required equipment recommendations and a cost benefit analysis.

Manufacturing Plan

To help ease PMIs transition into mass manufacturing our disposable torque wrench, a plan including all safety, recommended equipment and materials, a cost-benefit analysis, and a sustainability procedure was created. A comprehensive list of materials for one torque wrench includes one compression spring, four injection molded components, and five stainless steel screws

Polysulfone was the chosen primary material due to its high mechanical strength and its ability to be injection molded. The following table details the three injection molding machines we have recommended PMI consider purchasing [2].

	ROBOTDIGG 128T	ROBOTDIGG 72T	ENGEL (e-mac)
Price ($)	22500	11500	10000-50000
Type	Hydraulic	Hybrid	Electric
Clamp force (kN)	1280	320-520	500-3800
Screw diameter (mm)	38-40	19-32	18-60
Shot volume (cm^3)	256-280	22.6-92	20-735
Tie-bar spacing (mm)	428x386	255x220 - 300x300	370x320 - 830x830
Injection weight (oz)	8.1-8.9	0.7-2.9	0.66-23.86
Dimensions (ft)	15.7x4.3x5.6	10.8x3.6x5.2	

A future worth analysis was also performed by using the relative cost to produce one wrench and estimated the sale price and annual maintenance/utility costs. The first analysis was performed for a production of 750 wrenches in one year and the second represents 7,5000 wrenches/year.

$$FW = -(Cost\ of\ Injection\ Molder\ and\ Mols)\left(\frac{F}{P},5\%,10\right) - (Annual\ Cost\ of\ Prod)\left(\frac{F}{A},5\%,10\right) - (Other\ Annual\ Costs)\left(\frac{F}{A},5\%,10\right) + (Revenue)\left(\frac{F}{A},5\%,10\right) + Salvage$$

$$FW = -(24000)\left(\frac{F}{P},5\%,10\right) - (32844.02)\left(\frac{F}{A},5\%,10\right) - (62{,}400)\left(\frac{F}{A},5\%,10\right) + (112500)\left(\frac{F}{A},5\%,10\right) + 2000$$

$$FW = \$256{,}137.33$$

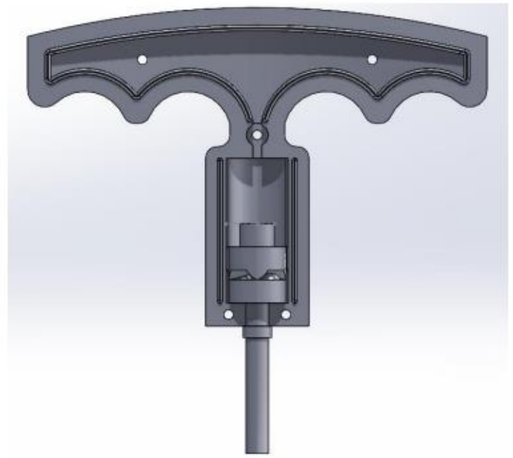
$$FW = -(24000)\left(\frac{F}{P},5\%,10\right) - (314643.75)\left(\frac{F}{A},5\%,10\right) - (62{,}400)\left(\frac{F}{A},5\%,10\right) + (1125000)\left(\frac{F}{A},5\%,10\right) + 2000$$

$$FW = \$9{,}446{,}806.80$$

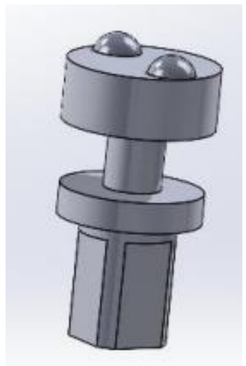
As safety is a big consideration in manufacturing, all materials were chosen to produce minimal safety risks for operators. Proper training is also required for all workers who will utilize the injection molding machine. In order to keep sustainability in mind, several plastics recycling companies were also researched so that PMI can get paid to reduce their material waste

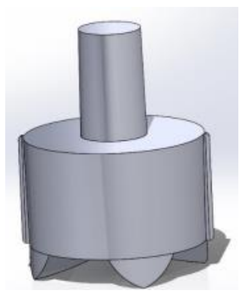
Design

The finalized design was composed of a two halved casing that also acted as a handle, an internal resistance plate, an internal shaft, a compression spring, and five screws. The handle was designed to correlate with current PMI torque wrenches, which fit comfortably in the hand.

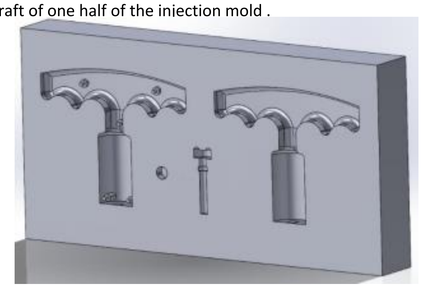


The two internal pieces were designed to interface with one another and at their peaks, the proper torque value will be outputted. The spring rests on top of the resistance plate and is further compressed when a torsional force is applied to the handle. Redesigns of the internal components included reducing diameters for better clearance, increasing thickness to increase compression, and changing the shaft end to accommodate for the testing methods required.





The final portion of the design includes a rough draft of the injection mold that will need to be created before production can start. The image below shows a rough draft of one half of the iniection mold .



Testing

Torque Test

	15 in-lb wrench			40 in-lb wrench		
Trial	Sample 1	Sample 2		Trial	Sample 1	Sample 2
1	3.27	4.72		1	2.61	1.88
2	3.3	4.5		2	2.19	1.73
3	4.21	4.7		3	2.84	1.53
4	3.218	4.52		4	2.5	1.63
5	3.228	4.86		5	3.06	2.18
6	3.44	6.9		6	2.57	2.66
7	3.94	6.12		7	2.87	1.79
8	2.81	6.19		8	3.14	1.73
9	3.18	7.98		9	4.08	2.1
10	3.08	8.37		10	3.5	1.5
11	3.32	4.7		11	4.34	2.12
12	3.35	5.3		12	3.5	2.29
13	2.86	6.37		13	2.11	1.83
14	2.57	5.99		14	4.09	1.7
15	2.661	4.77		15	3.75	1.81
16	3.67	4.48		16	5.07	2.21
17	4.43	5.34		17	4.09	1.52
18	3.75	4.01		18	5.12	2.06
19	3.06	4.56		19	4.78	1.899
20	4.06	4.59		20	5.79	1.89
21	2.57	4.49		21	5.48	1.766
22	3.11	5.4		22	4.9	1.873
23	3.64	4.2		23	4.89	2.3
24	2.95	4.75		24	5.33	1.6
25	3.71	5.2		25	5.1	1.94
26	3.6	4.45		26	5.24	1.97
27	3.05	4.67		27	5.1	1.79
28	2.41	5.3		28	5.18	1.65
29	2.91	4.13		29	5.48	1.62
30	2.69	5.26		30	4.99	1.85

The disposable torque wrench will be evaluated at two different torque readings, 15 and 40 lbf-in. The wrench should provide the amount of torque that it has been assigned, without exceeding the target value. If the target value is surpassed, the wrench could provide excessive tightening within a surgery and cause unwanted issues with the implanted device. To ensure patient safety and product reliability, five wrenches will perform 30 trials of torque tightening. Any value reading above the desired 15 or 40 lbf-in will result in a failure of the torque wrench.

Drop Test

3D printed and injection molded prototypes will be held one meter above the ground and dropped 30 times or until failure. The drop testing of this medical devices consisted of holding the device at the top of a meter stick and dropping the device onto a relatively hard ground, so that the ground absorbed the least amount of the impact, and all force was on the medical device. Torque wrenches were also dropped on three different angles: directly on the flat side of the wrench, at an angle between the handle and the attachment point, and directly on the attachment point [3]. Each angle was tested 30 times or until failure. Torque wrenches were inspected in between each drop to check for damage.

Angle 1: Flat															
	Test #	Square er	Pass/Fai	Test #	Square er	Pass/Fai	Test #	Square Er	Pass/Fai	Test #	Square er	Pass/Fai	Test #	Square End	
Torque wrench	1			2			3			4			5		
	1	pass	pass	1	pass		1	pass	pass	1	pass	pass	1	pass	
	2	pass	pass	2	pass		2	pass	pass	2	pass	pass	2	pass	
	3	pass	pass	3	pass		3	pass	pass	3	pass	pass	3	pass	
	4	pass	pass	4	pass		4	pass	fail	4	pass	pass	4	pass	
	5	pass	pass	5	pass		5	pass		5	pass	pass	5	pass	
	6	pass	pass	6	pass		6	pass		6	pass	pass	6	pass	
	7	pass	pass	7	pass		7	pass		7	pass	pass	7	pass	
	8	pass	pass	8	pass		8	pass		8	pass	pass	8	pass	
	9	pass	pass	9	pass		9	pass		9	pass	pass	9	pass	
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	29	pass		29	pass		29	pass		29	pass	pass	29	pass	
	30	pass		30	pass		30	pass		30	pass	pass	30	pass	

Fatigue Test

The wrench will specifically be analyzed utilizing a cyclic fatigue apparatus created by PMI. This is crucial to the overarching function of the wrench as it will need to be able to perform a set number of actuations during surgery. The maximum number of actuations, 60, occurs in spinal scoliosis correction surgeries. The testing goal was set to 2 r c

Test Subject Description	Pass/Fail based on 200 cycles
15 in-lb PLA wrench #1	Pass
15 in-lb PLA wrench #2	Pass
40 in-lb PLA wrench #1	Fail (31 cycles)
40 in-lb PLA wrench #2	Pass
40 in-lb PLA wrench #3	Fail (27 cycles)

Conclusions

In conclusion, the most important problems this torque wrench could rectify are issues that current industry torque wrenches cause. Torque wrenches currently on the market rarely ever hit their manufacturing set torque limit even within a plus or minus 10% range. The main issues a disposable torque wrench will solve are lowering cost, increasing the accuracy of pre-set torque values and ease manufacturing processes for PMI while also improving patient safety. Thorough research and planning were performed to better understand the torque wrench mechanisms and common failures. To create the most efficient torque wrench possible, it will be primarily composed of injection molded polysulfone. After design and testing, the group succeeded at achieving several key objectives including comfort, durability, and cost reduction. Hitting the pre-set torque value has remained a challenge for the team.

Future Directions

Since the 3D prototypes failed one or more of the testing protocols, revision needs to be made in the overall design. This may include new springs or an update to the internal mechanism. Exaggerations may need to be made to the internal resistance plate to lock it into only having vertical motion. The interface between the resistance plate and shaft may also need to be increased to have a greater compression difference for the spring. Higher spring ratings will also help to increase the torque output. In order to achieve accurate torque readings, spring forces will have to be calculated based on the compressibility of the spring, in addition to the length the spring can be compressed. Length of the casing of the internals may have to be adjusted to fit longer springs, of thickness of the internal components may have to be adjusted to compress the spring more or less. The length of the rod in the spring that holds the spring in place vertically may need to be extended to ensure the spring does not bow inside the casing. The inside of the T-handle may need to be adjusted to close the opening at the top, so the spring does not have an opening to get stuck in. In future revisions, PMI could also investigate the use of Belleville washer instead of compression springs. These do tend to have their own challenges when targeting a specific torque value, but this is something PMI is slightly familiar with.

Once the design has been finalized and validated, the wrench can be mass produced with an injection mold machine using the recommended material.

Literature Cited

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[3]"IEC 60601-1 Ed 3.2 Clause 15.3.4| IEC Webstore," *webstore.iec.ch*. https://webstore.iec.ch/preview/info_iec60601-1%7Bed3.1%7Db.pdf (accessed Apr. 26, 2022).

Acknowledgements

We would like to thank Trine University and Precision Medical Industries for their contribution to the project.

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