Department of Precision and Microsystems Engineering

Static Balancer Design for a Compliant Laparoscopic Grasper

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Preface

This thesis contains the results of my research I performed on the design of a static balancer for laparoscopic grasping instruments. It is a part of a larger research project done in collaboration with Promolding, Lencon, LUMC and Intespring aimed at accelerating medical device innovation within the EU.

The thesis is made up of three papers that signify the research and design steps taken. First, a literature research was conducted on 1 DOF static balancers. There I looked at the different ways static balancing could be achieved and made an overview of the existing static balancing designs. This paper was submitted to the ASEM conference in Boston 2015.

The second paper is about the design of a static balancing demonstrator intended for end-user testing and the design methodology used. It was presented at DMD conference in Delft 2014.

From that paper I learned the necessity for being able to accurately predict the balancing capabilities of static balancers and tune their force compensation.

Those lessons shaped the topic of the third and final paper. There I researched what parameters control the balancing performance of compliant bi-stable beams and put forward a novel stiffness tuning design.

I would like to thank all the students and members of the interactive mechanism group who helped by providing a fruitful research environment and numerous insights into my designs. Furthermore I thank *Tom Wagemakers* and *Dan Vlasveld* at Promolding for their guidance during my internship.

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REVIEW, CATEGORIZATION AND COMPARISON OF 1 DOF STATIC BALANCERS

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ABSTRACT

A static balancer is a mechanism used to force compensate mechanical systems and has been used in applications such as improving haptic feedback in surgical instruments and lowering motor loads in robotic systems. Currently no complete overview exists of all SB methods, this paper can be seen as an extension to earlier work by introducing more static balancing categories and methods. The goal is to have a comprehensive overview of state-of-the-art to aid designers in selecting the appropriate static balancer technology for mechanical systems. Existing designs are categorized based on the energy storage mechanism, e.g. elastic energy storage mechanisms. Critical design parameters are extracted from published literature to form the basis of comparison of the different categories. A performance criterium is defined to illustrate balancing capabilities as a function of system size. The three comparison parameters are: $\frac{CompensatedForce}{Volume}$, $\frac{SBStroke}{Volume}$, $\frac{Energy}{Volume}$ *The comparison results show that compliant flexure balancers are the best selection for balancing systems while keeping minimal size. Theoretical calculations show that there is still ample room to improve current balancers with regard to the chosen balancer criteria.*

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1 INTRODUCTION

Static balance (SB) can be defined as a system with one or more potential energy storing mechanisms that counteract the forces of actuation resulting in static equilibrium along a prescribed range of motion. Therefore, a statically balanced system has zero stiffness and constant potential energy. [1]
Many mechanical systems can fulfil the criteria stated above based on different energy principles. One of the most well known examples of a statically balanced system is the drawbridge where a mass is used to compensate for the weight of the bridge it self requiring less energy from the motors used to raise and lower the bridge. In this example the mass and its support structure that have the purpose of compensating the payload (weight of the bridge) is considered to be the static balancer or the energy storing mechanism.

The goal of this paper is to identify and compare methods for static balancing. The results offer a guideline to aid in the selection of technology for the design of a given mechanical system. *Dunning et al.* [2] published a overview of statically balanced compliant mechanisms (SBCM) and spring balancers we extend that overview here by including three more categories and introducing more performance parameters for comparison. Categories are created for proper comparison by considering the potential energy storage used by the static balancer e.g. gravitational or elastic energy. Critical design parameters are extracted from published literature to form the basis of comparison. The performance comparison criterium illustrates balancing capabilities as a function of system size.

2 Method

The literature survey was done using *Google scholar* and *Scopus* with the keywords listed below:

static balancer
neutral equilibrium
zero/neutral stiffness
constant potential energy
gravity/force/stiffness compensation
eliminate/remove/cancel stiffness.

Synonyms of the terms above were also considered. Papers were eliminated when no information could be extracted as input into the comparison criteria listed in table 1. To compare the balancers the design parameters are extracted from existing journal publications. A dash line in table 3, 4, 5 and 6 indicates that the information was not provided and could not be estimated. In the case a numerical value was not given it could often be estimated from plots and figures given or calculated based of other parameters presented in the paper. If we felt the value could be safely estimated The comparison criteria is an extension to the work of *Dunning et al.* [2]. Static balancers can have a linear or a rotational movement and additionally could be balancing more than one degree of freedom. To compare them using the same parameters, an effort is made to simplify them into 1 DOF balancers. Rotational movements are translated into a stroke in millimetres with the rotating degrees and lever length and in the case of multiple degrees of freedom we look at if the balancer can be seen as a combination of one degree of freedom balancers. If not we look at which DOF compensates the most force or if equal has a longer range of motion.
Of the selected design parameters *energy storage*, *compensated force* and *statically balanced stroke (SBstroke)* are used to compare the categories to each other by relating each to the working volume of the balancer here on forward just called volume. In static balancing the two main concerns are creating enough energy to balance the payload over a sufficient range of motion. We then relate it to *volume* since for designers size is most often a concern. The ratios tell us how much energy, force compensation and SBstroke per volume we can expect from a balancer in that category.

$$\frac{CompensatedForce}{Volume}[\frac{N}{mm^3}] \tag{1}$$

$$\frac{SBStroke}{Volume}[\frac{mm}{mm^3}] \tag{2}$$

$$\frac{Energy}{Volume}[\frac{J}{mm^3}] \tag{3}$$

3 Categories

Categorization will be done based on the balancers energy source. Since balancers store and release potential energy the energy-flow has to be reversible. In the literature search only designs utilizing *gravitational energy* and *elastic energy* were found that also published relevant criteria we were looking for. While there do exist other types of energy sources that could be used for static balancing, such as magnetic energy [3] few examples exist of designs for large range of motion utilizing it. The core energy categories are further divided based on the mechanism used as seen in table 2. All gravitational energy balancers utilized a combination of levers and masses to create compensating moments. Balancers using elasticity of material were categorised based on type of strain (torsion, bending and tension) and the mechanism used, e.g. coil springs, zero free length coil springs (ZFLS), torsion beams, buckling plates, preloaded plates, torsional springs and rubber bands/O-rings.
The following section gives a detailed description of the categories listed in table 2.

TABLE 2: *Static balancers categorised based on their energy storage principle, into sub-categories depending on the type of strain is utilized and finally after what type of mechanism was used to implement these principles into a design.*

Energy storage	Type of strain	Mechanism type
Gravitational energy		Mass + lever
Elastic energy	Torsion	Coil springs Zero free length springs Torsion beam
	Bending	Buckling plates Preloaded plates Torsional springs
	Tension	Rubber band / O-ring

TABLE 1: *Performance parameters extracted from publications later used for design comparison.*

Performance paramters	Unit	Explanation
Balancer error	%	Deviation from a ideal balanced system (zero force actuation / zero stiffness)
Compensated force	N	Force that the balancer compensates.
Statically balanced stroke	mm	Range of motion where static balance is achieved.
Full balancer stroke	mm	Full range of motion of balancer if greater than statically balanced ROM.
Added inertia	%	How much mass moment of inertia the balancer adds to the overall design, used exclusively for mass balancers.
Result type	Sim/Exp	Indicates wether theoretical simulations and/or experimental data is provided.
Monolithic	yes/no	Mechanisms made out of one piece have benefits such as simplicity, criteria used only for compliant flexure designs.
Energy storage	J	Maximum energy storage the balancer can achieve. (ref Cool)
Working volume	mm^3	Calculated as the entire volume needed to construct the balancer and use through its complete working range.

3.1 Gravitational energy

Moving a mass in the gravitational energy field is a reversible action that changes its potential energy fulfilling the criteria for static balancing. All balancers in this category, listed in table 3, utilize levers to create counteracting moment for balancing. Figure 1 shows the basic gravitational balancer where one of the masses is considered the payload. The mass and lever system has constant potential energy and the global centre of all the masses is fixed at the pivot point. These balancers are not influenced by tilting or acceleration thus suitable for dynamic systems.

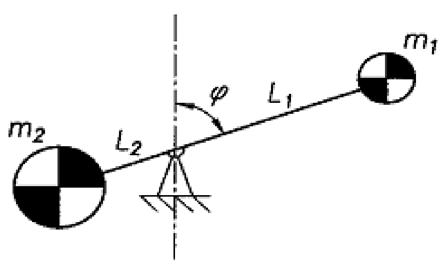


FIGURE 1: *See-saw mass balancer. By manipulating the variables so that m1*L1=m2*L2 holds the system will be in static balance and the global center of mass is fixed in the pivot point. This is the basis for SB utilizing masses and levers.* [1]

3.2 Elastic energy

Another widely used energy storage type used for static balancing is *elastic energy*. This can be done in three ways: bending, torsion or pure axial strain.

3.2.1 Torsion The most common torsional elastic element found in literature is a coil spring, despite it is often called a tension spring. When the spring elongates the wire undergoes torsion. Figure 3 shows a mass on a lever considered the payload which is balanced by a spring hidden within the structure.

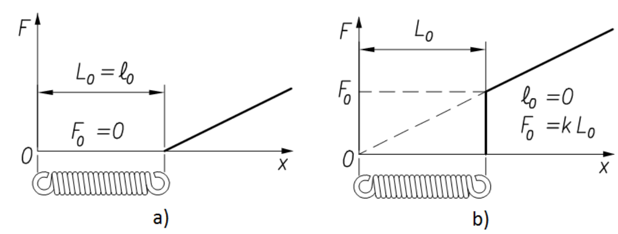


FIGURE 2: *Spring characteristics of: a) traditional coil spring with no initial tension, b) zero free length spring with initial tension of kL_0.* [4]

Coil springs have an initial length l_0. When elongated in a straight line, the force-deflection diagram (figure 2a) starts at the free-end, so initial length is of no concern. However in application where the springs rotate when stretched this length is cumbersome as using the fixed end of the spring as the origin is more logical. Measuring a rotating spring would result in a force-length diagram instead of the usually desired force-deflection. [4] Zero free length springs (ZFLS) have their force-length and force-deflection characteristics equal, meaning their initial length l_0 can be seen as zero (figure 2b). The most used methods to create ZFLS are by having a pretension equal to kL_0 in the wire [4], by use of a pulley and guide system where a spring is connected to a wire that leads through a pulley the spring origin is then taken as the centre of the pulley effectively hiding the free length or with a cam and follower system. The second torsional element found in published literature is a cantilever beam in torsion. An example is seen in figure 4 which are X-shaped torsion beams with a balancing out a mass on a lever.

3.2.2 Bending This category includes two different elements; torsional plate springs and compliant flexures. Torsional springs are commercially available all designs found created

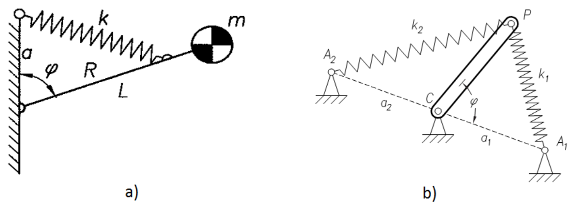


FIGURE 3: *Schematics of spring balancers. In picture a) we see a mass on a lever being balanced by a zero free length spring while picture b) shows two springs balancing each other.* [1,4]

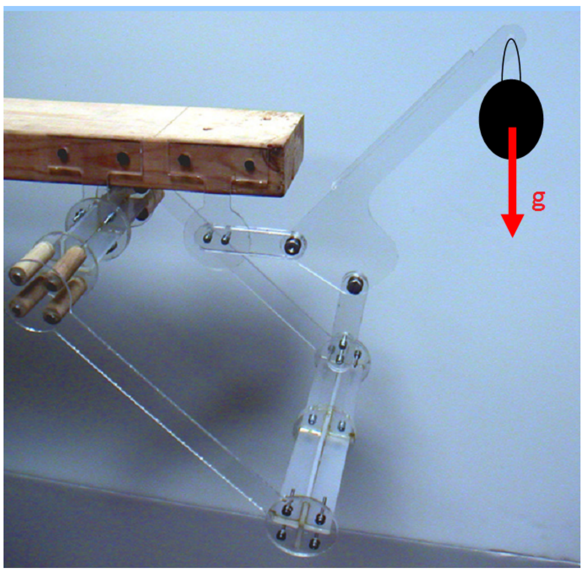


FIGURE 4: *Balancer utilising torsional beams. This prototype was constructed to balance out a load equaling 5N by combinging torsion beams and levers.* [6]

static balance by combinging torsion spring with levers to create moment compensation. Compliant flexures are sub-categorise into *buckling beams* and *pre-loaded beams*. The difference between the two being that buckling beams show a snap through behaviour that creates negative stiffness through buckling of the material as seen in figure 6b. Preloaded beams can create the same negative stiffness using spring configuration and pre-load (figure 6a).

3.2.3 Tension All tension balancers found in this review consisted of rubber bands due to their large deformations. [9] They like coil springs offer a elongation with one end fastened but their force-deflection profile is not linear.

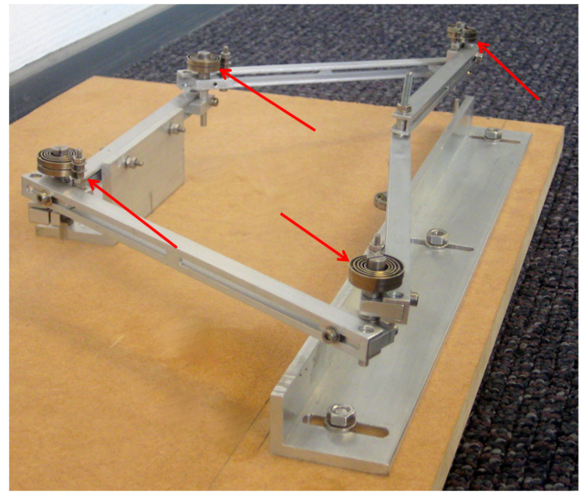


FIGURE 5: *Prototype built using torsion springs (red arrows), placing them on the joints of each of the levers allows these static balancing elements to take up minimal space.* [7]

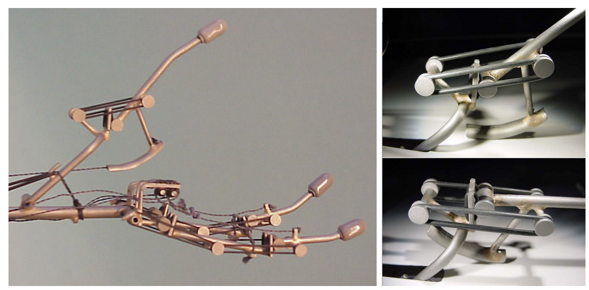


FIGURE 7: *Statically balanced prosthetic hand created by using o-rings that act as ZFLS.* [4]

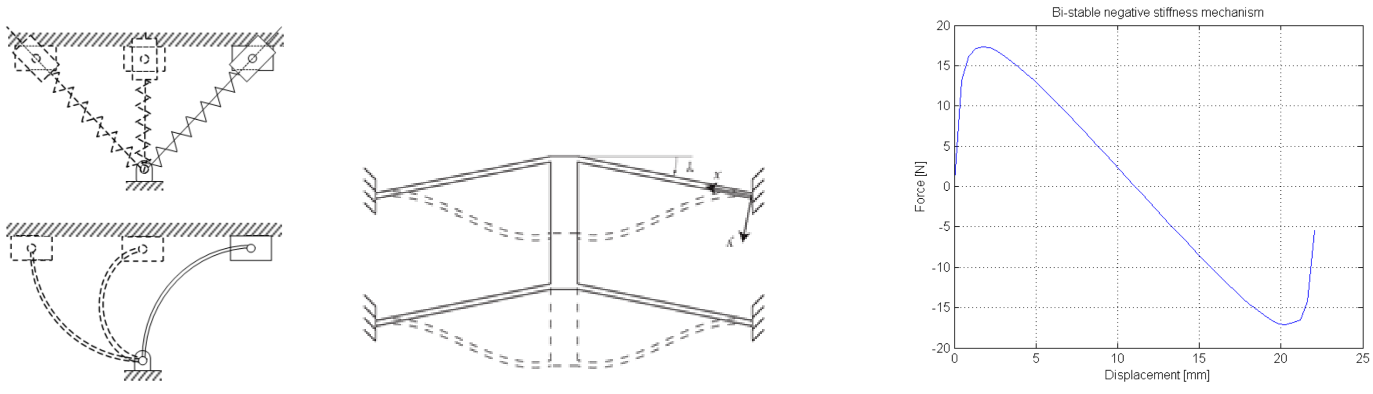
4 Results

4.1 Gravitational energy

Three papers [10–12] used gravitational energy to balance a system. One design was made as a prototype and reported experimental data.

4.2 Elastic energy

4.2.1 Spring balancers Ten papers were found that present coil spring balancer [13–20]. Thee of the used ZFLS by utilising a pulley system. Eight made a prototype including all of the designs using ZFLS. No difference is found between the energy storage or force compensation values of designs using regular coils springs versus those using ZFLS but it is noted that two of the ZFLS designs reported zero or close to zero balance error.



(a) (b) (c)

FIGURE 6: *Figure 6a shows Preloaded beams, placed such that a negative stiffness is created in part of the range of motion but the compliant elements are analogous to springs in this set-up. [8]. Figure 6b shows Buckling beams, in this configuration the mechanism is a monolithic structure and the material experiences a buckling effect that creates the snap through and negative stiffness. Designs in table 5 are sub-categorised as either BP or PP. Finally figure 6c shows their force deflection profile where a part of the range is negative stiffness which can be used to counter-act a positive stiffness creating static balance.*

TABLE 3: *Balancers using gravity as a en energy source. All designs paired masses with levers to create moment compensation. The added inertia comes from the extra weights used to create the static balance as compared to an unbalanced system.* [10–12]

Potential energy / Mass balancers							
Reference	Balance error [%]	Result type [sim/exp]	Energy Storage [J]	Comp. Force [N]	SB-Stroke [mm]	Size [mm^3]	Added inertia [%]
Bruzzone, Bozzin (2010)	-	sim	120.1725	181.485	490	7.297E+06	135
Chung, Lee (2001)*	0	sim	-	N / A	200	1.650E+06	-
Hamza, Diken (1995)	-	sim	181.348	215.82	1221	6.570E+07	122 / 150

*2DOF balanced adapted to 1DOF

4.2.2 Torsion beams One paper [6] designed a balancer using a torsion beam. Their prototype (figure 4) could compensate a force of 5N but no data regarding volume or stroke was reported, meaning this category could not be used for further comparison.

4.2.3 Bending Ten designs were found that fit into this category [2, 8, 21–25]. In this category we also further divide *compliant flexures* into *buckling beams* and *preloaded beams* as was explained before. No difference in energy storage or force compensation is found between these sub-categories for further comparison they are both taken as compliant flexures.

4.2.4 Torsional springs For this category two designs are found [7, 26]. Both were made into prototypes that balanced out their own weight but gave no data of what the weight was and only one of them reported the information necessary to calculate the stroke, leaving a gap in the comparison for torsional spring balancers.

TABLE 4: *Balancers using torsional strain. The mechanism column notes what type of mechanism was used in the design, coil springs (Spring), zero-free length springs (ZFLS) or a torsion bar of which there is only one design utilizing an X-shaped beam.* [6,13–20]

Elastic energy / Torsion balancers							
Reference	Balance error [%]	Result type [sim/exp]	Energy Storage [J]	Comp. Force [N]	SB-Stroke [mm]	Size [mm^3]	Mechanism
Brinkman, Herder, 2002	0.4	exp	2.176	4.905	295.16	1.190E+04	Spring
Cho, Lee, 2010	0%*	exp	49.1	55.917	1379.119	2.968E+05	Spring
Van Drosser, Barents, 2007	0%	exp	1.97181	9.81	180° / -	2.262E+04	ZFLS
Van Drosser, Barents, 2008	0%	exp	5.611	9.81	210.48	1.459E+06	ZFLS
Drent, Herder, 2004	-	exp	0.21	40.8408	39.27	3.994E+04	Spring
Herder, Berg, 2000	0.10%	exp	0.5338	172	4	6.035E+03	Spring
Koser 2009	-	sim	62.784	78.48	1884.96	5.543E+05	Spring
Najafi 2011	-	exp	0.05564	-	-	3.307E+03	ZFLS
Simionescu, Ciupitu, 2000	-	sim	67.1	215.82	1880	6.712E+06	Spring
Trease Dede 2004	5%	exp	-	5	-	-	X-Beam

*from simulation, experimental not reported

TABLE 5: *Balancers using bending strain and a compliant flexure mechanism. Balancer stroke is the full stroke of the mechanism while the SB-stroke is the part used for balancing. We distinguish if the design is buckling plates(BP) or pre-loaded plates(PP).* [2,8,21–25]

Elastic energy /Compliant flexure balancers									
Reference	Balance error [%]	Result type [sim/exp]	Energy Storage [J]	Comp. Force [N]	SB-Stroke [mm]	Balancer stroke [mm]	Size [mm^3]	Mechanism	Monolithic
Dunning (2012)	15.90%	exp	1.10E-01	-	-	-	6.55E+04	-	yes
Hoetmer, Woo (2010)	14.30%	exp	1.77E-02	1.7	1.7	-	3.33E+03	BP	no
Morsch (2010)	30.00%	exp	3.90E-02	153.4	23.6	-	6.45E+05	PP	no
Stapel, Herder (2004)	0.25%	sim	6.23E+01	15	0.3	-	5.08E+03	PP	yes
Tolou, Henneken, Herder (2009) cas	1.00%	sim	1.25E-06	0.003	0.05	0.4	9.60E+00	BP	yes
Tolou, Henneken, Herder (2009) cas	14.00%	sim	1.91E-07	0.0024	0.06	0.4	1.60E+00	BP	yes
Tolou, Herder (2010)	4.95%	sim	-	79.23	4.17	-	7.20E+02	PP	no
Ditske, de Lange (2008)	11.00%	sim	-	195	0.65	-	9.08E+02	BP	yes

5 Discussion

To compare the categorie,s we created three criteria ratios as shown in the methods chapter. Theoretical values have been calculated by *Cool et al.* [27] that show what maximum energy per volume we can expect out of each of the categories (ordered from most energy per volume to least.):

Mass balancers:

$$\frac{E_{max}}{V} = \frac{m_{max} g h_{max}}{V} = \infty \tag{4}$$

Coil spring balancers:

$$\frac{E_{max}}{V} = \frac{\tau_{max}^2}{4G} \tag{5}$$

Torsional spring balancers:

$$\frac{E_{max}}{V} = \frac{\sigma_{max}^2}{6E} \tag{6}$$

TABLE 6: *Balancers using bending strain implemented with torsion spring mechanisms.* [7, 26]

Elastic energy / Torsion spring balancers						
Reference	Balance error [%]	Result type [sim/exp]	Energy Storage [J]	Comp. Force [N]	SB-Stroke [mm]	Size [mm^3]
Radaelli (2009)	-	exp	0.12	N / A	395	1.144E+06
Zhu, Lamarche (2007)	-	exp	0.7853982	N / A	90°	2.408E+05

Bending balancers:

$$\frac{E_{max}}{V} = \frac{\sigma_{max}^2}{18E} \tag{7}$$

These can be used to supplement our comparison. In theory all balancer designs reliant on elasticity of material are limited by stress while a mass balancer has no limitation on energy storage. Figure 8 illustrates the main results from this literature study. It shows the comparison between mass-, coil spring-, torsion spring- and compliant flexure balancers on a reverse logarithmic chart. We can see from Figure 8 that compliant flexure balancers are able to store the most energy and compensate the most force per volume. Also tied with coil spring balancers as having the most range of motion for their size. Torsion springs come last in energy per volume. Coil springs designs store less energy and compensate less force per volume then compliant flexures and finally mass balancers have the lowest values for SB stroke and force compensation but come ahead of torsion springs for energy storage.

Few rotational spring designs could be used for comparison but this category can be seen as promising. Looking at the theoretical equations their absolute energy storage per volume is just below (50% lower) than coil springs. Torsion springs can be compact and both on average the torsion spring designs had a lower volume than coil spring designs.

Care must be taken when using this data to select a suitable balancer since here we consider all criteria equal. As an example, looking at the maximum energy storage equations of these mechanisms there we see that gravitational energy balancers have limitless energy storage potential while balancers that require elastic deformation are limited by stress of the material. Even though most elastic energy balancers have a better *Energy/Size* ratio. It was also found that all of the compliant flexure balancers had a straight linear motion while many of the mass- and spring balancers were only applied in balancing rotational movements.

Compliant static balancers can be made as *monolithic* structures which are fabricated out of one piece and have no joints or other

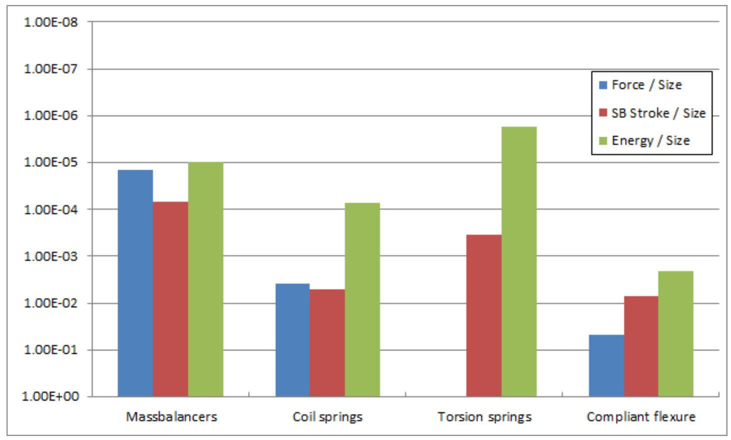


FIGURE 8: *Chart plot made from Tables 3-6 values are on a logarithmic scale and y-axis is reversed.*

friction inducing features. *Balancer error* was not reported in all papers and was defined as either the difference between the compensation stiffness of the balancer and the stiffness of the system to be balanced or the force difference. Those that did tests to record any kind of balancer error usually found that it was non zero. Compliant flexure balancers had the highest balancer error, they are also difficult to fabricate and hard to tune. [2] A few papers report their device is *fully statically balanced* but do not show measurements of that.

It is necessary to evaluate the design constraints for a given problem before selecting a balancer mechanism. Critical constraints include system weight, size and inertia limitations. In theory, simple mechanical systems can be balanced *a posteriori* using counter weights or torsion springs were size constraints are inactive. [28] On the other hand, design problems considering severe size constraints will be better of incorporating static balance in the design from the beginning.

6 Conclusion

An overview of existing static balancers adapted to 1DOF motions, classification and categorization to compare existing solutions to each other was presented.

It was shown that compliant flexure balancers showed the most promise for two of the comparison ratios ($\frac{CompensatedForce}{Volume}$, $\frac{Energy}{Volume}$) and was tied with coil spring balancers for the $\frac{SBStroke}{Volume}$ comparison. Most of the designs found were coil spring or compliant flexure balancers and most prototypes made were coil spring designs. Theoretical equations show that compliant flexure balancers have the lowest *maximum* $\frac{Energy}{Volume}$ which is not in contrast to the results just shows that current designs have not reached a theoretical maximum. Finally we state that these kind of numerical comparisons can be a meaningful guide for choosing a static balancer technology while keeping practical applications in mind.

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DEVELOPMENT OF AN ADAPTABLE TECHNOLOGY DEMONSTRATOR FOR ADVANCING COMPLIANT SURGICAL GRASPERS

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ABSTRACT

This work is part of a larger research effort to accelerate medical device innovation within the EU through academic & industrial collaboration. This paper presents the development of a technology demonstrating platform that will be employed for user-centered design testing. Technology demonstrators introduce critical features of functionality and comfort to end-users. User criticism is then interpreted to redefine performance requirements necessary for successful commercialization. Here, a technology demonstrator is developed to advance the design of fully compliant statically-balanced surgical graspers with superior force-feedback capabilities. The final demonstrator is a user-friendly, highly-adjustable stiffness compensator able to adjust it's compensation force of up to 75% by pre-load tuning.

1 INTRODUCTION

User-centred design methodologies have proven success through effective communication and testing within end-user envirnoments. [1] This work is part of a larger multidisciplinary effort to advance proof-of-concept technology towards fully compliant statically-balanced surgical graspers. The design offers improved force-feedback capabilities through the benefits of compliant mechanism design. The potential of the device has been proven within the medical market through proof-of-concept prototypes & related commercial medical products. [2–4] The device, shown in Fig. 1, consists of a compliant tool tip & a counteracting negative stiffness mechanism, or static balancer (SB). The tool tip is actuated by a central push/pull rod to open & close the device. The compliant monolithic (single-piece) de-

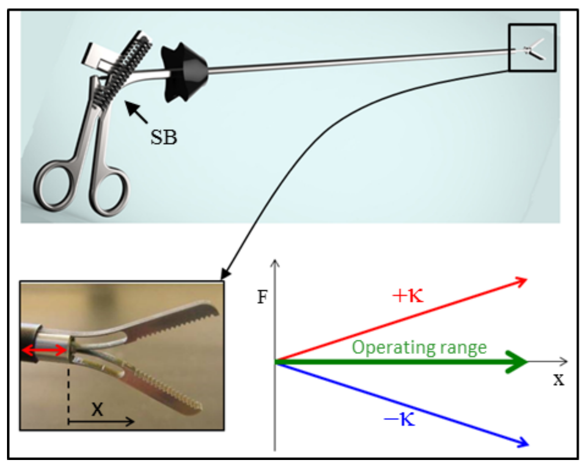

FIGURE 1: *Basic design of a statically-balanced surgical grasper with close up of compliant tool tip & operating force profiles.*

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sign offers direct input/output transmission by replacing traditional rigid-linkages with elastic members that transmit motion & force. When combining SB technology, the positive stiffness (k+) associated with articulating the compliant tool-tip is compensated by a counteracting negative stiffness (k-). The result is a zero-force operating range of motion. The underlining research is on compliant mechanism design to manipulate force-feedback response systems for graspers & alike. Here, product development methods facilitate the design of a technology demonstrating platform intended for extensive verification/validation testing of technological solutions. This work details the design of a linear SB mechanism developed to perform end-user testing. The following will offer the design methodology through this particular case study. Excluded work includes tool tip design (Patent Pending) & preclinical end-user testing.

2 Method

The design methodology employed in this project is illustrated in Figure 2. Design research filters the technical problem to form a basis of requirements. Technology demonstrators are then developed & evaluated within verification & validation testing to identify necessary modifications for successful commercialization. The process is repeated to satisfy all critical-users. Requirements will be created to compare the two concepts. Besides being able to stiffness compensate a range of compliant graspers (-k & ROM) various demonstrator requirements are taken into consideration that will improve the rate of success in end-user testing. Employing traditional design methods, existing

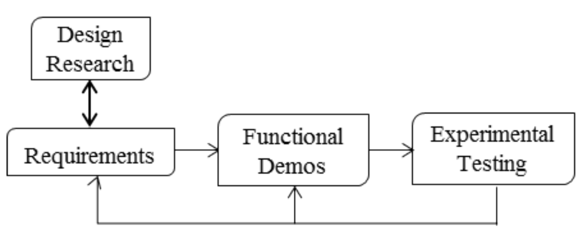


FIGURE 2: *Simplified user-centred design methodology that combines extensive design research with direct user-feedback to optimize product functionality & user acceptance.*

SB technology is surveyed, concepts are generated & then selected based upon a pre-defined design criteria. The final design is fabricated using traditional machining techniques. A Zwick??? tensile machine with custom made pieces is used to measure the demonstrator.

3 Results

3.1 Design results

Existing research & technology formulates the performance requirements of the device. [2–4] The selected mechanism functions according to the principles of static balancing using linear springs (Fig. 2). Two design concepts, which are illustrated in Fig. 2, differ by the primary rotational joint connecting user-input (actuation handle) and device-output (push/pull rod). The primary requirements of the functional demonstrator

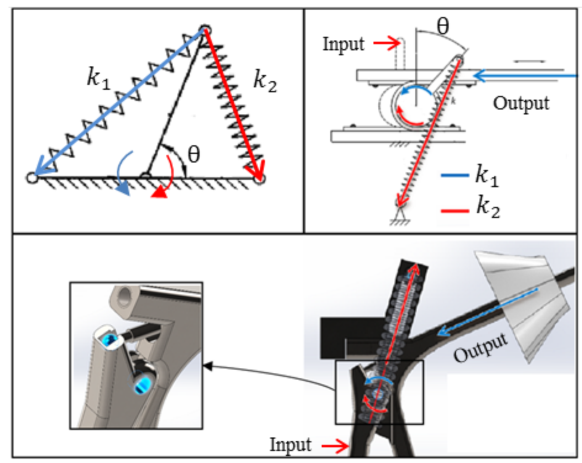
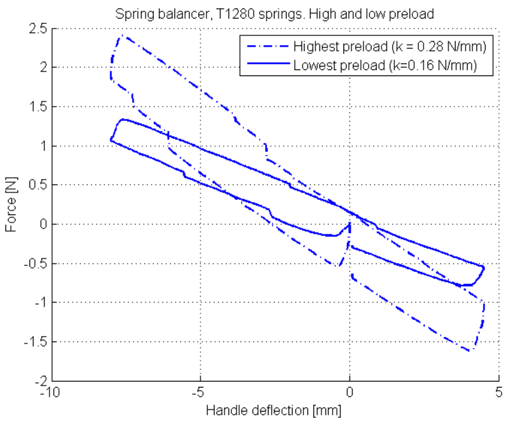
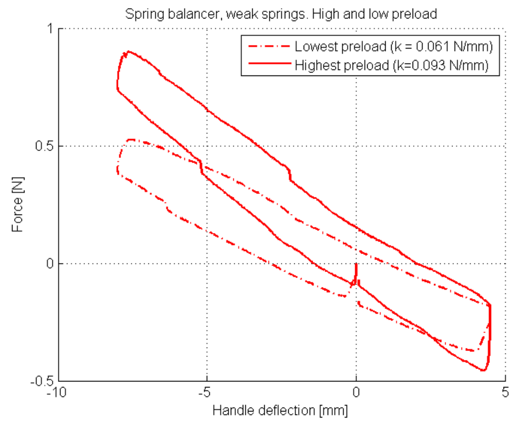


FIGURE 3: *(Left) Example mechanism illustrating the basic principles of static balancing with linear springs [4, 5], (Right) Roller Joint Concept: uses a wheel drum supported between elastic sheet supports [5], (Bottom) Revolute Concept: adopted from commercial graspers, combined with a prismatic joint transfers rotational to linear motion.*

are functionality, comfort, & adaptability. This allows effective demonstration of critical functions without distract of discomfort. Adaptable demonstrators permit design parameters to be manipulated during testing for introducing multiple/alternative modes of functionality. The selection criteria for the demonstrator is displayed in Table 1, with rankings favouring the revolute joint concept. Although both solutions provide adequate product performance, the revolute concept has superior adaptable capabilities. Using an donor laparoscopic device, the final design features quick interchanging capabilities of tool tip components, in addition to the balancing springs. Although friction is introduced into the system through mechanical joints (Fig. 3), the performance sensitivities linked to fabricating & assembling roller sheet supports outweighs the static frictional losses.



(a) *T1280springs*



(b) *Weaksprings*

FIGURE 6: Adjusting preload

Concept:	Rolling	Revolute
Product requirements		
Linear neg. stiffness	+1	0
Low friction	+1	0
ROM	-1	+1
=	+1	+1
Demonstrator requirements		
Ergonomics	-1	+1
Adaptability	0	+1
Fabrication & assembly	-1	0
Durability	0	+1
Tip rotation	0	+1
=	-2	+4
Total	-1	+5

TABLE 1: *Concept Comparison Chart.*

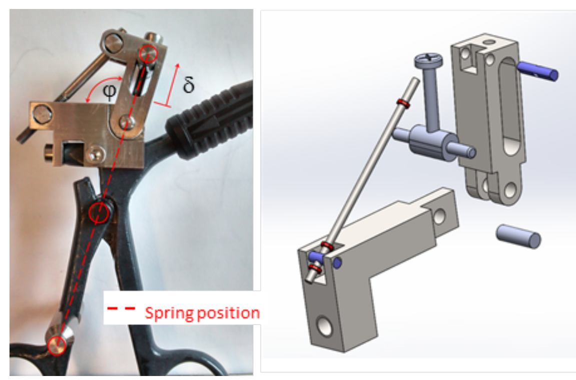


FIGURE 4: . *(Top): Donor instrument with integrated negative stiffness mechanism. Manipulating of $\delta \& \varphi$ allows adjustment for tool tip neutrual (stress-free) position and fine-tuning of $-\kappa$, respectively.*

3.2 Measurement results

Measurements are taken from the finger grip in the handle which has a lever action to the push-pull rod of 6:1. To verify the experimental set up a measurement was made without springs and tool-tip. The resultant fig. 5 shows that hysteresis in the set up is 0.06 and less. Using two sets of springs of stiffness $k_{T1280} = 1.5N/mm$ and $k_{weaker_spring} = 0.19N/mm$ the compensating stiffness slope was measured and pre-load (δ) was adjusted from minimum to maximum. Figure 6a shows that increasing the pre-load could increase the compensating stiffness by 75% and fig. 6b shows an increase of 52%. The angle (φ) adjustment in fig. 7 shows that compensation stiffness changed from 0.34 N/mm to 0.41 N/mm. A small stiffness variation was expected as rotating the top piece of the balancer does change the pre-load of the spring slightly. Symmetry of the graph was adjusted by moving the where the force crosses from positive to negative by up to 7 mm. A prototype of a compliant tool-tip was fabricated as seen in fig. 1. It's measurement (red line fig. 8) show it to have on average a linear profile. A matching spring was select and tuned to balance out this stiffness the results from fig.8 show that the compensated actuation is on average 0N but with a hysteresis of 1 N.

4 Discussion

The final design illustrated in Fig. 4 is a user-friendly, stiffness-adjustable demonstrator with critical component interchangeability. Two stiffness adjustment parameters ($\delta \& \varphi$) permit a continuous fine-tuning feature within predefined range of motions. By using a donor-device it's ensured that end-users

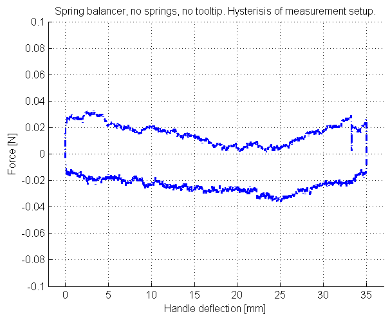


FIGURE 5: *Measure hysteresis of the demonstrator with out springs and tool-tip mounted.*

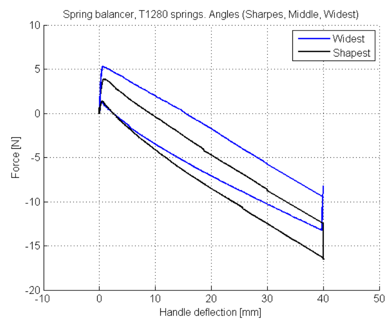


FIGURE 7: *Adjusting the angle φ. An increase in negative stiffness is noted as well as symmetry is change by changing where the graph crosses from positive force to negative.*

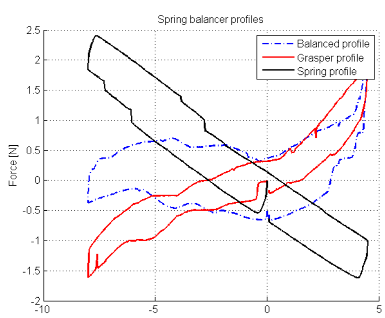


FIGURE 8: *Measurements of a compliant tool-tip prototype and a it's statically balanced profile. The profile is flat with a hysteresis of 1N which matches that of traditional linkage graspers.*

will be familiar with operating it. Tun-ability comes from allowing the springs to be swapped and further fine tuning via preloading (δ) and changing the angle φ. This creates a robust prototyping platform allowing tool-tips with various stiffness and neutral positions ranging from closed to open to be balanced by the same device. Including tuning of the compensation force is important also to negate any fabrication errors in the compliant tool-tips. [6]. Hysteresis of the balancer comes from the springs putting a force on the revolute joint increasing the friction.

5 Conclusion

The design methodology has led to a user-friendly demonstrator that permits quick interchanging of critical stiffness components. The stiffness adjustment features enable deeper research investigations into human-device feedback sensitivities & user-preferences. The device proved to have an compensation stiffness adjust-ability of up to 75% for one set of springs. This adaptability provides an effective testing-platform to complete extensive end-user testing of conceptualized tool tip designs. Although the main focus of this report has been user-centred design, the platform also integrates with verification testing procedures. Further work includes improving the demonstrator by using a new donor-handle and modifying the connection between the actuation handle and the push-pull rod to remove some minor backlash to improve user-experience. The final demonstrator will contribute to the advancement of compliant statically-balanced surgical graspers for improve force-feedback.

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DESIGN OF COMPLIANT STATIC BALANCERS WITH STIFFNESS TUNING FOR APPLICATION IN A LAPAROSCOPIC GRASPER

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ABSTRACT

Compliant mechanisms (CM) are an growing part of many different fields from MEMS to surgical devices. They offer a solution to classical mechanical drawbacks, such as friction, backlash, lubrication and assembly. One particular field of application concentrates on stiffness balance, also known as static balancing(SB), of mechanical systems. This research focuses on identifying critical design parameters of buckling bi-stable beams and their performance influence to be used for compensating the actuation stiffness of a compliant laparoscopic grasper. A finite element model verified by prototyping showed that beam designs using double pinned boundary conditions(BC) had a 260% and 128% higher negative stiffness then double clamped and clamped/pinned BC respectively. A novel stiffness tuning design was shown to vary the stiffness of double pinned bi-stable beams by up to 80%.

1 INTRODUCTION

Static balancers are defined as a energy storing mechanism that can counteract the forces of a mechanism creating a combined system of zero stiffness and constant potential energy [1]. Different ways exist to create static balancers all of which store and release potential energy. Compliant bi-stable beams offer the highest potential energy storing per volume of all existing SB designs [2] making them the primary choice for geometrically constrained design problems. Two classes exist of bi-stable beams, pre-loaded beams and buckling beams. This paper investigates the performance benefits of bi-stable beams based on prescribed design variables. Boundary conditions (BC) and geometry of compliant bi-stable beams suitable for static balancing (SB). The application is stiffness compensating a compliant grasper.

Previous work has been done on static balancers for laparoscopic balancers. Herder created a statically balanced rolling link design utilizing pre-stressed springs [1]. Herder and Van den Berg introduced a partially compliant spring balancing system for a that had a fully compliant grasping tip [3]. Stäpel and Herder did a feasibility study on a promising conceptual design but balance force errors and high stress were noted in the final design [4].

De Lange et al. performed topology optimizations through finite element analysis on negative-stiffness compensation mechanisms. Their method was promising but did not include stress constraints so their design showed considerable stresses and errors in the balancing force [5].

Tolou et al. showed a novel conceptual design of bi-stable beam segments and developed a mathematical model and finite element analysis to predict balancing behaviour. The findings show that balance force errors can be kept within 5% but stresses remained high, requiring material yield strengths approaching 1400 MPa [6].

Dunning et. al investigated negative stiffness performance of clamped/clamped bi-stable beams when manipulating starting angle and thickness of a beam. Preloading was also considered for stiffness tuning of the beam. Their research showed that the negative stiffness profile of bi-stable beams can be manipulated and their pre-loading tuning was capable of increasing the stiffness by 25% while also increasing range of motion by 230% [2].

The goal of this paper is to further investigate design parameters

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to control negative stiffness performance of compliant bi-stable beams. These results will then be used to present a feasibility study on achieving maximal negative stiffness for a range of motion of at least 2 mm within the constraints of a laparoscopic grasper. Figure 1 shows the position of the compliant balancer on the instrument, this position was chosen as having it outside of the body during surgery lessens sterilization requirements as well as giving a large design space.

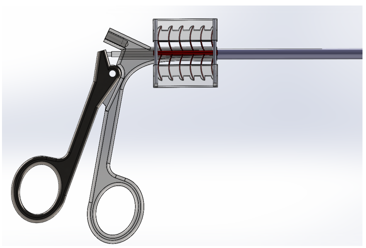


FIGURE 1: *Compliant balancer situated at the base keeping it's weight concentrated and allows for the largest design space for the balancer.*

2 Design requirements

To be useful in the application of laparoscopic graspers the design must meet the criteria listed in table 1. Dimension and weight requirements are based on measurements of traditional laparoscopic instruments already on the market. This represent the largest and heaviest housing at the base of the instrument that is accepted. A suitable compliant tooltip design was measured to find the lowest acceptable negative stiffness. Where a higher value would allow for more robust tooltips with stronger grasping forces. The stroke is an over estimation of the required range of motion for actuating the tool-tip. Being able to tune the force compensation of the bi-stable beams can offset manufacturing defects which compliant mechanisms are sensitive to [2]. Past balancer designs that took tuning into consideration also achieved less balance error than those who did not. The results of this research will be used in developing a commercial product. Therefore simple the design must be feasibly with medical grade materials.

3 Method

This chapter will present design concepts of the bi-stable beams and the design of the stiffness tuner in chapters 3.1.1 and 3.1.2 respectively. The finite element model used to predict the balancing performance is introduced in chapter 3.2. Finally chapter 3.3 shows the prototypes used to verify the design method.

Technical requirements	
Negative stiffness [k]	>25 N/mm
SB stroke	> 2 mm
Dimensions (l * w * h)	80 * 30 * 50 [mm]
Weight	< 220 grams
Product requirements	
Mass produceable	Simple construction
Medical grade materials	ISO-7153-1
Stiffness tuning	>10% variability

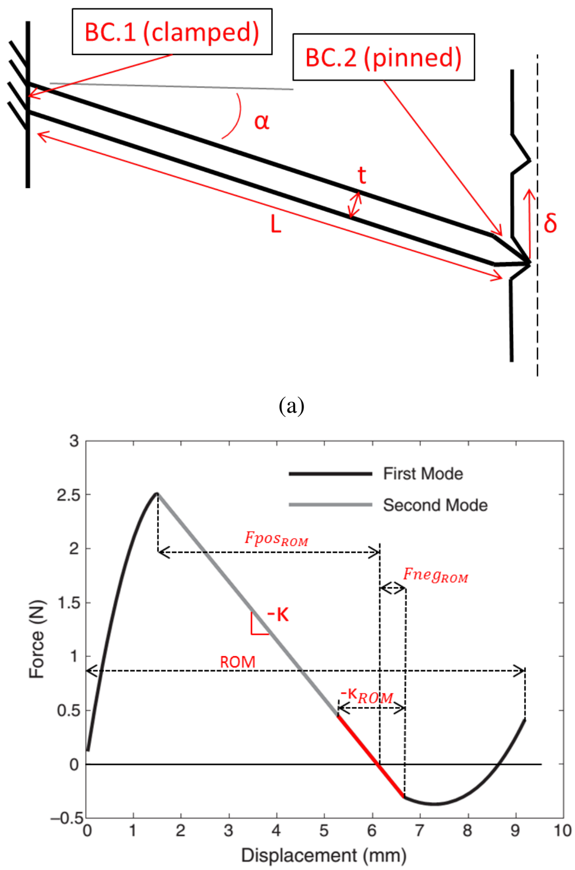
TABLE 1: *The minimum technical requirements the balancer must fulfil as well as it's size constraints and functional design considerations.*

3.1 Concepts

Comparison parameters	
σ_{max}	Maximum mechanical stress induced over the full ROM
$-K$	Negative stiffness at the useable ROM
$\frac{-K}{\sigma_{max}}$	Amount of negative stiffness created for the maximum stress.
$-K_{ROM}$	Useable ROM for static balancing. Symmetric around 0N origin.
ROM	Full ROM of mechanism from start til second equilibrium point.
$-\frac{K_{ROM}}{ROM}$	Percentage of the ROM useable for static balancing.

TABLE 2: *The parameters used to describe the balancer performance and compare the difference concepts.*

3.1.1 Beam design For a 2D construction we can constrain a beam endpoint in x,y and rotation around z axis. Clamped BC has all constraints active while pinned BC allows rotation around Z.
Three different beam cases will be considered. A beam with both boundary conditions clamped (double clamped), with one BC clamped and the other pinned (clamped/pinned) and finally a beam with both BC pinned (double pinned). Further the effect of changing the geometry design variables *thickness (t), length (l)* and *angle* (α) will be investigated for each of the three cases.
Figure 2a shows a typical bi-stable beam with the relevant variables and both boundary conditions.
The negative stiffness of figure 2b (second mode) is used to balance a positive stiffness. To accurately balance the positive stiffness of a compliant tool tip, the designer must control the negative stiffness variable ($-\kappa$) and the position when passing the origin. $-\kappa$ must be symmetric around the origin. The negative stiffness is calculated at that part of the ROM. σ_{max} represents the highest induced stress while taking the mechanism through out it's entire range of motion.
Table 2 shows comparison parameters that we will use to evaluate the effects of the design variables on balancing performance.



(a)

(b)

FIGURE 2: (a) Bi-stable beam with clamped/pinned boundary conditions. Actuating this beam in the direction of δ will result in the force deflection graph. A dotted mirror line shows the symmetry of the design.
(b) Typical force deflection graph of a bistable beam with double clamped boundary conditions.

3.1.2 Stiffness tuner design

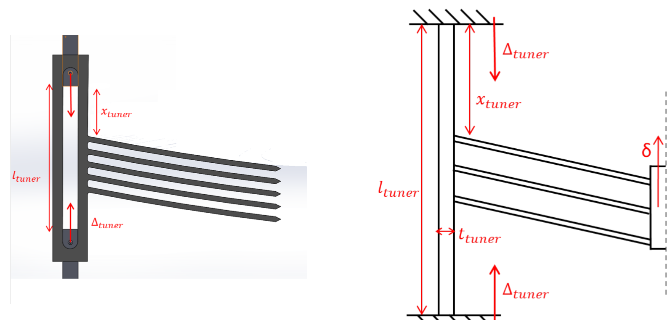
A novel design is put forward to tune the negative stiffness. Instead of the static end-point resting on a fixed wall as in figure 2a we now have spring element where if $k = \infty$ the design would be constrained as before but for lower spring stiffness the energy of the beam can dissipate into the spring element leading to lower stiffness slope. The highest negative stiffness is then when $k = \infty$ and can be lowered continuously until l_{tuner} is at its highest value.
This means the beams should be over designed to have higher negative stiffness then needed. This tuner design can be implemented in most applications save for those under design space constraints. For application in a laparoscopic grasper the spring element is a flexible beam where the bi-stable beams rest on a rendering can be seen in figure 3a and a equivalent drawing with the relevant design variables in figure 3b. The stiffness of the tuner beam can be altered by adjusting a slider resting behind it this would shorten l_{tuner}. The stiffness of the tuner in the middle can be described by the equation:

$$k = \frac{192 \cdot E \cdot I}{L^3} \tag{1}$$

For multiple pairs were each sits further from the middle of the beams their resulting spring equivalence would be:

$$k = \frac{48 \cdot E \cdot I}{x^2 \cdot (3l - 4x) \cdot n} \tag{2}$$

Where n is the number of beam pairs and x the distance to each beam. Giving each pair of bi-stable beams different force deflection profile which all add together to form the final profile. The variable manipulated for tuning in equation 1 is L^3 which means that this will be a non-linear tuner.



(a) .

(b) .

FIGURE 3: (a) CAD rendering of the stiffness tuner. By moving the two sliders (δ_{tuner}) the stiffness is adjusted as equation 2 shows. (b) l_{tuner} is the maximum length of the tuner and t_{tuner} thickness of the tuning beam. As before the design is symmetric and is mirrored at the dotted line.

3.2 Finite element model

To create the model on which we base or comparison we use ANSYS. The bi-stable beams are modelled using the 2-D elastic element BEAM3 with 3DOF capabilities. This element selection is based on its accuracy with light computational loads [6]. The analysis includes large deflection-effects.
The stiffness tuner is modeled as two beam segments with which can be simplified into a spring element modelled using the COMBIN14 element which is a spring element with a spring constant

calculated from equations 1 & 2 and a damping coefficient set to zero.

3.3 Prototypes

Prototypes were created to validate the FE model utilizing stainless steel sheet stock as the bi-stable beams (Figure 4) and measure on a force measurement stage.

First design used two bi-stable beam pairs each beam being 0.4 mm thick of length 44 mm and a 7.5° angle. Second design had three bi-stable beam pairs each of 0.2 mm thick beams and length 30 mm under a 11° angle. Finally a third design was tested with three beam pairs of the same design as the second design and an extra beam pair of 0.4 mm thickness with same length and angle (30 mm and 11°). All beams had a out of plane width of 5 mm.

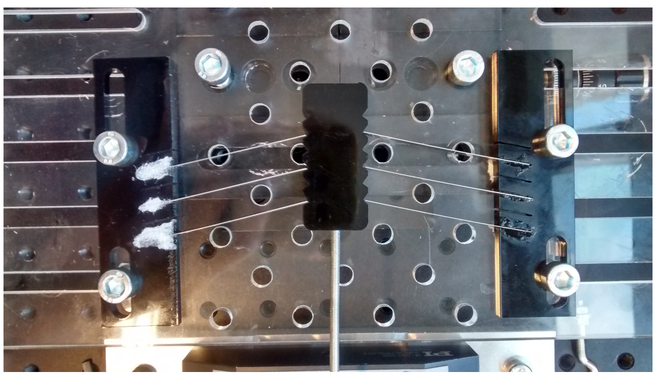


FIGURE 4: *Stainless steel sheet-stock prototype with clamped / knife joint boundary conditions.*

4 Results

To evaluate the design method prototype measurements and FEM results are compared. This model was then used to investigate the effect of the three different boundary condition cases and the beam geometry on the comparison parameters from table 2.

4.1 Prototyping

The results are shown in figure 5. Second mode of the measured force deflection curve matches the FE model within 5%. Due to fabrication errors each of the buckling beams did not connect at the same time which would explain the pre-buckling force deflection curve not matching up to the FE model. In the third design the FE model quickly diverges from the measurement after the 2nd mode ends while the other two designs follow the measurements closely. This confirms that our FE model accurately models the 2nd mode of the force deflection curve.

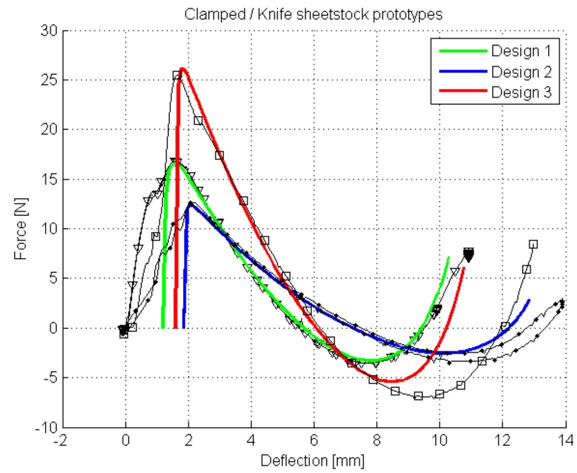


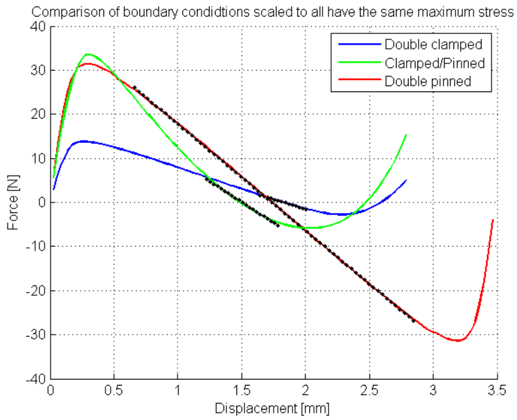
FIGURE 5: *Results from measurements of sheetstock prototype designs 1,2 and 3 compared to FE model.*

4.2 Boundary condition comparison

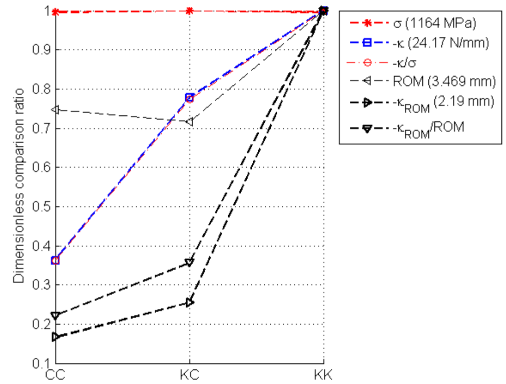
To maximize the balancing potential per volume we compare the boundary conditions by scaling the base design presented in table 3 for a beam with each of the three BC cases until they have the same maximum stress. This ensures they are storing as much energy as would be allowable by their material. A beam with double clamped BC and geometry as listed in table 3 will have a maximum stress of $\sigma = 1164MPa$ we scale the beams using the other two BC cases by increasing their thickness until they reach that same maximum stress. This increases the clamped/pinned beam thickness to $t = 0.59$ and the double pinned to $t = 0.64$. The results we see in figure 6a show that clamped/pinned and double pinned have the highest peak force. Figure 6b demonstrates that the double pinned beam has the highest negative stiffness ($-\kappa$) and $-\kappa_{rom}$ with the clamped/pinned coming second.

l = 20mm
t = 0.3mm
w = 5mm
$\alpha = 5$

TABLE 3: Typical beam geometry values. Chosen as being inside the design space available.



(a) .



(b) .

FIGURE 6: (a) Force deflection curves for the three BC cases scaled upp to all have the same maximum stress (σ_{max}). (b) Comparison ratio plot using the performance paramters from table 2. Double pinned performs the best with clamped/pinned coming in second.

4.3 Optimizing beam shape

The base design from table 3 is used and then each of the variables is changed to see the effects on the balance performance parameters.

From figures 7b,8b,9b we see that thickness is the best variable to manipulate to increase negative stiffness based on the amount of negative stiffness increase versus induced mechanical stress.

Adjusting the angle changes the range of motion(ROM) with little effect on negative stiffness after 3° while linearly increasing mechanical stress. Length as expected increases stiffness and maximum stress with a shorter length but as seen from the slope of the $\frac{-\kappa}{\sigma}$ ratio the benefit is not as favourable as changing thickness.

4.4 Tuner design

The design of the tuner makes it so that the stiffness is decreased as if rotated around a point in the middle of the beams ROM as can be seen in figures 16a,17a and 18a. This is very positive for the double pinned boundary condition case which is symmetric around that point. The other two cases don't pass the 0N origin for low stiffness of the tuner leaving them with a less tuning range. For our application a l_{tuner} of 30 mm was chosen with a t_{tuner} of 3 mm. This allowed for a sufficient stiffness change to gather the results.

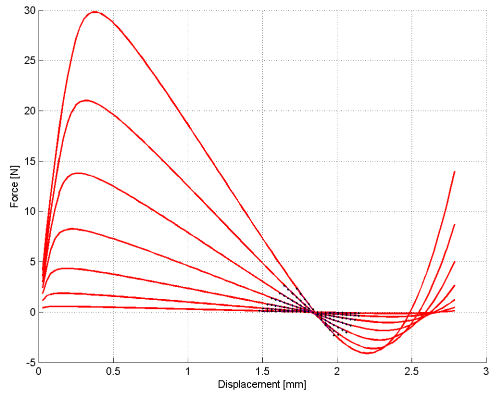
Figures 16b and 17b show that $-\kappa$ can be varied by up to 20% for double clamped beams before $-\kappa_{ROM}$ reaches half of its former value. And for the clamped/pinned case $-\kappa$ can be adjusted by up to 30% while $-\kappa_{ROM}$ goes down 50%.

From figure 18b we see that double pinned beams have a $-\kappa$ tuning range of 80% while their $-\kappa_{ROM}$ goes down to 56% of former value.

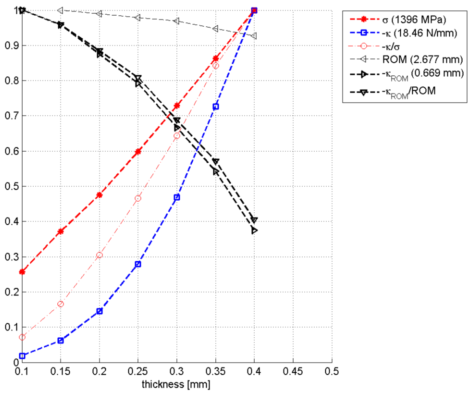
5 Discussion

For our laparoscopic static balancer based on the technical requirements a beam design using double pinned BC with lowest possible angle, $\alpha = 3°$ gives us $-\kappa_{ROM} = 2.1mm$, length chosen between 20-30 mm to leave ample room for stiffness tuner construction around the beams, then thickness could be used to maximize negative stiffness based on the construction material. A maximum number of beam pairs should be used with the above length and angle would give room for at least 20 beam pairs. This design would not exceed the yield strength of surgical steels such as martensite 420 or 440 both having yield strength lowest in 400 MPa and up to 1700 MPa. And would well pass all the technical requirements set forward.

The stiffness tuner is capable of adjusting $-\kappa$ by up to 80% and with the already large range of motion of the double pinned beams the loss of $-\kappa_{ROM}$ is not an issue. So the feasibility of creating a static balancer for a laparoscopic grasper has been proven by the results of this paper. A specific design will not be put forward but we feel the results show that the static balancer can fit a variety of compliant tooltips.

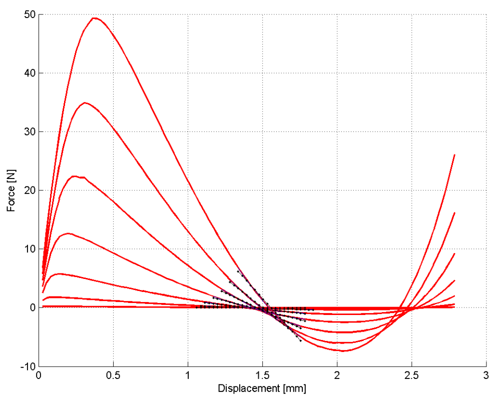


(a) CC thickness

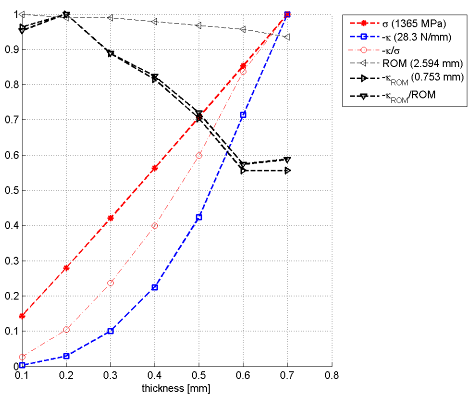


(b) CC thickness ratio

FIGURE 7: CC thickness F/D and ratio

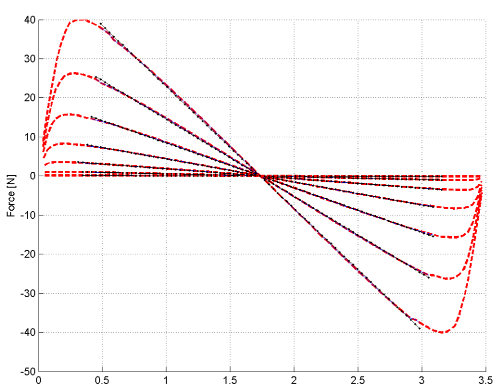


(a)

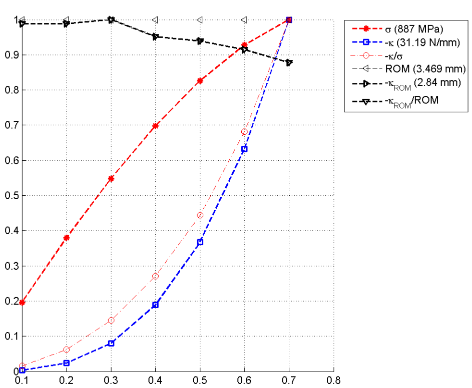


(b)

FIGURE 8: KC thickness F/D and ratio

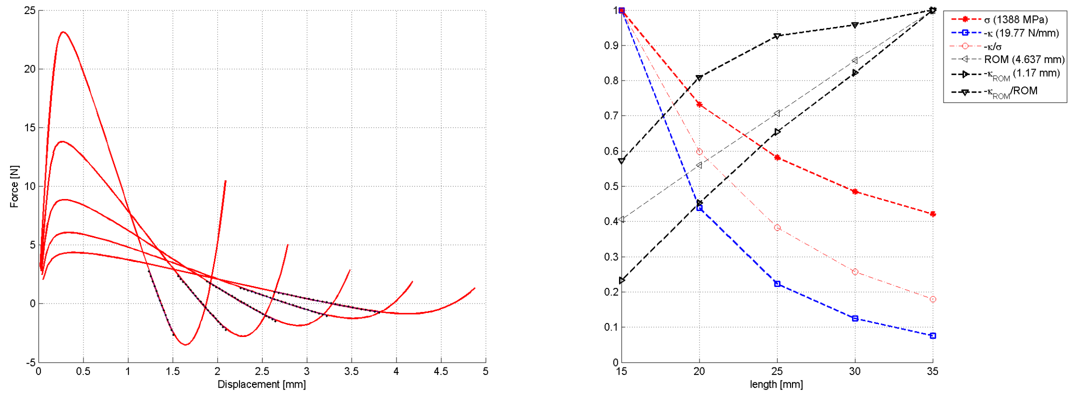


(a)



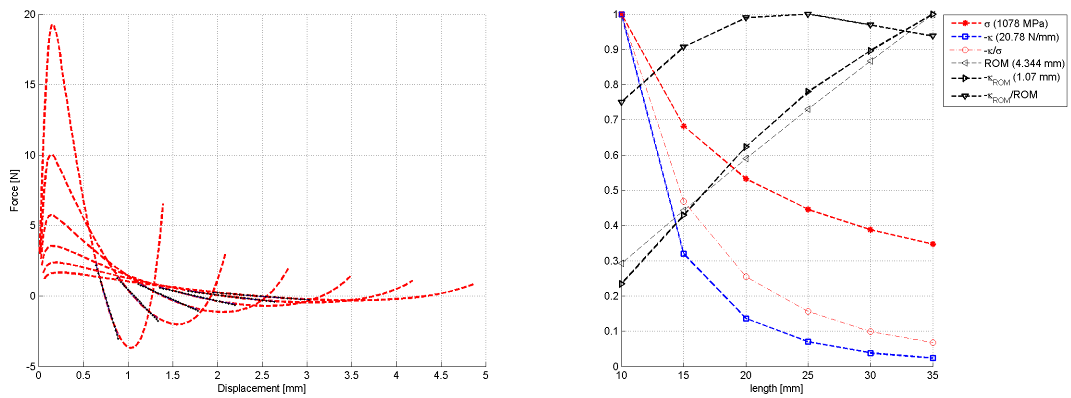
(b)

FIGURE 9: KK thickness F/D and ratio



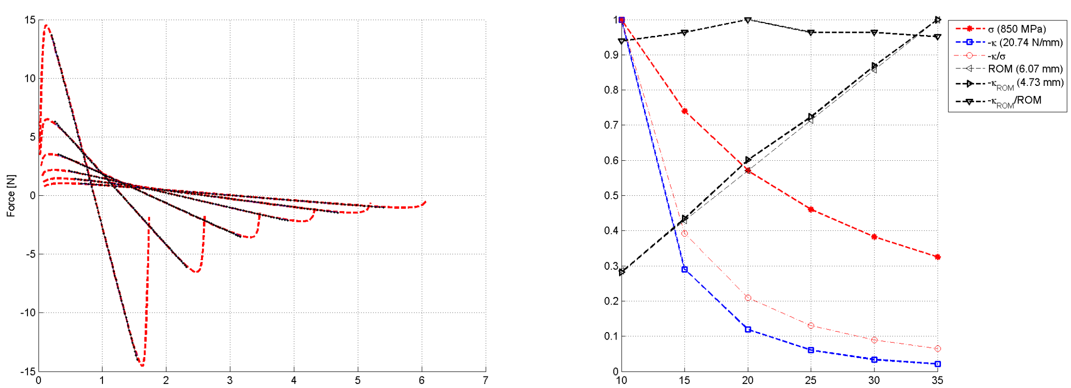
(a) (b)

FIGURE 10: CC length F/D and ratio



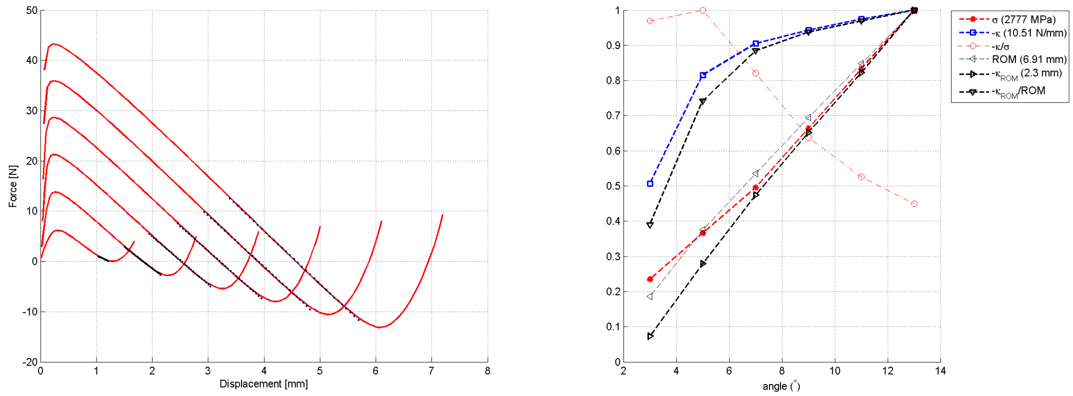
(a) (b)

FIGURE 11: KC length F/D and ratio



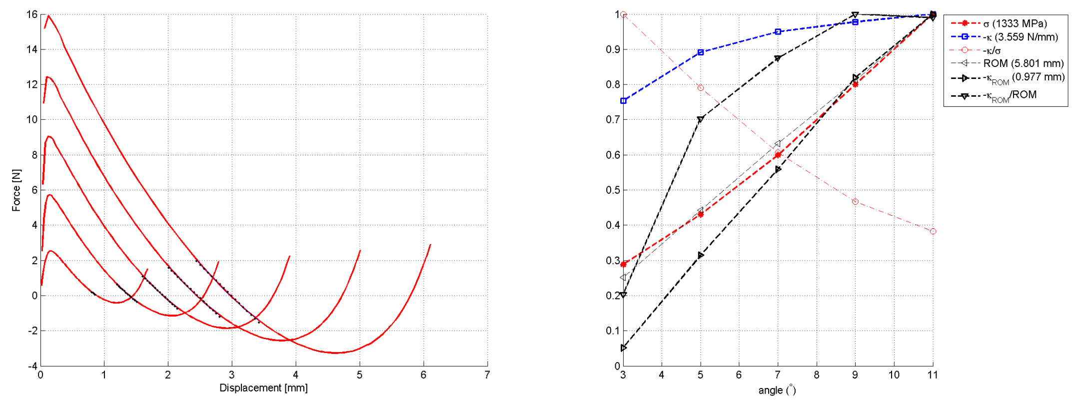
(a) (b)

FIGURE 12: KK length F/D and ratio



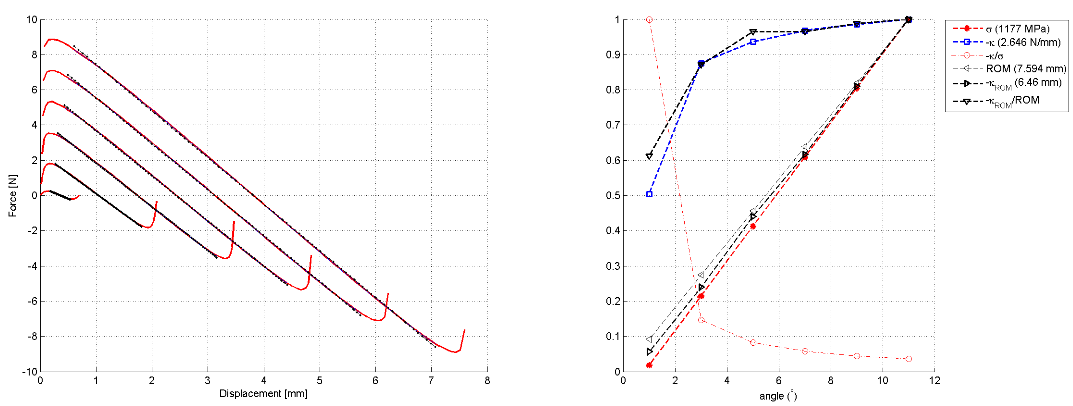
(a) (b)

FIGURE 13: CC angle F/D and ratio



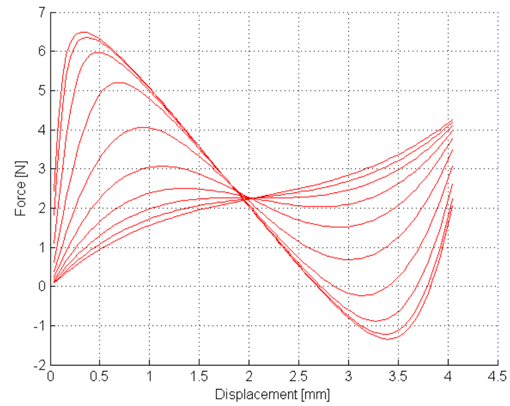
(a) (b)

FIGURE 14: KC angle F/D and ratio

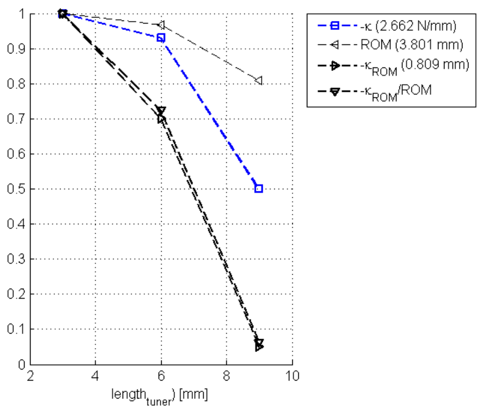


(a) (b)

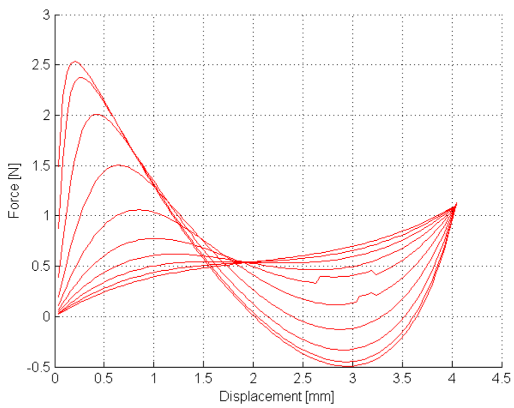
FIGURE 15: KK angle F/D and ratio


Force [N]
Displacement [mm]

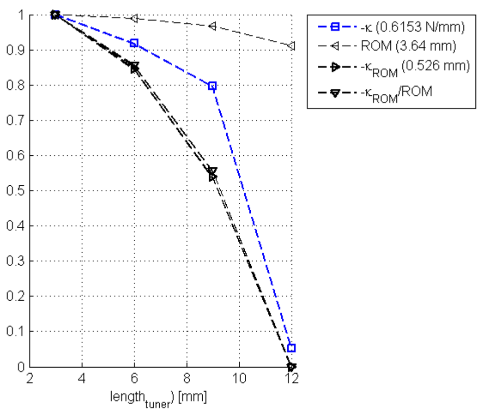
(a) .


-κ (2.662 N/mm)
ROM (3.801 mm)
-κROM (0.809 mm)
-κROM/ROM
length_tuner) [mm]

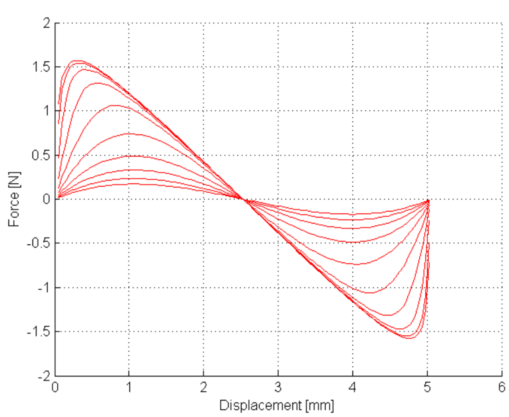
(b) .


Force [N]
Displacement [mm]

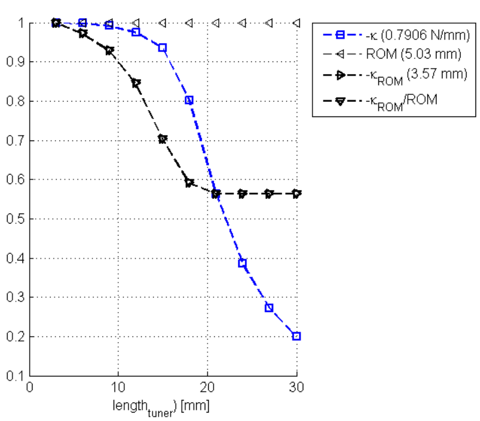
(a) .


-κ (0.6153 N/mm)
ROM (3.64 mm)
-κROM (0.526 mm)
-κROM/ROM
length_tuner) [mm]

(b) .


Force [N]
Displacement [mm]

(a) .


-κ (0.7906 N/mm)
ROM (5.03 mm)
-κROM (3.57 mm)
-κROM/ROM
length_tuner) [mm]

(b) .

6 Conclusion

Ways to manipulate and control the negative stiffness slope of bi-stable beams with three different sets of boundary conditions was put forward. It was shown this can be a step in optimizing for a balancer based on technical requirements and a feasibility study was presented showing how these findings could be used to design a static balancer for a compliant laparoscopic grasper. A set of performance parameters was used to compare the three BC cases showing the double pinned beams demonstrate the balancing performance. With pinned/clamped beams coming second.

A novel design for a stiffness tuner was presented showing promise in being able to continuously tune the stiffness of a bi-stable beam balancer. While it showed the most success for double pinned beams, it was able to tune the stiffness of pinned/clamped and double clamped beams to a lesser extent. Based on past research it was shown that being able to tune a design post-production can make up for manufacturing errors.

Future work will be to create a tunable static balancer based on these results.

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APPENDIX A

1 LUMC sterilization report

Based on the instruments that are already in use in the operation room we can extract requirements for the new instrument concept. Those requirements are considered the minimum for the new instrument. The following questions were asked at a mini internship at the LUMC sterilization department.

What makes pre-cleaning needed?
A: Visible dirt and debris. All instruments are disassembled and rinsed but they specifically look for dirt and blood stains that are then brushed. For shaft instruments they always rinse through the shaft and use a small wire brush as seen in Figures 1 and 2 to clean the inside. If the instrument looks clean by visual inspection then it is good.
What do you consider the most difficult instrument to clean?

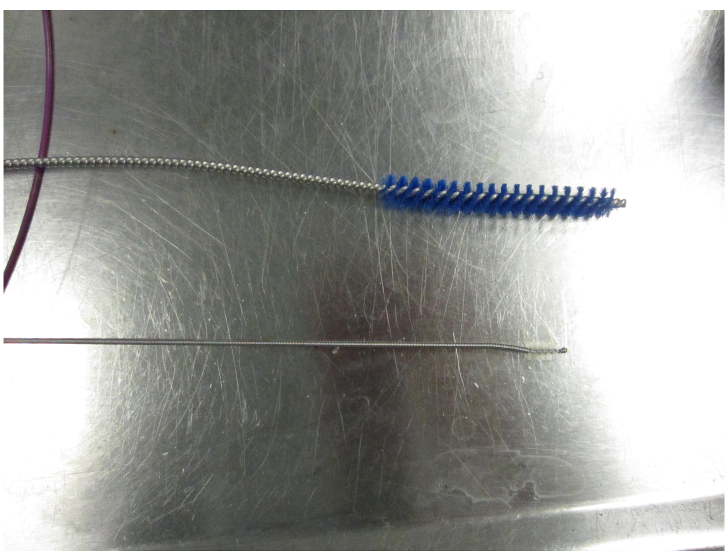


FIGURE 1: *Pipe cleaner used to reach hard places.*

A: The Medronic Multi Axial Screwdriver because you don't have access to the inner shaft so hard to rinse and to fit a brush in there (in a question below). Also the AESCULPA PM973R laparascopic grasper specifically the small teeth on the tip are very hard to clean. The teeth are very fine and almost always have blood spots and debris in them that seems to be hard to clean out. If they don't brush it thoroughly in pre-cleaning then they will find that after the washing machine procedure that there is still clotted blood in the small teeth (see more in case studies).

What makes an instrument difficult to clean in your opinion?
A: No specific answer it depends on the instrument, usually if it's hard to get it apart wearing gloves that's a problem. In the past more instruments had screws in the design that they had to take apart, but now most of the have change the design to use a different system like clicking in place.

Does dismantling instruments without pre-cleaning save time compared to pre-cleaning without dismantling?
A: There are instruments that cant be dismantled that need pre-cleaning and there are instruments that can be dismantled that dont need pre-cleaning.

Do you know any compliant/flexible instruments. General experience with processing flexible instruments?
A: Did not have much experience with compliant or flexible instruments, there was one that they sometimes get but did not have at the time that has a flexible tip that will bend like a finger when a screw on the handle is turned. No difference in cleaning that one and the other instruments, flushed through the tube and brushed. They say that having the instrument compliant or flexible is not a problem as long as it can be taken apart to be cleaned easily. Most of the staff is used to many different procedure so if a compliant tool would for some reason require a different strategy it should be ok. .

Does the procedure change for instruments with small or big housings?
A: No difference for them regarding cleaning and sterilization.

What are the common difficulties with cleaning/sterilizing shift-shaft instruments?
A: Not being able to take the instrument apart so that they can take the inner and outer shaft apart. If they can take it apart so it's easy to flush and even better can get a small narrow brush (pipe cleaner shape?) then it's even better.

Smallest diameter shift-shaft instrument?
A: Only had regular 5mm diameter laparoscopic push pull instrument, did not know of any smaller in diameter that had a push pull activation method.

Are there minimum or maximum feature sizes about? For example, inner shaft or lumen diameters?
A: There is close to no limit on how narrow the lumen of a shaft can be, the smallest they clean is 0.9mm and it sterilizes and cleans out very well. The wall thickness should not be too much and on most instruments seem to have a 1-3mm.

What problems that commonly occur during cleaning (general instruments & shift-shaft instruments)? What are common reasons for having to dispose (trash) an instrument?
A: The instrument cant be cleaned or sterilized after an operation then it is taken out of rotation and the CDS call upstairs to let know of the problem. (Medtronic drill as an example)
Where does the disposed instrument go? A: If it was disposed because it could not be cleaned/sterilized they will send it back to the producer with comments who will sometimes take it apart and clean it.

Do any additional steps get taken to keep/fix the problem instrument?
A: They will communicate with the producer to see if they can fix or change the design to make cleaning & sterilization easier, in the case of the Medtronic drill they are doing exactly that and in the meanwhile the producer is cleaning the drills for them since they can take it a part.

What are some of the best & worst devices that can be dis/assembled?
A: For laparoscopic devices specifically there is not much difficulty in dis/assembly. For other devices there are some that contained small screws that were difficult to handle with gloves. In the past devices had more screws and some even very small parts that were difficult to disassemble with the rubber gloves (dishwashing gloves) they use when disassembling the dirty instruments. Now most companies have changed their designs so that it is easier and almost none of them contains very small screws anymore.

Does the procedure change for instruments with small or big housings?
A: From the cleaners perspective there is no difference between instruments with small or big housing, they one device that Is bulky so it doesn't fit in the tray like the other laparoscopic devices but they have a different set up for that one see pictures. So they just connect

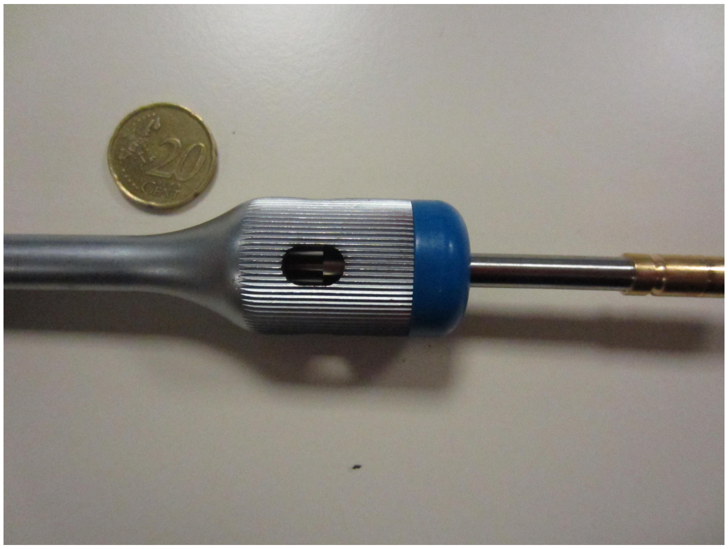


FIGURE 2: *In the pictures above we see the Medtronic drill, the CSD department want them to change the design so that the blue cap can be taken off to allow for easier rinsing and brushing furthermore they want to slide the whole rod out so they can rinse and brush through the shaft so change either end of the rod so that is possible. .*

FIGURE 3: *Medtronic drill.*

a plastic tube to the instrument and to where water will flush through during the washing process.

What are the common difficulties with cleaning/sterilizing shift-shaft instruments (instruments with push-pull rod activation)?

A: The laparoscopic instruments they regularly clean (graspers and cutters) all clean out the same and have a similar structure. They can be taken apart into 3 parts (outer and inner sheath and the mechanism itself) and they flush through the sheaths and use a wire brush to clean the inside. Most difficulty is when there has been a long time since the instrument was used so they have clotted blood stuck in the hinge of the tip.

Are there minimum or maximum feature sizes (inner/outer diameter) we should know about? & its relationship to debris causing issues.

FIGURE 4: *Setup to flush instruments with big housing that do not fit in the regular tray setup.*

A: In their opinion if the laparoscopic instrument can be taken apart so that the sheath can be flushed and be reached with a brush on the inside then there is no problem in having the diameter much smaller. They regularly flush and clean a laparoscopic needle with 0.9mm inner diameter and it sterilizes very well and also an instrument used in eye surgery (Ellip FX E215947) that has an inner diameter of 1.4mm.

What problems commonly occur during cleaning (general instruments & shift-shaft instruments)?
A: Same as above, clotted blood can cause a problem but in general not many difficulties.

What are common reasons for having to dispose (trash) an instrument?
A: Usually if an instrument is taken out of rotation it is not a problem with cleaning and sterilization the Medtronic Screwdriver mentioned before and again in the case studies is a case that doesnt happen often. Sometimes the instruments will break or not function correctly which would then be handled by another department (maintenance). Another case was an orthopaedic instrument that was very hard to assemble since it had three very small inside of it that had to be placed precisely, assembling it took 30-45minutes which was considered too long. The company worked on changing the design to rectify the problem.

Do any additional cleaning steps get taken to keep/fix the problem instrument before throwing it away?
If an instrument cant be sterilized or is malfunctioning they will report it and the company will usually work to change the design to fix the problem (see Medtronic Screwdriver case). Also depends on the instrument what steps are taken, if its an old instrument that has

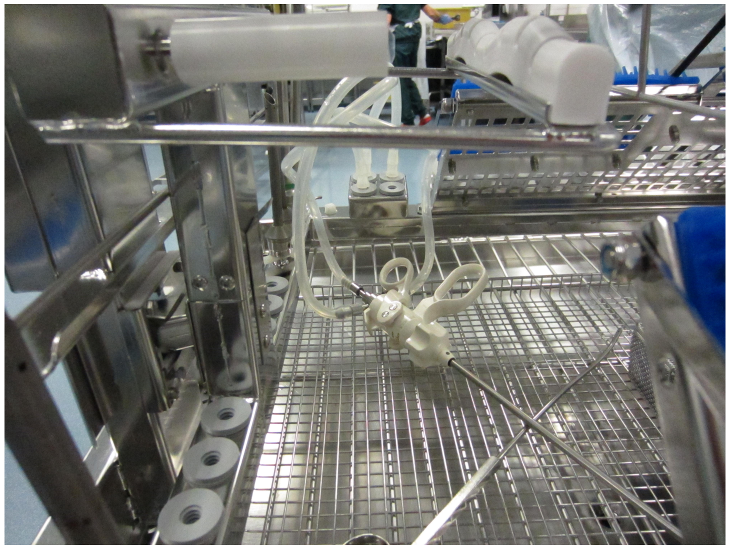


FIGURE 5: *Another angle of big housing flush setup.*

already had good use then they might just dispose it and buy a new one, if its a flaw in the design that causes it to break then they will talk to the producer of the instrument. If its a very expensive instrument even if its not new they might repair it all depending on whats most cost efficient. As an example inexpensive clamps will get replaced frequently while expensive electrical cables used for some instrument will be cleaned even though these cables dont handle the cleaning process well and can usually only be used and cleaned around 10 times.

Where does the disposed instrument go?
Dont know about disposed regular instruments but they have simple disposable instruments like scissors and tweezers that are made out of cheap metal that they dispose in a special container that is then recycled.

Does the sterilisation department order the new instrument? Or who?
A: Ordering new instruments is a whole procedure that the sterilization department is a part of. When ordering new instruments it is done in collaboration between surgeons, sterilization department, maintenance department and budget department. Often a company will develop a new instrument and invite surgeons from many different hospitals to come and check it out, usually the surgeons might have some comments on what they would like to change and the company tries to accommodate them and change the design if need be. The hospitals will often get the instrument for a trial period.
The sterilization and maintenance department will also have some comments if they feel the device should be changed. A final decision is then made to buy the instrument with all this in mind.
Cleaning Is almost always done in house there are rare cases where they might send a instrument to the maker to get it cleaned if they cant do it, a complex instrument that was not meant to be taken apart for example but has gotten dirty. Maintenance is often in house but sometimes the producer will take care of maintenance and they will send them the instrument or the producers sends someone to the hospital to repair the instrument there.

Additional information that I got from talking to the staff and asking various questions.
Usually the instruments come down to the CDS for cleaning roughly 2 hours after and operation, but it can happen for example if they have unplanned surgeries that the instruments dont get cleaned until after 12 hours. Blood can take from minutes up to an hour to clot and it gets worse the more time passes.

Most of the blood that they find inside the shaft of laparoscopic instruments is in the inner sheath, very little blood usually inside the black outer sheath, Figures 3 and 4 show the inner and outer sheaths.
Different hospitals have different cleaning facilities so that limits what instruments they can cean. LUMC as a university hospital does all possible operations so their sterilization department is more equipped to deal with different and various instruments. It might not be

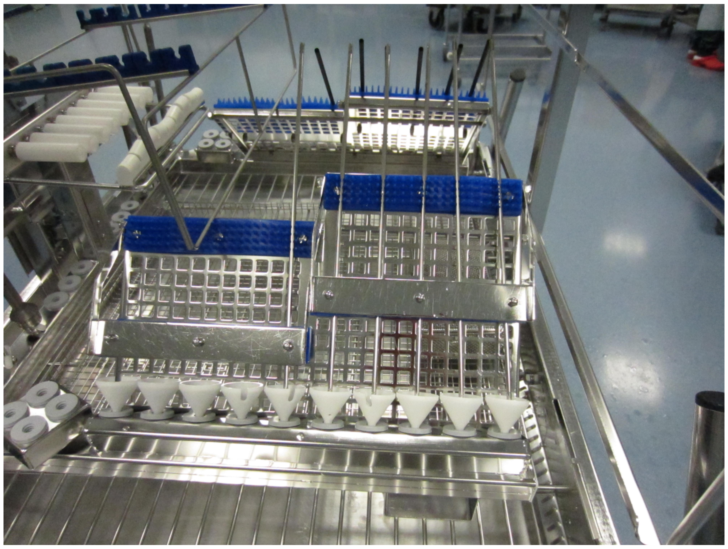


FIGURE 6: *Instrument tray.*

FIGURE 7: *Instrument tray.*

the case for smaller hospitals. Companies will sometimes look to this when finding out what hospitals they can sell their instruments too.

1.0.1 LUMC sterilization equipment

6 washers / disinfectors (53 mintues, 1h06m for implants) Getinge 8666
1 bigger washer / disinfector Getinge
1 ultrasound cleaner Getinge
4 autoclaves Getinge
1 sterilizer for urgent cases (takes roughly 25 minutes to do the sterilization program. They can with quick pre cleaning get the

instrument ready in almost 30minutes.) Davenport Turbi Ster20
1 plasma sterilizer Johnson Johnson STERRARD100NX

The order in which it is used:

1. Pre cleaned by hand and disassembled, involves rinsing with cold water and brushing, depends on the instrument. Inspected by eye and all visible blood and gunk is removed.

2. Placed in the tray in a specific way, shaft instruments are placed in special holders that are connected by a tube so that the shaft is rinsed, small parts are placed in containers so that they dont get lost during washing and fragile instruments have their own custom containers that make sure they dont get damaged.
3. Placed in a machine that also rinses away dirt with very strong flow of cold water.

FIGURE 8: *Instrument tray.*

4. Placed in ultrasound if possible for the instrument.

5. Placed in the washing machines that goes through several different washing programs with different chemicals including a chemical that gives metal parts a shine coating and another chemical that acts as a lubricant for joints.

6. Instruments taken out and let to cool down, and then assembled this is the first manual task after step 1 since steps 2-5 are automatic on a conveyer belt.

7. Wrapped in autoclave paper and placed in autoclave.

This is the basic step by step for most instruments some instrument require a different cleaning approach. Some fragile instruments (commonly eye surgery instruments) cant handle the pre clean machine (step 2) so they skip that step and go straight to step 3 but are rather carefully pre cleaned by hand.
Instruments that contain certain plastics that cant handle the 120C that is the minimum the autoclave operates at will be placed in the plasma sterilization instead.
Electric cables and certain fragile instruments also cant handle the plasma sterilizer but there are no instruments that cant handle either

the plasma or the autoclave.
My notes: So in general the plasma can come instead of the autoclave if needed and it seems to be ok to skip the ultrasound machine if they are carefully pre-cleaned by hand.

1.0.2 Instrument trays To position instruments correctly, trays with positioning incisions are used. Dismantable instruments can positioned together in one tray. Also special racks are used with tubes and holders. Please take example pictures, if possible with the instruments.

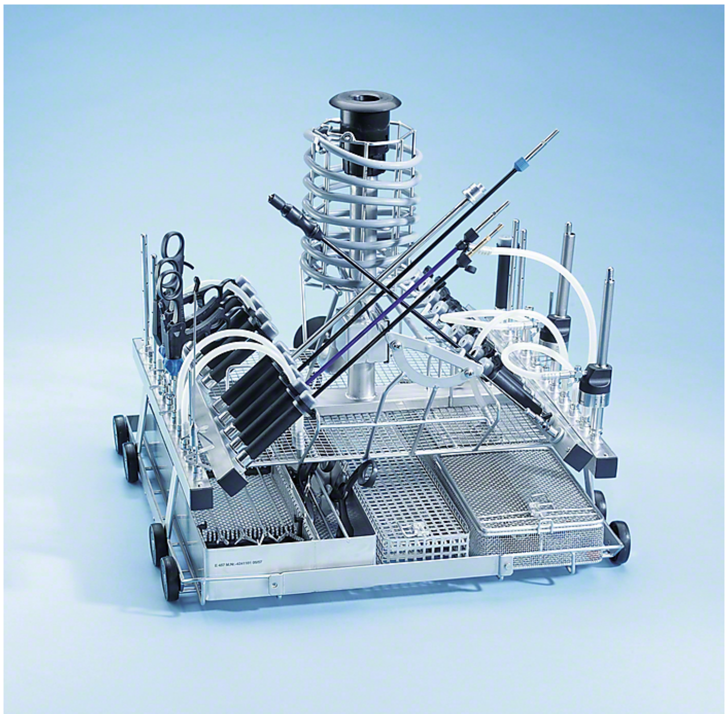


FIGURE 9: *Instrument tray.*

1.0.3 Case studies with instruments that are difficult or easy to clean at LUMC **Wolf laparoscopic punch** that was taken out of regulation due to high actuation forces. Measurements showed that opening of the handle requires on average 8N and closing 11N. However the difficult actuation was caused not by organic material between pushrod and shaft but by a damaged tip and therefore too tight fit between tip and chamber.

Aesculap grasper, this is example of an instrument that can be easily assembled and disassembled. However close observations at the tip showed that after sterilisation a peace of organic tissue was found in the mechanical hinge system on a location normally field by plastics. On one side of the hinge the inner blue plastic protection layer of the fissure is missing (4 by 7 mm) (Figure 3). Moreover, the Grey protection layer on one of the grip parts is damaged and cracked (Figure 4). Also a strange cut is found above the main hinge axel that fixates the hinge in the fissure (Figure 5). This requires further comparison with other instruments from the same brand and line. Till now it is unclear to me where the missing parts are (patient or washing machine etc.) my advice is to take more samples from this brand and line to check for cracks and missing protection layers.

FIGURE 10: *Instrument tray.*

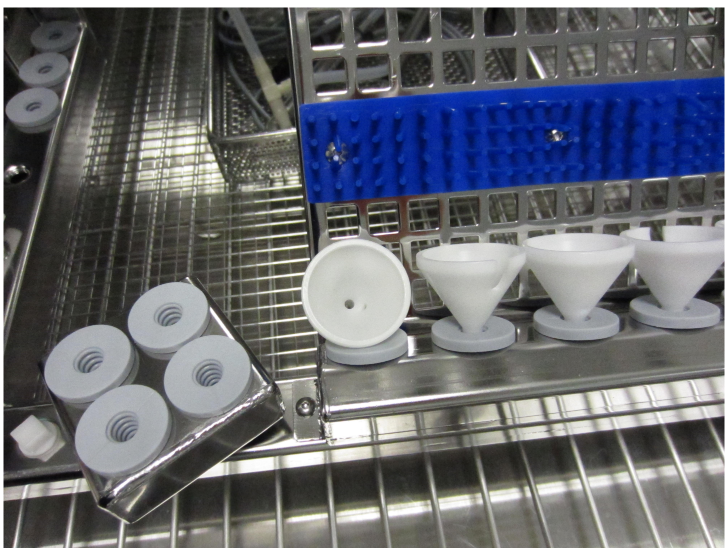


FIGURE 11: *Instrument tray.*

Aesculap grasper (different tip)

The following tip on the Aesculap grasper was considered by one employee to be that hardest to clean since the gripping part has tiny teeth that is very hard to get into unless using a very fine brush, takes some time to brush in pre-cleaning and if they dont then after all the washing steps you can still find small blood clots or organic material stuck in the teeth. Also the circular inner surface of the grasper tip (pointed at by one of the arrows) was quite difficult to inspect since the edge was very small.

The 4-bar hinge mechanism (arrow) was not considered too difficult to clean since it was relatively open and water could pass through, especially if the blood was fresh so it was un-clotted. If the instrument had to wait for a couple of hours before it was cleaned then it was more difficult to clean out the hinge and teeth.

Ellip FX E215947 eye surgery instrument.

This eye surgery equipment is an example of an instrument that has different cleaning procedure from the rest of them. All cleaning is

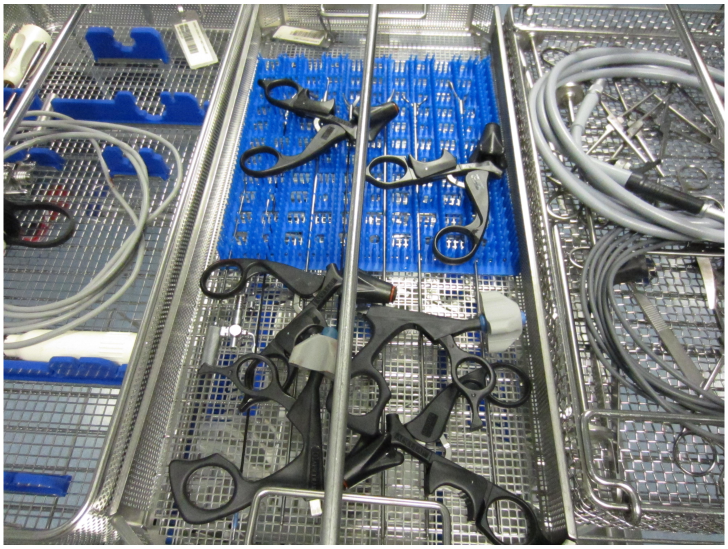


FIGURE 12: *Instrument tray.*

FIGURE 13: *Wolf punch.*

done by hand so it does not go through the pre-clean rinser, ultrasound or washing machine but is all cleaned by hand and then sterilized as usual, so they skip steps 2-5 of the washing process detailed above. Usually very little blood on these instruments since it is only used in eye surgery and some kind of saline solution goes through the tubes. So cleaning is not that difficult. They use something called reverse osmosis water mixed with the same soap used in the washing machine. They us a syringe to flush it through the small tubes on the instrument and through the instrument tips. After that the same this is done with 70% ethanol then the instrument is considered clean and ready for sterilization.

1.0.4 Ideal design requirements

Design comments from sterilization staff.

FIGURE 14: *Wolf punch.*

FIGURE 15: *4-bar Aesculap grasper with a crack in the protection layer.*

Complicated are not a problem the only limitation on how complicated they can be in taking apart is that it should be completely doable with latex gloves.

Regarding springs and compliant things, they are no problem if they dont wrap tightly around something.

For example in figure 18 there is a low stiffness spring that wraps around a shaft. This is a CO2 inflator (veres canule) and the spring never goes inside the body so usually is not dirty so its no problem. O-rings, rubbers are also no problem and handle all sterilization procedures. So using springs for static balancing should not be a problem as long as they are in the handle.

Complicated structures that have small gaps so water can reach is not a problem to clean and sterilize especially when done quickly after use, should take into account the worst case scenario is always that the blood is clotted which makes things more difficult.

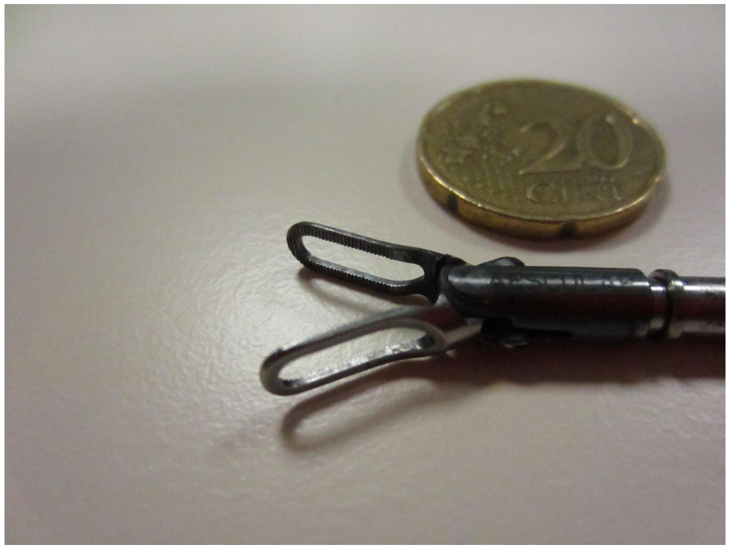
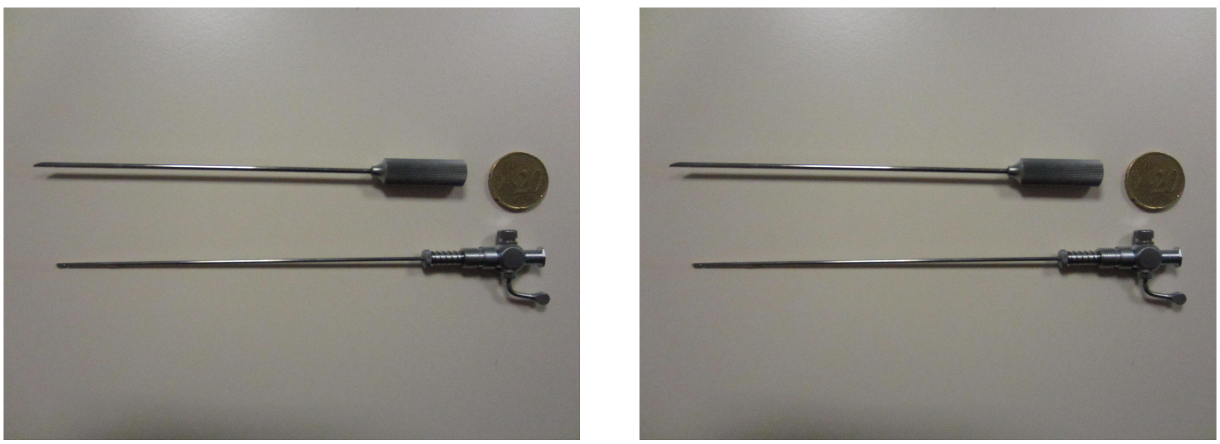


FIGURE 16: *4-bar Aesculap grasper*

FIGURE 17: *The Ellip FX eye instrument*

Different hospitals have different equipment so when hospitals are buying new instruments it can depend on their sterilization department what they can buy and if they can sterilize it. So a complicated design might be OK for some hospitals and not for others.

Visual inspection is an important factor of the cleaning process so thinking about this choosing colors carefully that allow the inspector to see blood and tissue more easily might be a good idea.



(a) . (b) .

FIGURE 18: Veres needle from Stopler instruments.

APPENDIX B

1 Compliant tooltip measurements

Using a tensile testing machine I set out to measure the stiffness of compliant tooltip previously used in a older prototype. To do so I created a set up that minimises the measurement error but as well protects the gripper since we still wanted to put the prototype back together in a working way. Two 0.1 mm spring steel plates were used on the surface since the clamp has teeth that might leave a lasting mark further more a rod was placed through one of the holes of the end and on this rod two steel fasteners on the tensile machine would act to pull on the gripper mechanism as can be seen in Figure
1. Care was taken to make sure that measurement errors were not present so we wanted to clamp the gripper so that it's push pull rod

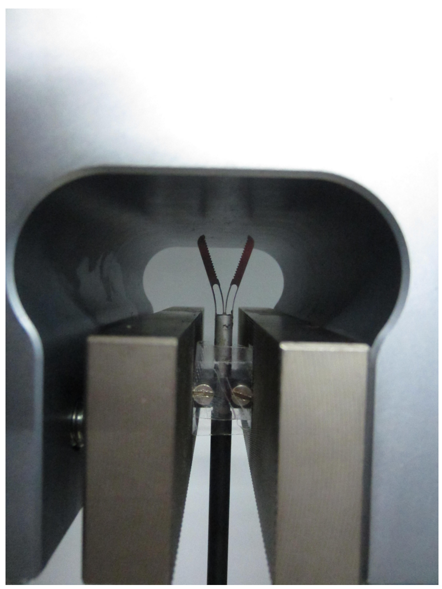


FIGURE 1: *Clamping the compliant tooltip in the tensile machine.*

was perfectly vertical and then apply a force on the rod at the ends. By using this setup as we see in Figure 2 there is an extra moment because of the rod at the end but we also are very sure that we are applying a vertical force and the rod is believed stiff enough to not have to much of an effect. Another benefit with this setup over clamping it on both ends is that we have no pre-stress. When clamping a work piece on both ends it is very difficult to have it oriented in such a way that there is no pre stress in the system, we did try that setup and always when applying the second clamp the rod was pushed a tiny bit in the vertical direction.

Unfortunately it was not possible in this machine to measure the pulling and pushing stiffness in one go so another setup was made for pushing. Then we still had the gripper clamped on top but now we wanted a perfectly horizontal surface pushing on the bottom of

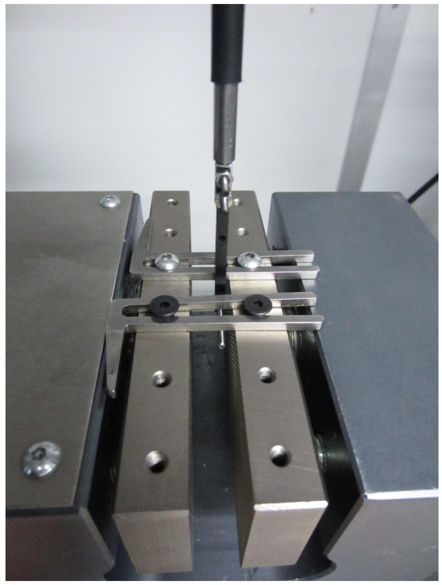


FIGURE 2: *Bottom of the setup.*

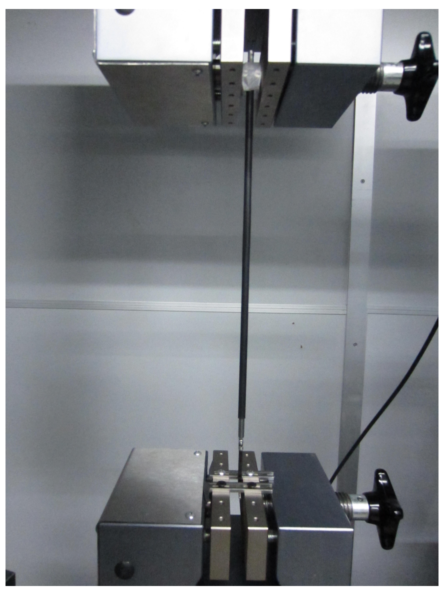


FIGURE 3: *Push pull rod aligned to be vertical.*

the pus/pull rod. We used an aluminium piece that had been machined specifically for this machine and has a horizontal surface.

The results of the experiment were quite good and multiple tests were made. Accuracy of the load-cell on the tensile machine is 0.1N wich is sufficient for our forces but the fluctuations can be seen in the results, still a good linear approximation could be made of the linear part to estimate the stiffness. As we can see the results are roughly 23N/mm with a range of motion of 0.6 mm.

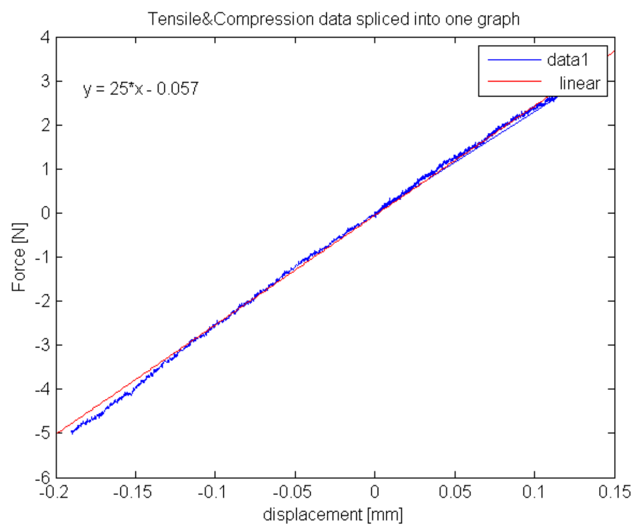


FIGURE 4: *Results of the compliant tooltip measurements. A stiffness of 23N/mm with a range of motion of 0.6 mm.*

APPENDIX C

1 MATLAB code

```
function [stress,k,negK_rom] = beam_tuner_comparison_ansys_plotting(l_tuner,t_tuner)
%Goal is a function that outputs a stiffness value k
%Input can be length&thickness of beams, angle, radius of curvature etc.
tic
%% Write values into a file that ansys code picks up
variable_string = {'FINISH'
                   '/CLEAR'
                   '/OUTPUT'
                   '! Variables for optimization'
                   horzcat('t_tuner =',num2str(t_tuner));
                   horzcat('l_tuner =',num2str(l_tuner));
%                    horzcat('l =',num2str(l))   ;
%                    horzcat('alpha =',num2str(alpha))   ;
%                    horzcat('t1 =',num2str(t))
%                    horzcat('w =',num2str(w)) ;
                    };
fid = fopen('ansys_variables.txt', 'w');
for i=1:length(variable_string)
    fprintf(fid,'%s\r\n', variable_string{i});
end
fclose(fid);
[status,result] = ..
system('copy ansys_variables.txt+beam_tuner_ansys_model.txt Tuning_ansysmodel.txt');

%% Input location of file to run and working directory
work_dir = '" "'; %string to work directory
ans_code = '" "'; %location of ansys code
output = '" "'; %where output file should be written

%% delete ansys log file if it exists to
%%stop ansys from crashing after a unsuccsessful run
if exist('...\wdir\file.lock','file')
    delete('...\wdir\file.lock')
end

%% Put use input into a string to parse in the dos command, spaces very important.
parse_str = ['"...\ANSYS Inc\v145\ansys\bin\winx64\ANSYS145.exe" -b -dir ' work_dir ' -i ' ans_code ' -o '
    output];
dos(parse_str);

end
```

APPENDIX D

1 Ansys APDL code

```
!!!!!!
!!!!!! Bi-stable beams using BEAM3 model, works for clamped and knife joint BC.
!!!!!!
!!!!!!
!!!!!!
!!!!!!
!!!!!!
!!!!!!

FINISH
/CLEAR
/OUTPUT

! ADJUSTABLE parameters--------------------------------------------------------

  E = 196e9    ![Pa] ,E-modulus
  v = 0.3       ![  ] ,Poisson Ratio
  l = 20e-3    ![m]  ,Length of each beam (symmetric mechanism)
  w = 5e-3     ![m]  ,Width beams
  t1 = 0.3e-3    ![m]   ,Thickness beams
  alpha = 5    ![deg]   ,Angle of inclined tips
  factor_S = 1.6   ![]    ,must be <2, how large the deflection should be
           !    can be 2 for knife/knife, ~1.6-1.7 for clamped.
  k_stiff = 10000000 ![N/m] ,stiffness of the tuning spring
  a = w/2
  b = t1/2

  t_tuner = 3e-3

! FIXED parameters-------------------------------------------------------------
  c = 1000e-3     !radius of curvature of pre-curved beams, 1 for straight beams
  al_r = alpha*3.14157/180   ![rad],convert deg. to rad.
  R = sqrt((0.5*l*cos(al_r)+c*sin(al_r))**2+(-0.5*l*sin(al_r)+c*cos(al_r))**2)
  travelrange = factor_S*l*sin(alpha*3.14157/180)      ![mm]

  curve_center_x =  0.5*l*cos(al_r)+c*sin(al_r)
  curve_center_y = -0.5*l*sin(al_r)+c*cos(al_r)

  curve_center_x2 =  1.5*l*cos(al_r)-c*sin(al_r)
  curve_center_y2 = -0.5*l*sin(al_r)+c*cos(al_r)

  Ix = w*t1**3/12 !mass moment of inertia around x for a square shape
  Ix_ellipse = acos(-1)*a*b**3/4 !mass moment inertia around x for ellipsoid whose radius along the
```

```
                        ! y-axis i b. a > b.
  Ix_tuner = w*t_tuner**3/12


!--------------------------------------------------------------------------------------------

! Define element
  /PREP7
  ET,1,BEAM3 !Define local element from the element library
  !ET,2,COMBIN14,0,1, , !Create a spring for tuning purposes
  ET,2,BEAM3        !Beam element for tuner

! Real constant
  R,1,w*t1,Ix,t1, , , ,
  !R,1,acos(-1)*a*b,Ix_ellipse,b
  !R,2,k_stiff,0,0, , , , ,! Real constant of the spring element
  R,2,w*t_tuner,Ix_tuner,t_tuner, , , ,

! Material properties
  MPTEMP,1,0   !defines a temperture table for material properties
  MPDATA,EX,1,,E !defines property data to be assosciated with the temperture table
  MPDATA,PRXY,1,,v
  !
  !Mat. properties for the spring element.


! Define keypoints (small curvature in beam, to avoid axial buckling in straight beams)
  K,1,0,0,,
  K,2,curve_center_x,curve_center_y
  K,3,l*cos(al_r),-l*sin(al_r)
  !K,4,curve_center_x2,curve_center_y2
  !K,5,2*l*cos(al_r),0

  !Spring keypoints
    !K,10,-10e-3,0

! Draw arc between keypoint
  LARC,1,3,2,R,
  !LARC,5,3,4,R,

  !Spring
    !LSTR,1,10,

! Glue the lines to one beam
  !LGLUE, ALL,

! Mesh, create elements
  LESIZE,1, , ,100, ,1, , ,1, !Specifies the division and spacing ratio on unmeshed lines, n is ANGSIZ: The
    division arc spanned by the elemend edge...
  TYPE,        1    !Activates an element type number to be assigned to subsequently defined elements
  REAL,        1
  LMESH,       1   !Generates nodes and line elements along lines.

  !Mesh for spring element
    ! LESIZE,2, , ,100, ,1, , ,1,
    ! TYPE,2
    ! REAL,2
    ! LMESH,2

! Define constraints
  !DK,1,ALL,0!, , , ,ALL, , , , ,
  DK,1,UX,0
```

```
  DK,1,UY,0
  DK,1,UZ,0
  DK,1,ROTZ,0
  !DK,5,ALL,0
  DK,3,ROTZ,0
  DK,3,UX,0
  DK,3,UY,travelrange
  DK,3,UZ,0

  !Spring constraints
    !DK,10,ALL

! Defining Analisis specifications
  NLGEOM,1      !Includes large-deflection effects in a static or full transient analysis.
  AUTOTS,0      !Automatic time stepping or load stepping, on or off, 1 is use automatic
  NSUBST,100,0,0   !number of substeps taken this load step
  OUTRES,ALL,1      !Controls the solution data written to the database.

! Solve the analysis
  /SOL
    SOLVE
    FINISH

  ! Plot deformed shape
    /POST1
      PLDISP,1

! Stress analysis
!*VEC,smax_vec,D,ALLOC,100
*DIM,stresses,ARRAY,100,2,1, , ,

SET,FIRST
*DO,i,1,100,1
  SET,NEAR,,,,i/100 !
  !Plot the stresses and extract highest value from the plot
  ! etable,smax,nmisc,1 ! make table smax using maximum stress
  ! etable,smin,nmisc,2 ! make table smin using maximum stress
  ! pletab, smax, NOAV ! plots the stress values in the smax table
  ! *GET,smax_max,PLNSOL,0,MAX
  !   *SET, stresses(i,1,1), smax_max
  ! pletab, smin, NOAV ! plots the stress values in the smin table
  ! *GET,smax_min,PLNSOL,0,MIN
  !   *SET, stresses(i,2,1), smax_min

  !Sort the stress table and extract the highest value, no plotting. Works in batch mode
  etable,smax,nmisc,1 ! make table smax using maximum stress
    ESORT,ETAB,smax,0,1
      *GET,smax_max,SORT,0,MAX
        *SET, stresses(i,1,1), smax_max

  etable,smin,nmisc,2 ! make table smin using maximum stress
    ESORT,ETAB,smin,0,1
      *GET,smax_min,SORT,0,MAX
        *SET, stresses(i,2,1), smax_min


  SET,NEXT
*ENDDO


! Plot graph
  /POST26
```

```
    NSOL,2,2,U,Y,          !Displacements node 2
    RFORCE,3,2,F,Y,        !Forces node 2
    XVAR,2
    PLVAR,3

  /AXLAB,X,DEFLECTION [m]        !Renaming axis labels
  /AXLAB,Y,FORCES [N]
  /REPLOT

! Save time history variables to txt-file given path (create folder,adjust'name' &'path'!)
! Writing a second file is possible if 'name' is changed before, (it overwrites)
  !/POST26
    *CREATE,scratch,gui
    *DEL,Tafla_EXPORT
    *DIM,Tafla_EXPORT,TABLE,100,1 !create a table with 100 rows
    VGET,Tafla_EXPORT(1,0),2
    VGET,Tafla_EXPORT(1,1),3
  /OUTPUT,'BC_compar_KK_scale','txt','C:\...'
    *VWRITE,'UY','FY','Stress'
    %C, %C, %C
    *VWRITE,Tafla_EXPORT(1,0),Tafla_EXPORT(1,1),stresses(1,1,1),stresses(1,2,1)
    %G, %G, %G, %G
  /OUTPUT,TERM
    *END
  /INPUT,scratch,gui

! !------------------------------------------------------------------------------------------------
```