Laparoscopic Grasper for Minimally Invasive Laparoscopic Surgery

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Abstract

Minimally invasive laparoscopic bowel surgery involves the use of laparoscopic graspers through incisions no larger than 5mm. Laparoscopic graspers (Figure 1), allow the surgeon to grab and maneuver tissue with high precision without completely cutting open the abdomen. Our client, Dr. Heise has requested that we design a new laparoscopic grasper head. The current laparoscopic grasper heads all have a scissor design, which creates a high pressure area at the apex of the lever arms. The bowel tissue taken up by the grasper can be damaged or torn as a result of this disproportional pressure distribution. Dr. Heise requested the design of a grasper head that applies equal pressure along the length of the lever arms. Our elected design applies equal pressure by the introduction of a moveable joint along the length of each lever arm. A prototype will be made of our elected design once we perform more material research and develop a way to connect our grasper head the current shaft and handle utilized.

Background

Laparoscopic Surgery:

Laparoscopy is a minimally invasive surgical procedure specific to the surgical sites within the abdomen and/or pelvic cavity. This surgical technique requires a laparoscope, a thin telescope (approximately 5mm in diameter) with a light source to obtain an illuminated and magnified perception of the surgical site. The laparoscope is fitted with a fiber-optic cable running to and from a cold light source, an attached video camera, and inserted into a 5-10mm incision.

The grasping instrument is an additional laparoscopic device inserted through an incision (5-15mm diameter side port) where the grasper head is 5-10mm in diameter. This device is used to securely grasp internal structures for purposes of facilitating observation, excision and biopsy procedures. Other thin instruments may also be introduced through similar incisions. During surgery, the abdomen is inflated with CO_2 or N_2 gas to enlarge the operative field.

Problem Motivation:

Adhering to the existing minimally invasive surgical system, blood loss and post-operative pain must be minimized. The development of a more efficient laparoscopic grasper would minimize the risk of complications, leading to a faster recovery time for the patient. In order to achieve this, our goal is to design a grasping clip that can effectively grasp and/or restrain tissue from the operative field while adhering to safety concerns by not rupturing or damaging the surrounding tissues.

Problem Statement:

During laparoscopic surgery, small grasping clips are used to hold tissue away from the site of surgical procedure. Current clips concentrate greater pressure on the area of tissue closest to the joint of the grasping device. This sometimes causes the tissue to be expelled from the grasping instrument, possibly damaging the tissue. The goal of this project is to equalize the pressure across the length of the clip. Due to the small entrance incision, the prospective device must have a diameter less than or equal to 5 mm. Because the grasping instrument must be designed for internal use, precautions must be taken to minimize moving parts and safety hazards.

Design Constraints:

The device design must be able to withstand: the sterilization process for surgical instruments, the pressure differential created during laparoscopic surgery, exposure to corrosive substance (ie blood, tissue, etc.) and fit through a 5mm incision. The sterilization processes utilized by hospitals include ultrasonic cleaning and steam autoclave. During the sterilization process devices with ratchets are opened to allow for all containments to be removed (Spectrum, 2005). Ultrasonic cleaning involves the use of high frequency sound waves around 18kHz that is sent through a solution of neutral pH at room temperature (Ultrasonic, 1994). The high frequency sound waves cause small bubbles to form which grow in size due to alternating high and low pressure created in the solution. When the bubbles reach resonant size, they implode and jet off at high speeds. This high velocity jet of air is what removes contaminants from the surgical instruments. Steam autoclave involves high pressure steam (103kPa) at an elevated temperature (121°C) to remove all contaminants from the surgical instrument (Spectrum, 2005).

The body cavity is filled with carbon dioxide or nitrogen gas via a 5mm port during laparoscopic surgery. This creates a pressure differential between the operating room and the body cavity. As a result, the device must be able to withstand the change in pressure when it is inserted and removed from the body cavity. The grasper should also retain full function in the higher pressure environment created in the operative field in the abdomen.

Blood, tissue, and surgical residue are very corrosive and can lead to the degradation of the surgical device (Spectrum, 2005). These corrosive substances can cause pitting and staining of the instruments. Therefore, only material that are resistant to corrosion can be utilized to construct the device.

Minimally invasive laparoscopic surgery involves the use of three to four 5mm to 10mm incisions. Surgeons will sometimes use graspers to pull a piece of bowel out of the body to observe more closely. Thus, the grasper must be small enough that it can safely pass through the port when the grasper is in open position.

Current Device

The current laparoscopic grasper used includes a ratcheted handle, a shaft 48 cm in length, a mass between 200g and 500g, a grasper head that has an open height of 5mm, and opens at an angle of 55 to 65 degrees (Figures 1 and 2). The device is made from 300 to 400 series surgical stainless steel. The grasper head can rotate around the handle's central axis 360 degrees. Rotation is controlled by a knob near the handle. The market value of the device is between $300 and $1,000.

Figure 1: *Current laparoscopic grasper used for minimally invasive laparoscopic surgery. Device consists of three parts (moving from left to right) grasper head, shaft, and handle.*

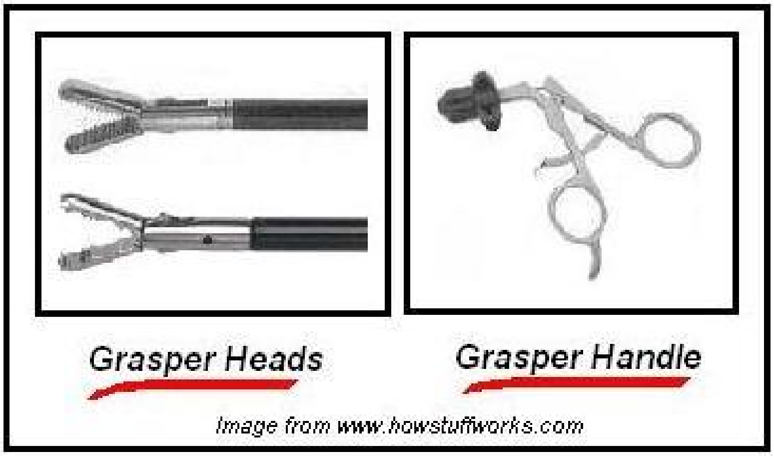

Figure 2: *Current laparoscopic grasper heads (left) used for minimally invasive laparoscopic surgery. Current laparoscopic grasper handle used (right).*

Competition

Several companies sell similar devices to figures 1 and 2; however, no device has been found which incorporates our client's idea. The change in the mechanism of the hinge would produce an entirely unique grasper design. All current designs employ the angular closure of the grasper, similar to scissors. The client wants a device that will close in a vertical motion, with the grasper ends parallel to on another. A research group did publish a paper describing the idea of curving the grasper head to minimize the effects of the high pressure area. This design has not gone into production and is not available to surgeons for laparoscopic bowel surgery.

Alternative Design Descriptions

Our group developed three possible designs to address our problem statement and general project specifications. The first design, (Figure 3), is adjustable along one plane. The upper jaw is hinged, and accordingly moves to alleviate the immediate pinching response of the current design (Figures 1 and 2) by its ability to flex around that pivot point on the upper jaw. This design is relatively simple, in that it uses all of the existing grasping mechanisms, and is there is only one mechanical deviation.

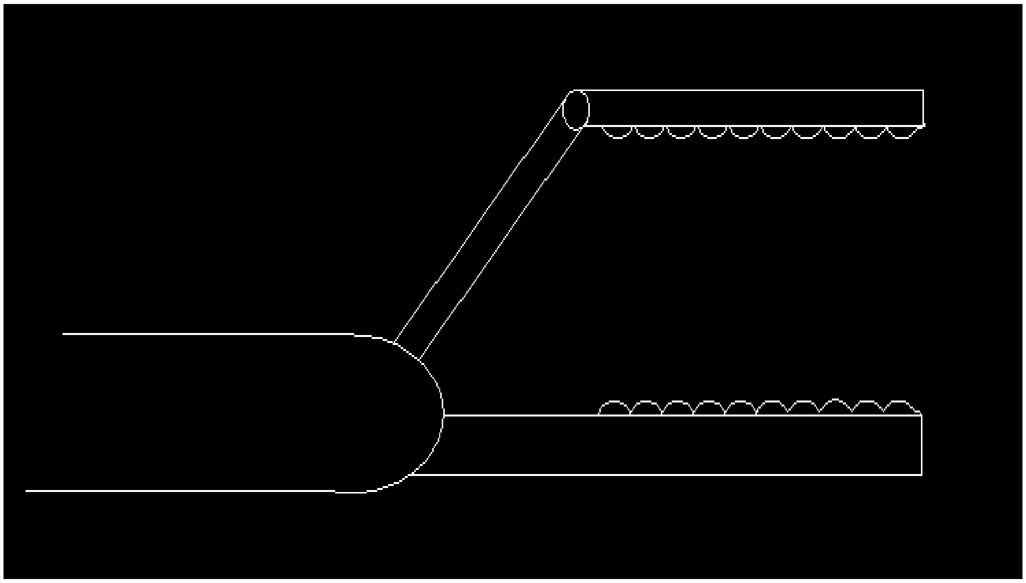

Figure 3: *Design #1*

Conversely, there are some concerns with this design proposition. Only one side moves, allowing limited mobility. Our client has praised the current design's ability to operate on a dual opening system, because of its ability to open a bit wider and the symmetry that it contributes. The proposed hinge joint also presents an area for adjustment in that there is space between the hinged members as it opens and closes. This area could snag tissue or disrupt the interior. A proposed solution for this development is a flexible material that would cover this space; however, this is not a final decision and more thought needs to address all of the facets of this proposed material covering.

The second design (Figure 4) was our 'out of the box' proposal. This model was created from cranial snake kinetics research. In this research it was found that the vertical force vector was applied to the quadrate bone, the bone connecting the upper and lower snake jaws (Figure 5).

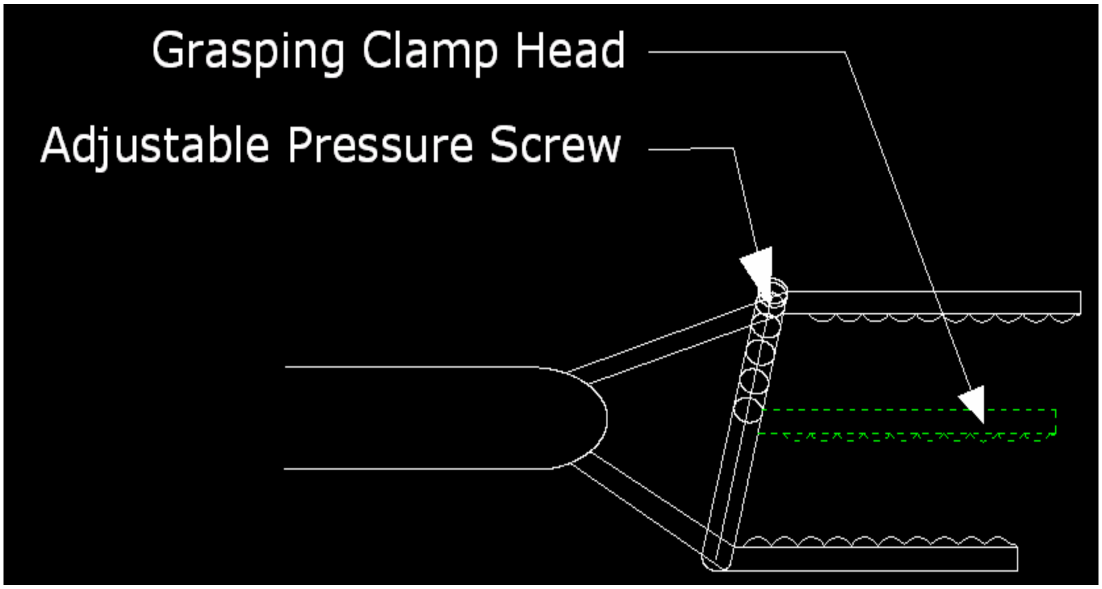

Figure 4: *Design #2.*

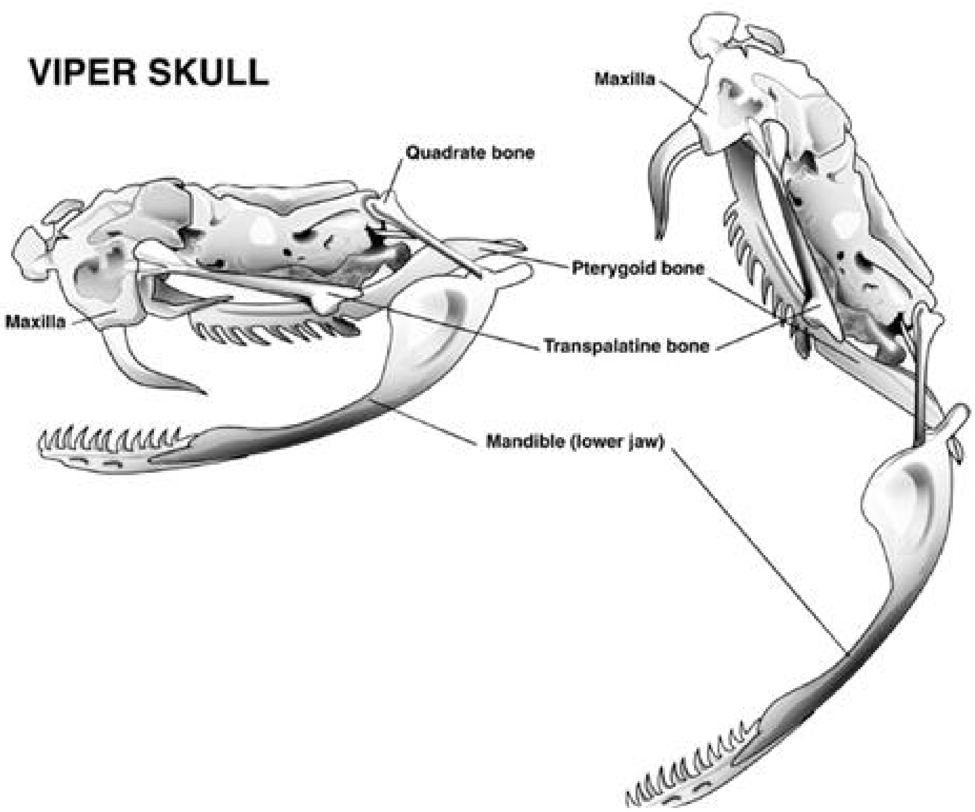

Figure 5: *Rotation of the quadrate bone is the central factor in jaw elongation. This is also the mechanism that allows the lower jaw upon extension to be parallel to the upper jaw.*

This vertical force vector pushed this almost horizontal bone completely vertical, allowing the maximum distance between the two jaws. From there, the hinge on the upper-side of the lower jaw allowed it to grasp the anterior side. This was our deviation from the snake model. In order to close, we needed a ratchet to bring the two grasping jaws together.

This design, upon closure, distributes pressure extremely well, because of the device's ability to close the two jaws horizontal with respect to each other. The ratchet pin on the vertical front allows for the mechanical quantification of pressure to be addressed. On the other hand, this vertical ratchet piece, would account for a difficult mechanistic transition from the horizontal motion and the vertical ratchet/screw system to close the system. This would be rather laborious and adds several mechanical complications into the system. Also, the vertical component would need to be retracted or collapsed simultaneous to the clamping, so as not to leave it protruding in the cavity. This mechanistic requirement provides another complication.

The third design (Figure 6) is a mirror of the first design, addressing its duel jaw mobility limitation. This provides another degree of difficulty in the scheme of mechanical function, but the symmetry allows the system to more effectively distribute pressure. Design #3 includes a hinge joint on each member that enables the system to close horizontally alleviating the pinching effect of the current design. This design would also allow for a clean integration with the existing handle and into the existing market.

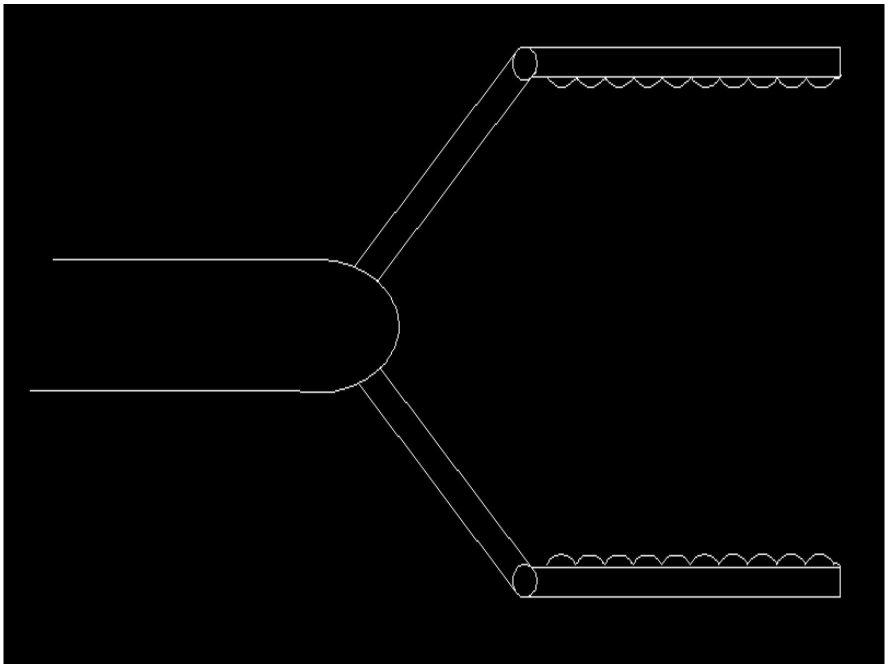

Figure 6: *Design #3.*

Design Matrix:

	Cost Effectiveness (1-3)	Even Pressure Distribution (1-10)	Ease of Use by Surgeon (1-10)	Feasibility / Practicality of Design (1-10)	Meets Design Specs. (1-10)	Safety (1-10)	Total
Design #1	3	3	8	7	8	5	34
Design #2	1	9	6	4	6	4	30
Design #3	2	7	8	6	9	8	40
Current Design	3	1	8	9	7	6	34

Final Design

As shown, design #3 scored the highest on the design matrix which weighs the pros and cons of each design. Design #3 best meets the clients requirements and, when constructed, will fit the current handle design. The pressure difference through the length of the jaw member is minimized. Therefore, we plan to begin material research as well as prototype research and construction our third design.

Materials:

As stated in the client requirements, the device must ultimately endure sterilization, possibly multiple times per day. The durability required limits material options. For the prototype, however, it may be unrealistic to machine a to-scale prototype from a material that meets the aforementioned sterilization requirements and stays under the one hundred dollar budget. Other prototyping materials must be investigated further before construction can begin.

Future Research:

Both the mechanical and material constraints must be addressed before prototype construction begins. The internal mechanism for joint movement and control should fit the current handle design. Dr. Heise provided the group with an older model of the grasping device for sizing and mechanical reference. A design for controlling the joint mechanics still needs to be developed. General future research includes machining material, joint construction possibilities, and mechanical interface with handle.

Future Work:

Most importantly for the future of the project, a prototype representation of the design must be constructed. The possibilities of construction will be consulted with advisors and Dr. Heise to indicate the most effective and feasible method of construction. Dr. Heise also indicated the possibility of including a pressure sensor to alert the surgeon as to the amount of pressure translating from his/her grip to the tissue surface. Adding a sensor would be relatively easy for an actual-size (~5 mm) prototype provided the pressure sensor is small enough to be housed between the wavy outer tissue gripping edges of each jaw member. A LabView program con be created, also relatively easily, to interpret and graph the data as well as audio-visually indicate a predetermined traumatic pressure level.

References

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Appendix A

Product Design Specifications for BME 200/300 group 9: Grasping Instrument

(October 24, 2006)

Group members: Lynn Murray, Becky Jones, Richard Bamberg, and Ann Sagstetter

Problem Statement: During laparoscopic surgery, small clips are used to hold tissue away from the site of surgical procedure. Current clips concentrate greater pressure on the area of tissue closest to the joint. This sometimes causes the tissue to be expelled from the grasping instrument with possibility of traumatizing the tissue. The goal of this project is to equalize the pressure across the length of the clip. Due to the small entrance incision, the prospective device must have a diameter less than 5 mm. The grasping instrument must be designed for internal use, thus precautions must be taken to minimize moving parts and safety hazards.

Client requirements:

- Equalize pressure across grasper head
- Limit bulkiness
- Small (5 mm in diameter)
- Must be reusable and easily sterilized
- Possibly attach pressure/force sensor
- Cost limit $100

Design requirements: Since the device is relatively expensive and multiple graspers could be required for surgery, the device will be used often. The device should provide equal force across the entire surface of the tissue to which it is grasping. The jaws of the clip must lay flat together in order to be inserted or removed from the body. Moving and/or sharp parts must be minimized to protect the interior of the bowel on which the surgery is being performed. These conditions must be met in conjunction with a design that is sturdy, easy to sterilize and produce a good grip.

a. *Performance requirements:* The device could be required at multiple points throughout one surgery and possibly several times a day. Most of the force applied to the grasper will be applied and controlled by the surgeon.

b. *Safety:* The device is meant for internal use and therefore must not contain sharp or moving points that could damage the tissues. Sterilization should occur between every use of the device. The possible sterilization techniques used on this device are ultrasonic cleaning and steam autoclave. Ultrasonic cleaning involves placing the instrument in a neutral pH solution where it will be bombarded by bubbles created by high frequency sound waves. Steam autoclave utilizes high pressured steam to clean the instrument.

c. *Accuracy and Reliability:* The grasper must be capable of opening 55 to 65 degrees such that it can maximize the range in which it can grasp the intended tissue. The grasper must also effectively grip the tissue without damage. When the grasper is completely open, the vertical distance of the opening must be 10mm.

d. *Life in Service:* Due to the relatively high cost for such a small device we would like to optimize the life in service. The high rate of use may cause the grasper to be worn out; however, it is more likely that the mechanical components will wear out before the clip itself would. The clip will be manufactured from 300 to 400 series surgical stainless steel, because this material is stress resistant, yet operatively feasible.

e. *Shelf Life:* The shelf life of the clip is not completely dependent on the material alone, but rather proper care of the surgical instrument, as well. The stainless steel can become stained if the surgical instrument is not cleaned after use. Blood, pus, and tissue can cause pitting, staining, and discoloration to occur on the instrument. Surgical stainless steel contains a chromium alloy which acts to prevent corrosion and scratches.

f. *Operating Environment:*
Temperature range: Room Temperature (25°C) - Autoclave (121°C).
Pressure: Room Pressure (101.3kPa) - Autoclave Pressure (103kPa).
Corrosion from fluids: Exposed to Nitrogen or CO_2, Water, Blood, Bodily Fluids, Steam.
Must withstand Torque through the entirety of the shaft from head to handle 48 cm in length. Head must have enough force to grip a specimen and must withstand wear and tear of surgery.

g. *Ergonomics:* Scissors motion on handle in connection with the gripping head. Withstand torque from the clamping force of the scissor handles through the wires in the shaft to the grasping head. The device must have a long narrow shaft with a gripping head at the end. The shaft must be able to connect and fit to the current handle used.

h. *Size:* Head and shaft must fit through a 5mm-10mm canula. Handle size will correspond to finger and hand size of surgeon. The handle uses a scissor configuration.

i. *Weight:* Grasper weights may vary between 200g and 500g.

j. *Materials:* Surgical Stainless Steel/autoclave tolerant. Prototype: steel, various alloys

k. *Aesthetics, Appearance, and Finish:*

Texture: Smooth, no sharp edges that could catch on innards.

2. Production Characteristics

a. *Quantity*: The client wants one prototype made by the end of the semester.

b. *Target Product Cost*: Currently the device is typically marketed between $300 and $1,000. However, only $100 is available for the production of a prototype.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required for the device since it will be directly used on a patient. The device must be safe to use inside a human body and the parts must be secure such that they will spontaneously decompose while working on a patient. Surgical stainless steel will be used, which has already been FDA approved. The ridges on the grasper must be soft enough that it will not tear or damage the bowel lining (lumen), yet provide a strong enough grip to hold tissue when the device is being used.

b. *Customer*: The client wants a design that can fit through a 5 mm port and will be compatible with the current surgical technique.

c. *Patient-related concerns*: The device will need to be reusable. Therefore, it is imperative that the device can effectively undergo the sterilization process used on surgical tools.

d. *Competition*: There are similar devices that exist. However, no device has been found which incorporates our client's idea. The change in the mechanism of the hinge would produce an entirely unique grasper design. Current designs all involve the angular closure of the grasper, similar to scissors. The client wants a device that will close in a vertical motion, with the grasper ends parallel to one another to equally distribute the forces across the jaw planes.