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INTELLIGENT MODULAR TOOL FOR EMERGENCY SURGICAL TREATMENT DURING PAYLOAD-CRITICAL MISSIONS

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ABSTRACT

During any extended mission to an extreme environment (i.e. the International Space Station, a lunar base or a manned mission to Mars) the chances of an otherwise minor injury becoming life threatening grow to be significant. In order to address these concerns, equipment must be provided to diagnose and treat a wide range of possible afflictions while direct contact with Earth-based physicians is impossible. Minimally invasive surgery (MIS) is an excellent treatment option due to its history of decreasing trauma in patients and speeding recovery. In an effort to provide the maximum functionality for any given MIS procedure, an intelligent modular surgical system has been designed and is being further refined to assist surgeons and other practitioners during medical procedures without necessitating the inclusion of many different instruments. The overall design approach was to identify the functions of existing technology and then to design a device that combined functionalities whenever possible to minimize the overall complexity of the design. The intelligence in the design is intended to make finding instruments easier for the individual performing the surgical procedure rather than replace humans in the operating theater. This paper presents analysis quantifying the payload reduction achieved by the new modular design as it pertains to extended missions to extreme environments. In addition to assisting surgeons, this system will take approximately 25% less space than the current equivalent MIS tools.

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With the continuing mission of the International Space Station (ISS), the proposed lunar base and manned missions to Mars (O'Brien and King 2004, Watson and Benedetto 2004) comes a corresponding increase in time away from Earth. Along with this increase in time comes an increase in risk: if an astronaut suffers some otherwise minor injury or illness during time off-planet, the chances of mortality increase greatly. Since it takes 24 hours to return an astronaut from the ISS, 7 days to return from the Moon and 9-12 months to return from Mars (Agha 2005), definitive care by a terrestrial physician is far from certain in any emergency situation.

According to a recent publication, on a 2.4-year trip to Mars, a 7-member crew can expect to experience one emergency given an emergency incidence rate of 0.06 events/person-year for the general populace (Summers et al. 2005). The emergency incidence rate for astronauts is likely to be lower due to the intense training and ultra-selective medical screening they undergo; however, unforeseeable illness or accidents can happen at any time, and the loss of even one crewmember is unacceptable.

In a 1993 study, Houtchens divided a list of possible injuries and illnesses into three classes based on severity of symptoms. Class 1 impairments are not usually life-threatening and will resolve themselves with minor prescription or nonprescription medications; examples of Class 1 injuries are headaches, mild ulcers, sinusitis and urinary tract infections. Class 2 impairments include air embolism, chemical burns, open or closed chest injuries, uncomplicated heart attacks, and appendicitis; these require immediate stabilization or treatment to provide in-flight recovery or evacuation. The final class of impairments, Class 3, includes explosive decompression, massive crushing injuries or open brain injuries and would require prompt evacuation after resuscitation if possible (Houtchens 1993). Since Class 1 impairments would not normally require invasive treatment and Class 3 impairments would most likely be fatal, the major focus of emergency treatment in-flight should be concentrated on the Class 2 type of impairment.

Due to the wide range of possible injuries or illnesses that might require treatment over a 2 ½ year voyage to Mars or extended Lunar stay, the surgical system designed must be able to accommodate a wide range of functions. Since the volume of a spacecraft is limited and therefore storage space is at a premium, the living quarters, workspace or experiment bays of a given craft will most likely need to double as emergency surgical bays, as investigated in the NASA Extreme Environment Mission Operations (NEEMO) habitat, Aquarius (Anvari et al. 2007, Rentschler et al. 2007). Due to this multi-tasking of rooms and work surfaces, and considering the safety of the patients and operators, the surgical solution used must contain fluids and tissues released during the surgical procedure in order to prevent contamination of work surfaces or infection of other personnel.

Previous investigations have determined that both open surgery and minimally invasive surgery (MIS) are viable in microgravity (Campbell et al. 1993, Campbell et al. 1996, Campbell et al. 2001, Link et al. 2001, Panait et al. 2004). Open surgery is what most people think of as “surgery”: a large incision allowing the surgeon direct access to the patient's affected area. As its name suggests, MIS is much less invasive than traditional surgery, is applicable to a wide range of procedures, decreases trauma to patients, and helps decrease fluid loss and infection risk to patients, which is of major concern in a space vehicle, due to the high concentration of particulates in microgravity (Campbell et al. 1996, Campbell et al. 2001). In MIS, only 3-5 incisions, each measuring approximately 1 cm in length, are made to give surgeons indirect access to the affected area (Hunter and Sackier 1993, Richardson and Hunter 2000). The abdominal cavity is inflated with an inert gas (usually CO_2), creating a work space within the patient. Long slender instruments, a camera and light source are then inserted into the inflated cavity through plastic tubes, called trocars, allowing the surgeon to perform the operation without coming into direct contact with the patient’s internal tissues.

The purpose of this study was to evaluate the impact of a new modular surgical system (which was designed for a wide range of treatments) on reducing payload requirements for extended missions to extreme environments, as well as to demonstrate the usefulness of an overall approach to the design of tools for a specific set of goals.

MATERIALS AND METHODS

Surgical System

In order for an MIS surgical system to provide the widest range of procedures design criteria were solicited from an MIS surgeon at the University of Nebraska Medical Center (Nelson et al. 2007). A multifunction surgical system (shown in Figure 1) was designed using Functional Decomposition techniques and other established design methodologies (Dieter 2000) to interface with current MIS surgical equipment while combining repeated functions within single design parameters or features; therefore it has a hollow tool shaft less than 10 mm in diameter, allowing it to be used with commercially available trocars. Also, to further decrease the total volume of surgical equipment necessary on board, the system was designed for multiple uses, so initial sterility and the ability to sterilize multiple times were also considered. The unit was designed to be as small and light as possible, while still requiring minimal power, to lower reliance on potentially limited power reserves during an emergency procedure.

Though MIS reduces the trauma caused to a patient compared to traditional surgery, it has been shown that the removal and reinsertion of MIS instruments can cause unnecessary trauma to a patient during the surgery (Vallancien et al. 2002). The surgical system shown in Figure 1 was designed to accommodate up to six functional tool tips within a rotary chamber contained within the tool. The combination of multiple functionalities within one housing was a direct consequence of using Functional Decomposition techniques (Dieter 2000) in the design process; positioning and actuation of each tool tip is accomplished with the same tool shaft, reducing the overall complexity of the MIS task. The result is that a procedure can be performed without having to remove the tool's shaft from the patient, decreasing the trauma from tool insertion and removal and lowering the infection risk to the patient. This multifunctionality also helps reduce the total number (therefore volume and weight) of surgical tools necessary to complete a procedure.

The tool is powered and occasionally controlled using software installed on a PC. This means that minimal special equipment will be required to run the instrument – only software that can be installed on any computer currently onboard. Though certain functions of the tool, specifically the indexing of the multiple tool tips, are electronically controlled for speed and accuracy, the tool is operated manually during a procedure. This not only limits the amount of power required to operate the tool, but also ensures that the tool will not fail due to power loss during the procedure. Since a highly trained surgeon who is accustomed to the tools necessary might not be available, the tool was also designed ergonomically. The handle is sized to accommodate a wide range of hand sizes and strengths, all the buttons are located for accessibility and the forces involved in the mechanisms are designed for easy actuation.

Finally, with the inclusion of multiple functional tips within the same tool comes an increase in the complexity of the instrument. Because of the aforementioned possibility of a non-surgeon having to use the surgical tool (a tele-mentored situation), a small measure of artificial intelligence was designed into the tool to help streamline the procedure and reduce the cognitive load on the operator. It has been shown that this intelligence helps decrease the amount of time required to perform a surgery (Miller et al. 2007), which will help reduce the cognitive load on the crewmember performing the operation.

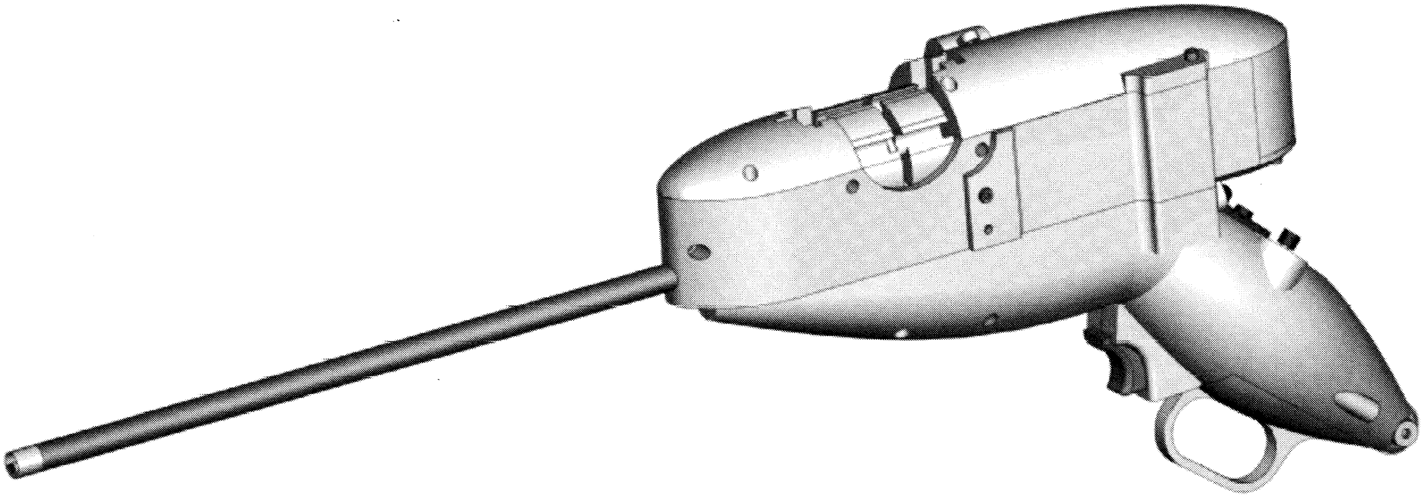

Figure 1. The modular minimally invasive surgical tool was developed to be interfaced with commercially available MIS trocars, will house up to six MIS tool tips, is sterilizable, low-volume, low-power and manually actuated, lending itself well to deployment aboard a spacecraft in an emergency.

Volume & Weight Determination

In an effort to compare the volumes and weights of traditional MIS tools and the modular tool under development, a comparison was made between commercially available sterile tools and the computer (CAD) model of the tool under development. The modular tool was designed to accommodate up to six functional tips, so video of 22 surgical procedures performed at the University of Nebraska Medical Center was analyzed to determine the six tools to include in this study. The video indicated that several mechanical tools were represented in a majority of procedures. Commonly available analogues include: ENDO GRASP™, ENDO DISSECT™, ENDO SHEARS™, ENDO CLINCH II™, ENDO BABCOCK™ & ROTICULATOR ENDO DISSECT™ (Covidien AG. http://www.covidien.com. Mansfield, MA). Of course, more tools were used during the procedure to provide cautery, suction, irrigation, suturing and stapling; however, these tools were not included in the current version of the modular tool due to their size or complexity, so they were not considered in the volume/weight analysis.

Five of the six tools mentioned above were weighed with and without their sterile packaging, and the packaging was measured to determine the total occupied volume. Through the measurement of these tools, a relationship was found between the size of the tool and the volume and weight of the packaging. A CAD model of the sixth tool, the ENDO BABCOCK™, was used for analysis since an actual tool was not available, so certain assumptions needed to be made, as discussed further in the "Results & Discussion" section. Paired t-tests were run to compare the length, width, height and weight of the packaging as measured to respective calculated package dimensions, which were then used to find the size of the package for the ENDO BABCOCK™. The weights of all packaging and MIS tools were summed to find the total shipping weight of the six traditional MIS tools.

Since the modular tool is currently under development, the volume and weight measurements were based solely on the CAD model developed using SolidWorks® (SolidWorks Corporation. http://www.solidworks.com. Concord, MA). The same proportionality used to extrapolate the volume and weight of the ENDO BABCOCK™ packaging was used to estimate the volume and weight of the modular tool's packaging.

Table 1. Dimensions of commercially available MIS tools and their sterile packaging. Values were used to determine the ratio of package dimension to tool dimension. Column 1 is the tool dimension, column 2 represents the package dimension as measured, column 3 is the difference between the measured tool and package dimensions and column 4 is the calculated estimate of the package dimensions.

		Tool	**Package**	**Difference**	**Package (calc)**
ENDO DISSECT	L (mm)	479.425	558.800	79.375	561.658
	W (mm)	106.363	158.750	52.388	152.083
	H (mm)	19.050	26.314	7.264	25.870
ROTICULATOR ENDO DISSECT	L (mm)	523.875	582.613	58.738	606.108
	W (mm)	114.300	158.750	44.450	160.020
	H (mm)	20.638	28.854	8.217	27.457
ENDO GRASP	L (mm)	465.138	558.800	93.663	547.370
	W (mm)	119.063	158.750	39.688	164.783
	H (mm)	19.050	26.314	7.264	25.870
ENDO SHEARS	L (mm)	473.075	558.800	85.725	555.308
	W (mm)	107.950	158.750	50.800	153.670
	H (mm)	20.638	26.314	5.677	27.457
ENDO CLINCH II	L (mm)	465.138	558.800	93.663	547.370
	W (mm)	117.475	158.750	41.275	163.195
	H (mm)	20.638	26.314	5.677	27.457

RESULTS & DISCUSSION

Volume Determination

Table 1 shows the dimensions of the tools and packaging as measured. The measured differences between length, width and height of a tool and its packaging were averaged over all of the tools, resulting in a length difference of 82.23 mm, a width difference of 45.72 mm and a height difference of 6.82 mm. These averages were then added to the respective tool dimensions to obtain the calculated package dimensions, shown in the fourth column of Table 1. A Kolmogorov-Smirnov (K-S) test of normality, performed using MINITAB (Minitab, Inc., State College, PA), verified that the data were normally distributed (all $p > 0.15$). These calculated package dimensions were then compared to the measured package dimensions using a paired t-test in MINITAB. It was found that the calculated dimensions were not significantly different from the measured dimensions ($p_L = 0.999$, $p_W = 1.000$, $p_H = 1.000$), indicating a strong correlation between tool dimensions and package dimensions.

Since the calculated package dimensions correlated with the measured dimensions, package dimensions were then calculated for the ENDO BABCOCK (for which packaging was unavailable; see "Materials & Methods" section) and for the modular tool. The overall dimensions of the BABCOCK and modular tool packaging are shown in Table 2. The calculated volume of the modular tool is 0.011 m^3 and the calculated volume of the six modular tools is 0.015 m^3. The modular tool takes up 25.3% less space than the six tools it replaces. This will reduce the total amount of space required for emergency medical equipment onboard, resulting in either a smaller craft or the inclusion of other equipment in the payload.

Table 2. Calculated size requirements for packaging of tools based on CAD models.

		Tool Dimensions	Package Dimension
ENDO BABCOCK	L (mm)	510.000	592.233
	W (mm)	100.000	145.720
	H (mm)	25.000	31.820
Modular Tool	L (mm)	553.390	635.622
	W (mm)	190.678	236.398
	H (mm)	66.523	73.343

Table 3. Measured and calculated weights (in grams) of traditional MIS tools based on physical samples, CAD models and calculated parameters. Columns 1-3 are measured values; column 4 is a weight as calculated using a CAD package; column 5 is the corrected weight based on the SolidWorks model; columns 6 & 7 are adjusted weights of tools and packaging using multipliers and additions, respectively, as discussed in the "Weight Determination" section.

	Tool + Packaging (g)	Packaging (g)	Tool (g)	SolidWorks Weight (g)	Tool Weight (calc) (g)	Total Weight (*) (g)	Total Weight (+) (g)
ENDO DISSECT	138.7	84	54.7	*	*	126.96	149.86
ROTICULATOR ENDO DISSECT	217.3	112.5	104.8	77.27	98.74	243.24	199.96
ENDO GRASP	175.5	97.4	78.1	61.39	78.45	181.27	173.26
ENDO SHEARS	137.4	83.5	53.9	43.63	55.75	125.10	149.06
ENDO CLINCH II	175.8	98.4	77.4	61.72	78.87	179.65	172.56

Weight Determination

The measured masses of the five tools and available packaging are shown in Table 3. CAD models were developed based on measurements of actual tools; however, despite the care with which the measurements were taken, a small amount of measurement error was introduced, and no information about the precise material properties of the existing tools was available. These factors led to the need for a more theoretical approach to weight determination. The ratio of the weight calculated by SolidWorks to the measured weight was calculated for each of the four tools with SolidWorks models and averaged. This factor was then used to calculate the "actual" weight of each tool. This calculated weight was then compared to the measured weight using a paired t-test in MINITAB. Again, there was no statistical difference between the measured and calculated weights ($p = 0.869$) and data were normally distributed ($p = 0.094$), so the average factor was used to calculate the weight of the BABCOCK (139.58 g) and modular (1454.11 g) tools based on the SolidWorks models.

Since no packaging was available for the BABCOCK tool, the weight of its packaging as well as that of the modular tool needed to be estimated. Two methods were attempted: multiplicative and additive. To find the multiplier, the measured weight of each tool was divided by the measured weight of the tool and its packaging. To find the additive factor, the weights of the five available packages were averaged. These results of the multiplication and addition methods are shown in the 6th and 7th columns of Table 3, respectively, all of which are normally distributed ($p > 0.15$). Paired t-tests were again conducted in MINITAB to compare the results to the actual measured total weights, and it was found that the additive method provided a closer total weight (difference = -0.16 g, $p = 0.978$) than the multiplicative method (difference = -2.30 g, $p = 0.759$).

Using the additive method, the weight of the BABCOCK tool and its packaging was calculated as 234.74 g; therefore the weight of all six traditional tools and their packaging was calculated to be 1079.44 g. The same technique applied to the modular tool resulted in a calculated weight of 1549.27 g. Based on these calculations, the modular tool and packaging is approximately 44% heavier than the six equivalent traditional tools. At first glance, this seems like an unacceptable increase, due to the aforementioned weight requirement on a spacecraft, however there are other factors that affect the outcome.

The traditional tools are only rated as single-use instruments, so multiples will need to be packed onboard to plan for additional casualties. Granted, the calculations in Summers et al. (2005) state that only one emergency is to be expected on the Mars mission, but using the modular tool, that fact is irrelevant: the modular tool was designed for multiple uses, meaning that it can be sterilized multiple times and reused so that if another emergency occurs, it can be dealt with by astronauts without needing to pack extra tools. If one extra emergency were planned for using the traditional tools, that brings the total weight of MIS tools up to 2158.88 g, 28% more than the one modular tool required, and the weight increase from using the modular tool would be justified.

Extension of Methodology

The analysis described in this paper has demonstrated that task- and/or environment-based criteria can be used to guide designers towards more efficient solutions to optimization problems, specifically payload minimization in this case. This process of moving from a set of goals through a redesign phase and towards an optimized design can be generalized in the following steps:

1) Identify key functional requirements and decompose into sub-functions;
2) Correlate functional domain (design requirements) to physical domain (design parameters) of current design;
3) Identify areas of redundancy or unnecessary complexity in functional/physical correlation;
4) Redesign to eliminate redundancy/complexity;
5) Evaluate new design against original functional requirements;
6) Iterate through steps (2-5) if necessary.

The process of breaking down and analyzing the desired function of a system, device, or process (Steps 1 & 2) is called Functional Decomposition (Dieter 2000); what was decomposed in this case was the process of minimally invasive surgery (Nelson et al. 2007) with special attention being paid to the goal of space savings. The output of functional decomposition can be a diagram, an outline, or any other breakdown representing *what* the system, device, or process should do or accomplish.

Correlating the elements of the functional decomposition to physical objects, components, or design features is the translation to *how* the desired functions are accomplished. In this case, the iterative process above exposed a multiple-tool surgical paradigm in which the individual components (tools) shared common functional (tool positioning and actuation) and physical (individual tool shafts) elements. Based on the functional constraints of payload (space and weight), the optimization goal was to simplify the paradigm by incorporating as few elements as possible. Therefore, the simplification of the functional decomposition of the surgical task led to the multifunction tool design shown in Figure 1 (Nelson et al. 2007). The evaluation of this new design against the functional (space) constraints is the main focus of this paper; however, generalizing this process using the steps outlined above illustrates how a systematic design methodology can be applied to space and/or weight optimization problems encountered in many disciplines, and it gives a more complete sense of the potential applications of the work presented in this paper.

CONCLUSIONS

It has been shown that a modular surgical tool will meet most of the requirements necessary to perform minimally invasive surgical procedures aboard a spacecraft. This modular tool, while increasing the weight required for a single set of surgical instruments, will decrease the total weight required to provide multiple surgical interventions, should they arise. It also takes up significantly less space on board, allowing more equipment to be stored which could possibly save the lives of astronauts. The fact that the tool is multi-use and multi-function results in fewer instruments to keep sterile and requires less valuable storage space on board a craft dedicated to this type of equipment.

The uses of this surgical system are not limited to space travel. Any application where volume or weight is of concern could benefit from the use of this tool, such as deep sea submarine missions, other naval uses at sea, missions to the Antarctic, use in battlefields or even rural communities. With the increase in data infrastructure, the possibility for surgeons to tele-mentor non-surgeons giving emergency medical treatment is increasing by leaps and bounds, and this tool would facilitate this development by allowing surgeons to impact directly how instruments are deployed anywhere in the world. The functional design techniques discussed in the previous section provide a valid approach to designing tools for these applications.

Although it looks promising, the development of the surgical tool is not complete. Currently, the investigators are finalizing a prototype of the device based on the CAD models and beginning to validate the functionality of the tool and verify the weight and size requirements for the packaging. Having a physical prototype will enable the investigators to analyze the stresses (both mechanical and physiological) present during the tool's use. This can potentially allow designers to eliminate even more weight from the tool through optimization, creating an even more efficient use of weight in payload-critical applications such as spaceflight, as well as to assess the possible ergonomic impact of the tool on surgeon performance.

The device was originally intended to be sterilized using a specific method (STERRAD; Advanced Sterilization Products. http://www.sterrad.com. Irvine, CA), but this method might not be the method of choice on board a spacecraft. The materials and motors in the device must be tested further to ensure sterility using a range of methods.

Finally, the device as designed is intended for manual use, but its potential applications to robotic telesurgery are obvious. The only commercially available telesurgery system currently on the market is the da Vinci Surgical System (Intuitive Surgical, Inc. http://www.intuitivesurgical.com. Sunnyvale, CA). It is likely that a multi-function tool such as this one will increase the efficiency of robotic surgery, leading to its widespread use and acceptance.

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