Surgeons' Perspectives on User-Designed Prototypes of Microsurgery Armrests

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Microsurgery is considered one of the most demanding surgical techniques. In a recent American Society of Reconstructive Microsurgeons survey, respondents reported that about half their procedures lasted 8 hours or longer and 8% had tremor during their surgery. Thus, the aim of this study was to define user-centered design requirements for a microsurgery armrest, create low-fidelity armrest design concepts and evaluate microsurgeons' perspectives on the advantages/disadvantages of five potential design concepts. Direct and videotaped observations of microsurgery, user brainstorming during a co-creation workshop and semi-structured interviews were used. The resulting five microsurgery armrest concepts were presented pictorially through semi-structured interviews, where microsurgeons defined armrest design requirements as: a) an armrest that allows the surgeons to be as close as possible to the patient; b) adjustable to accommodate different procedures sites and surgeon preferences; c) rigid enough to support arms; d) is not difficult to set up; nor e) large or bulky; and f) complies with operative sterility rules. This study illustrated how involving the users (microsurgeons) early in the design process provides useful perspectives on design requirements and implementation barrier for a cost-effective ergonomic microsurgery armrest to foster sound ergonomic surgical practice and reduce musculoskeletal health risk factors during microsurgery.

INTRODUCTION

Microsurgery is a specialized field of surgery requiring an operative microscope. The practice of microsurgery has expanded into many surgical subspecialties such as plastic and reconstructive surgery, neurosurgery, ear nose and throat surgery, and ophthalmology. The number of reconstructive microsurgeries has reached more than 5.8 million procedures annually (ASPS, 2016). Microsurgery has positively impacted patient outcomes; however, the microsurgery demands may compromise microsurgery providers' health, and career longevity.

Microsurgery is considered one of the most highly demanding approaches in surgery due to many factors (Patkin, 1981). Microsurgery procedures are relatively lengthy (e.g., tissue transfers may last around 500 minutes) (Ross, Ariyan, Restifo, & Sasaki, 2003) and microsurgeons stand in fixed postures for most of the procedures (Howarth, 2017). Fixed postures result from double-sided microscope operation which constrain the surgeon's gaze, reduce comfort (Franken et al., 1995) and force microsurgeons to operate in awkward postures (Ross et al., 2003; Statham et al., 2010).

Constrained and non-neutral microsurgery postures, along with sustained muscle exertions without sufficient arm and hand support, have been identified as risk factors for musculoskeletal injuries (Buckle & Devereux, 2002; Harms-Ringdahl, Ekholm, Schuldt, Nemeth, & Arborelius, 1986; Rempel, Harrison, & Barnhart, 1992), neck fatigue and trapezius strain (Patkin, 1977), and cervical and thoracic pain (Capone, Parikh, Gatti, Davidson, & Davison, 2010). Musculoskeletal symptoms and injuries were prevalent in up to 81.5% of in microsurgeons (Capone et al., 2010; Sivak-Callcott et al., 2011; Sivak-Callcott, Mancinelli & Nimbarte, 2015), including muscle strains (64%), cervical pain (27%), shoulder injuries (18%), carpal tunnel syndrome (18%), and peripheral (i.e. ulnar and radial) neuropathy (15%) (Capone et al., 2010). Previous OR improvements focused on the operating microscope and magnification to enhance the microsurgery technical skills. However, minimum effort was directed toward developing interventions to decrease musculoskeletal injury risk.

Stable hands are important for the precise movements required for microsurgery (Endo & Kawahara, 2011) where the suture employed is about the diameter of a human hair. The need for arm support in microsurgery has been appreciated since the late 1970s (Nissenbaum, Meckler, & Acland, 1979). However, microsurgeons who do standing microsurgery do not have any dedicated arm support. Unsupported arms increase the shoulder muscular load and increased tremor (Chen, Dailey, Naze & Jiang, 2012; Fargen, Turner & Spiotta, 2016; Nissenbaum et al., 1979; Safwat, Su, Gassert, Teo & Burdet, 2009). A microsurgery armrest should enable surgeons to perform safer operations with the meticulous dexterity that is required for complex reconstructive procedures. To date, there have been no user–centered design efforts devoted to developing an intervention that would decrease the ergonomic risk factors in microsurgery. Specifically, microsurgeons' perspective on interventional armrest design requirements has not been studied or documented.

The aim of this study was to define user-centered design requirements for a microsurgery armrest, design low-fidelity armrest concepts and evaluate microsurgeons' perspectives on the advantages/disadvantages of potential design concepts.

METHODS

Study Design and Setting

In a quaternary hospital system, a multi-disciplinary research team of ergonomists, industrial designers and microsurgeons identified the need for development of armrest that can support the surgeons' arms and hands during the work

under the operative microscope. Thus a multiple-phase process was completed to generate design requirements using low-fidelity models to ensure the high-fidelity prototype would be usable and feasible for use in microsurgery procedures.

I. Observation Phase

Ergonomists and industrial designers observed and video-recorded seven surgeons during three procedures for a commonly performed microsurgery (microsurgical breast reconstruction). These recordings were reviewed by all multi-disciplinary research team members to identify the surgeons' postures while performing different tasks. During this phase, the current practice of supporting microsurgeons' arms and hands was identified and subsequently shared with microsurgeon partners for clarification on the standards and impact of arm and hand support during microsurgery.

II. Co-Creation Workshop Phase

A co-creation workshop generated low-fidelity design concepts to support surgeon's arms and hands during microsurgery. The multi-disciplinary research team sent invitations to surgeons, surgical trainees, undergraduate students, graduates students, post-doctoral fellows, industrial designers and other researchers within the same institute not all previously involved in this project. Participants attended a short introductory session in the beginning, which included information about the microsurgery procedures, microsurgery workload and the need for a microsurgery armrest. Then, participants were divided into small groups and asked to develop innovative microsurgery armrest designs using different low-cost materials. Pictures and short video clips from the microsurgery cases were shown throughout the session. Participants then presented their designs and received quick feedback from the other participants. Participants were then asked to combine different design concepts for final creations. At the end of this co-creation workshop, five armrest design concepts had been developed (Figures 2 - 5).

III. Semi-Structured Interviews Phase

A convenience sample of 6 microsurgeons from the department of Plastic and Reconstructive Surgery across two campuses of the medical center participated in a qualitative study to critique the five different armrest design concepts. Each microsurgeon consented to complete a single 30-minute semi-structured interview.

A semi-structured interview question guide to identify the advantages and disadvantages of each design concept was developed. Questions were added regarding potential barriers to the implementation of each armrest design and possible mitigations. An iterative process was undertaken to develop the open-ended questions for the semi-structured interviews, with the aim to get information about other areas not covered by the questions.

For consistency, one ergonomics researcher with a medical degree completed all face-to-face (one by phone) 30-minute semi-structured interview sessions. During all interviews, pictures (paper demonstration) of the five different armrest design concepts were used to help the microsurgeons answer the questions. The semi-structured interviews were digitally recorded and transcribed by the interviewer and a qualitative research analyst for analysis.

Table 1 Semi-Structured Interview Questions.

Number	Question
1	What do you see as pros and cons to this design?
2	What is the most suitable way to fix it?
3	How easily do you think you could set up this device?
4	How easily do you think you could adjust this device? Before the Anastomosis? During, if needed?
5	Do you think this device would provide the right/enough support and flexibility to complete an anastomosis?
6	Would it be rigid or flexible enough?

Data Analysis

Thematic and content analysis were used to identify themes (general desirable characteristics) for the design requirements. The data were reviewed by one trained qualitative research analyst. The analyst carefully listened to all the recorded interviews and read the entire transcripts. The transcripts were analyzed using descriptive open coding, and six themes were ultimately identified from the grouped codes. NVivo software was used for data organization (NVivo 10.1, QSR International Pty Ltd).

RESULTS

I. Observation Phase

A total of three microsurgery breast reconstruction cases were observed. Video was recorded and analyzed to identify the three segments of breast reconstruction where the operative microscope was used: preparing the breast site before connecting the harvested tissue; vein anastomosis; and end-to-end arterial anastomosis. These three segments of the microsurgery take around 2 to 3 hours for a single-side reconstruction. Microsurgeons completed the microsurgery standing with either unsupported upper arms and hands, hands supported on sterilized folded towels over the patient's body, or hands and fingers supported directly on the patient's body. Results were summarized to present a needs assessment to the multidisciplinary team in the co-creation workshop.

II. Co-Creation Workshop Phase

Five microsurgery armrest design concepts were identified at the co-creation workshop (Figures 1-5).

III. Semi-Structured Interviews Phase

The six themes (A-F in Table 2) describing what the 6 microsurgeons identified as being desirable characteristics for design requirements of armrests. Individual quotes are referenced with a participant number and theme letter in parentheses following the quote.

Table 2. Microsurgery Armrest Design Themes

A	Not between the patient and the surgeon
B	Adjustable to different surgeons and different surgical site
C	Rigid and fixable after self-adjustment
D	Easy to set up and take off
E	Not large device
F	Sterile

First Design: Tuck-Away Armrest (Figure 1)

This design had cushioned-supports for each hand attached to OR bed, able to be tucked away. This design was favorable because it was attached to the OR table. "I like

attaching to the OR table a lot … I think that is a good position for it." (Microsurgeon 4, theme B)

The forearm support was seen as favorable in this design. "…I think that is a good idea in general, a good design for the forearm support." (Microsurgeon 1, theme C) It is not bulky "and I think doesn't seem to take up a lot of space, so would not be a cumbersome." (Microsurgeon 1, themes A and E) Participants voiced concerns over sterility. Putting a clamp directly on an OR table may automatically make it not sterile. While one surgeon said that a drape makes sense, another suggested, "If the tool is sterile, it's a lot better – we don't have to drape it." (Microsurgeon 4, theme F) Another said "Cover like a long tiny bag over the device and clamp it on so that it stays sterile as well." (Microsurgeon 6, theme F) The adjustability was also a concern "It will be useful if it had multiple articulations, not just one. So it may become more flexible … you may have to readjust" (Microsurgeon 5, theme B)

Figure 1 Tuck-Away

Adjusting the device to the proper height each time was seen as essential "Going up and down, giving you more variability … will be easier to use … stuck in one position or one height you just stop using it … so I think something that is adjustable, will give you support with a lot of adjustment is important." (Microsurgeon 2, theme B) However, the need for adjustment was a possible 'con' since it would require education and there would be the danger of a surgeon not adjusting it properly and injuring themselves or the patient.

Surgeons suggested that they would rather adjust devices themselves than rely on nurses to adjust the armrest for them. Surgeons also suggested that locking the device after adjustment to make it rigid was preferable. "Rigid. Yeah, definitely something that I can adjust myself but once I lock it in that position, [it] stay[s] there such that when I am tying my stitches, it has to be rigid." (Microsurgeon 5, themes B and C)

While set up was considered a 'con' because there are two devices (one for each hand) to set up and time to set it up would add time to the procedure. However, the two-piece set up was still considered a 'pro' to have nothing obstructing you in getting close to the patient. "I think no problem to have two separate devices, it seems to be more efficient even though it takes so much longer but as it attached to the patient bed it should be very easy to set up" (Microsurgeon 6, theme D) "Each arm independently, yes I think that is essential." (Microsurgeon 2, theme B) "Ideally, adjustable independently for each arm and allows me to stand right next to the patient." (Microsurgeon 5, theme B)

Second Design: Platform/Board Armrest (Figure 2)

This design has cushioned-supports for arms and hands for both sides in one board attached to patient bed, able to be attached and detached. The flat surface was noted as a 'con' in this design. This design was generally considered too bulky, not flexible enough, and it couldn't provide individual arm rests so that hands/arms can be at different levels, "You can't have your two hands like parallel at the same level, you know, especially if you are working in a hole, you may need different angles and not always you have the vessels aligned" (Microsurgeon 5, theme B) "Your arm is going to be at different levels, and so the board will be uneven." (Microsurgeon 2, theme B)

The design also moves the surgeon away from the patient, which was seen as a 'con'. "It will inhibit your ability to get closer to the patient. That is my biggest concern if it is spreading across; it has to be something that it will not inhibit your ability to get right up against the patient." (Microsurgeon 6, themes A and E)

Free movement of arms and hands in this design was seen as a 'pro' – "you can move around so that not like the other one where you have your position. It takes a lot of effort to move the arm board, where in this one you can raise your arm and shift them to the right or to the left without having to adjust anything on the table." (Microsurgeon 6, theme B)

Figure 2 Platform/Board Armrest

Third Design: Puppet Armrest (Elastic Rubbery Tube) (Figure 3)

This design has a rubbery tube for each hand attached to hard surface above the patient bed. Movability (elasticity) was considered a 'pro' of this design, although some expressed concerns on making the bands sterile. There was also much discussion about movement and position in relation to the microscope, while some participants did not prefer something coming from the ceiling because the microscope could be between the ceiling and the patient "I like the one point of fixation to your hands. It is with a lot of variability and the rotation of your arms, your hands; your wrists your hands are not fully immobilized." (Microsurgeon 1, themes B and D) Attaching the Third Design to the microscope was not seen as an option "any slight movement in the microscope is a big problem". (Microsurgeon 5, theme D) "I don't think you want to attach to the microscope and you wouldn't want to attach to the ceiling." (Microsurgeon 6, theme D)

Figure 3 Puppet Armrest (Elastic Rubbery Tube)

Pressure distribution and concern over the elastic being too 'bouncy' were discussed. "I would rather have something rigid like a metal, not something elastic … I like the concept but I wish it was rigid." (Microsurgeon 5, theme B) "I think the cons if it is rope like that it doesn't distribute the pressure of your arm evenly so it will get uncomfortable… So I would want something that will more evenly distribute the weight of my arm, but not dig at it." (Microsurgeon 1, theme C) "I would worry that you still have to maintain, it would not be like 100 percent rest your arm, I would worry that you still have to hold it because that bouncy thing would be too bouncy." (Microsurgeon 6, theme C)

One clinician described this design as more complex and time-consuming and those factors may make adoption into practice more difficult. "It seems a bit more complicated to hook it up and for sterility purposes because you will have to

put your arms in it, so if there is a way that we could apply the good features of that to another design that would be great..., I think it would be a bit more complicated for adoption." (Microsurgeon 1, theme F)

Fourth Design: Puppet (Wide Band) (Figure 4)

This design included a band for arm and hand on each side attached to standing strong bar. The band was preferable to the tube in the Third Design. "Definitely a band, not a tube. Especially if it's a long case it can create problems. The pressure is not evenly distributed." (Microsurgeon 5, theme C) Microsurgeons were concerned about the elasticity as well "And again for the one that is more like a band, there is some spring to it which may not be a desirable feature, because it may affect your ability to perform the task with precision" (Microsurgeon 1, theme C) "I think having a wider band would be more optimal - something that supports both the palms but then still give us some freedom. … Still some support but it still flexible so it is not stiff band and my wrist has to be as neutral." (Microsurgeon 2, theme C)

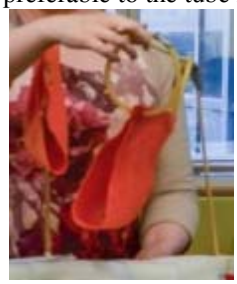

Figure 4 Puppet (Wide Band)

The place to hold the device, adjustability and sterility remained as a concern "Well I guess looking at it, the challenge for either design is…where do you hook it up? And I think also once it hooked up to whatever thing, also adjusting the height properly is another thing which maybe a bit more difficult. …. Sterility may be also a bit more challenging." (Microsurgeon 1, theme F)

Fifth Design: Free Standing Armrest (Figure 5)

This design is a standing surgical table with armrest area for each side and one prototype with a foot rest area and metallic bar for the surgeon's body to lean on. The space taken up by the free-standing armrest was viewed as a limitation of the design. Most surgeons preferred something affixed to the bed to the idea of something free-standing. "Much preferred to something attached to the bedside …One potential concern is sometimes we have mats on the floor to help support our backs. Sometimes we have steps and that might get in the way" (Microsurgeon 2, themes D and E) "Anything that puts me further back from the table is going to increase my back pain, not decrease it because I am leaning over." (Microsurgeon 4, theme A and E) "I don't like it at all because it will put you too far away from the patient… not feet but centimeters and every centimeter counts. Also, you have to consider you have the microscope in the way, I don't think it is too great." (Microsurgeon 5, themes A and E)

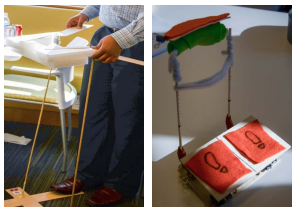

Figure 5 Free Standing

DISCUSSION

Following observation of the tasks and practices in the OR for identification of the problems, constraints, and conditions, the co-creation workshop facilitated the development of five unique design concepts. The use of a qualitative semi-structured interview approach, microsurgeons identified advantages and disadvantages of the five design concepts, and formalized six themes describing desirable characteristics they would want in an armrest design. These themes (Table 2) are user-defined design requirements for the actual microsurgery armrest prototype. Although these themes may seem obvious for any design for microsurgery armrest, no one design concept included all required themes. For example, the Free Standing Armrest (Figure 5) was perceived as easily set up and could be conceivably designed to support enough weight for arms and hands. However, this design concept put the microsurgeon farthest away from the patient's body/ surgical site.

Devices that distance the surgeon from the patient will require increased surgeon trunk flexion to reach the microscope and the surgical site. This will worsen the surgeon's musculoskeletal risk by requiring them to stand in even more awkward positions for long surgical durations. Therefore, the armrest must be attached to the patient bed but not between the surgeon and the patient.

Armrests should be easy to set up and take down without significantly interrupting the surgical procedure. Any difficulty in the device set up may increase the operative time. Any increase in the operative time will increase the procedure cost (Macario, 2010). If microsurgeons find it very difficult or costly to use, they will not use it any more.

Tremor and fatigue are compromising factors to achieving good results in microsurgery. Unsupported arms and hands negatively influence microsurgeon performance, while supporting the arms minimizes trapezius activity, which can enable the surgeon to perform microsurgery with less fatigue and tremor (Nissenbaum et al., 1979). Nissenbaum concluded that the microsurgery support surface should be like a table, "rigid," and extend all the way under the forearm from the elbow to under the ulnar finger. In our study, microsurgeons requested a device that is rigid because they usually operate on tiny anatomical structures (e.g., trying to connect two ends of an artery, vein or nerve with diameters averaging 2 mm). Such a rigid surface provides the support to complete the necessary microsurgical tasks with lower muscular load on the shoulder and neck muscles as well as tremor (Endo & Kawahara, 2011; Nissenbaum et al., 1979). In addition, the microsurgery armrest needs to be adjustable to accommodate differences in patient body habitus, surgeons' anthropometry and other adjacent equipment such as an operative table arm board.

Semi-structured interviews are one of the most common methodologies used in the health care setting to collect useful information from select audiences (DiCicco-Bloom & Crabtree, 2006) and was very useful in this product design phase. The microsurgeons were able to reflect on the armrest design concepts from the perspective of their daily microsurgery practice experience. One of the advantages of using semi-structured interviewing for data collection over other methodologies (e.g., questionnaires) was that interviews provided more flexibility for the interviewee to reflect more accurately and in-depth as well as provide follow-up.

Early engagement of users in the design process is essential for the success of any product design (Heinbokel,

Sonnentag, Frese, Stolte, & Brodbeck, 1996). Designers are not able to anticipate all problems that users may face, so including the end-user in the design process will increase the accuracy of design requirements (Kujala, 2003) and likely save iterative design time (Kujala & Mäntylä, 2000). Early engagement of microsurgeons in this project enriched the design requirements generated and may accelerate further prototyping. The multi-disciplinary team members and participants in the co-creation workshop created armrest designs. However, after they imagined actual OR use, the microsurgeons in the semi-structured interviews were able to more accurately identify potential implementation barriers since their experience is different than other team members in the co-creation workshop. Involving users early in the design helps ensure users are satisfied and more receptive to the design (Wilson, Bekker, Johnson, & Johnson, 1996) which may ease implementation.

This study had some limitations, including a small sample size. The microsurgeons were from a single institution and a single surgical specialty (Plastic and Reconstructive Microsurgery). Design concepts were demonstrated on paper during the interviews. The interviewer was a novice in conducting semi-structured in-depth interviews, but the interviewer had experience in both human factors and surgery, which enabled him to deliver the questions easily. Microsurgeons faced difficulty commenting on usability aspects of the design concepts (e.g., questions 5 and 6 in the semi-structured interview questions) without actual physical design mock-ups. However, the microsurgeons were the subject matter experts and their opinion is essential for the success of any intervention in their microsurgery practice.

In conclusion, microsurgeons were able to aid in the creation of design concepts and identify themes for the ergonomic microsurgery armrest design. The semi-structured interview was a useful qualitative approach to collect essential design requirements directly from the users. This approach will facilitate the development of a device prototype for testing with microsurgeons and may expedite future implementation. This approach of defining design requirements for a new surgical device through 1) observation, 2) multi-disciplinary design co-creation, and 3) semi-structured interviews of experts, could be applied to the design of other medical devices for improved operating conditions.

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