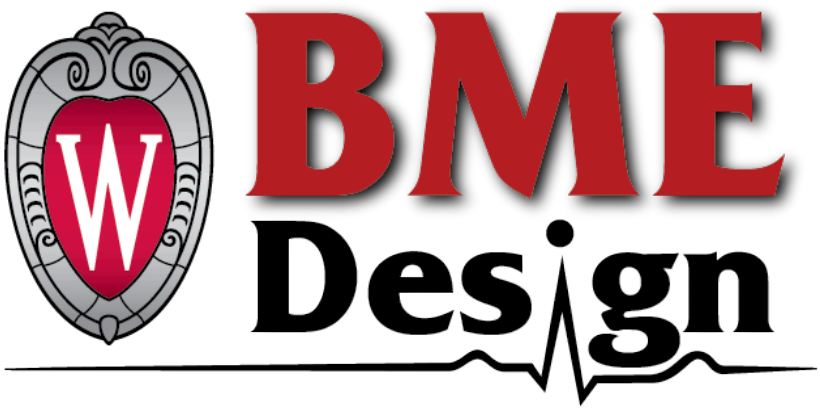

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Digital Traction with Japanese Finger Sleeves

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BME 200/300 Design Project

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Function

Design a device that allows for precise digital control and support of the components of the human hand through the use of Japanese finger sleeves or a similar universal type of support. This device will be designed to allow for controlled and stable traction during relevant procedures so that proper positioning of the hand can be attained with minimal manual effort.

Client requirements

- The device must support the patient's hand for approximately 50 minutes during fracture casting and be usable during surgery.
- Patients lie with their elbows bent at 90° and their hands suspended by finger sleeves; the sleeves must not compress the fingers, as this could cause stiffness.
- Reusable (due to economic constraints, single-use is not feasible), sterilizable design required.
- Materials must be:
    - Strong, elastic, and latex-free (non-allergenic).
    - MRI-compatible (no metal components).
- Sizing:
    - Multiple sleeve sizes needed.
    - An adaptive "one-size-fits-all" or an adjustable options are preferred.
- Functionality:
    - Provide a high-friction grip to allow stabilization and dexterity during traction and surgical use without restricting circulation.
    - The design must allow for the natural flexion and extension of finger joints, ensuring the tendons can glide smoothly within their sheaths during any minor patient movement or adjustment [1].
- Smart/Innovative features (desired but not mandatory):
    - Sensors to track finger pressure, bending angles (0–90°), and usage duration.
    - Alert system if complications occur: optional.
- Must be durable, cost-effective, and suited for high patient volume (~25,000 orthopedic patients every 6 months).
- No copyright required; aim for a "modern, smarter" tool.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**
        i. The sleeve must securely support the full weight of a patient's hand and forearm through a single fingertip without tearing, stretching permanently, or slipping off. The team's target is for the sleeves to support a static load of at least 22-44 N per finger as a safety factor.
        ii. The device must maintain its elasticity, strength, and surface texture through a minimum of 50 cycles of use.
        iii. The inner surface of the sleeves must provide sufficient friction to prevent the finger from slipping out under load.
        iv. The outer attachment point must securely hold the suspension mechanism.
        v. The sleeve material must stretch to accommodate various finger diameters, with the team's goal being a 15-25% stretch beyond a relaxed state. This retraction should be enough to provide a secure and snug fit while not being so tight that it causes harmful or uncomfortable finger constriction.
        vi. If implemented, the device will have "smart" monitoring capability that measures the traction force in each finger. The target shall be to keep the displayed force within 0.5–5 N of the actual load in order to accurately detect delicate manipulation or alert the physician if a dangerous level of force is being applied. The sensor would also have integrated wireless (e.g., Bluetooth) transmission for real-time data analysis.

    b. **Safety**
        i. All materials must be medical-grade, non-toxic, and hypoallergenic (specifically latex-free) to avoid skin irritation or allergic reactions.
        ii. The design must avoid finger compression to prevent cutting off circulation (ischemia) or causing nerve damage during the 50-minute procedure.
        iii. The entire device must be made from non-metallic, MRI-compatible materials to ensure it is not a projectile risk and does not generate heat or artifacts that could harm the patient or corrupt imaging data.
        iv. The device must be designed and tested to have a significantly higher load-bearing capacity than expected in use to prevent catastrophic failure (e.g., tearing) that could result in patient injury from a falling arm.
        v. The design and materials must be compatible with standard hospital sterilization techniques (e.g., steam autoclave, chemical sterilants) without degrading, to prevent cross-contamination between patients.

c. **Accuracy and Reliability**
    i. If multiple sizes are produced, each size must consistently and accurately fit the intended range of finger diameters.
    ii. Any integrated sensors that are implemented (e.g., for force) must provide accurate and repeatable readings within the specified target ranges (e.g., ±0.1 N accuracy for force sensing) to be clinically useful for monitoring.

d. **Life in Service**
    i. The finger sleeves must reliably perform at least 500 full uses over their service lifetime. Each use is 50 minutes under load, so a total active operational time of 420 hours.
        1. Idrissa Pouye General Hospital receives 25,000 orthopedic patients every 6 months. Assuming that 17.5% of all orthopedic visits are DRFs, the finger sleeves will be used about 8750 times per year [2].
        2. The finger sleeves should maintain full function after 2 years.
        3. There will be a stock of 36 sets of finger sleeves assuming 25 DRFs per day and a 1.5x sterilization turnover buffer.
    ii. Elastic and sensor components should endure 100,000 loading cycles within the expected operating force range (0.5-50 N), with sensor accuracy drift less than ±5% [3].

e. **Shelf Life**
    i. In storage, device components should retain functionality for at least 3 years under temperatures between 10-30 °C, in relative humidity less than 70%, and away from direct UV light.

f. **Operating Environment**
    i. Device must function in standard operating room conditions: 20-24 °C, 20-60% relative humidity [4].
    ii. Surfaces should be resistant to corrosion or degradation by blood, saline, antiseptics, and common disinfectants.
    iii. Device must be able to tolerate occasional jostling or movement without loss of alignment or sensor calibration.
    iv. Device must be MRI compatible with no ferromagnetic metal parts and any electronics shielded or safely located to avoid interfering with imaging.

g. **Ergonomics**
    i. Limit peak interface pressure to 50 N/cm², below reported pressure pain thresholds [5].

ii. Inner finger sleeves must provide a coefficient of friction of 0.4 under standard operating room conditions to ensure grip, while remaining below 1.0 to avoid excessive shear and possible skin damage [6].
iii. Limit axial traction force per digit to 50 N to avoid excessive loading on finger joints and the DRF site [7].

h. **Size**
   i. The device must fit within the surgical field without interfering with other instruments [8].
   ii. Should accommodate all hand and finger sizes, with universal or multiple sleeve sizes.
   iii. Must be compact enough to not block MRI coils or distort imaging [9].
   iv. Adjustability is an important component, both to increase or decrease tension or create smaller or larger overall structure [10].

i. **Weight**
   i. Must be lightweight for easy handling and help reduce surgical fatigue in a delicate surgical procedure.
   ii. Heavier components risk displacement forces within the MRI machine. Therefore, lower weight improves safety [11].
   iii. Smaller and lighter japanese finger sleeve components means less surface area contact with skin, reducing risk of irritation [12].

j. **Materials**
   i. Materials must be non-ferromagnetic, non-conductive, and biocompatible. Plastics, ceramics or composites, as well as titanium are all possible materials. They must be able to handle sterilization methods [13].
   ii. No material can be irritable to the skin, causing redness, swelling, burning, or itching [14].

k. **Aesthetics, Appearance, and Finish**
   i. Must be finished with a non reflective material, which will avoid glare from surgical lights.
   ii. Include any padding where soft tissue would ever come into contact with solid material, for patient safety.
   iii. The device has no major need to be aesthetically pleasing, as it will need to be more functional than anything.

2. **Production Characteristics**
   a. **Quantity**
      i. The client's goal for the project is to develop a single digital traction device that aids performance and reduces the difficulty of standard orthopedic hand and wrist procedures. The product should be able to accurately manipulate finger tension in both the right and left hands during

surgery while still allowing the client to easily maintain its function and sanitation through extensive use.

b. **Target Product Cost**
    i. The client has not given the project a set budget yet for prototyping. They mentioned that they would pay for things as we need them.
    ii. The university allots a budget of $50 for use in the Design Labs.
    iii. The device is intended for use in a hospital in Senegal, where economic resources are more limited, the end product should be relatively lower in cost compared to similar products on the market.

3. **Miscellaneous**
    a. **Standards and Specifications**
        i. International Standards
            1. ISO 13485:2016: Medical devices: Quality management systems [15]
                a. Covers requirements for the quality management system for medical devices. Globally recognized and expected by regulators worldwide.
            2. ISO 14971:2019: Medical devices: Application of risk management to medical devices [16]
                a. Methodology for identifying, evaluating, and controlling device risks.
            3. ISO 10993-1:2018: Biological evaluation of medical devices: Evaluation and testing within a risk management process [17]
                a. Provides framework for biological safety assessment of materials in contact with the patient's skin or body.
            4. ISO 15223-1:2021: Medical devices: Symbols to be used with information to be supplied by the manufacturer [18]
                a. Standardized labeling.
        ii. United States Additional Regulations
            1. 21 CFR Part 820: Quality System Regulation [19]
                a. The FDA's legally binding quality management regulation for medical devices marketed in the U.S.
    b. **Customer**
        i. The potential customers for this device include teaching hospitals, surgical centers, rehabilitation clinics, and any other medical facility that performs upper-extremity orthopedics. At this stage, the client will be the primary source used to validate the device's ability to securely hold individual fingers and apply precise, adjustable traction to each digit. Since the device is intended for use in resource-constrained settings such as Idrissa Pouye General Hospital in Senegal, the customer is particularly interested

in a cost-conscious and sterilizable design that minimizes the need for replacement. They are also looking for a modular approach that allows a single device to be compatible with MRI and accommodate a wide range of finger sizes. Long-term, the customer envisions expanding use of the device to other medical facilities where reproducible digital traction would improve workflow and clinical outcomes.

c. **Patient-related concerns**
    i. This device will be used during delicate orthopedic procedures where precise hand positioning is essential, making patient safety a top priority. To protect patients from injury, the design must maintain structural integrity under duress and also provide consistent traction forces without exceeding safe limits for finger joints. This means the sleeves must support the full weight of the patient's upper arm while avoiding any sort of constriction that could cut off circulation or cause nerve injury. The materials used in the device must be medical-grade, hypoallergenic, and non-metallic to prevent skin irritation and ensure MRI compatibility. Also, the device's surfaces must resist degradation from blood, saline, and any disinfectants common to a medical setting.

d. **Competition**
    i. Competing Design #1: MPR Hand Traction System [20]
        1. The MPR Hand Traction System is a modular device that suspends the patient's hand using finger traps and an adjustable frame that allows stable positioning during orthopedic procedures of the upper extremity surgeries. It also offers adjustable traction and can accommodate a wide range of hand sizes.
        2. While the product fits many of the client's criteria, it provides limited adjustability for fine-tuning individual finger forces and also has a metal frame that makes it incompatible with MRI environments. Furthermore, MPR does not list the cost of the device publicly due to prices being negotiated on a contract basis, making it difficult to assess its affordability for resource-limited hospitals.

    iii. Competing Design #2: Standard Finger Trap Suspension Systems [21]

        1. This device uses a stainless steel chain-and-pulley mechanism to distribute traction weight across three or more digits and prevent overloading of a single finger.
        2. The system is fully autoclavable, making it a common option for hospitals that are looking to avoid single-use devices.

3. Although this option is simple, it again lacks the ability to independently adjust traction forces for each finger and also does not offer any built-in monitoring to ensure consistent loading. This can lead to variability and makes it difficult to replicate the specific traction conditions needed for delicate upper extremity procedures.

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