THE UNIVERSITY of WISCONSIN MADISON

Digital Traction with Japanese Finger Sleeves

Product Design Specifications

BME 200/300

Section 303

Client:

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Function

The product must provide mechanical and digital traction to precisely position the arm and fingers during hand and wrist orthopedic procedures. The product must utilize Japanese finger sleeves to provide traction and tension through the digits to prevent broken bones from tangling while also stabilizing the arm. The product aims to minimize the manual traction efforts from hospital staff.

Client requirements

The client, Mr. Pape Samb, of Jamarek Corp, requested the following specifications of the product design for the digital traction with Japanese finger sleeves project.

- Support the arm at 90-180° during surgery or casting for at least 50 minutes.
- Pull traction at 10% of the patient's body weight.
- The device should allow for the wrist to rotate 180° during the procedure.
- The finger sleeves should not compress the fingers to limit stiffness and complications.
- The finger sleeve material should be strong, elastic, and latex-free to prevent allergic reactions.
- Accommodate different hand sizes through adjustable sizing finger sleeves or multiple sleeve sizes.
- A cost-effective, reusable design that can be sterilized without compromising functionality.
- Durable design to survive high-volume hospital traffic (~25,000 orthopedic patients every 6 months).
- The overall traction device should use non-ferromagnetic material to be MRI compatible.
- The device should have a robust base that can clamp onto the procedure table and be modular for ease of transport and storage.
- Potentially include sensors to detect elbow bending angle, finger pressure, and usage duration and alert if complications arise.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**
        i. The sleeve must fully secure and support the full weight of the patient's hand/forearm without damage such as tearing, permanent stretching, or slipping off the patient's hand. The target load for the sleeves to support is no more than 60 N total as a safety factor [1].
        ii. Devices must maintain peak elasticity, strength, and surface texture through a minimum of 50 uses.
        iii. Inner finger sleeves must provide a coefficient of friction of 0.4 under standard operating room conditions to ensure grip, while preventing slippage under load [2].

iv. The base frame of the device must securely hold the suspension mechanism.
v. The sleeve material must be able to stretch to adequately wrap around different finger lengths. The material will aim to stretch 15-25% beyond the relaxed state, which should secure the fingers without overconstricting them [3].
vi. The device will have monitoring capabilities that will measure and display the total traction load applied.

b. Safety

i. Medical-grade material must be nontoxic and hypoallergenic (latex-free) to avoid skin irritation/allergic reaction [4].
ii. Design must avoid excessive finger compression (<5 N) to minimize the risk of circulation loss (ischemia) or nerve damage during the procedure [5].
iii. The entire device must use non-ferromagnetic materials that are MRI compatible to prevent projectile risks, heat risks, and other risks that may harm the patient or corrupt imaging data.
iv. The device must have a minimum safety factor between 2.5 and 6. This will prevent catastrophic failure, like tearing, that could result in a falling arm and thus injury. [6]
v. The materials of the design must be compatible with standard hospital sterilization techniques, such as steam autoclaving, chemical sterilants, etc. It must be able to withstand this without degrading, to prevent any cross-contamination. [7]

c. Accuracy and Reliability

i. For multi-size compatibility, each finger sleeve must consistently and accurately fit the intended range of finger diameters.
ii. Any force sensors must provide accurate and repeatable readings within ±0.1 N accuracy to be clinically viable for training.

d. Life in Service

i. The finger sleeves must reliably perform at least 50 full uses and autoclave sterilization cycles over their service lifetime [8].
    1. Idrissa Pouye General Hospital receives 25,000 orthopedic patients every 6 months. Assuming that 17.5% of all orthopedic visits are Distal Radial Fractures (DRF), the finger sleeves will be used about 8750 times per year [9].
    2. The finger sleeves should maintain full function for 3 months.
    3. There will be a stock of 40 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 (<60 N), with sensor accuracy drift less than ±5% [10].

e. Shelf Life

i. The device must retain functionality for at least 3 years in standard storage conditions: 10-30 °C, relative humidity less than 70%, and away from direct UV light [11].

f. Operating Environment

i. The device must function in standard operating room conditions: 20-24 °C, and 20-60% relative humidity [12].
ii. Surfaces should be resistant to corrosion or degradation by blood, saline, antiseptics, and common disinfectants [13].
iii. The device must tolerate occasional jostling or movement without loss of alignment or sensor calibration.
iv. The device must be MRI compatible with no ferromagnetic metal parts and any electronics either shielded or safely located to avoid interfering with imaging.

g. Ergonomics

i. Limit peak interface pressure to 50 N/cm², which is below reported pressure pain thresholds [2].
ii. Inner finger sleeves must remain below a coefficient of friction of 1.0 to avoid excessive shear and possible skin damage [14].
iii. Limit total axial traction force to 60 N per finger to avoid excessive loading on finger joints and the DRF site [1].

h. Size

i. The device must be small, easily movable, and fit within the surgical field without interfering with other instruments [15].
ii. Should accommodate all hand and finger sizes, specifically for the Senegalese, whose typical finger length is 8.26 cm for females and 8.69 cm for males with a diameter of 1.94±0.10 cm in females and 2.11±0.12 cm in males at the PIP joint of the largest finger [16].
iii. Must be compact enough to not block MRI coils or distort imaging [15].
iv. Must be adjustable to increase or decrease tension and create a larger or smaller overall sleeve structure [17].
v. Must be able to fit easily and securely on a bedside without disrupting the patient's procedure or recovery.
vi. Must be able to withstand the force of the magnetically-induced torque proportional to magnetic field strength, indicating a small consolidated device [18].

i. Weight

i. The device must be lightweight for the following reasons:
    1. Easy handling and help reduce surgical fatigue in delicate surgical procedures.
    2. Reduce the risk of interfering with radiofrequency energy during scans [19].

j. Materials

i. The product must be MRI-safe, designed with nonferromagnetic materials, non-conductive, and tissue-compatible.
ii. The material must be non-irritating to prevent patient pain, tissue damage, skin irritation, and swelling. [13]
iii. The material must withstand 50 cycles of sterilization [19].

iv. The product must be made with ceramic, plastic, titanium, or non-magnetic materials in order to be usable in both the MRI machine and operating room [20].

k. Aesthetics, Appearance, and Finish

i. The material must be finished with a non-reflective material to prevent glare that can occur due to the surgical light.
ii. Padding must be available where any soft tissue would come into contact with hard material to ensure patient safety.
iii. This device has no major need to be aesthetically pleasing, as functionality is prioritized.

2. Production Characteristics

a. Quantity

i. The main goal for this project is to develop a single digital traction device to precisely position the fingers and arm during orthopedic hand and wrist surgery, such as wrist arthroscopies. The product should accurately apply finger tension in both the left and right hands during surgery, while still allowing the client to easily maintain its structure and cleanliness through repeated use.

b. Target Product Cost

i. The client has not yet provided a set budget for prototyping and prior steps.
ii. The university allows for a budget of $50 for use in the Design Labs.
iii. The device is designed for utilization in a hospital in Senegal, where financial resources are less available. The final product should be of a relatively low cost compared to similar products on the market.

3. Miscellaneous

a. Standards and Specifications

This device will be classified as a Class 2 medical device. Power traction equipment are classified as Class 2, non-powered traction devices are classified as Class 1, and non-invasive traction components are classified as Class 1 [22], [23], [24], [25], [26]. The device must abide by the following standards:

i. ISO 10993-1:2025 - Biological evaluation of medical devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process [13].
    1. This standard provides guidance for evaluating the biological risks related to materials, design choices, and tissue contact during use.
ii. ISO 10993-10:2021 - Biological evaluation of medical devices Part 10: Tests for skin sensitization [4].
    1. This standard specifies the procedure for assessing medical devices and their materials with regard to their potential to cause skin sensitization.
iii. ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes [27].
    1. This standard establishes a framework to ensure consistent design, development, production, and delivery of medical devices during their intended use through regulatory requirements and risk management.

iv. ISO 14971:2019 - Medical devices — Application of risk management to medical devices [28].
    1. This standard specifies terminology, principles, and processes for risk management of medical devices to identify hazards and estimate and control risks.
v. ISO 15223-1:2021 - Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements [29].
    1. This standard specifies symbols used to express medical device information.
vi. ISO 17664-1:2024 - Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices [7]
    1. This standard specifies requirements for the processing of medical devices prior to reuse including: initial treatments, preparation before cleaning, cleaning, disinfection, drying, maintenance, packaging, and sterilization.
vii. IEC 60601-1-8:2006 - Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems [6].
    1. This standard specifies basic safety and performance requirements and tests for alarm systems employed in medical electrical systems.
viii. IEC 60601-1-11:2015 - Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [30].
    1. This standard applies to basic safety and performance of medical electrical equipment for use in home healthcare environments regardless of operator.
ix. IEC 62304:2006 - Medical device software — Software life cycle processes [31].
    1. This standard defines the life cycle requirements for medical device software, establishing a set of processes, activities, and tasks.
x. IEC 62366-1:2015 - Medical devices Part 1: Application of usability engineering to medical devices [32].
    1. This standard specifies processes for manufacturers to analyze, develop, and evaluate the usability and safety of medical devices to mitigate risks with correct and normal use.
xi. 21 CFR 888.5850 - Nonpowered Orthopedic Traction Apparatus and Accessories [23].
    1. This federal regulation applies to nonpowered orthopedic traction apparatuses aiding in exerting therapeutic pulling forces on a patient’s body with nonpowered traction accessories.
xii. 21 CFR 888.5890 - Noninvasive Traction Component [22].

1. This federal regulation applies to noninvasive traction components that do not penetrate the skin in a medical device used to apply therapeutic pulling forces on the skeleton

xiii. 21 CFR 890.5900 - Power Traction Equipment [24].
1. This federal regulation applies to powered traction equipment intended for medical use in conjunction with traction accessories to exert a therapeutic pulling force on a patient's body

xiv. 21 CFR 890.5925 - Traction Accessory [25].
1. This federal regulation applies to nonpowered accessory devices intended to be used for medical purposes with powered traction equipment to exert therapeutic pulling forces on a patient's body.

xv. ANSI ST79:2006 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities [8].
1. This standard covers steam sterilization in health care facilities, guiding healthcare professionals in the proper use of processing equipment.

b. Customer

i. This device is intended for use in hospitals, surgical facilities, rehabilitation centers, and other medical facilities that are involved in orthopedics. The customer's most crucial priority is that the device is able to safely hold traction on the patient's fingers. The device needs to be able to hold the arm upright for casting and horizontally for surgery. The client would prefer that the traction system be electronic and detachable for when it goes into the MRI, but the priority is getting a device that works safely and reliably. The customer wants thorough testing to ensure the device's safety.

c. Patient-related concerns

i. This device is intended to be used during surgery and rehabilitation of the hand, making safety and stability critical. The design must be able to withstand the traction forces along with secondary forces due to use in the operating room without losing stability. To maintain the safety of the patient, the sleeves and the traction system must support the weight of the patient's arm with minimal risk of failure due to the delicate nature of rehabilitation and surgery [22], [22], [23], [24], [25], [27], [28]. The sleeves cannot compress the patient's fingers to constrict blood flow [5]. The sleeve and device need to be made of medical-grade, hypoallergenic, latex-free, and non-ferromagnetic materials to prevent any adverse reactions in the patient or an MRI machine [4], [13].

d. Competition

i. Competing Design #1: Digi Grip [33], [34]
1. The Digi Grip is a manual traction system intended for use in physical therapy. It features an adjustable-height IV pole with a custom attachable plate to suspend the fingers from. The associated finger sleeves are like finger traps and are connected to the custom plate using chains.
2. The traction in this system is very simple. An arm sleeve is wrapped around the user's bicep, and weights are attached to the bottom so that the elbow is at a ninety-degree angle and pulls vertically on the fingers.

3. This device is very similar to what the client is looking for, but it is lacking in a few areas. While this device has a lot of mobility, the base is unstable and therefore unsuitable for use while casting hands. It is also unable to be adjusted horizontally so that traction can be applied to the hand while in surgery, making it ill-suited to the client's needs.

ii. Competing Design #2: Traction Wrist Tower [17]

1. The Wrist Tower was a custom-made medical traction device developed by surgeons. The design features a circular base plate with a cuff that locks the arm in. There are height-adjustable rods that extend from the base and attach to a traction plate. The plate has finger spacers that allow it to pull the fingers in traction without them slipping through. The traction is performed using a tourniquet system.
2. This device is an adequate solution to adding traction to the hand during surgery, but it needs to be developed further. The system for traction needs to be improved to reduce compression on the fingers. This device also cannot be used to apply casts because it interferes with the forearm, making it unsuitable for our client.

iii. Competing Design #3: Traction Reducer

1. This design is fully attached to a table. It features a multi-jointed arm that extends from the table with a traction device attached to it. The traction device is a winch that connects to strings with finger traps. The arm is held in place by a cushioned support attached to the table.
2. This design is an effective design for surgery, but it is immobile and unable to be used during casting of the arm. It is also very complex and would be expensive to make. While this design is effective, it does not suit the need to be mobile and low-cost in our client’s environment.

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