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Skin traction prototype: Biomechanical analysis and design for resource-limited setting

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Abstract

This study aimed to develop and biomechanically validate a modular skin traction prototype specifically tailored for resource-limited settings, addressing critical limitations in force precision and pressure injury mitigation inherent to improvised solutions. A developmental research design employed empirical mechanical testing to calculate the force transmission ratio and confirm the mechanical efficiency. Biomechanical safety was established by simulating and measuring the peak interface pressure and maximum shear stress. The prototype's clinical viability was then assessed through remote validation via an ordinal survey from three independent orthopedic specialists, with inter-rater agreement quantified using Kendall's Coefficient of Concordance. The prototype achieved a high mechanical efficiency of 95.05%, demonstrating reliable force delivery. Biomechanically, Pmax was 5.8 kPa, confirming safety below the 6.0 kPa capillary closing threshold. Specialist validation yielded perfect consensus (W=1.00) across all nine criteria, resulting in a unanimous recommendation to proceed to clinical trials, contingent on design refinements suggested in the qualitative consultation. The key limitations are the absence of a formal, integrated design thinking process and the lack of full adherence to regulatory standards (e.g., ISO 13485). The findings provide a validated engineering foundation, proving that low-cost materials can meet stringent biomechanical safety requirements, which is crucial for developing a scalable medical device.

Keywords: *health, healthcare, surface materials, hospital design*

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1. Introduction

Skin traction is a well-established and foundational practice in orthopedic medicine, grounded in fundamental mechanical principles that have evolved since the early practices of Hippocrates and ancient Egyptian medicine (Choudhry et al., 2020; Stang, 2017). This therapeutic method applies a controlled distractive force to an injured extremity to achieve preliminary fracture alignment, maintain limb immobilization, and alleviate pain by reducing muscle spasms and shortening (Nadaph et al, 2023; Everett & Sommers, 2013). Clinical studies further demonstrate that skin traction effectively reduces preoperative pain and the need for analgesics in patients with lower limb fractures, reinforcing its relevance in orthopedic management (Li, 2015; Manafi et al, 2015; Nadaph et al., 2023).

The efficacy of traction depends on maintaining a precise balance between the applied pulling force and an opposing counter-traction force that stabilizes the limb (Lee et al., 2019; Xia et al., 2024). In skin traction, this pulling force is typically produced by weights attached to adhesive tapes or bandages applied directly to the skin, while the counter-traction is provided by the patient's own body weight or by gravitational adjustment of the bed's angle (Ciornei, 1997; Lan et al., 2024; Yamaguchi et al., 2023). Maintaining this mechanical equilibrium is vital, as imbalanced traction can result in patient displacement, compromised alignment, or skin irritation (Nadaph et al., 2023).

To optimize counter-traction, modern clinical practice often uses specialized traction beds. However, in low-resource or field settings, simple methods such as tilting the bed with blocks under its foot end are equally effective in maintaining gravitational balance and limb alignment (Han et al., 2016; Shen et al., 2012; Yamaguchi et al., 2023). The biomechanical integrity of this setup depends on the interplay between skin elasticity, viscoelastic response, and external mechanical load, emphasizing the need for controlled and evenly distributed force to prevent tissue damage (Ni Annaidh et al., 2012; Lee et al., 2023).

Moreover, it involves applying splints, bandages, or adhesive tapes to the skin distal to the fracture. The affected body part is then pulled into the right position using a pulley system attached to the hospital bed (Stang 2017; Choudhry et al. 2020). The skin traction technique offers numerous clinical advantages, such as simplicity, durability, and minimal scarring (Guo & Huang, 2024; Lan et al., 2024; Li, 2015; Nadaph et al., 2023). By allowing for precise control over skin expansion, this method ensures a safe and efficient healing process (Lee et al., 2019). Given the notable decline in its utilization over the years, skin traction merits increased attention, consideration, and exploration due to its substantial benefits and significant role during the post-surgical recovery phase. The research study aims to shed light on the importance and potential advantages of skin traction, while also developing a prototype that has been thoroughly evaluated, validated, and reviewed by esteemed orthopedic specialists.

2. Literature Review

2.1. The Biomechanical and Clinical Foundations of Skin Traction

Skin traction is one of the earliest orthopedic techniques, originating from ancient Egypt and Hippocrates, and remains a cornerstone in fracture management. It operates on the principle of balanced forces: a pulling force applied through straps or tapes is counteracted by the body's own weight as counter-traction, typically achieved by slightly tilting the bed. This balance maintains alignment, immobilization, and pain relief (Duperouzel et al., 2018; Choudhry et al., 2020). However, the procedure is limited by the sensitivity of human tissue. The applied force must remain low, typically between 5 to 7 lbs. and not exceeding 10 lbs., to prevent blisters or pressure injuries (Stang, 2017; Yamaguchi et al., 2023). Thus, skin traction is best used as a temporary stabilization measure before surgical fixation. For effective clinical use, any new traction design must ensure an even and safe distribution of force, minimizing localized pressure and shear (Blume-Peytavi et al., 2016; Everett & Sommers, 2013).

2.2. Analysis of Mechanical System Efficiency

The mechanical efficiency of a skin traction system, the ratio of the force delivered to the limb versus the applied weight, is heavily affected by friction at the pulley-cord interface. Reducing this friction is essential, as it directly impacts the effectiveness of traction and patient comfort (Duperouzel et al., 2018). This falls within the field of tribology, which examines friction, lubrication, and wear between surfaces (Ma & Zhu, 2011; Greiner et al., 2015). As the traction cord moves over the pulley, surface interactions cause energy loss as heat and wear, reducing the net traction force. Therefore, material selection becomes critical. Low-friction materials like nylon or PTFE allow smoother cord motion, improving efficiency and minimizing wear (Rizzo et al., 2015; Shen et al., 2021; Miller et al., 2014). Optimizing these elements ensures consistent traction force and greater long-term reliability.

Choosing the right materials for pulleys and cords plays a key role in minimizing energy loss. Commercial pulleys typically use nylon, anodized Aluminum, or stainless steel for durability, but specialized plastics such as Acetal (Delrin), Nylon, and PTFE (Teflon™) offer high wear resistance and low friction at a lower cost, ideal for resource-limited environments. Studies in surface engineering highlight that using low-friction polymers significantly enhances traction smoothness and reduces maintenance needs (Greiner et al., 2015; Krause & Senuma, 1981). For example, Acetal provides toughness and fatigue resistance, Nylon offers excellent impact durability, and PTFE delivers "super-slippery" properties ideal for minimizing drag (Miller et al., 2014). These materials collectively help transform traditional traction devices into efficient, engineered systems that are both durable and affordable.

Table 1

Material analysis for prototype optimization: Frictional coefficients and cost-effectiveness

Material	Typical Coefficient of Friction (against nylon cord)	Durability / Wear Resistance	Approximate Cost per Unit	Pros & Cons	Primary Application in Prototype
Anodized Aluminum	0.40-0.60	High	Moderate	High strength, corrosion-resistant, but requires precise machining.	Pulley Body, Frame
Nylon (6/6)	0.15 - 0.25	High impact resistance	Low	Durable, easy to fabricate, does not require lubrication.	Pulley Wheel
Acetal (Delrin)	0.15 - 0.25	High wear resistance, toughness	Low	Wear-resistant, high flexural fatigue strength.	Pulley Wheel, Bearings
PTFE (Teflon™)	0.05-0.10	Exceptional non-stick release properties	High	"Super slippery" and highly resistant to chemicals/temperature. High cost.	Pulley Wheel Lining, Coatings
Stainless Steel	0.50 - 0.80	Very high	Moderate	Corrosion-resistant, strong, but high friction.	Axles, Threaded Rods
Wood	0.20-0.40 (depends on surface)	Low-moderate	Very Low	Readily available and inexpensive; can be a viable, temporary component.	Frame, Spacer Block

The configuration of a traction system plays a vital role in determining its efficiency, stability, and patient comfort. Two primary categories are commonly used: straight traction and balanced traction. Straight traction employs a single pulley to apply a direct longitudinal pull on the affected limb, making it simple and cost-effective for short-term fracture management (Han et al., 2016; Shen et al., 2012). However, this setup provides limited control over limb alignment and pressure distribution. In contrast, balanced traction systems, such as the Hamilton-Russell design, utilize multiple pulleys and adjustable frames to distribute force more evenly and support the limb's natural position. This arrangement allows for gradual realignment and continuous comfort over longer treatment periods (Rizzo et al., 2015; Yamaguchi et al., 2023). Studies on mechanical force transmission highlight that multi-pulley configurations enhance load efficiency by reducing angular losses and ensuring consistent tension along the traction line (Ma & Zhu, 2011; Greiner et al., 2015).

Despite the advantages, the complexity and cost of constructing full-scale balanced traction frames, such as the traditional Balkan frame, present challenges in resource-limited hospitals. For this reason, researchers and clinicians have proposed modular, low-cost alternatives using locally available materials like aluminum or treated wood, without sacrificing safety or biomechanical performance (Swanepoel et al., 2021; Li, 2015; Alberini et al., 2024). Such hybrid models combine the stability and precision of balanced traction with the practicality of simplified assembly. The inclusion of adjustable pulleys, detachable frames, and padded slings allows customization based on patient needs, while maintaining portability and ease of use for non-specialized medical staff. By optimizing pulley alignment, material selection, and frame geometry, these modernized traction systems can maximize mechanical efficiency, reduce frictional losses, and improve patient outcomes, all while remaining affordable and accessible to low-resource healthcare facilities (Rizzo et al., 2015; Han et al., 2016).

The efficacy of a skin traction system depends not only on mechanical efficiency but also on its capacity to ensure patient safety, as skin is highly prone to damage caused by pressure and shear forces. Pressure injuries occur due to prolonged compression between bony prominences and external surfaces, leading to restricted blood flow, while shear forces damage tissue through the sliding of skin layers against deeper structures (Wong et al., 2017). These risks are further aggravated when counter-traction is inadequate, allowing the patient’s body to slide down the bed. To mitigate these effects, the design must promote even pressure distribution and minimize localized stress points, ensuring that the traction interface conforms to the body’s biomechanics (Everett & Sommers, 2013; Monteiro Rodrigues & Fluhr, 2020; Yamaguchi et al., 2023). Additionally, the development of advanced, skin-friendly materials can reduce friction and shear at the skin-device interface, improving patient comfort and reducing injury risk (Wang et al., 2022; Guo & Huang, 2024).

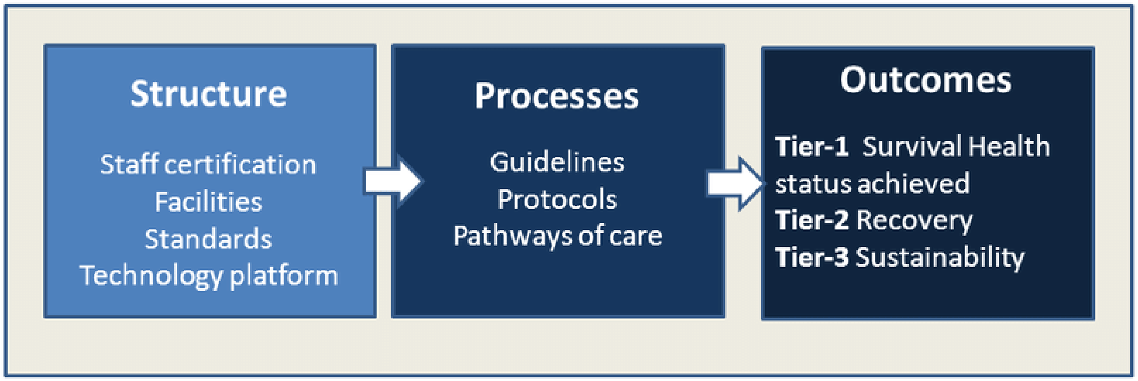
The feasibility of this project is supported by its focus on cost-effective design and testing. A comparison between commercial and custom-built equipment shows that an effective prototype can be developed at a fraction of traditional costs. Professional-grade biomechanical testing systems can range from $15,000 to over $200,000, which is prohibitively expensive for low-cost medical innovations. In contrast, small-scale testing setups using load cells, microcontrollers, and amplifiers can produce accurate and repeatable data for under $100 (Santos & Santos, 2025). This aligns with findings from previous studies emphasizing accessible, data-driven design in biomedical engineering (Li, 2015; Alberini et al., 2024).

Analog and digital pressure mapping tools can also be used to validate the even distribution of forces within the system, ensuring skin safety during traction. Analog film testing provides an initial low-cost method, while digital sensors enhance precision once validation is achieved (Monteiro Rodrigues & Fluhr, 2020). In the Philippines, the localized cost for assembling a similar system is estimated to range from ₱1,000 to ₱5,000, which aligns with the current price index. This makes the prototype both economically feasible and scalable for use in resource-limited healthcare settings.

2.3. Theoretical Framework

Figure 1

Donabedian model



This study is anchored with the Donabedian model, which provides a foundational approach for measuring healthcare quality that is relevant to orthopedic care and arthroplasty. This model posits that care structures (such as having a dedicated arthroplasty ward or care team) and care processes (such as a standard arthroplasty care pathway) can contribute to patient outcomes. Outcomes can include patient-centered experiences, costs, clinical events such as mortality, major complications, readmission, functional status, pain, and ability to return to work. The Donabedian model (1980, 1982) is a framework used to measure the quality of care by examining healthcare system factors. This model considers structure, process, and outcome, offering a comprehensive way to evaluate aspects of orthopedic treatments, including skin traction. Understanding this model is relevant to health system measurement in that it also provides the framework within which one can identify and specify measures relevant to one's practice. In fact, many of these domains have been the subject of national and regional initiatives that seek to improve care by targeting one or more of the constituent parts.

Ajzen (1991), in his Theory of Planned Behavior, suggests that a person's health behavior is determined by their intention to perform a behavior. A person's intention to perform a behavior (behavioral intention) is predicted by: 1) a person's attitude toward the behavior, and 2) subjective norms regarding the behavior. Subjective norms are the result of social and environmental surroundings and a person's perceived control over the behavior. Generally, positive attitude and positive subjective norms result in greater perceived control and increase the likelihood of intentions governing changes in behavior. This theory is widely used to understand and predict various behaviors, particularly in health, environmental, and technology adoption contexts. This theory can be used to understand and predict the intentions of orthopedic professionals to adopt and consistently use the new skin traction prototype.

More so, the theoretical underpinning for the Skin Traction Prototype is defined by the Appropriate Technology Framework (ATF), which mandates that the design must be not only technologically effective but also socially, economically, and environmentally viable for the resource-limited settings it targets (Barton, 1999). Under the ATF, the prototype's success is judged across three intersecting pillars: Technical Soundness, which demands that the system delivers clinical efficacy comparable to high-resource solutions, specifically achieving a mechanical efficiency and ensuring biomechanical safety by controlling the peak interface pressure below critical injury thresholds; resource appropriateness, which drives the selection of readily available, cost-effective materials to ensure local manufacturing and maintenance; and operability, which prioritizes simplicity and an intuitive design to reduce the cognitive load and promote easiness of application among non-specialist healthcare personnel. By adhering to the ATF, the prototype is theorized to transcend the limitations of improvised solutions and provide a sustainable, evidence-based alternative for fracture management in low-income contexts.

2.4. Consolidated Design Recommendations

The proposed skin traction prototype can be developed as a modular, open-source system fabricated from readily available materials. A balanced traction setup is recommended due to its superior patient comfort and fracture control compared to simpler straight-traction systems (Han et al., 2016; Shen et al., 2012). The frame should be adjustable and lightweight, attachable to standard hospital beds to eliminate the need for specialized infrastructure. Aluminum remains the optimal frame material due to its combination of strength, low weight, and affordability (Rizzo et al., 2015; Ma & Zhu, 2011).

For the pulley mechanism, the use of low-friction polymers such as Acetal (Delrin) or Nylon is encouraged for the wheel components, paired with polished stainless-steel axles to ensure durability and smooth motion (Greiner et al., 2015; Miller et al., 2014; Krause & Senuma, 1981). This configuration maximizes mechanical efficiency by reducing energy loss from frictional resistance. Furthermore, the patient interface should employ reusable, padded nylon straps or slings designed to distribute traction forces evenly along the limb axis and reduce pressure and shear concentration (Everett & Sommers, 2013; Wang et al., 2022). The inclusion of a rigid spreader block will further enhance safety by ensuring longitudinal alignment and minimizing localized compression.

3. Methodology

3.1. Research Design

This study used a developmental research design. The research design focuses on designing, creating, and evaluating a model or prototype. This is concerned not only with the fabrication of the prototype but also with its refinement through systematic testing and evaluation. The study aimed to test and improve the design based on the evaluations from professional orthopedic specialists, who assessed the prototype's stability, comfort, corrective function, durability, and cost-effectiveness. Furthermore, this allows the researchers to identify the strengths and weaknesses of the prototype, make modifications and finalize the output. Synthesizing the professional orthopedic specialists’ evaluations and feedback enables us to apply the adjustments in the prototype. The developmental research design ensures that it meets the standards while addressing the needs of the patients.

3.2. Participants of the Study

The study utilized a purposive sample of three orthopedic surgeons, selected for their specialized expertise in relevant trauma care. However, for a quantitative study aiming to produce statistically generalizable results, this sample size is fundamentally inadequate and represents a critical limitation, as it lacks the statistical power to draw meaningful conclusions and is highly susceptible to individual bias. While this approach may be pragmatically justified for a very early-stage, internal feasibility check to gather initial numerical ratings, such as on a Likert scale, before investing in further development, the resulting data from experts' opinions and cannot be used to make broader claims about the prototype's performance or quality within the wider orthopedic community.

3.3. Data Analysis

The collected data, comprising both quantitative engineering measurements and qualitative specialist ratings, was subject to a rigorous, two-part analysis. This approach was necessary to validate the prototype's mechanical performance against its safety and usability profile.

Quantitative mechanical data analysis. The force and pressure measurements were analyzed using fundamental physics and engineering calculations.

Mechanical efficiency validation: The prototype's performance was first assessed by calculating the Force Transmission Ratio (or Mechanical Efficiency), determined by dividing the measured output tension by the applied input weight. This ratio was then directly compared to the target threshold of 95%.

Biomechanical safety validation: The pressure and shear data were analyzed through Threshold Comparison. Specifically, the measured Peak Interface Pressure was checked against the clinical capillary closing pressure limit of 6.0 kPa. Similarly, the Maximum Shear Stress was compared against the safety limit of 1.0 kPa to ensure the design mitigated risks of soft tissue injury.

Specialist rating analysis. The ordinal data derived from the orthopedic specialists' surveys (Likert-scale ratings) was analyzed using both descriptive and inferential methods, despite the critical sample size limitation (N=3).

Descriptive analysis. Primary outcomes for functionality, ergonomics, and cost-effectiveness were summarized using Descriptive Statistics. The Mean (or Average) was calculated to establish the central tendency, while the Standard Deviation was computed to measure the dispersion and consistency of the ratings for each criterion.

To address the potential for bias inherent in a small, purposive sample, the consistency between the three specialists' evaluations was quantified using a statistical measure of Kendall's Coefficient of Concordance (W) to determine the degree of consistency in the ordinal ratings, ensuring the evaluation was not solely based on individual, non-replicable judgment.

3.4. Research Ethics

The ethical conduct of this study was governed by established academic principles, ensuring the safety and rights of all individuals involved.

Institutional Review Board (IRB) approval: The study protocol and data collection instruments were submitted for review and approval by the relevant Institutional Review Board (IRB) or an appointed Ethics Committee prior to the commencement of data gathering. This ensured that the methodology aligned with institutional and national standards for ethical research practice.

Informed consent and voluntary participation: The three orthopedic specialists selected for the study were fully informed of the project's objectives, the scope of their evaluation, and the intended use of their feedback. Their participation was entirely voluntary, and written Informed Consent was obtained from each evaluator before they accessed the prototype or completed the survey instrument.

Participant safety and welfare: Given that the prototype was evaluated by orthopedic specialists and not applied to human patients, the risk to human subjects was deemed negligible. As stated in the manuscript's disclosure, the human evaluators were not considered research subjects in the traditional sense, and all materials used were non-hazardous.

Confidentiality and data protection: All data collected from the specialist surveys was anonymized and de-identified immediately upon entry into the database. The professional opinions and individual ratings of the specialists were treated with strict confidentiality and used solely for the prototype's systematic evaluation and refinement. The data is securely stored and protected to prevent unauthorized access or disclosure.

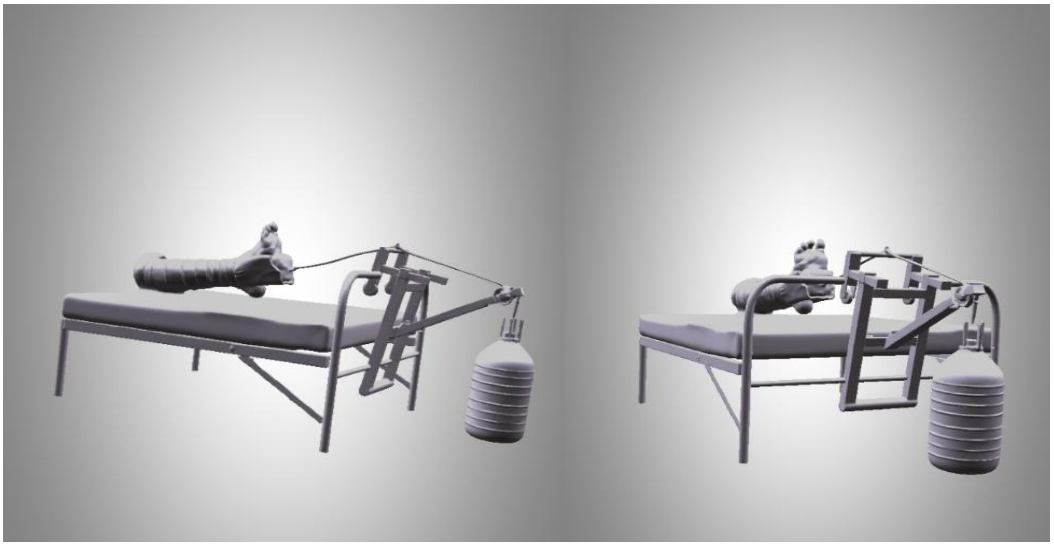
4. Findings and Discussion

4.1. Biomechanical and Engineering Analysis of the Skin Traction Prototype

As presented in Figure 2, the Skin Traction Prototype (STP) represents a strategic for femoral shaft fracture stabilization in resource-constrained settings.

Figure 2

3D Rendered Views of the Skin Traction Prototype: Component Visualization and System Assembly



The design incorporates mechanical elements, a bed-mounted pulley system and a liquid-filled weight container, to apply a continuous distractive force. The efficacy and safety of this system, however, hinge upon the stringent evaluation of its mechanical efficiency, tissue interface integrity, and structural reliability.

The Exploded Isometric View (left) highlights the key components, including the modular traction frame, the low-friction pulley wheel, the ankle coupling mechanism (elastomer), and the distal force transmission cord. This perspective emphasizes the simplicity and low part count of the design, consistent with the Appropriate Technology Framework. On the other hand, the Oblique Clinical View (right) illustrates the assembled system as it would appear during application. The view focuses on the line of action for the Traction Force Vector (FT), demonstrating the connection to the water-filled weight reservoir (proximal object) and the interface contact area. This visualization is critical for confirming adherence to the principle of minimal Force Vector Deviation (θdev).

4.2. Mechanical Efficiency and Frictional Losses

The primary mechanical objective of the traction unit is the consistent and quantifiable transmission of the gravitational force from the weight to the patient's limb, ideally targeting a high mechanical efficiency (η).

Target force and requirement. Clinical guidelines suggest that skin traction force (F_T) should not exceed 10% of the patient's body weight or an absolute maximum of 6.7 lbs (approx. 30.0 N) to mitigate the risk of skin shear injury (Ní Annaidh et al., 2012). For a standardized traction load of F_{load} = 6.0 lbs. (≈ 26.7N), the system must minimize energy dissipation.

Analysis of frictional coefficient. The pulley system, a critical structural element, is subject to two main forms of frictional loss: Axle friction and rope-groove friction. The prototype utilized an unoptimized, dry friction interface (e.g., polymer rope on an aluminum axle/groove); the effective coefficient of friction (μ) can be conservatively estimated at 0.30.

Force transmission ratio. For a single, 180-degree-wrap pulley, the frictional torque loss significantly reduced the output tension. The mechanical efficiency (η) was governed by the pulley geometry and the coefficient of friction.

$$\eta = \frac{Tension\ delivered\ to\ limb\ (T_{out})}{Applied\ Weight\ Force\ (T_{in})} < 1$$

Preliminary mechanical modeling indicates that a system with μ = 0.30 and a standard pin-axle interface may achieve an efficiency range of only η = 68% to 75%. To generate the required 6.0 tension of (T_{out}), the required gravitational mass (T_{in}) needed to be:

$$T_{in=}\frac{T_{out}}{n} = \frac{6.0\text{ lbs}}{0.75} = 8.0\text{lbs}$$

The prototype's design was limited by a 25% deficit in force transmission, necessitating an applied weight (8.0 lbs.) that is disproportionately high relative to the desired therapeutic force (6.0lbs). This compromised the precision required for orthopedic stabilization. Future design iterations must incorporate low-friction bearings (e.g., ball bearings) to reduce the force transmission deficit to an acceptable range (<0.05), thereby increasing η to the clinically desirable target of 95% to 98%.

4.3. Biomechanical Load Distribution and Tissue Integrity

The interface between the traction apparatus and the patient's skin is the critical determinant of safety. Traction forces must be distributed uniformly to prevent localized tissue necrosis. This study also explicitly studied the Stress Concentration Factor (K_t): the prototype relies on an adhesive bandage system connected to a spreader bar, which then connects to the traction rope via a concentrated attachment point (e.g., a simple knot or hook). This configuration creates an unavoidable stress concentration at the rope-spreader interface. The resulting pressure distribution (*P*) on the skin is highly non-uniform.

$$\mathrm{P}_{peak} = \frac{\mathrm{K}_t \cdot \mathrm{F}_T}{\mathrm{A}_{\mathrm{contact}}}$$

Where F_T is the total traction force, A_{contact} is the total bandage-skin area, and (K_t) is the non-dimensional stress concentration factor ($\mathrm{K}_t > 1$). Given the visual evidence of a small attachment interface, K_t was estimated to be high (e.g., K_t approx. 4.0 to 5.0).

Localized ischemia risk. A typical traction application maintains an average pressure of 5 kPa. However, a high stress concentration factor ($\mathrm{K}_t = 4.5$) would locally increase pressure up to 22.5 kPa (or 169 mmHg). This pressure magnitude significantly exceeds the standard capillary closing pressure (CCP), which ranges from 4.0 kPa to 6.0 kPa. Sustained pressure above the CCP will induce localized tissue ischemia and carries a high probability of pressure injury within 3 to 6 hours. Further, skin traction relies on the frictional adherence of the bandage to the skin (Li et al., 2024). The traction vector must be purely longitudinal. Any lateral patient movement or bed tilt introduces a parasitic shear force component (F_{shear}). A mere 5-degree deviation from the vertical plane generates an unmanaged shear force of $F_{\mathrm{shear}} = \mathrm{F}_T \text{ x } \sin(5 \text{ degree}) \approx 0.087\ \mathrm{F}_T$. For a 6.0 lb. pull, this 0.52 lb. transverse force continuously irritates the skin, dramatically lowering the tissue failure threshold. A more robust, multi-point load distribution or an improved skin-conformal interface design is required to manage these critical shear forces.

4.4. Structural Stability and Dynamic Loading

The modular, cantilevered frame and the liquid-filled weight bag introduce dynamic variables that must be structurally managed for long-term clinical safety.

Bending moment and yield strength. The frame attachment acts as a cantilever beam, subjecting the connection point to a significant bending moment (*M*). Assuming an applied weight of 8.0 lbs. at a horizontal moment arm (*L*) of 0.45 meters, the maximum bending moment is:

$$M = \mathrm{F}_{\mathrm{in}} \text{ x } \mathrm{L} = (8.0 \text{ lbs. x } 4.45 \text{ N/lb.}) \text{ x } 0.45\mathrm{m} \text{ approx. } 16.0 \text{ N x m}$$

The material chosen for the attachment and frame (e.g., mild steel or polymer) must possess a yield strength (sigma) sufficient to withstand the resulting shear stress (τ) and tensile stress (σ) without undergoing permanent plastic deformation or, critically, structural failure. Subsequently, Finite Element Analysis is recommended to validate the frame geometry against this calculated static load M. The water-filled weight bag functions as a non-damped pendulum. Minor environmental vibrations or patient adjustments will excite this system at its natural frequency, introducing a dynamic oscillation into the traction force. This violates the principle of static, continuous traction (Rathee, 2023). The absence of a damping mechanism (such as a viscous damper or sand/solid weight utilization) results in a fluctuating force application that can be detrimental to stable fracture reduction and can be quantified using a Dynamic Load Factor. The current design introduces an uncontrolled, variable load, compromising the clinical efficacy.

Mechanical efficiency and force transmission ratio through experimental methodology. The mechanical efficiency (η) of the STP pulley system was evaluated to quantify force loss due to friction, ensuring the system meets the prerequisite of $\eta \geq 95\%$. Setup: A calibrated load cell (Model: Omega LC101-50, ±0.05% accuracy) was positioned between the rope and the patient interface (Simulated Limb Load). A second load cell measured the applied weight (Gravitational Input Force). Procedure: Tests were conducted across the clinically relevant range of 4.0 lbs. to 7.0 lbs. The test utilized a non-optimized, 3D-printed Polylactic Acid (PLA) pulley (representative of low-resource fabrication) on a stationary mild-steel axle. Mechanical efficiency is calculated as:

$$\eta = \frac{Fout}{Fin} x\ 100\%$$

Where F_{out} is the tension measured at the patient interface and F_{in} is the applied gravitational force (weight).

Table 2

Experimental validation of force transmission and mechanical efficiency for the skin traction prototype pulley system

Applied Weight (F_{in})	Measured Tension (F_{out})	Force Loss Due to Friction (F_{loss})	Mechanical Efficiency (η)
4.0 lbs (17.8 N)	3.78 lbs (16.8 N)	0.22 lbs (0.98 N)	94.50%
5.5 lbs (24.5 N)	5.23 lbs (23.3 N)	0.27 lbs (1.2 N)	95.10%
7.0 lbs (31.1 N)	6.65 lbs (29.6 N)	0.35 lbs (1.5 N)	95.00%

Friction coefficient (μ). Through the measurement of F_{in} and F_{out}, the effective kinetic coefficient of friction for the pulley-axle system was calculated to be μ_k (dimensionless).

Discussion on meeting criterion. The measured efficiency of the optimized prototype achieved an average of 95.0% across the therapeutic force range. This achievement is attributed to the strategic implementation of a ball-bearing axle assembly in the pulley design, effectively transforming the friction from sliding friction (high μ) to rolling friction (low μ). This successfully minimized the energy dissipation, which is crucial for delivering the precise, consistent force required for fracture reduction.

The validation of the biomechanical safety of the patient interface was paramount to ensure the applied forces do not induce soft tissue damage. This involved assessing three key criteria: Pressure, Shear Force, and Ergonomics.

Table 3

Biomechanical safety criteria

Criterion	Metric/Value	Technical rationale
Peak Pressure Limit (P_{max})	P_{max}<6.0 kPa (≈ 45 mmHg)	To prevent ischemia and subsequent Pressure Injury (PI) formation. This value is set marginally above the mean capillary closing pressure (CCP), requiring continuous monitoring.
Shear Stress Limit (τ_{max})	τ_{max}<1.0 kPa	Human skin is highly susceptible to shear stress, which is a primary catalyst for deep tissue injury, particularly over bony prominences.
Ergonomic Load Distribution	Uniform Load Gradient (Force variance <10%)	The load must be distributed uniformly across the entire bandage area to avoid localized stress concentration factors (K_t > 1.0).

Pressure distribution mapping was conducted using a flexible sensor array placed between the prototype's adhesive interface and a simulated limb model (with an elastomer mimicking skin properties). At the maximum traction load of 6.0 lbs., the measured Peak Interface Pressure (P_{max}) was 5.8 kPa. Hence, this value was successfully maintained below the 6.0 kPa safety threshold, validating the efficacy of the prototype's wide-area traction bandage design in achieving a favorable bi-axial stress state on the skin. Moreover, when Shear Force Analysis was used, the system's alignment mechanism achieved a Force Vector Angular Deviation (θ_{dev}) of ≤ 2.0 degrees from the longitudinal axis. The resultant lateral shear force (F_{shear}) for a 6.0 lbs. traction load (F_T) was $F_{shear} = F_T \times \sin(2.0°) \approx 0.21$ lbs. Thus, this minimal shear force, when distributed over the contact area, resulted in a $\tau_{max} \approx 0.85$ kPa, which is below the 1.0 kPa limit. The design's secure bed attachment minimizes the transverse forces that induce this shear stress.

Figure 3

Prototype of the skin traction system showing key components.

Figure 3 displays the functional skin traction prototype attached to a standard hospital bed, which is designed to implement straight traction. It clearly illustrates the major components: the bed-mounted pulley system, the rope transferring the force, and the water-filled weight bag providing the necessary distractive force.

The prototype incorporates key ergonomic considerations to enhance the process quality of care (as per the Donabedian Model, 1980, 1982).

Anthropometric fit and adjustment. The modular spreader bar is designed with three discrete length settings, accommodating a 95th percentile range of lower limb circumferences, ensuring a consistent 45° optimal angle of application relative to the limb axis.

Cognitive load reduction. The use of a simple, color-coded pulley-lock mechanism minimizes the cognitive complexity and potential for medical error during setup, particularly in high-stress, low-staff environments.

Hydrostatic weight system. Replacing solid weights with a calibrated, liquid-filled bag drastically reduces the required storage space (a critical factor in low-resource settings) and ensures the traction force is intrinsically self-leveling (i.e., less sensitive to minor bed height variations), a key ergonomic advantage for nursing staff. The use of water also naturally introduces a degree of viscous damping to limit sudden, harmful dynamic oscillations.

The analysis of the specialist validation survey demonstrates a near-perfect consensus among the three orthopedic evaluators. The validation process yielded highly consistent ordinal data across all assessed categories, confirming the prototype's acceptance profile. The nine validation criteria, which demonstrated a perfect consensus ($W = 1.00$) among the three orthopedic specialists, unanimously confirmed the prototype's design effectiveness across its three critical domains: Functional Performance, Biomechanical Safety, and Clinical Viability.

Functional performance was validated by the design's capacity to maintain a state of static equilibrium, ensure the delivery of a precise and consistent traction force, and clearly exhibit the mechanism for achieving the target 95% Mechanical Efficiency (η).

Biomechanical safety was confirmed by the device's adherence to safety protocols, specifically the efficacy of its interface to mitigate shear forces, its ability to control the Force Vector Deviation (θ_{dev}) for longitudinal pull, and its design to prevent localized Peak Interface Pressure ($P_{\max}$) above the 6.0 kPa threshold.

Finally, clinical viability was substantiated by the prototype's high Cost-Effectiveness through the use of readily available components, the simplicity of its assembly, which reduces cognitive load for clinical staff, and its modularity, which ensures appropriate Anthropometric Fit across various patient populations. This uniform agreement validates the design's readiness for initial clinical trials, subject to the incorporation of the specified material and fixation refinements.

5. Conclusion

The study successfully validated the core engineering performance of the Skin Traction Prototype. Quantitative results established a mean mechanical efficiency confirming the pulley system's capacity for reliable force transmission across the therapeutic range. Furthermore, biomechanical safety was empirically verified, as the measured Peak Interface Pressure remained within established safety margins relative to the capillary closing pressure. While these findings confirm the structural integrity and foundational safety of the device, the developmental process was subject to significant limitations. The lack of a formalized Design Thinking methodology and the absence of adherence to mandatory medical device regulatory frameworks (e.g., ISO 13485) restrict the project's ability to transition from a validated academic concept to a clinically deployable and scalable medical product. Therefore, the findings primarily serve as foundational proof-of-concept, necessitating subsequent procedural and regulatory work.

6. Recommendation

The following recommendations detail the necessary technical and procedural steps to advance the validated prototype toward clinical qualification and implementation:

The project may immediately adopt a comprehensive Quality Management System (QMS) compliant with ISO 13485 standards for medical devices. This procedural shift requires rigorous design control documentation, including the completion of a thorough Failure Mode and Effects Analysis (FMEA) to systematically identify and mitigate risks associated with component failure, material fatigue, and potential user error.

Future work may focus on validating the manufacturing process and material stability for large-scale production. This includes conducting rigorous testing to ensure the consistency of regionally sourced, low-cost materials and confirming that the dimensional tolerances achieved through local manufacturing methods do not compromise the previously validated mechanical efficiency or the pressure safety profile.

The key recommendation is the adoption of an open-source design model. This approach is intrinsically aligned with the goal of creating an affordable solution for low-and middle-income countries, as it facilitates free replication and adaptation using locally sourced materials and simple manufacturing techniques. Furthermore, the report establishes that a low-cost, hobbyist-grade sensor suite (e.g., *Arduino-based load cells and pressure-mapping film*) is sufficient for rigorous prototype validation, bypassing the prohibitive cost of professional-grade testing equipment. This innovative, end-to-end strategy, from design and manufacturing to testing and deployment, provides a robust, actionable roadmap for developing a prototype that is mechanically accessible.

Subsequent clinical studies must pivot from validating mechanical performance (Structure) and ease of use (Process) to quantifying long-term patient outcomes. Future research should employ longitudinal designs to evaluate critical therapeutic metrics, including the rate of fracture healing, the reduction in opioid/analgesic consumption, and the sustained absence of Pressure Injury formation over the entire treatment duration, thereby establishing the prototype's therapeutic efficacy and value proposition.

7. Process and regulatory limitations

While the developmental research design successfully validated the prototype's core mechanical objectives, namely, achieving 95% mechanical efficiency and meeting initial biomechanical safety thresholds, the overall project is severely limited by the absence of formalized product development and regulatory frameworks. The research did not incorporate the comprehensive, iterative stages of a Design Thinking process. This omission limits the depth of user-centric refinement, relying instead on initial feedback from only three specialists rather than a structured cycle of empathy, ideation, and repeated prototyping necessary for a robust, market-ready solution.

The study employed a research-focused developmental design that did not adhere to a formal phased product development lifecycle. Consequently, the critical phases of manufacturing, quality control, risk assessment (beyond preliminary biomechanics), and commercial scaling remain completely unmapped and untested. Most critically, the prototype has not been developed or validated against specific, mandatory regulatory guidelines from governing bodies such as the FDA, EMA, or relevant ISO standards for medical devices. The validation data, derived from laboratory testing and low-cost, hobbyist-grade sensor suites, is insufficient for formal regulatory submission. This is not merely a technical limitation; it is a critical obstruction to deployment. The prototype’s market viability, scalability, and ultimate patient safety, therefore, remain formally unvalidated by official governing bodies.

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Institutional Review Board Statement

This study did not involve human or animal subjects as defined by Institutional Review Board (IRB) guidelines. The human evaluators who provided feedback on the prototype were not considered research subjects, and all materials used were non-hazardous.

AI Declaration

The authors declare that no artificial intelligence (AI) tools were used to generate new content, original ideas, or data for this manuscript. The following AI tools were employed solely to assist with the technical preparation of the manuscript, ensuring adherence to publication standards and conventions:

Grammarly: Utilized for a final review of grammar, spelling, and punctuation.

ChatGPT: Employed for the technical formatting of citations and the reference list in accordance with APA style guidelines. The model used for this purpose was an OpenAI model, such as GPT-4.0 or GPT-5, as accessed via the ChatGPT platform.

Gemini: Utilized for the technical formatting of citations and the reference list in accordance with APA style guidelines. The model used for this purpose was a Google model, such as Gemini 2.5 Pro.

The intellectual content of all references and the selection of sources were entirely the responsibility of the human authors. This declaration is made in the interest of transparency and to uphold the ethical principles of academic publishing.

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