Novel Distraction-Unloader Knee Braces for Medial Compartment Knee Osteoarthritis (Technical Report)

Knee Braces Alleviate Osteoarthritis Disparities

(STS Research Paper)

A Thesis Prospectus In STS 4500 Presented to The Faculty of the School of Engineering and Applied Science University of Virginia In Partial Fulfillment of the Requirements for the Degree Bachelor of Science in Biomedical Engineering

> By Mira Zineddin

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Technical Team Member: Anna Dugan

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Dr. Coleen Carrigan, Department of Engineering and Society

Dave Johnson, Icarus Medical

Cole Yantiss, Icarus Medical

Max Ronkos, UVA Health Prosthetics & Orthotics

Sociotechnical Problem

Our study evaluates a new distraction-unloader knee brace for patients with medial compartment osteoarthritis (OA) as a solution to the limitations of the current gold standard, total knee replacement (TKR). As a major surgery, TKR is delayed until pain and immobility are unbearable. An ideal treatment would offer earlier OA relief to delay or avoid surgery.

Furthermore, many patients, especially racial minorities, face barriers to TKR approval due to comorbidities like obesity and diabetes, which increase surgical risks (Ezomo et al., 2020). Additional obstacles, such as costs up to \$20,000 (Losina et al., 2015), lack of insurance, distrust of surgeons, recovery time, and physical therapy expenses, disproportionately impact low-income and minority groups (Chun et al., 2021; Goodman et al., 2023). TKR dissatisfaction rates are high at 20% versus only 10% for hip replacements (Wang et al., 2021). Limited implant longevity makes 70 the ideal TKR age, yet nearly half are performed on patients under 65, with the fastest-growing group being 45–55 (Franklin et al., 2020; Perdisa et al., 2023). Other surgical options exist but are less common and have similar challenges, including limited implant life, high revision rates, complications, lengthy recovery, and costs (McCormack et al., 2021).

Knee braces offer a non-invasive solution for slowing OA progression while addressing systemic barriers tied to TKR. For example, they are suitable for patients barred from surgery due to age, comorbidities, or location. Their lower risk helps build patient trust, and their reduced cost improves accessibility, mitigating healthcare disparities (Lee et al., 2017).

This paper examines ways to enhance knee brace functionality and accessibility. First, I propose research methods to evaluate the technical advancements of distraction-unloader knee braces. Second, using the STS framework of user configuration, I explore how knee braces can

reduce healthcare disparities in knee OA by addressing intersecting factors such as race, gender, geography, disability, and class, compared to TKR surgery.

Technical Topic

Knee OA is the most common orthopedic disorder in adults, accounting for roughly 60% of OA cases and affecting 365 million people worldwide (Long et al., 2022). As the knee's medial compartment bears the highest load during motion, it is especially prone to cartilage breakdown and pain. Medial compartment OA treatments therefore aim to offload force and correct knee alignment to slow deterioration (Gueugnon et al., 2021).

High surgical costs and wait times drive the demand for non-surgical options. Current non-brace options, like intra-articular injections, mainly offer short-term relief without addressing the underlying causes of chronic pain (DeRogatis et al., 2019). Current unloader knee braces typically use a three-point loading system to relieve medial compartment pressure. While studies usually indicate improved patient outcomes, it would be ideal to develop a brace that can offload even more force without increasing rigidity or tightness, as the most common complaints regarding braces are discomfort, skin irritation, and varicose veins. Additionally, the three-point system is suboptimal, as it risks overloading the knee's lateral compartment in exchange for offloading the medial compartment (Parween et al., 2019).

A novel surgical approach, knee distraction, aims to realign the joint and increase joint-space width (JSW) between the patella and femur to offload the medial compartment. A previous study found that knee distraction surgery delayed planned TKRs by 5 years on average, with significant outcomes like increased JSW, cartilage thickness, and improved patient-reported outcome measures (PROMs) (Intema et al., 2011). Further studies indicate that knee distraction surgery can achieve improvements in JSW and PROMs comparable to or exceeding those of

knee implant surgeries like high tibial osteotomy (van der Woude et al., 2017). While effective, knee distraction surgery still involves surgical barriers. Our study seeks to determine if an external distraction-unloader knee brace could achieve comparable outcomes to surgical knee distraction without these barriers.

Unlike standard three-point unloader braces, distraction-unloader braces use a hinge to apply a distraction force when standing, offloading more force without increasing rigidity (Gueugnon et al., 2021). This mechanism may promote OA recovery by mimicking effects seen in knee distraction surgery, such as increased JSW and knee functionality. Our study evaluates the Adonis[®] distraction-unloader brace from Icarus Medical for ease of use and long-term clinical efficacy using PROMs, imaging, and gait analysis.

The Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Visual Analog Scale (VAS) are validated and quantitative PROMs ideal for longitudinally evaluating symptoms, quality of life, and knee functionality in knee OA patients (Parween et al., 2019). The Orthotics and Prosthetics Users Survey (OPUS) will track patient satisfaction with the brace's design (Peaco et al., 2011). Demographic data, including age, gender, race, education, native language, income bracket, and BMI will be collected to examine potential variations in satisfaction and patient-reported outcomes based on social determinants of health.

Regarding imaging, the standing weight-bearing anteroposterior lower limb radiograph is the gold standard for evaluating structural changes in knee OA. While reductions in minimum medial compartment JSW are a hallmark of OA progression for both men and women, women often experience additional dynamic deformities regarding the femoral bowing angle (FBA), joint line convergence angle (JLCA), hip-knee-ankle angle (HKA), and distal femoral valgus

resection angle (DFVRA). These imaging metrics can longitudinally track dynamic deformities and account for potential sex-specific differences in OA progression (Lu et al., 2019).

To assess the Adonis[®] brace's effects on movement, motion analysis will be conducted to collect the following spatiotemporal gait parameters: step length, stride length, cadence, and gait speed (Laroche et al., 2014). The knee adduction moment (KAM) will be measured as it closely correlates with medial compartment loading—especially during early stance phases—and is therefore used to evaluate the offloading efficacy of orthopedic devices (Kutzner et al., 2013).

In summary, we will evaluate the Adonis[®] distraction-unloader knee brace as a non-surgical solution for medial compartment OA through PROMs, imaging, and gait analysis. To ensure accessibility and patient adherence, we will optimize the brace's user-friendliness before market distribution, as discussed in the following STS section.

STS Topic

The barriers to accessing surgical technology for OA can be analyzed through the STS framework of user configuration, which examines how a designer's assumptions about users become embedded in the technology's design and accessibility (Woolgar, 1990). For example, Barla (2023) applies user configuration to spirometers, explaining how designers' faulty assumptions about Black bodies led to the perpetuation of racial healthcare biases and disparities.

In designing TKR surgery, many assumptions are made about patients: that they are comfortable with TKR, receive appropriate referrals, trust their surgeon, can afford the procedure and follow-up care, have social support, language services, and health literacy to navigate post-care, and are financially stable enough to manage the disruptions in work, caregiving, and daily responsibilities during recovery.

To illustrate how surgical barriers conflict with these assumptions, consider the following hypothetical cases:

Paulina, a 45-year-old Guatemalan immigrant and single mother in an underserved urban area, has knee OA but cannot afford TKR or the time off work and caregiving duties it requires—barriers disproportionately faced by women, low-income individuals, and racial minorities (Demiralp et al., 2019; Goodman et al., 2023). Additionally, Paulina's wariness of surgery reflects the medical mistrust experienced by marginalized gender and racial groups due to experiences with systemic healthcare discrimination (Antony et al., 2024; Ezomo et al., 2020). Language barriers add to the difficulty of navigating the healthcare system, and her young age makes her a suboptimal candidate for TKR as she will likely need costly revision surgery (Perdisa et al., 2023).

For Paulina, a knee brace represents an ideal alternative. The average brace costs \$365 (Nin et al., 2022), with prolonged use becoming significantly cost-effective after 4 months (Lee et al., 2017), addressing Paulina's primary concern of affordability. Additionally, Paulina has access to a healthcare center she can visit to ensure the brace still properly fits. These follow-ups are highly effective at minimizing the brace's possible side effects of skin irritation and discomfort (Lee et al., 2017).

James, a 90-year-old Black man with advanced medial compartment OA, lives alone in rural Wisconsin, where limited infrastructure, lack of specialized centers, and unreliable transportation make it difficult to reach a high-volume hospital. These geographic and care access barriers disproportionately impact US rural and minority populations and extend globally to low- and middle-income countries (Cyr et al., 2019; Grimes et al., 2011). James' advanced age

makes surgery risky. James also lacks family support and physical therapy access, both of which are essential for TKR rehabilitation (Jette et al., 2020).

A knee brace offers James a non-surgical and home-deliverable solution, helping him overcome transportation and hospital access barriers. While customized braces accommodate diverse sizes and lower-limb deformities, pre-sized braces are equally effective and enable mass manufacturing, increasing accessibility and affordability—a benefit for both James and Paulina (Paluska & Mckeag, 2000). A key design assumption is that the brace will be intuitive and easy to use, even for patients like James who have limited vision or hand immobility. OPUS is therefore a crucial metric in the Adonis[®] brace's clinical trial because it enables us to evaluate this assumption regarding usability–a factor essential for ensuring the brace's cost-effectiveness and patient adherence (Gueugnon et al., 2021; Lee et al., 2017).

In summary, user configuration highlights how faulty assumptions regarding surgery accessibility perpetuate healthcare disparities across the intersecting power structures of race, class, gender, geography, and disability. Systemic healthcare inequities limit access to advanced surgery for minority and low-income patients (Ezomo et al., 2020; Goodman et al., 2023). Surgery's reliance on hospitals excludes those in underserved or remote areas (Cyr et al., 2019; Grimes et al., 2011). Minority groups face added challenges in TKR approval due to a higher prevalence of disabilities like diabetes (Ezomo et al., 2020). Women may experience unequal assessment due to doctors' assumptions of women's bodies, leading to delays in surgical referral (Mandl, 2013). Women, racial minorities, low-income individuals, and chronically disabled patients express greater concerns about costs, recovery time, caregiving duties, and mistrust of surgeons or hospitals (Demiralp et al., 2019; Ezomo et al., 2020; Goodman et al., 2023). Noting

these systemic barriers and faulty assumptions spotlighted by user configuration, we will assess the Adonis[®] knee brace as an accessible and cost-effective alternative for OA patients.

Conclusion

Our proposed clinical trial evaluates the Adonis[®] distraction-unloader knee brace as a non-surgical intervention for medial compartment OA using PROMs (KOOS, VAS), usability surveys (OPUS), demographic data, imaging, and gait analysis.

User configuration highlights how design assumptions regarding affordability, ease of use, and demographics impact medical technology accessibility. Our brace aims to overcome the systemic barriers blocking patients from TKR. Partnerships with clinics, subsidized pricing, and home delivery will alleviate financial and geographic barriers. Simple, user-friendly design will enhance accessibility for patients with limited healthcare literacy, language barriers, hand mobility, or visual impairments. OPUS feedback will guide design improvements, while demographic data will help identify and resolve usage disparities.

With optimized user-friendliness and distraction mechanics, the Adonis[®] brace offloads knee stress without the rigidity of traditional three-point unloader braces. If successful, it could provide an accessible, non-invasive alternative to knee distraction surgery, delaying or reducing the need for surgical implant interventions like TKR while addressing systemic barriers that disproportionately impact underserved and marginalized communities.

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