

Research Article

Utilization of a 3D Printed Customized Knee Extender Device and An At-Home Video Rehabilitation Program on Patient Outcomes in Rural Areas Following ACL Surgery

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d Clinical research isn't just what Eleanor Gibbons does—it's what she is passionate about. For two decades, she has had the privilege of contributing to studies that advance science, improve care, and ultimately change lives.

With 20 years of experience spanning research coordination, regulatory oversight, and operations leadership, Eleanor has built her career around two driving forces: excellence in research execution and a deep commitment to people—the patients she serves and the professionals who make this work possible.

Currently, she manages a team of approximately 30 Clinical Research Coordinators at Sanford Health, where she focuses on developing staff, streamlining processes, and ensuring every study meets the highest ethical and operational standards. She also serves as adjunct faculty for the University of South Dakota's Clinical Research Coordinator Certificate Program, sharing her experience with the next generation of research professionals.

Eleanor is passionate about mentoring, building strong teams, and creating research environments that are not only compliant and efficient—but also compassionate, innovative, and sustainable.

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Background

Physical therapy is a critical component of postoperative rehabilitation after ACL surgery. However, access to formal physical therapy is not universal, and patients who do not receive adequate rehabilitation may experience worse postoperative outcomes. The primary objective of this study was to evaluate whether the addition of a low-cost, desktop 3D-printed knee extension device and at-home video program led to an increased rate of obtaining full knee extension following anterior cruciate ligament reconstruction in the early postoperative period.

Hypothesis/Purpose:

We hypothesized that there would be no difference in the percentage of patients achieving full knee extension by six weeks or in overall knee range of motion between the study and control groups. Secondary outcomes included device compliance, device issues, knee effusion, pain levels, usage characteristics, and skin/wound reactions.

Methods

This was a prospective, randomized, controlled pilot study. 32 participants aged 15–48 years with primary ACL ruptures were enrolled and randomized into two groups: a control group that received standard postoperative physical therapy rehabilitation, and an experimental group that received the same rehabilitation supplemented with a knee extension device and an at-home, video-guided exercise program. Patients were assessed over a 6-week postoperative period, recording knee circumference, range of motion, pain scores, time to full extension, safety, and device-related issues. Categorical variables were analyzed using chi-squared tests, and continuous variables were analyzed using t-tests and ANOVA.

Results

There were no differences between groups in six-week knee range of motion, knee circumference, pain scores, or time to full knee extension. Although a greater proportion of patients in the experimental group achieved full extension by Week 2, this difference was not statistically significant ($p = 0.70$). No adverse outcomes were reported in either group.

Conclusion

Overall, there were no statistically significant differences in outcomes between the control and study group. This study found that incorporating an at home video program and a custom low-cost desktop 3D printed knee sling into the postoperative ACL rehabilitation was safe, utilized appropriately, and had excellent patient compliance.

INTRODUCTION

Physical therapy is a critical component of postoperative rehabilitation after anterior cruciate ligament reconstruction (ACL-R) surgery. A comprehensive rehabilitation protocol allows patients to have a gradual and controlled return to activities over time. ACL-R recovery is typically between 9–12 months to return to athletic activity. Missed milestones or delayed progress in this timeline are not optimal and can be a source of frustration and decreased outcomes for patients and their care team. With a multidisciplinary team approach and regular follow-up with medical staff, these setbacks can be identified early and addressed. However, access to physical therapy after ACL-R is limited

in many parts of the world, including global care areas and rural areas of the United States. Patients who do not receive physical therapy are at risk of worse outcomes and/or delays to full recovery. With an estimated 150,000 to 250,000 ACL injuries occurring annually in the United States alone, this disparity in care warrants exploration.

The early stages of the rehabilitation protocol can present a struggle for many patients, as postoperative pain and inflammation discourage stretching and exercising, leading to difficulty attaining full knee motion. However, the importance of meeting these goals is critical, as poor or delayed therapy can lead to loss of knee motion (Capin et al. 2019; Cronström et al. 2023; Joreitz et al. 2016; Kotsifaki et al. 2023; Mauro et al. 2008; Shelbourne and Gray 1997; Shelbourne and Klotz 2006). Loss of motion is a potentially

debilitating complication following ACL-R, with loss of extension being more common than loss of flexion (Mauro et al. 2008). Inability to regain full extension in the early postoperative period can increase the difficulty of progressing in rehabilitation. Furthermore, inability to obtain full knee extension can cause patients to walk with a bent-knee gait, increasing quadriceps strain and increasing patellofemoral joint contact forces, which can lead to quadriceps weakness, fatigue, and patellofemoral pain (Mauro et al. 2008; Sachs et al. 1989). In addition, loss of knee extension after ACL-R has been associated with development of cyclops lesions within the intercondylar notch of the knee, a significant cause for reoperation (Delaloye et al. 2020; Moran et al. 2023).

In an ideal postoperative course, patients would be regularly seen by a multidisciplinary team. There are regions of the globe where patients do not have access to this type of care. To provide appropriate postoperative care for these patients, an alternative to formal physical therapy must be developed. For some, a home exercise program combined with periodic visits with the surgical team is the solution. For others, a solution could be explored with telerehabilitation or an at-home video rehabilitation program (Dunphy and Gardner 2020). The goals of any effective alternative solution would be to provide guidance, encourage proper exercise technique, and set attainable milestones in order to track rehabilitation progress. This solution would have to be readily available, low in cost to the patient and the treatment team, and simple to use. Additionally, to facilitate and standardize a rehabilitation program, it would benefit medical specialists to have standardized medical devices that can help facilitate the telerehabilitation process remotely.

3D printing technologies are rapidly expanding throughout medicine and in the field of orthopaedics. They offer a potential solution to healthcare disparities with the ability to create standardized devices that can be distributed into rural and remote locations. Low-cost desktop 3D printers are becoming more readily available and can be utilized in outpatient and rural clinical sites with minimal training. This technology has the potential to enable rapid, customized development of medical devices to improve patient care and facilitate treatments. There is significant research supporting the importance of postoperative physical therapy; however, there is no literature exploring the use of a desktop 3D printed knee sling to facilitate or be incorporated into physical therapy programs. This application requires further research and study before widespread clinical application.

The purpose of this study was to evaluate whether the addition of a low-cost, desktop 3D printed knee extension device and an at-home video program led to an increased rate of obtaining full knee extension following anterior cruciate ligament reconstruction (ACL-R) in the early postoperative period. We hypothesized that there would be no difference in the primary outcomes of knee extension and flexion motion between the study and control groups. Secondary outcomes included assessing device compliance, de-

vice issues, knee effusion, pain levels, usage characteristics, and skin/wound reactions.

MATERIALS AND METHODS

This prospective, multi-center, randomized, clinical trial pilot study enrolled 32 participants (16 per group) aged 15–48 years with primary ACL ruptures. This study was conducted at two hospital sites located in rural areas of the United States in 2025. Institutional Review Board approval was obtained for this study. Participants were randomized into two groups: a control group that received standard postoperative physical therapy rehabilitation, or an experimental group that received the same rehabilitation supplemented with a 3D printed knee extension device and an at-home, video-guided exercise program. The devices were provided to the experimental group at no cost.

Outcomes were assessed over a 6-week period following ACL reconstruction. Clinical assessments with knee range of motion and circumference measurements occurred at the time of surgery (baseline), at 2 weeks postoperatively, and at 6 weeks postoperatively. A blinded study team member measured knee circumference at the top of the patella, maximum active knee flexion, and maximum knee extension using a flexible tape measure and a goniometer. Data collection included additional weekly surveys to assess compliance, safety, pain scores, time to full knee extension, and device-related issues. Full knee extension was verified using a quantifiable audible mechanical “click” device placed under the knee; engagement of the click indicated successful full extension.

The 3D printed knee device used in the experimental group was designed for universal fit to support the physical therapy regimen. The author team designed the knee sling over a 6-month period using Fusion 360 (Version 2.0.15995, Autodesk Inc., San Francisco, CA). Each device was fabricated at the orthopaedic clinic using a desktop 3D printer and flexible thermoplastic polyurethane (TPU) at a cost of \$7.60 USD per device. The printer used for making the devices was a PRUSA MK3S+ (purchased for \$600 USD). The knee extension device consisted of a pad positioned over the knee with a suspended basket beneath it. A fully completed device could be generated with three printing files (Figure 1 & Figure 2). The basket accommodated standard water bottles (1lb/bottle) to apply a downward force, facilitating full knee extension. A 3D-printed foot holder maintained proper leg alignment during passive stretching (Figure 3). Water bottles acted as standard and reproducible weights. The basket allowed for scalability with multiple water bottle attachment points in the bottom of the basket as well as a space in the basket for placement of additional bottles.

Statistical analyses were performed using chi-squared tests for categorical variables and t-tests and ANOVA for continuous variables. Sample size calculations were conducted. While pilot data was not available for sample size calculation, effect sizes were estimated for the analysis. For non-inferiority analysis, we assumed a response rate in the control arm and experimental arm of 0.7 and 0.5 respec-

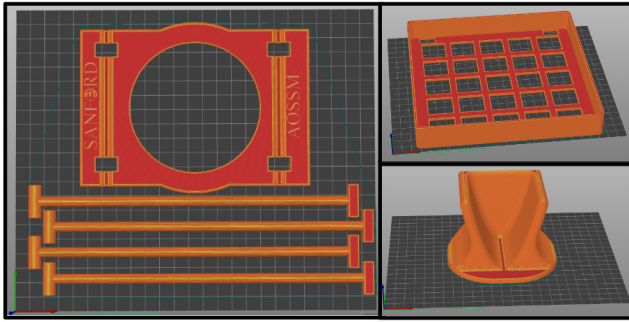


Figure 1. 3D models prepped for printing. In the setup used by the authors, all pieces necessary for a complete knee sling device were able to be completed in three prints.

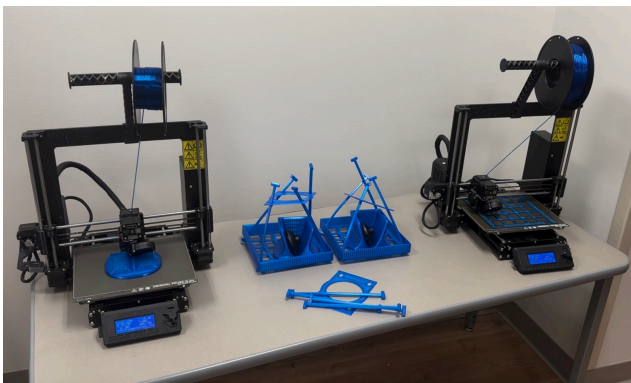


Figure 2. 3D printing setup with finished and partially completed knee devices.

tively with a delta of 0.2, $\alpha = 0.05$, and $\beta = 0.2$, demonstrating a total of 26 patients needed for statistical power of 80%. A higher sample size of 28 was selected, split equally into the two study groups, with 14 in each group. With an anticipated dropout rate of 50% enrollment was planned up to 56 participants, but this was unnecessary as none of our enrolled patients dropped from the trial. Final enrollment was 32 participants with 16 in each group.

RESULTS

Baseline demographic characteristics demonstrated no statistically significant differences between the control and experimental groups, confirming comparability between cohorts ($p = 0.72$) (Table 1). There were no statistically significant differences between groups in any primary or secondary outcome measures over the study period. However, several noteworthy trends were identified.

More patients in the experimental group reached full extension by Week 2, but this was not statistically significant ($p=0.70$). By the 6-week assessment, both groups had achieved comparable extension outcomes (Figure 4).

Postoperative swelling, as reflected by increased knee circumference, was evident at the 2-week postoperative visit, consistent with expected inflammatory response following ACL reconstruction. Knee circumference measure-



Figure 3. *Top Left:* Assembled knee extension device with water bottles attached as weight. *Top Right:* Foot holder. *Bottom:* Knee extension device in use with weight suspended under the knee.

ments in both groups trended toward a return to baseline by the 6-week time point ($p = 0.71$). Both groups experienced a statistically significant reduction in knee range of motion at the 2-week postoperative visit ($p < 0.01$), reflecting early postoperative stiffness, followed by a statistically significant improvement to near-baseline levels by the 6-week visit ($p < 0.01$) (Figure 5).

Pain trajectory also differed between groups. Participants in the experimental group reported higher initial pain scores which subsequently declined more rapidly than in the control group. By the final assessment, mean pain scores in the experimental group were lower than those in the control cohort, suggesting a potential benefit of the experimental protocol, although the difference was not statistically significant ($p = 0.19$). Pain scores in the control group remained stable throughout the 6-week study period (Figure 6).

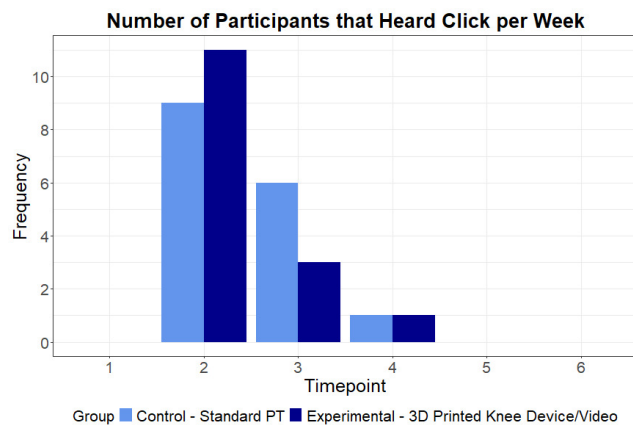
Notably, no adverse events or device-related complications were reported during the study. Device compliance among participants in the experimental group was high, with all participants reporting regular use as prescribed. No device malfunctions, structural failures, or issues with component integrity occurred. Furthermore, no patients experienced wound irritation, skin breakdown, or discomfort at incision sites related to the device's points of contact.

DISCUSSION

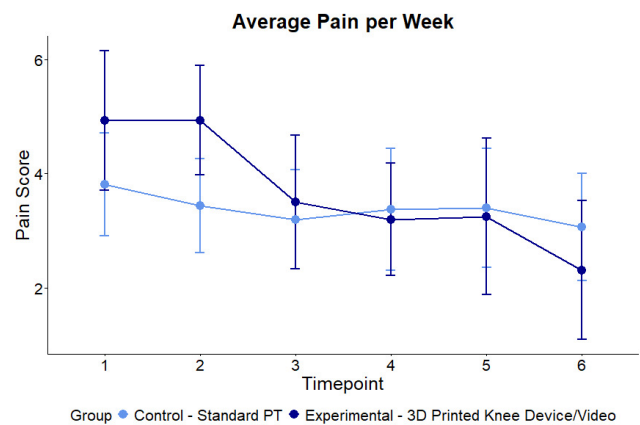
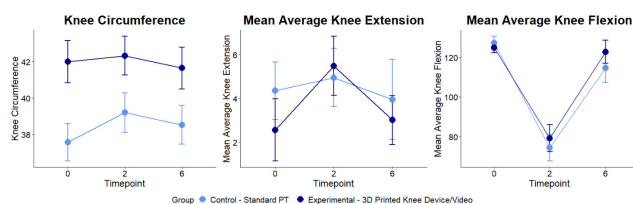
This prospective, randomized pilot study evaluated the safety, feasibility, and preliminary efficacy of adding a low-cost 3D printed knee extender device used in conjunction

Table 1. Demographic information.

		Control (n=16)	Experimental (n=16)	P-value
Age	Mean (SD)	19.4 (4.16)	23.9 (9.54)	0.0987
	Median [Min, Max]	17.5 [15.0, 29.0]	19.5 [15.0, 48.0]	
Gender	Female	7 (43.8%)	9 (56.3%)	0.724
	Male	9 (56.3%)	7 (43.8%)	
Race	White	16 (100%)	16 (100%)	1
Ethnicity	Hispanic or Latino	0 (0%)	1 (6.3%)	1
	Non-Hispanic	16 (100%)	15 (93.8%)	
Region	Fargo	10 (62.5%)	10 (62.5%)	1
	Sioux Falls	6 (37.5%)	6 (37.5%)	
Affected Knee	Left	6 (37.5%)	9 (56.3%)	0.479
	Right	10 (62.5%)	7 (43.8%)	
Smoking Status	Former	0 (0%)	1 (6.3%)	1
	Never	16 (100%)	15 (93.8%)	
Diabetes Status	Non-Diabetic	16 (100%)	16 (100%)	1
Work Status	Full time	2 (12.5%)	5 (31.3%)	0.17
	Minor	9 (56.3%)	4 (25.0%)	
	Student Full time	5 (31.3%)	7 (43.8%)	
Athletic Status Category	No	3 (18.8%)	6 (37.5%)	0.432
	Yes	13 (81.3%)	10 (62.5%)	

**Figure 4. Full knee extension achieved by timepoint.**

More patients in the experimental group were able to create the 'click' sound using the testing device under the knee to assess for full knee extension before the control group; however, this finding was not statistically significant ($p = 0.70$).

**Figure 6. Pain associated with using the 3D-printed device was well controlled throughout the study period.****Figure 5. Knee measurements at the time of surgery (time 0), 2 weeks postop, and 6 weeks postop. No significant differences were noted between groups.**

with a structured, video-guided home rehabilitation program to formal physical therapy following ACL reconstruction. Although no statistically significant differences were observed between the experimental and control groups, several clinically meaningful trends emerged that support further investigation.

Participants utilizing the 3D printed knee sling demonstrated a tendency toward earlier achievement of full knee extension compared to those receiving standard physical therapy alone. Restoration of full extension is a critical milestone in postoperative ACL rehabilitation, as early deficits are associated with poorer long-term functional outcomes. The earlier return to full extension observed in

the experimental group, even if not statistically significant in this pilot study, suggests that the device may provide an effective adjunct to conventional therapy by promoting consistent passive extension and patient engagement outside of formal therapy sessions.

Pain patterns also differed between groups. The experimental group reported higher pain scores initially but experienced a more rapid decline in pain by six weeks, ultimately demonstrating lower average pain scores than the control group. This pattern may reflect improved pain related to earlier full extension and decreased stiffness. Improved knee extension may reduce compensatory strain and contribute to pain reduction over time. These findings align with prior studies emphasizing the relationship between early motion restoration and improved comfort and functional outcomes following ACL reconstruction (Gage et al. 2019; Månsson et al. 2013; McHugh et al. 1998; Shaarani et al. 2013; de Valk et al. 2013).

Both groups exhibited increased knee circumference at the first postoperative visit, consistent with expected post-surgical effusion and edema. The subsequent reduction to near-baseline circumference by six weeks suggests that neither group's treatment regimen exacerbated the inflammation more than the other. Similarly, range of motion demonstrated the expected postoperative course with an initial decrease followed by significant recovery by the 6-week follow-up. This further confirmed that the experimental protocol was safe and did not impair or worsen the rehabilitation process compared to standard physical therapy.

Importantly, no adverse events or device-related complications were reported. The 3D-printed knee sling was well-tolerated with no noted issues with skin breakdown, incisional irritation, or mechanical failure. High participant compliance each week underscores the practicality of the design and feasibility of incorporating 3D-printed devices into early rehabilitation protocols. The total material cost of \$7.60 per device in TPU filament and the accessibility of desktop 3D printing technology highlight the device's potential to provide affordable, readily accessible rehabilitation tools to patients. The TPU material could be chemically sterilized and reused on other patients, however, in

our study, all patients utilized new devices in the study population. This reusability application, however, is especially valuable in rural or resource-limited settings where access to rehabilitation may be limited.

Several limitations should be acknowledged. As a pilot trial with a small sample size, the study was not adequately powered to detect small, but potentially statistically significant differences that are present in a large population. Additionally, this study was limited to a six-week postoperative period. This captured data from the short-term postoperative period does not provide insight into long term outcomes. Both populations received standard physical therapy to prevent any safety issues or adverse outcomes. However, a future study to measure the effect of a telerehabilitation protocol with the 3D printed knee sling in comparison to standard physical therapy will better assess the clinical impact of these treatments. Similarly, longer-term assessment of function, strength, and patient-reported outcomes would provide a more comprehensive understanding of the device's potential benefits. Finally, while compliance was self-reported and appeared high, objective monitoring of device usage would strengthen future analyses.

Despite these limitations, this study supports the safety, feasibility, and potential utility of adding a customized, low-cost, desktop 3D-printed knee device and at-home video rehabilitation program as an adjunct to traditional ACL rehabilitation. The observed trends toward earlier extension, faster pain resolution, and high user satisfaction warrant further exploration and standardization to assess clinical significance and explore the broader implications of custom 3D-printed technologies. Future work should explore the use of the knee extension device and the home video-guide rehabilitation program in isolation compared to traditional rehabilitation, as this would be more applicable to rural and resource-limited settings.

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SUPPLEMENTARY MATERIALS

Table 1: Demographics

Download: <https://journaloei.scholasticahq.com/article/162884-utilization-of-a-3d-printed-customized-knee-extender-device-and-an-at-home-video-rehabilitation-program-on-patient-outcomes-in-rural-areas-following-a-attachment/352532.xlsx>

Figure 1

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Figure 2

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Figure 3

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Figure 4

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Figure 5

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Figure 6

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Video

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