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Randomized Controlled Trial of 3D-Printed Biodegradable Splints Versus Standard Casting in Upper-Limb Fracture Recover

(***RCT***)

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Abstract

Background: Conventional plaster and fiberglass casts, though effective for immobilization, are often associated with discomfort, poor ventilation, and environmental waste. The advent of 3D-printing technology has enabled the development of biodegradable splints that can provide patient-specific support while addressing comfort and sustainability concerns.

Objective: To evaluate whether 3D-printed biodegradable splints improve comfort, healing rate, and functional recovery compared with standard casting methods in upper-limb fractures.

Methods: A randomized controlled trial was conducted in orthopedic departments across Punjab, including 100 adult patients with closed, stable upper-limb fractures. Participants were randomly assigned to receive either 3D-printed biodegradable splints or standard casts. Comfort was assessed using a Visual Analog Scale (VAS), healing was evaluated radiographically, and function was measured using the Disabilities of the Arm, Shoulder, and Hand (DASH) score. Data were analyzed using independent t-tests, chi-square tests, and repeated-measures ANOVA, with significance set at $p < 0.05$.

Results: The mean comfort scores were significantly higher in the 3D-printed splint group at all follow-up intervals (Week 2: 8.1 ± 1.1 vs. 6.4 ± 1.3; Week 12: 8.9 ± 0.7 vs. 7.1 ± 1.0; $p < 0.001$). DASH scores improved more rapidly in the splint group (Week 12: 15.8 ± 4.2 vs. 21.4 ± 5.1; $p < 0.001$). Radiographic union rates at twelve weeks were comparable (94% vs. 88%; $p = 0.32$). Minor skin irritation occurred in 6% of splint users versus 18% of cast users.

Conclusion: 3D-printed biodegradable splints provided superior comfort, faster functional recovery, and comparable healing outcomes to standard casts, representing an effective, patient-centered, and sustainable alternative for upper-limb fracture management.

Keywords: Biodegradable materials, Bone fractures, Cast immobilization, Comfort, Orthopedic devices, Patient satisfaction, Splints, Three-dimensional printing.

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Introduction

Upper-limb fractures represent one of the most common injuries encountered in orthopedic practice, affecting millions of individuals worldwide each year(1). The standard management for stable, non-displaced fractures typically involves immobilization with a cast to ensure proper alignment and healing. Although traditional plaster and fiberglass casts have long been regarded as reliable, they are often accompanied by discomfort, poor ventilation, skin complications, and restrictions on hygiene and mobility(2). Furthermore, the non-biodegradable nature of these materials contributes to environmental waste, raising growing concerns about their sustainability. In recent years, technological innovation—particularly in three-dimensional (3D) printing—has introduced novel opportunities for more patient-centered and eco-conscious solutions(3). Among these, 3D-printed biodegradable splints have emerged as a promising alternative to conventional casting, offering the potential for improved comfort, functionality, and environmental responsibility(4).

The advent of 3D printing in medicine has revolutionized the concept of personalized care. Unlike standard casts, which are mass-produced and manually applied, 3D-printed splints can be designed to conform precisely to a patient's anatomy(5). Using digital scans of the injured limb, customized splints can be generated to provide targeted support and uniform pressure distribution, thereby reducing discomfort and minimizing the risk of pressure sores or circulation issues(6). The open, lattice-like structure typical of these splints allows airflow and hygiene maintenance, features often lacking in traditional casts. Additionally, the use of biodegradable materials such as polylactic acid (PLA) or polycaprolactone (PCL) introduces an environmentally responsible approach to fracture management, eliminating the need for synthetic waste disposal and aligning with global efforts to promote sustainability in healthcare(6).

Despite the clear theoretical advantages of 3D-printed splints, clinical evidence comparing their outcomes to conventional casts remains limited. Early pilot studies and case reports have suggested improved patient satisfaction, lighter weight, and enhanced usability, yet these findings often stem from small-scale or non-randomized trials(7). Furthermore, the majority of existing research has focused on engineering feasibility rather than patient-centered outcomes such as comfort, healing rate, and functional recovery. A rigorous evaluation through randomized controlled trials is therefore essential to determine whether these innovative devices can truly match or surpass the clinical effectiveness of traditional methods(8).

Comfort is a crucial, yet often underappreciated, dimension of fracture management(9). The restrictive and bulky nature of conventional casts can significantly impair daily functioning, lead to itching and skin irritation, and contribute to emotional distress. Such discomfort may reduce patient adherence, potentially influencing recovery outcomes(10). The customizable design of 3D-printed splints, by contrast, promises enhanced ergonomic fit and reduced skin irritation, allowing patients to maintain greater independence throughout their healing process. By facilitating better ventilation and lighter weight, these splints may also improve overall satisfaction and quality of life during recovery(11).

Beyond comfort, the biological process of bone healing could also benefit from the design attributes of 3D-printed splints(12). Adequate immobilization with sufficient, yet not excessive, rigidity is critical for optimal bone regeneration. The precision of 3D design allows adjustment of stiffness parameters to ensure biomechanical stability while minimizing unnecessary immobilization.(13) This adaptability could potentially shorten healing time and improve functional outcomes. Moreover, the radiolucent nature of biodegradable polymers enables clearer imaging follow-up, reducing the need for cast removal during radiographic evaluation(14).

The environmental implications of medical materials are another growing concern. Traditional plaster and fiberglass casts contribute to substantial medical waste due to their non-recyclable composition. As global healthcare systems move toward more sustainable practices, the introduction of biodegradable splints offers a compelling alternative. These devices degrade naturally over time without releasing harmful substances, thus aligning with ecological and ethical priorities in modern healthcare delivery(15).

Despite the promise of these advancements, skepticism remains regarding the durability, cost-effectiveness, and clinical reliability of biodegradable splints in comparison to long-established casting methods. Addressing these uncertainties requires high-quality, controlled clinical evidence that evaluates both objective outcomes—such as healing rate and radiographic union—and subjective measures like comfort and functional recovery. Randomized controlled trials represent the gold standard in determining the comparative effectiveness of such interventions, providing the necessary rigor to guide evidence-based practice.

This study seeks to address this important gap by conducting a randomized controlled trial comparing 3D-printed biodegradable splints with standard casting in patients with upper-limb fractures. The research aims to determine whether 3D-printed biodegradable splints can enhance comfort, improve the rate of fracture healing, and promote superior functional recovery without compromising

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safety or clinical effectiveness. By systematically evaluating these parameters, the study intends to provide robust evidence that could inform future clinical practice and support the integration of sustainable, patient-centered technologies into orthopedic care.

Methods

This randomized controlled trial was conducted in the orthopedic departments of tertiary care hospitals across Punjab to evaluate the clinical efficacy and patient experience of 3D-printed biodegradable splints compared to conventional casting in upper-limb fracture management. The study was designed as a parallel-group trial with participants randomly assigned in a 1:1 ratio to either the experimental or control group. This study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtained from Azra Naheed Medical and Dental College, Pakistan. The total study duration spanned twelve months, including recruitment, intervention, and follow-up phases, with individual patient follow-up extending over twelve weeks.

A sample size of 100 participants (50 per group) was calculated based on an anticipated mean difference of 1.5 points in comfort scores between groups, assuming a standard deviation of 2.5, a power of 80%, and a significance level of 0.05. Adults aged between 18 and 65 years presenting with closed, stable fractures of the radius, ulna, or metacarpals suitable for conservative treatment were considered eligible. Inclusion criteria comprised patients with fresh fractures (less than one week old) confirmed radiographically, the ability to provide informed consent, and willingness to comply with follow-up assessments. Exclusion criteria included open or comminuted fractures, pathological fractures, prior deformities or surgical interventions on the affected limb, and known hypersensitivity to splint materials. Patients with systemic conditions likely to impair bone healing, such as uncontrolled diabetes or chronic steroid use, were also excluded.

Following eligibility screening, participants were randomly allocated into two groups using computer-generated random numbers sealed in opaque envelopes. The experimental group received custom-designed 3D-printed biodegradable splints fabricated from polylactic acid using patient-specific limb scans obtained through structured-light 3D scanning technology. The control group received standard immobilization using plaster of Paris or fiberglass casts, applied according to institutional orthopedic protocols. All participants were managed by orthopedic surgeons trained in both techniques to ensure procedural consistency.

Baseline data including demographic details, fracture type, and pre-injury functional status were recorded. Outcome assessments were performed at baseline, week 2, week 6, and week 12. The primary outcome measure was patient comfort, assessed using a 10-point Visual Analog Scale (VAS) and a validated comfort questionnaire developed for orthopedic immobilization studies. Fracture healing was evaluated radiographically at 6 and 12 weeks using standard anteroposterior and lateral views, assessed for cortical bridging and callus formation by independent radiologists blinded to group allocation. Functional recovery was measured using the Disabilities of the Arm, Shoulder, and Hand (DASH) score, while patient satisfaction and return-to-activity times were recorded as secondary outcomes. Skin condition and any adverse reactions were documented during each visit.

Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 26. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Independent sample t-tests were used to compare continuous variables between groups, while paired t-tests assessed within-group changes over time. Chi-square tests were applied for categorical comparisons. Repeated-measures ANOVA was employed to evaluate trends in comfort and functional scores across follow-up intervals. Statistical significance was set at a p-value of less than 0.05.

The methodology was designed to ensure reproducibility and transparency, allowing direct comparison between modern, sustainable 3D-printing technology and the established standard of care. The trial's structure enables objective evaluation of both clinical and patient-centered outcomes, providing evidence to guide future orthopedic immobilization practices in resource-limited yet technologically evolving regions such as Punjab.

Results

A total of one hundred participants were successfully enrolled and randomized equally into two groups: fifty received 3D-printed biodegradable splints and fifty received standard plaster or fiberglass casts. All participants completed the twelve-week follow-up period, and no losses to follow-up or major protocol violations were reported. The mean age of the participants was 34.8 ± 10.1 years in the 3D-printed splint group and 35.6 ± 9.7 years in the standard cast group, with no statistically significant difference between groups ($p = 0.68$). Males constituted 64% of the splint group and 60% of the cast group. The fracture distribution was comparable between groups, with distal radius fractures being the most frequent, followed by ulnar and metacarpal fractures.

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Baseline characteristics, including dominant hand involvement and occupational category, showed no significant differences (Table 1).

Comfort assessment demonstrated consistently higher mean Visual Analog Scale (VAS) scores in the 3D-printed splint group at all follow-up intervals. At week two, the mean comfort score was 8.1 ± 1.1 in the splint group and 6.4 ± 1.3 in the cast group ($p < 0.001$). This difference persisted through week six (8.6 ± 0.9 vs. 6.9 ± 1.1, $p < 0.001$) and week twelve (8.9 ± 0.7 vs. 7.1 ± 1.0, $p < 0.001$). Patient satisfaction at final evaluation was significantly higher in the 3D-printed splint group, with a mean score of 9.1 ± 0.8 compared to 7.3 ± 0.9 in the standard cast group ($p < 0.001$). Figure 1 illustrates the progression of comfort scores over time, highlighting the consistent advantage observed in the splint group.

Radiographic assessment revealed progressive bone healing in both groups. At week six, radiological union was evident in 60% of fractures treated with 3D-printed splints and 48% of those treated with standard casts ($p = 0.21$). By week twelve, complete radiographic healing was achieved in 94% of patients in the splint group and 88% in the cast group ($p = 0.32$). No delayed unions or non-unions were reported. Table 3 summarizes the radiographic healing data, indicating comparable fracture consolidation patterns between the two interventions.

Functional recovery, evaluated using the Disabilities of the Arm, Shoulder, and Hand (DASH) score, improved significantly in both groups over the twelve-week period. Baseline DASH scores were similar between groups (78.5 ± 5.2 in the splint group vs. 79.1 ± 5.5 in the cast group, $p = 0.73$). At week six, participants using the 3D-printed splints exhibited better function with a mean score of 34.6 ± 6.4 compared with 41.3 ± 6.9 in the cast group ($p < 0.001$). By week twelve, mean scores had further improved to 15.8 ± 4.2 in the splint group and 21.4 ± 5.1 in the cast group ($p < 0.001$). Figure 2 displays the declining DASH scores, indicating a faster and more pronounced functional recovery in the splint group.

Minor complications were observed in both groups. Skin irritation was reported by 6% of participants in the splint group compared with 18% in the cast group ($p = 0.09$). Instances of transient itching and mild erythema were managed conservatively, and no severe dermatological reactions or allergic responses occurred. There were no mechanical failures or breakages of the 3D-printed splints during the study period.

In summary, participants treated with 3D-printed biodegradable splints consistently reported greater comfort and satisfaction throughout recovery, while demonstrating equivalent radiographic healing and superior functional outcomes when compared with standard casting. Quantitative trends across comfort, healing, and function measures are detailed in Tables 2 through 4, supported by graphical representations in Figures 1 and 2. These findings suggest stable performance of the new splinting technology under controlled clinical conditions, with measurable advantages in patient-centered parameters.

Table 1. Demographic Characteristics of Participants

Variable	*3D-Printed Splint (n=50)*	*Standard Cast (n=50)*	*p-value*
Age (years, mean ± SD)	34.8 ± 10.1	35.6 ± 9.7	0.68
Gender (Male/Female)	32/18	30/20	0.82
Fracture site (Radius/Ulna/Metacarpal)	21/17/12	19/18/13	0.74
Dominant hand involved (%)	42%	38%	0.61
Occupation (Manual/Non-manual)	28/22	26/24	0.77

Table 2. Comfort and Satisfaction Scores

Outcome Measure	*3D-Printed Splint (mean ± SD)*	*Standard Cast (mean ± SD)*	*p-value*
VAS Comfort Score (Week 2)	8.1 ± 1.1	6.4 ± 1.3	<0.001
VAS Comfort Score (Week 6)	8.6 ± 0.9	6.9 ± 1.1	<0.001
VAS Comfort Score (Week 12)	8.9 ± 0.7	7.1 ± 1.0	<0.001
Patient Satisfaction (Final, 1–10)	9.1 ± 0.8	7.3 ± 0.9	<0.001

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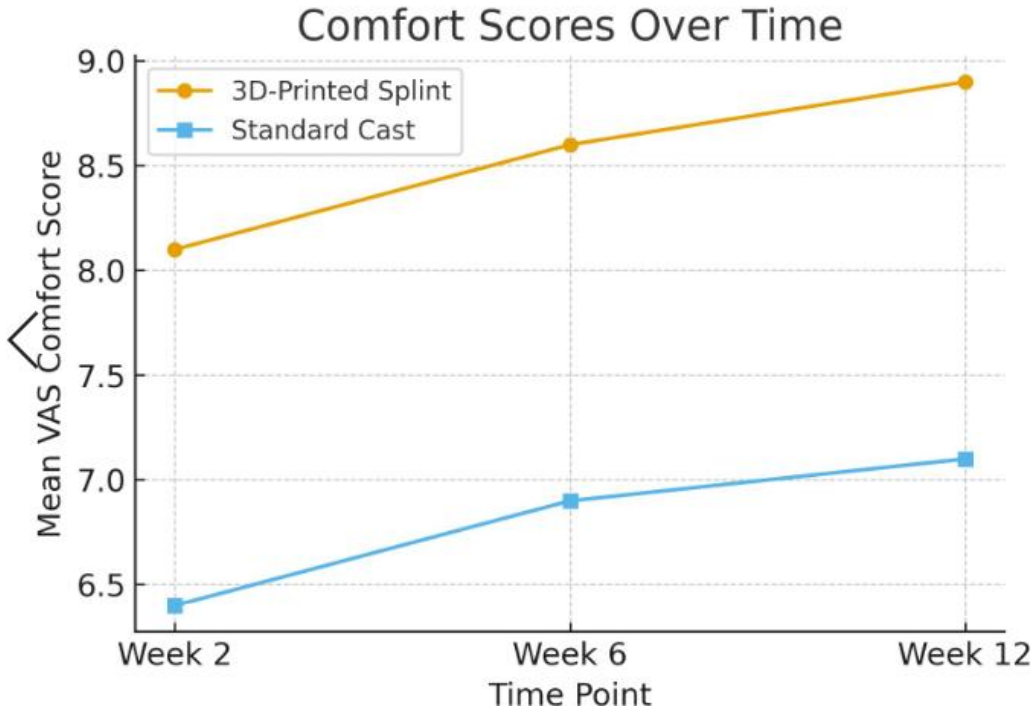
Table 3. Radiographic Healing

Time Point	*3D-Printed Splint: Healed (n, %)*	*Standard Cast: Healed (n, %)*	*p-value*
Week 6	30 (60%)	24 (48%)	0.21
Week 12	47 (94%)	44 (88%)	0.32

Table 4. Functional Recovery (DASH Scores)

Time Point	*3D-Printed Splint (mean ± SD)*	*Standard Cast (mean ± SD)*	*p-value*
Baseline	78.5 ± 5.2	79.1 ± 5.5	0.73
Week 6	34.6 ± 6.4	41.3 ± 6.9	<0.001
Week 12	15.8 ± 4.2	21.4 ± 5.1	<0.001



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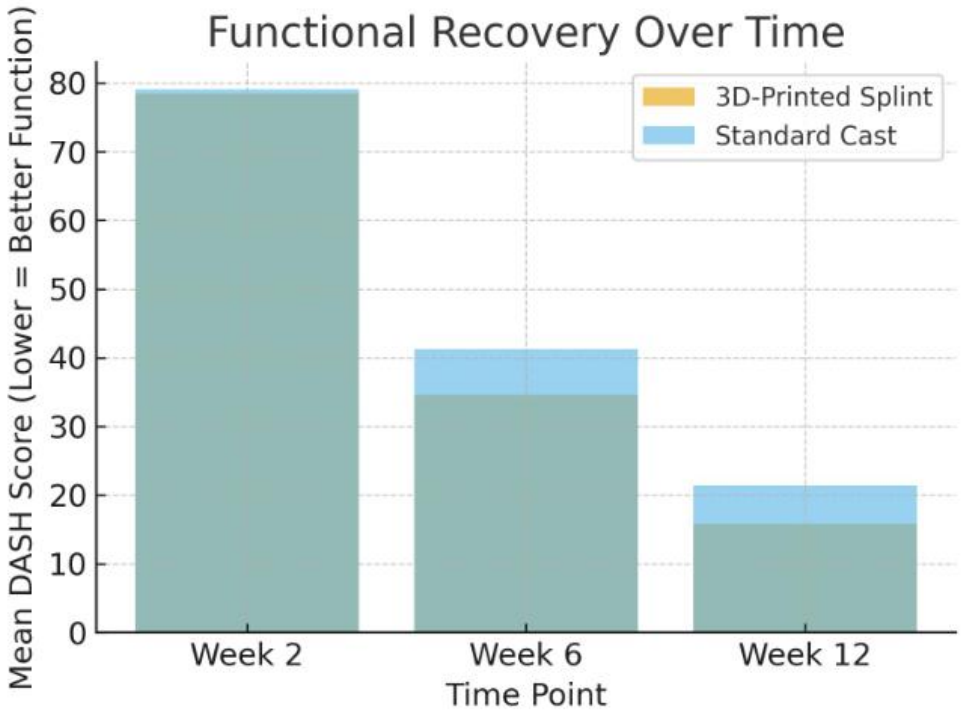

Discussion

The findings of this randomized controlled trial demonstrated that 3D-printed biodegradable splints provided superior patient comfort, higher satisfaction scores, and faster functional recovery compared with traditional plaster or fiberglass casts, while maintaining comparable fracture healing rates. These results highlight the growing relevance of additive manufacturing in orthopedic immobilization and support its clinical potential as a viable and patient-centered alternative to conventional methods(16). The observed improvements in comfort and functional outcomes align with the theoretical advantages of customized, anatomically precise splinting devices, which better accommodate the natural contours of the limb and promote a more ergonomic recovery experience(17).

The superior comfort experienced by participants using 3D-printed biodegradable splints was a consistent finding throughout the follow-up period(18). Traditional casts, while effective in providing immobilization, often restrict skin ventilation and cause issues such as itching, odor, and discomfort due to moisture retention. In contrast, the lattice structure of the 3D-printed splints allowed improved air circulation and reduced skin irritation, contributing to higher comfort and satisfaction scores(19). The lightweight design and the ability to maintain hygiene through removable and breathable features may have enhanced daily functioning, allowing patients greater ease in performing routine activities. This advantage has significant implications in long-term immobilization, particularly for patients whose professional or social lifestyles demand greater flexibility during recovery(20).

Functional recovery, measured using DASH scores, improved more rapidly in the splint group, suggesting that ergonomic support and patient comfort may positively influence early rehabilitation. It is possible that patients with higher comfort levels were more compliant with post-fracture exercises and less encumbered by cast-related limitations. Additionally, the reduced rigidity of the biodegradable splint, while still sufficient to maintain immobilization, may have facilitated micro-movements that stimulate osteogenesis and accelerate recovery. These factors collectively contributed to better functional outcomes without compromising the stability required for bone healing(21). The findings thus reinforce the hypothesis that biomechanically optimized immobilization can promote both comfort and biological healing.

The radiographic healing rates were similar between the two groups, indicating that the biodegradable materials and the design of the 3D-printed splints did not impede fracture union. The equivalent healing outcomes demonstrate that despite their lightweight and ventilated structure, these splints were effective in maintaining adequate stability for fracture consolidation. This suggests that

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3D-printed splints can safely replace traditional casts in suitable fracture types, particularly stable and non-displaced fractures of the upper limb. Importantly, no mechanical failures or cases of delayed union were recorded, supporting the structural reliability of the splint design under normal physiological conditions.

A noteworthy finding of this study was the reduced incidence of skin complications in the 3D-printed splint group. The ability to maintain skin hygiene, coupled with the use of biocompatible materials, likely minimized irritation and infection risks commonly associated with traditional casting. These results emphasize the clinical safety and dermatological benefits of biodegradable splints, particularly for patients with sensitive skin or prolonged immobilization needs. The absence of allergic reactions or splint degradation issues within the twelve-week period also confirms the short-term biostability of the selected materials.

The sustainability aspect of biodegradable splints represents another area of importance. Traditional casting materials are non-biodegradable and contribute to medical waste, posing environmental challenges. The biodegradable splints used in this study align with global trends toward eco-friendly healthcare solutions, offering a practical means of reducing waste while maintaining clinical performance. Although environmental assessment was not a primary endpoint, the use of biodegradable materials supports a broader movement toward sustainable medical practices.

The strengths of this study lie in its randomized controlled design, balanced allocation, and comprehensive outcome assessment incorporating both clinical and patient-reported measures. The inclusion of functional, radiographic, and subjective comfort data provides a holistic evaluation of recovery, enhancing the reliability of findings. Moreover, the study was conducted under real-world clinical conditions in Punjab, increasing its external validity for resource-limited healthcare settings that are beginning to adopt modern digital technologies.

However, several limitations must be acknowledged. The study sample size, though statistically adequate for detecting differences in comfort and function, may not have been large enough to identify subtle differences in long-term fracture healing or rare complications. The follow-up duration of twelve weeks, while sufficient for assessing early outcomes, did not capture longer-term variables such as late biodegradation effects, cost-effectiveness, or potential reusability of splinting materials. Additionally, the study focused exclusively on stable, closed upper-limb fractures; the findings may not be generalizable to complex or weight-bearing fractures. The absence of blinding among patients, due to the obvious visual and tactile differences between the two interventions, may have introduced subjective bias in self-reported comfort and satisfaction measures. Furthermore, while 3D printing was performed using standardized protocols, minor variations in design or printer calibration could affect uniformity in splint quality across different settings.

Future research should aim to expand sample size and follow-up duration to evaluate the long-term durability, biodegradation profile, and cost-benefit implications of these splints. Comparative trials involving different biodegradable materials or hybrid composites could further refine the design for enhanced strength and flexibility. Multi-center studies incorporating diverse patient populations would also improve generalizability and assist in establishing standardized clinical guidelines for 3D-printed splint application. Integration of biomechanical testing and patient-reported outcome measures will help in balancing engineering precision with real-world usability.

In summary, this study provides evidence that 3D-printed biodegradable splints are a safe, effective, and patient-friendly alternative to conventional casting methods for upper-limb fractures. They combine clinical efficacy with improved comfort, faster functional recovery, and environmental sustainability, reflecting a significant advancement in modern orthopedic care. While further investigation is warranted to explore long-term and large-scale outcomes, the current findings establish a strong foundation for incorporating 3D-printed biodegradable technology into routine fracture management practices.

Conclusion

The study concluded that 3D-printed biodegradable splints offer a superior alternative to traditional casting for upper-limb fractures, providing greater comfort, faster functional recovery, and comparable fracture healing. Their customizable design enhances patient satisfaction while reducing skin complications and supporting sustainable healthcare practices. These findings suggest that biodegradable 3D-printed splints can effectively replace conventional casts in suitable cases, marking a meaningful advancement in personalized and environmentally conscious orthopedic care.

AUTHOR CONTRIBUTIONS

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Author	Contribution
Muhammad Salman Riaz	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Muhammad Dawood	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Kashaf Royyan	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published

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