Abstract

Advances in digital fabrication have transformed the landscape of medical-device design, enabling individuals without formal training to participate directly in the creation of assistive technologies. This dissertation investigates how such “co-creative” processes foster the circulation of creativity among heterogeneous stakeholders—patients, designers, physicians, and business managers—during the development of TOMERE, a penile-clamp-type device designed to mitigate post-prostatectomy urinary incontinence and thereby enhance patient quality of life (QOL) .

Employing a single-case design research framework, this study integrates in-depth, semi-structured interviews with four principal actors—identified as the patient-developer, industrial designer, urologic surgeon, and commercial manager—and eight hours of recorded dialogue coded according to five creative activities: problem identification, solution formulation, decision-making, value creation, and empathy (as delineated in the Japan Creativity Society’s “Shin Creativity” model). To triangulate qualitative insights with outcome data, purchaser surveys (n = 130) were administered following two sequential iterations of the device (TOMERE v2 and v3), and free-text responses were analyzed via co-occurrence network mapping to elucidate patterns in user experience and satisfaction.

Findings reveal that the patient-developer took primary responsibility for problem identification and solution ideation, leveraging lived experience to define precise design requirements. Decision-making responsibilities were shared by the patient and manager to balance user needs with market and production feasibility, while the physician contributed chiefly to value creation by grounding design choices in clinical efficacy and safety considerations. The designer’s role was characterized by high levels of empathic engagement, synthesizing divergent perspectives into iterative prototypes that achieved both ergonomic comfort and aesthetic coherence. Comparative analysis of user feedback demonstrated a substantive reduction in reports of discomfort and leakage from v2 to v3, accompanied by elevated satisfaction scores and testimonials describing restored confidence in daily activities, travel, and social engagement.

By mapping the fluid interplay of creative roles throughout successive development phases, this research elucidates the mechanisms by which experiential, professional, and commercial knowledge converge to accelerate patient-centered innovation. Methodological rigor is supported through the integration of layered qualitative coding and social-network visualizations of stakeholder interactions, alongside detailed thematic analysis of free-text comments. Although the single-case approach limits broad statistical generalizability, the case protocol offers a replicable template for longitudinal tracking of co-creative dynamics across diverse assistive technologies and cultural contexts.

This study extends theory by articulating an analytical lens that captures both the individual and collective dimensions of co-creative design, and offers practical guidance for multidisciplinary teams seeking to deliver affordable, clinically relevant solutions that measurably improve everyday life for patients. Future research should apply this protocol to multiple, varied cases to verify its portability and explore the influence of differing health-care infrastructures and patient populations on co-creative efficacy. Ultimately, by demonstrating how structured co-creative processes can yield tangible QOL enhancements, this work contributes to the evolving paradigm of participatory medical innovation.

Keywords: *Co-Creation, Creativity, User innovation, Digital Fabrication, Medical Assistive Device*