

Expanded digital prosthetic services: Health policy insights from a system dynamics simulation model

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Abstract

Background

Globally, only 5–15% of amputees have access to prosthetic care, and nearly half abandon their devices or drop out of care. Digital technology in prosthetics offer potential to improve accessibility and mobility outcomes, yet evidence on system-level impacts and policy levers remains sparse. This study uses system dynamics modelling to examine the influence of digital prosthetics on major lower-limb amputee mobility and identify leverage points for health policy.

Methods

We extended an existing system dynamics model of prosthetic care and market dynamics with variance-based sensitivity analysis using Sobol' indices. We sampled 45–47 uncertainty parameters to simulate two scenario ensembles: one under demographic equilibrium (94000 runs) and another under demographic growth (98000 runs). Sensitivity indices were then computed at mid- and end-points of the simulation horizon to identify dominant drivers and interaction effects.

Results

Demographic growth conditions primarily affected the magnitude of amputee mobility outcomes rather than altering behaviour modes, indicating structural robustness. However, sensitivity analysis revealed strong interaction effects and temporal shifts in parameter influence. Service capacity parameters dominated early phases, while market formation parameters governed long-term market growth and mobility outcomes. Resources-related parameters shifted from early reliance on external resources to later endogenous generation. Upstream prevention emerged as a significant lever only under growth scenarios, moderating amputee inflows and alleviating systemic bottlenecks.

Conclusions

Policy interventions should prioritize phased strategies: (1) expand prosthetic service capacity to address early bottlenecks; (2) accelerate market legitimacy and infrastructure development to sustain digital prosthetics growth; and (3) strengthen upstream prevention given projected rises in amputations. Based on these leverage points, we further outline actionable policy measures, including regulatory reform, reimbursement modernization, workforce development, and integration of PAD surveillance into prosthetics demand forecasting. Effective coordinated action in these areas could bring about systemic shifts necessary for improving amputee mobility and health system efficiency.

Background

The World Health Organization (WHO) reports that approximately 0.5% of any population require prosthetic and/or orthotic care [1]. A third of this population is expected to require lower-limb prosthetics, translating to a global rule-of-thumb of about 1 in 600. Historically, prosthetic innovation and investments were driven by the aftermath of wars to serve injured soldiers under strong national mandates. Today, however, amputation rates are primarily linked to chronic health conditions amongst the general population rather than trauma. In industrialized economies, more than 90% of lower-limb amputations are a result of peripheral arterial disease (PAD) [2–4]. Yet, this health-driven need has received far less public attention or policy support compared to historically war-related prosthetic interventions.

Prosthetic intervention for major lower-limb amputees is an important aspect of rehabilitation to restore functional mobility, prevent complications and comorbidities, as well as improve psychosocial well-being and overall quality of life [5–7]. Yet, globally the existing prosthetic system provides access to care for only 5–15% of amputees on average, according to WHO estimates [1], and with poor results: about 1 in 2 amputees abandon their prosthetic device or drop out from care altogether due to dissatisfaction with the process and results [8]. Without functional mobility, amputees experience difficulties in workforce reintegration and incur additional costs for their healthcare, their families, and the larger health and welfare systems [1, 9, 10]. This represents an unnecessary loss to the individual, family, and to society that timely and proper prosthetic intervention can overcome.

Digital prosthetics (e.g., data-driven solutions, 3D scanning, ML/AI-based expert systems, 3D printing, and other related technologies) are increasingly presented as viable alternatives to traditional handcrafted methods [11, 12]. These technologies enhance process efficiency by enabling faster and more precise socket design and fitting, significantly reducing manufacturing and delivery times [12]. Digital workflows also support better data integration, material optimization, and scalable production models that can be deployed flexibly, including mobile fitting units. Such attributes allow prosthetists to expand capacity, fit more amputees into their schedules, and deliver care closer to where amputees live. Given these advantages, the expansion of digital prosthetic services represents a compelling case for public health policy interventions aimed at improving access and efficiency in prosthetic care. Nevertheless, effective and actionable policy is best informed by rigorous research. Despite growing interest in digital prosthetics there remains a notable lack of studies assessing their broader impacts on public health outcomes beyond technical feasibility. This leaves a critical evidence gap for policymakers seeking to make informed decisions.

Recently, Rajah et al. [13] developed and validated a system dynamics simulation model to examine how digital prosthetic service provision influences the healthcare system for major lower-limb amputees. In public health, system dynamics models simulate patient flows, resource bottlenecks, and feedback-driven interactions using a network of stocks and flows governed by ordinary differential equations [14, 15]. Through scenario analyses for different levels of digital prosthetics market growth, Rajah et al. [13] highlight three critical simulated impacts on amputee mobility proportion and the net socio-economic benefit of digital prosthetics – calculated as productivity gains from return to work minus healthcare

costs, social payments, and family opportunity costs. First, even under pessimistic technological adoption (i.e., less than 10% market share by 2050) mobility proportion improves by 3% over baseline, while realistic and optimistic scenarios (i.e., less than 50% and up to 80%) yield gains of 19% and 25%, respectively. Second, across all scenarios, the net benefit exceeds the additional reimbursement burden on national health insurance by a factor of 15, on average. Third, in the optimistic scenario, demand outpaces fitting capacity, creating bottlenecks that constrain the mobility and economic outcomes despite high market penetration.

While these findings quantify the potential of digital prosthetics to deliver substantial health and socio-economic benefits, the model's equilibrium-based design (adopted due to data scarcity) introduces uncertainty in the scenario analysis that remains underexplored. Moreover, the original study does not systematically analyse policy levers beyond broad scenario framing. This paper addresses these gaps by extending the model through variance-based sensitivity analysis to quantify the contribution of parameters to output uncertainty and, in turn, conducting a systematic policy search by identifying leverage points. Leverage points are locations in the modelled system where small changes result in considerable changes in the outputs, making them critical for policy design and decision support [16, 17]. Building on this analysis, we derive and discuss potential actionable health policy insights to target these leverage points across three areas: resources for market formation, prosthetics service capacity, and upstream prevention. Interventions in these areas could bring about the necessary shifts in the system to improve patient outcomes over time.

Methods

Model description

We first describe the modelled system structure of patient flows in the health care system for major lower-limb amputees and the market dynamics surrounding prosthetics service provision. For a detailed technical model description and validation, see [13]. With reference to the health system components in Fig. 1, patients flow into the primary care continuum for major lower-limb amputations either due to traumatic injuries or due to PAD. Since most cases are attributed to PAD, the effectiveness of primary prevention efforts such as early screening, smoking cessation, nutritional, and physical activity programs mediate the extent of patient flow (prevention pressure loop) [18, 19]. Upon hospital discharge, amputees deemed medically eligible for a prosthesis are referred to a prosthetist for fitting – either traditional or digital prosthetics depending on respective market shares and service accessibility. Amputees may opt to drop out from prosthetic care during the various stages of the fitting process or, due to improper fit and dynamic alignment, abandon, or underutilize their definitive devices at the end of the process [20]. In such instances, these amputees live with limited mobility unless they later decide to re-enter prosthetic care (prosthetics re-entry loop). Even those who achieve full mobility through a successful fit enter a continuous three-year cycle of prosthetic care to replace their degraded devices (prosthesis lifecycle loop) [21].

The model further considers the effects of an emerging digital prosthetics market on patient flows. Compared to traditional services, word-of-mouth diffusion about digital prosthetics' successes is expected to influence individual dispositions of amputees in relation to digital prosthesis uptake, retention, and re-adoption over time (prosthesis attractiveness loops) [22, 23]. As the rate of digital fittings grows and eventually surpasses traditional fittings, we expect the growing reputation of digital prosthetics to reinforce its market growth, thus capturing more of the prosthetics referral pie (digital growth loops). However, accessibility is constrained by the prosthetics service capacity. If the demand for fittings (driven by new referrals, re-adoption, and replacement) outweighs the fitting capacity of existing prosthetists, the digital prosthetics accessibility diminishes (access constraint loops). This causes bottlenecks in the patient flow and amputees who cannot be accommodated in the prosthetics system must endure longer waiting times. Accessibility can be improved through the expansion of prosthetic clinics to accommodate more patients, but this occurs over the longer term as there are significant delays involved in capacity expansion due to limited numbers of prosthetists and delays to train new specialists (market access loops). Here, the model adjusts the number of digital prosthetic clinics proportionally to the market share with a delay time.

The prospects of market growth for digital prosthetics, however, are also dependent on other market formation processes represented in the market sub-system module (see Fig. 2). Based on technological innovation systems theory, innovation development and knowledge diffusion, by way of investments in R&D, is required for the formation of a niche market of any emerging technology (knowledge and technology development loops) [24, 25]. The amount of resources allocated for R&D is determined by the level of guidance of search, which refers to the visibility and promise of the new technology amongst relevant system actors [24, 25]. As the guidance of search increases, the new technological innovation is prioritized for resource-allocation, thus allowing the technology to grow. In turn, this contributes to the technological legitimacy of the emerging digital prosthetics [26], which is further bolstered by the reputation amassed from word-of-mouth diffusion. As the perceived legitimacy of digital prosthetics accumulates (through the knowledge and innovation attractiveness loops), more entrepreneurs are attracted to the market, bringing with them market-oriented entrepreneurial activity and external resource streams (from private or public investors) into the market system [25, 26]. Entrepreneurial activities with external backing bring about two added benefits: (1) reduction in the perceived risk involved for new entrants, and (2) rise in the total resources available for technological and market development (external engine loop).

Yet for market sustainability, the emerging niche market must be able to generate its own internal financial, material, and human capital resources over the longer term to supplant external funding streams [25]. In that respect, the digital prosthetics sector must increase its market size to capture more market share and generate more internal resources (internal engine loop). The expansion of the market is dependent on two components: entrepreneurial activities and established market infrastructure, which facilitate the "creation of a demand for the emerging technology" [25](p. 56). Entrepreneurs in the system must develop intermediary networks, formal market rules and regulations, and other infrastructure that give the sector its market legitimacy (system building and legitimacy loops) [26]. This,

in turn, reinforces market-oriented activities by reducing market formation uncertainty and the perceived cost to participation [27].

A nascent market, however, could be stifled by the incumbent regime, which attempts to diminish its market legitimacy and disincentivize new entrants (resistance loop). For instance, resistance could take the form of lobbying or competitive innovation of existing technologies for performance improvements, known as the sailing-ship effect (sailing ship loop) [28, 29]. Regime resistance can only be overcome if the emerging sector can endogenously develop its market infrastructure and “become less dependent on external dynamics” [26](p.1838). In this sense, the success of digital prosthetics market growth is determined by the extent of synergistic growth in entrepreneurial activities, market infrastructure, market legitimacy, and market size. With an expansion of digital prosthetics market share, more amputees can be accommodated in the prosthetic care continuum, thus improving accessibility and mobility.

Variance-based Sensitivity Analysis

To quantify the contribution of input parameters to uncertainty in model outputs, we applied variance-based sensitivity analysis, specifically using Sobol’ indices [30, 31]. This approach decomposes the total output variance into contributions attributable to variations in individual parameters and their interactions with other parameters in the model. The first-order Sobol’ index (S_i) measures the proportion of variance explained by a single parameter, while the total-order index (S_{Ti}) captures its combined effect, including interactions. Following the Saltelli sampling scheme [30], two independent sample matrices (A, B) are generated using quasi-random Sobol’ sequences. Each matrix contains samples for all uncertain parameters, drawn from their specified ranges. For each parameter, an additional matrix ($A_B^{(i)}$) is generated by replacing the parameter’s values in A with those from B, while keeping all other parameters fixed. This design isolates the influence of each parameter without confounding effects from simultaneous changes in other parameters, thereby supporting the estimation of S_i and S_{Ti} .

In the original study, the simulation model was initialized in equilibrium by holding the total population size constant and setting the initial value of population stocks to their dynamic equilibrium values [13]. While this was done to account for uncertainty in amputee numbers across stages of the care continuum and to isolate impact of digital prosthetics care, excluding population growth may understate real-world variability given that lower-limb amputations are projected to grow [1]. To address this, we performed two variance-based sensitivity analyses under different initial conditions: one with population held in equilibrium and another with population growth. For the former, we sampled 45 uncertain parameters in model for which there are no reliable estimates from the literature (see Table 1). For each parameter, we drew 2000 base samples from a wide uncertainty range (usually $\pm 50\%$ from the value estimated from expert opinion). The Saltelli design resulted in 94000 model runs with unique combinations of sampled parameter values.

For the latter design, we repeated the sampling with two additional parameters: Total fertility rate [1.756, 3.15] and Reference PAD incidence rate multiplier [1, 2]. By varying fertility rate above the calibrated equilibrium value and PAD incidence above the estimate found in literature, we simulate uncertainty scenarios where both the general population and amputee population grow at differing rates. This generated a second ensemble of 98000 model runs. In turn, the two separate ensembles allow us to compare the Sobol' indices under equilibrium and growth scenarios and test the robustness of parameter importance under demographic change. The above procedures were implemented externally in R (version 4.5.1) and imported to the simulation modelling software, Stella Architect version 4.0, for external sensitivity analyses.

We then imported the simulated Amputee Mobility Proportion outputs into R and computed Sobol' indices using the Sobol2002 function from the sensitivity package version 1.30.2 [32]. For each ensemble, we estimated S_i and S_{Ti} for every parameter at two time points: month 120 (midpoint of simulation horizon) and month 480 (endpoint). We further obtained 95% confidence intervals for the estimates via bootstrapping with 2000 resamples. For interpretability, we report and visualize only the subset of parameters that exhibited non-negligible sensitivity (average indices across both timepoints > 0.01). These parameters represent potential leverage points in the system, where targeted interventions are most likely to influence model outcomes. The full sensitivity results for all varied parameters, alongside the data and codes, are provided in [33].

Table 1
Parameters and uncertainty ranges applied for Saltelli variance-based sampling scheme.

Sector	Parameter	Range	Units
Population	Time taken for prevention to take effect	[60, 180]	months
	Maximum effect of amputations on PAD incidence	[1, 3]	dimensionless
	Steepness effect of amputations on PAD incidence	[1, 3]	dimensionless
	Time to report PAD-related admission	[18, 54]	months
Prosthetics Care	Reference Eligible for Prosthesis dropout multiplier	[0.5, 1.5]	dimensionless
	Reference Initial Device dropout multiplier	[0.5, 1.5]	dimensionless
	Reference Mature Limb dropout multiplier	[0.5, 1.5]	dimensionless
	Reference Readoption multiplier	[0.5, 1.5]	dimensionless
	Fitting success fraction [Digital Prosthesis]	[0.5, 0.9]	dimensionless
	Fitting success fraction [Traditional Prosthesis]	[0.3, 0.6]	dimensionless
	Time to perceive fitting rate	[18, 54]	months
	Steepness effect of fitting rate on dropout	[1, 2]	dimensionless
	Steepness effect of fitting rate on readoption	[3, 9]	dimensionless
	Maximum effect of fitting rate on readoption	[1, 3]	dimensionless
Innovation Diffusion	Time to diffuse knowledge	[6, 18]	months
	Time to develop innovation	[6, 18]	months
	Time to decay knowledge/innovation	[30, 90]	months
	Time to adjust guidance of search	[1.5, 4.5]	dimensionless
	Guidance of search effectiveness factor	[0.125, 0.375]	dimensionless
	Time to mobilise resources	[3, 9]	months
	Sensitivity of resources to market size	[0.5, 1.5]	dimensionless
Market Formation	Weight of technological legitimacy	[0.3, 0.7]	dimensionless
	Relative weight of reputation	[0.4, 0.8]	dimensionless
	Relative weight of resistance	[0.4, 0.8]	dimensionless

Sector	Parameter	Range	Units
	Time to perceive legitimacy	[6, 18]	months
	Steepness effect of digital fitting reputation on legitimacy	[0.1, 0.3]	dimensionless
	Steepness effect of legitimacy on entrepreneurial activity	[0.2, 0.6]	dimensionless
	Steepness effect of total resources on entrepreneurial activity	[1.25, 3.75]	dimensionless
	Weight of perceived legitimacy	[0.3, 0.7]	dimensionless
	Time to adjust entrepreneurial activity	[6, 18]	months
	Steepness effect of total resources on market infrastructure	[1.25, 3.75]	dimensionless
	Steepness effect of entrepreneurial activity on infrastructure	[0.2, 0.6]	dimensionless
	Weight of entrepreneurial activity	[0.3, 0.7]	dimensionless
	Time to adjust market infrastructure	[30, 90]	months
	Time to adjust market size	[12, 36]	months
	Relative external resources size	[2.5, 7.5]	dimensionless
	Variable input fraction	[0.125, 0.375]	dimensionless
	Market size threshold	[0.025, 0.075]	dimensionless
	Mean position of relative market size for sailing ship effect	[2.5, 7.5]	dimensionless
	Spread effect of relative market size on sailing ship effect	[0.125, 0.375]	dimensionless
	Maximum sailing ship effect	[0.125, 0.375]	dimensionless
	Time to adjust regime resistance	[6, 18]	months
	Sensitivity of clinics to market size	[0.25, 0.75]	dimensionless
	Time to adjust clinics	[12, 36]	months
	Prosthetist per clinic	[1, 3]	prosthetist/clinic

Results

Figure 3 presents the simulated outputs of the Amputee Mobility Proportion variable across the two scenario conditions. The mobility proportion is calculated as the fraction of eligible amputees who are successfully fitted with a prosthetic device (whether traditional or digital) and are fully mobile. The remaining amputees are limited in their mobility either due to drop out from the prosthetics care or abandonment of the device, or due to wait time for prosthesis replacement. In both equilibrium and growth initial conditions, the simulation model captures a wide range of mobility outcomes for the amputee population within the 95% confidence interval: from a declining proportion approaching 5% after an early local maximum to an increasing proportion reaching up to 40% by the end of the simulation horizon. The initial growth spurt, even under pessimistic conditions, is explained by the relatively small amount of external resources that flow into the market subsystem that generates limited digital prosthetics market growth before collapsing as the resource flow is cut off [13]. Whereas, under more optimistic conditions, the rise in amputee mobility is ultimately dampened by accessibility constraint as demand for prosthesis fitting outpaces available capacity [13].

The growth scenario consistently projects a relatively lower level of mobility across the simulation horizon compared to the equilibrium scenario. Under growth scenarios, more people are susceptible to major-lower amputations from either traumatic injuries, or to a larger extent, PAD progression. The larger volume of cases amplifies pressure on prosthetic care capacity, creating bottlenecks in the patient flows that reduce overall mobility. Yet, both ensembles produce similar behavioural trajectories within their respective confidence intervals. In other words, demographic changes primarily influence the magnitude of outcomes (numerical sensitivity) rather than altering the underlying behaviour mode. This suggests a degree of robustness to parametric uncertainty within the tested ranges and initial conditions, although the contribution of parameter interactions warrants further analysis when interpreting output variance. To explore these effects, we conducted a Sobol' sensitivity analysis. Figure 4 presents the variance decomposition results, which quantifies the contribution of individual sensitive parameters and their interactions on output (Amputee Mobility Proportion) variability. The blue markers represent the mean S_i with 95% confidence interval, indicating the direct contribution of individual parameters. Red markers represent the mean S_{Ti} with 95% confidence interval, capturing both main effects and interactions. Parameters are ranked by sensitivity, determined by averaging the mean S_{Ti} estimates, and included if it accounts for more than 0.01 of the output variability.

Parameters governing prosthetic service capacity rank among the most influential drivers of output variance across both scenario conditions. Under equilibrium conditions (Fig. 4a), prosthetists per clinic exhibited the highest sensitivity indices at month 240, which reflects its critical role in determining the dynamics of the system at the early phase of market growth. In this phase, prosthetic accessibility is constrained by fitting capacity at the clinic level. Given that the relative success of digital prosthesis fitting rate is a driver of market formation, increasing prosthetists per clinic improves the fitting throughput in the early phase and thus enables stronger market formation dynamics. By month 480, however, the influence of prosthetists per clinic declines as market expansion is less reliant on staffing density within existing clinic capacity to increase throughput; rather, market expansion allows for the

number of clinics to scale through its internal dynamics. Consequently, we observe that the sensitivity of clinics to market size, which governs the rate at which new clinics are established in response to market growth, emerges as a more influential parameter later in the simulation.

Under growth scenario conditions (Fig. 4b), these dynamics persists but with notable differences: the influence of the above service capacity parameters diminishes relative to equilibrium. Here, rising amputee numbers amplify fitting demand, creating more bottlenecks in patient flows and reducing prosthetic accessibility despite service capacity expansion through clinic staffing. In other words, the leverage of increasing prosthetist density alone is diminished; the system increasingly depends on clinic expansion through market dynamics to offset the rising demand pressure. Since the growth conditions more closely approximate the real-world system, these findings suggest that workforce expansion should be complemented by policies that accelerate market formation for capacity expansion.

Among the parameters governing market formation, the weight of perceived market legitimacy exhibited the highest sensitivity, followed by the weight of entrepreneurial activity. Both these parameters govern the strength of the reinforcing feedback loop between perceived legitimacy, entrepreneurial activity, and market infrastructure (see Fig. 2). Higher weights on legitimacy and entrepreneurial activity amplify this loop, partially offsetting structural resource constraints during early market formation and fuelling sustained internal resource generation during later market growth. This dynamic is further shaped by the moderately sensitive steepness effect parameters that determine the rate at which legitimacy, entrepreneurial activity and infrastructure stocks accumulate. Interestingly, the adjustment times for market infrastructure and market size are influential in month 240 but becomes less so in month 480. This reflects the importance of delays in market development during the early phase of growth – there are path dependencies in market formation; systems that adjust faster in the formative phase achieve greater scale later. These findings suggest that policies aimed at accelerating legitimacy and entrepreneurial incentives, combined with reducing infrastructure development delays, are essential for robust market formation.

The other main set of market formation parameters relates to resources in the system. The market size threshold and sensitivity of resources to market size jointly determine the volume of internal resources generated in the system. Both parameters exhibit relatively low sensitivity in month 240 but become influential by month 480. During early market formation, internal resource generation is minimal because market size remains below the sustainability threshold, making these parameters less consequential. As the market expands and crosses this threshold, resource generation accelerates and these parameters become critical for sustaining growth and scaling market infrastructure. Conversely, the external resources size is more influential in earlier phase of market growth compared to month 480, as external resources play a pivotal role in initiating market development before internal resource flows become more dominant. This finding suggests that external resource support for the digital prosthetics market should be front-loaded in policy design, ensuring sufficient resource flows during early growth phase. As the market matures, policies should pivot to ensuring sustainable endogenous growth.

The final notable parameter relates to PAD prevention: maximum effect of amputations on PAD incidence. This parameter determines the magnitude of the effect of PAD prevention on incidence rates. As the number of PAD-related amputations rises, the model assumes that prevention efforts will scale (with a delay) and inversely influence PAD incidence rates. This creates balancing feedback that controls rising PAD population size. The sensitivity analysis shows that the effect parameter is largely inconsequential under equilibrium conditions since PAD prevalence remains stable. Under growth conditions, however, its influence becomes significant (Fig. 4b) as PAD cases increase sharply and amplifies demand for prosthetics services. This finding demonstrates that prevention measures, while having limited impact in stable populations, become a critical lever under demographic growth for controlling long-term prosthetic demand and improving future accessibility.

Discussion

In this paper, we have identified three broad groups of leverage points shaping amputee mobility outcomes: service capacity, market formation, and PAD prevention. Our sensitivity analysis shows that these domains do not exert influence uniformly over time; there are strong interaction effects and temporal shifts in parameter influence under different scenario conditions. Service capacity parameters dominate early phases, while market formation parameters related to legitimacy and entrepreneurial activity become critical for long-term market growth. Resource-related market formation parameters also shift in influence over time – early growth is more reliant on external resources while endogenous internal resource generation become pivotal later. Importantly, PAD prevention emerges as a policy lever only under demographic growth, moderating amputee inflows and alleviating the bottlenecks in the prosthetic care system. In the remainder of this section, we translate these model-based insights into health-policy implications and recommend specific measures to target the identified leverage points.

Capacity Expansion

Our sensitivity analysis identified service capacity parameters as critical levers in the system, driving substantial output variance in both scenarios. These parameters determine the accessibility of prosthetic services by either expanding or constraining fitting capacity. The results show amputee mobility is sensitive to clinic-level staffing at early phase but become more dependent on service expansion through clinic expansion. Importantly, growth conditions amplify demand for fittings and the persistent bottleneck in prosthetic service provision even at high levels of market growth [13]. This finding aligns with WHO's concern that the majority of amputees do not have access to prosthetic services, partially due to the "limited availability of products" and "lack of qualified personnel," which is likely to worsen as the amputee population is expected to grow [1].

Scaling up digital prosthetics could be key to increase fitting throughput and mitigate the accessibility problem. A shorter manufacturing and provision process through digital solutions increases the fitting capacity per prosthetist. Moreover, digital technology reduces the requirement for fixed capital

investments at the point of care and enables prosthetics providers and clinical operators to distribute services beyond standard clinical settings. For instance, providing mobile services through a Distributed Care Networks model [34] could be a viable solution for improving accessibility, particularly for amputees living in rural areas. Here, health agencies and regulatory authorities could authorize digital prosthetics and distributed care models where quality assurance, infection control, data protection, and device traceability are ensured [1]. Digital prosthetics also enable a more streamlined education that can reduce the long training duration required for traditional manufacturing and provision processes (e.g., eight years in Canada to practice). A shorter educational pathway, in turn, could attract more prosthetists to the field and increase the overall number of personnel. Health education institutes, in coordination with national accreditation bodies, could modernize curricula to include digital design, scanning, and additive manufacturing, along with bridging programmes for upskilling traditional practitioners. Regardless of the medium, the results highlight a need for intervention in the supply of prosthetic services for better mobility outcomes.

Digital Market Formation

Our findings point to two interrelated challenges in the digital prosthetics market: the collective action problem of building legitimacy and infrastructure, and the sequence of resource support over time. External resources (e.g., financial, material, and human capital allocated to innovation and market development) are key to fuelling the initial growth, which attracts entrepreneurial activities with knock-on feedback effects to other key system components [25]. This is particularly critical given the current nascent stage of the digital prosthetics, where market penetration and internal resources remain low. However, the resources required for infrastructure building are substantial, and the benefits often spill over to competitors, discouraging unilateral investment. This dynamic reflects the collective action problem inherent in market formation: no single actor can overcome structural barriers alone [27]. Therefore, efforts to build market legitimacy by market actors should go beyond building one's own internal capabilities, and oriented toward developing market infrastructure and the legitimacy necessary for expanding the initial niche market – to enable the endogenous generation of internal collective resources for sustained growth. To overcome collective-action barriers, public actors such as health ministries and innovation agencies could provide targeted early-stage resource support (e.g., matched grants, challenge funds, or public-private consortia) to accelerate open-infrastructure development. Such investments reduce appropriability concerns and crowd-in entrepreneurial activity, consistent with open-innovation principles [35].

Regulatory and reimbursement frameworks further compound barriers to market entry and development, which disincentivizes investment in the emerging system. For instance, digital-based 3D printed sockets require extensive and costly regulatory (FDA) approvals in the United States, as opposed to traditional sockets that have been grandfathered in. In particular, it would be desirable to establish clear regulatory pathways for additively manufactured sockets and digital workflows. Reimbursement policies for prostheses are also established with language privileging the traditional manufacturing process (e.g., “based on plaster cast” in Italy [36]). More effective reimbursement policies would focus on functional

outcomes and language that would be technology neutral. Moreover, prosthetist licensing and insurance to practice explicitly requires a traditional education, focused on the manufacturing process, to service patients and provide final devices for reimbursement. Operational licensing also requires premises to install equipment specific to traditional prosthetic fitting that is not relevant for digital prosthetics (e.g., oven and air extraction units in Germany). In this regard, licensure requirements for prosthetic practice and operation could be modernized to create a more level playing-field between traditional and digital prosthetics. Such interventions help alleviate the lock-in effects of current institutional constraints; in turn, they contribute to accelerating market legitimacy and entrepreneurial activity, and importantly, reducing structural delays for scaling market infrastructure. Ultimately, the extent of intervention in this area determines the speed and scale of digital prosthetics adoption, with significant implications for amputee mobility outcomes.

Prevention

The field of public health, in general, has moved toward upstream root-cause prevention for chronic conditions [37]. Similarly, we consider the policy insights for upstream intervention. Under growth scenarios, the model is sensitive to the effect size of PAD prevention (driven by changing trends in PAD-related amputations). This points to the importance of primary prevention strategies to curb the rise of PAD prevalence – a priority made urgent by WHO projections of a doubling in amputee population by 2050 due to medical conditions [1] and the significant time delays inherent in prevention efforts before benefits materialize.

Given the gravity of PAD as a chronic condition, there have been calls to action for scaling up public health interventions for raising awareness, screening for early detection, and treatment for deterring progression [18, 38]. Public health agencies along with medical professionals, payers, and health systems seeking to improve care delivery, should not lose sight of such prevention efforts – be it to prevent PAD incidence altogether, or to prevent progression to critical limb ischemia for those diagnosed. To operationalize prevention within service planning, health agencies could implement or strengthen surveillance and planning by integrating PAD incidence and progression monitoring into long-term prosthetic demand forecasting and capacity planning. In parallel, incentive alignment could be pursued by tying chronic-disease management incentives [e.g., 39, 40] to prevention and early-treatment targets in vascular care, thereby slowing progression to critical limb ischemia and amputation. Consequently, effective intervention in this area would improve population health in general and dampen the growth in the amputee population over time, and potentially reduce health disparities, which would improve prosthetics accessibility through reduced demand and raise the mobility proportion.

Coordinated Action

Translating these findings into practice calls for coordinated implementation across the three domains – capacity expansion, digital market formation, and prevention – under a shared governance framework

that integrates prosthetics into routine health-system functions (policy, products, personnel, and provision), consistent with WHO standards [1]. Table 2 summarizes the specific policies, actors, and indicative timeframes for such coordination action. Taken together, this approach addresses near-term bottlenecks in service capacity, strengthen market formation dynamics, and structurally moderates long-term demand pressures through prevention.

Table 2
Policy roadmap for coordinated action in prosthetics care.

Policy Area	Priority Actions	Policy Actors	Timeframe
Capacity Expansion	Authorize and implement distributed prosthetics services in suitable premises where quality assurance and infection control are met; expand clinic capacity where needed.	Health regulators; service operators; infection control bodies.	Short (authorization); Medium term (scale up).
	Modernize education and accreditation to include digital design, scanning, additive manufacturing in curricula and licensure requirements; create upskilling pathways for existing licensed practitioners.	Educational institutes; national accreditation bodies; professional societies.	Short to medium term
Digital Market Formation	Provide regulatory clarity for digital prosthetics and workflows in national guidelines.	Health regulators; standards bodies.	Short term
	Modernize reimbursement and insurance policies with technology-neutral, outcome-focused language (e.g., “suitable and quality-assured medical device”).	Health agencies; payers.	Short term
	Modernize operational licensure to recognize digital workflows and prune legacy requirements unrelated to digital care.	Health regulators; licensing authorities.	Short to medium term
	Provide early-stage resource support (e.g. grants, public-private consortia) for building open infrastructure.	Health agencies; innovation agencies; industry consortia.	Short to medium term
Prevention	Accelerate public health efforts to prevent PAD incidence and progression.	Health agencies.	Long term
	Strengthen PAD incidence and progression surveillance to forecast and plan for prosthetics capacity.	Health agencies; hospital networks.	Medium to long term
	Align chronic disease management incentives to prevention and early-treatment targets in vascular care.	Payers; service providers; hospital networks.	Medium to long term.

Limitations and Further Research

Policy interventions in the areas described above are designed to target high-leverage points within the system and thus significantly improve mobility outcomes for major lower-limb amputees and society. However, we recognize that different countries have different healthcare financing, coverage, and regulatory requirements that may differentially affect innovation and technology development, access to and distribution of care. The simulation model presently assumes that prosthetics care is covered by national health insurance through a reimbursement scheme. In the United States, for instance, payment for and access to prosthetics would depend on the type of insurance coverage one has (e.g., Military/Veteran Association, Medicare, Medicaid, private insurance). While we have kept the recommendations broad enough to generalize across contexts, further policy analysis and response will vary depending on the country in question. In this regard, future work could adapt the simulation model to other country-specific prosthetic care systems.

Additionally, the simulation model is highly sensitive to fitting success rate for both digital and traditional prosthesis (see Fig. 4). These parameters are unlikely to serve as strong policy levers since their variability reflects clinical factors and data uncertainty rather than structural dynamics. While there is some empirical support for the probability of success for the traditional [8], the probability for digital is assessed to be higher based on expert opinion and initial evidence of improved design and comfort. Given this uncertainty, we used a wide range of parameter values in the sensitivity analysis. Future empirical research should prioritize measuring and estimating the probabilities for different prosthesis types to reduce the uncertainty in model outputs. Furthermore, robust national-level data collection on indicators related to market share (e.g., number of prosthetic clinics and user populations by prosthesis type) would help address data scarcity. Importantly, longitudinal datasets can aid model calibration and likelihood weighting of parameter ranges, thereby narrowing uncertainty bounds even within the more conceptual market subsystem.

Lastly, our policy insights are derived from parametric leverage points that have the most influence on system outcomes. However, this approach does not offer deeper insights into the feasibility, operational complexity, or political economy of implementing specific policies to effectively target those leverage points. Successful policy adoption depends on both leverage points and implementation dynamics. Future work should complement systems modelling with implementation science approaches to embed policy structures and adaptive feedback mechanisms within the simulation model. Doing so could reveal potential policy resistance [41] and adaptive strategies to ensure that digital prosthetics deliver measurable improvements in patient outcomes and system efficiency.

Conclusion

Our study contributes to the limited literature on digital prosthetics. Apart from the original study [13], to our knowledge, there are no other studies that explore the plausible impacts of digital prosthetics in the health and prosthetic care system for major lower-limb amputees. In this study, we extended the model-

based analysis to better account for uncertainty and identify leverage points in the system. Our analysis points to three broad health policy areas for improving prosthetic services and amputee mobility: First, expansion of prosthetics fitting capacity to meet demand and improve accessibility; second, sufficient market formation resources to support a sustained growth pattern in digital prosthetics; and third, upstream PAD prevention to address the root cause of major lower-limb amputations, which would also ameliorate capacity constraints. To support such improvements, we recommended multiple policy measures relevant to health policy planners. Coordinated action in these policy areas can significantly disrupt the incumbent prosthetic system and bring about an expanded and more efficient services for major lower-limb amputee rehabilitation. Our findings suggest that digital prosthetics provide a promising pathway for leveraging modern digital technologies to improve prosthetic accessibility and patient outcomes. Without strategic policy interventions to transform national amputee care systems, these benefits risk remaining unrealized.

Abbreviations

WHO: World Health Organization

PAD: Peripheral arterial disease

S_i : First-order Sobol' index

S_{Ti} : Total-order Sobol' index

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All codes and data generated and analysed during the current study are available in the Zenodo repository, <https://doi.org/10.5281/zenodo.18649367>.

Competing interests

C.J.H. is an amputee, co-founder, minority shareholder, and Chief Technology Officer of ProsFit Technologies with a professional interest in digital prosthetics service provision. He was also a member of the International Society for Prosthetics & Orthotics (IPSO) Industry Advisory Group between 2018 and 2022. C.J.H. had no input in the formal analysis and conclusions drawn from the simulation results. His contributions were limited to providing sector knowledge on prosthetic-care pathways, current market conditions, and contextualization of policy implications. Research independence of the primary researcher (J.K.R) was formally codified in a collaboration agreement and no compensation was provided for this work. All other authors declare that they have no competing interests.

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Authors' contributions

Conceptualization: J.K.R., C.J.H., W.C., P.G., and B.K.; methodology: J.K.R.; formal analysis: J.K.R.; investigation: J.K.R.; data curation: J.K.R.; visualization: J.K.R.; validation: J.K.R., C.J.H., W.C., P.G., and B.K.; supervision: P.G. and B.K.; writing – original draft preparation: J.K.R.; writing – review and editing: J.K.R., C.J.H., W.C., P.G., and B.K. All authors read and approved the final manuscript.

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Figures

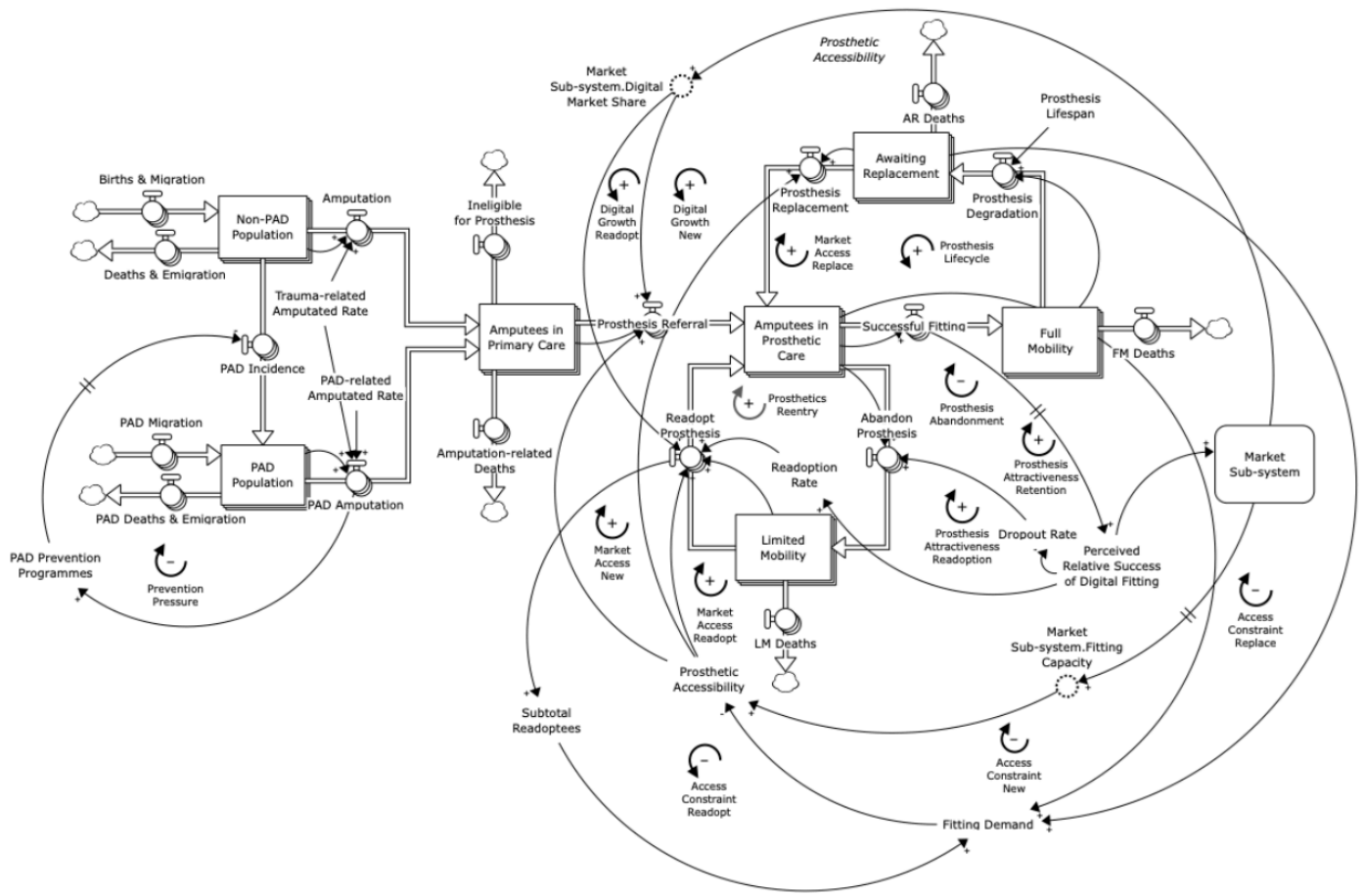


Figure 1

Simplified stock-flow diagram of the health and prosthetic care system adapted from [13](CC BY 4.0).

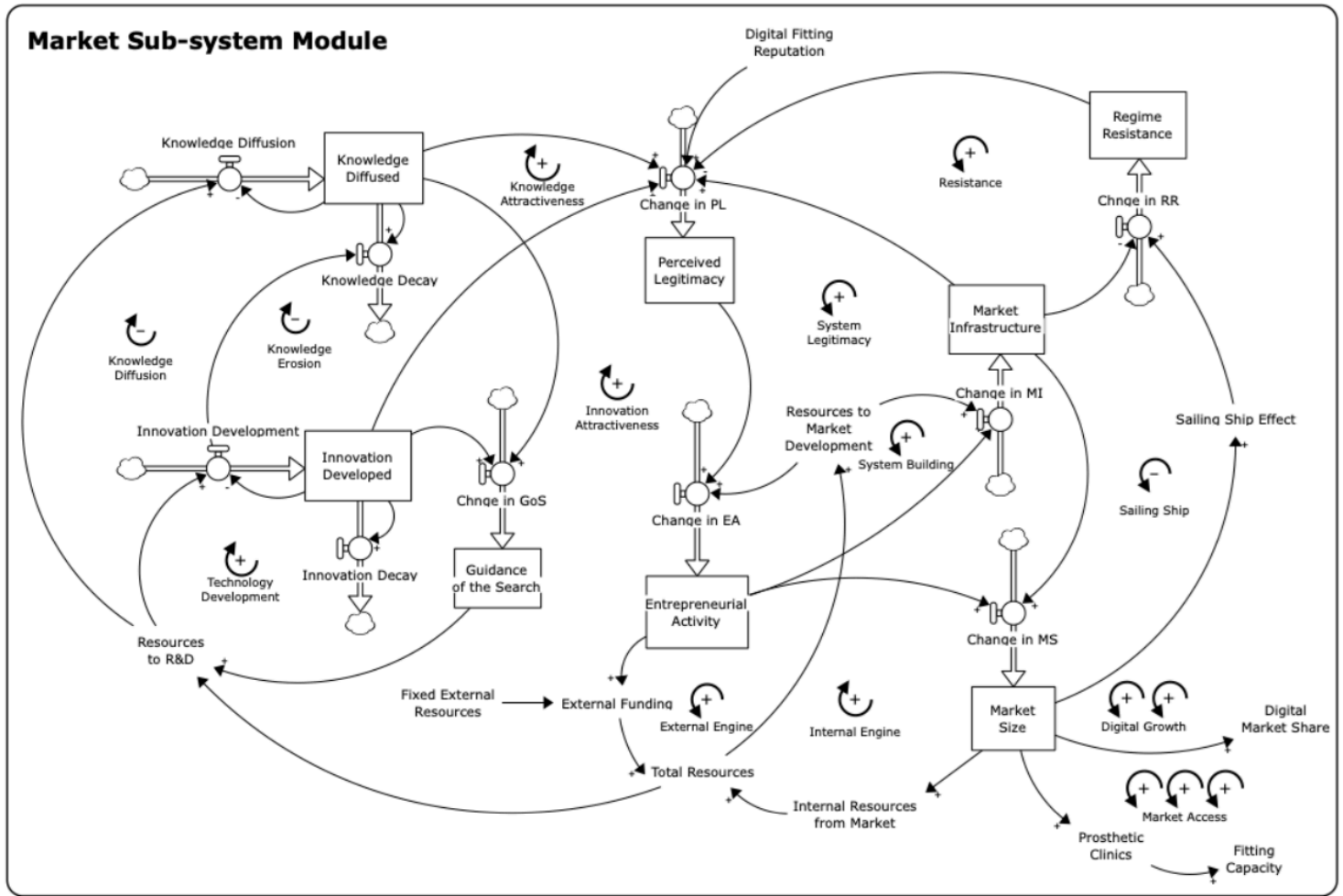


Figure 2

Simplified stock-flow diagram of the market subsystem adapted from [13](CC BY 4.0).

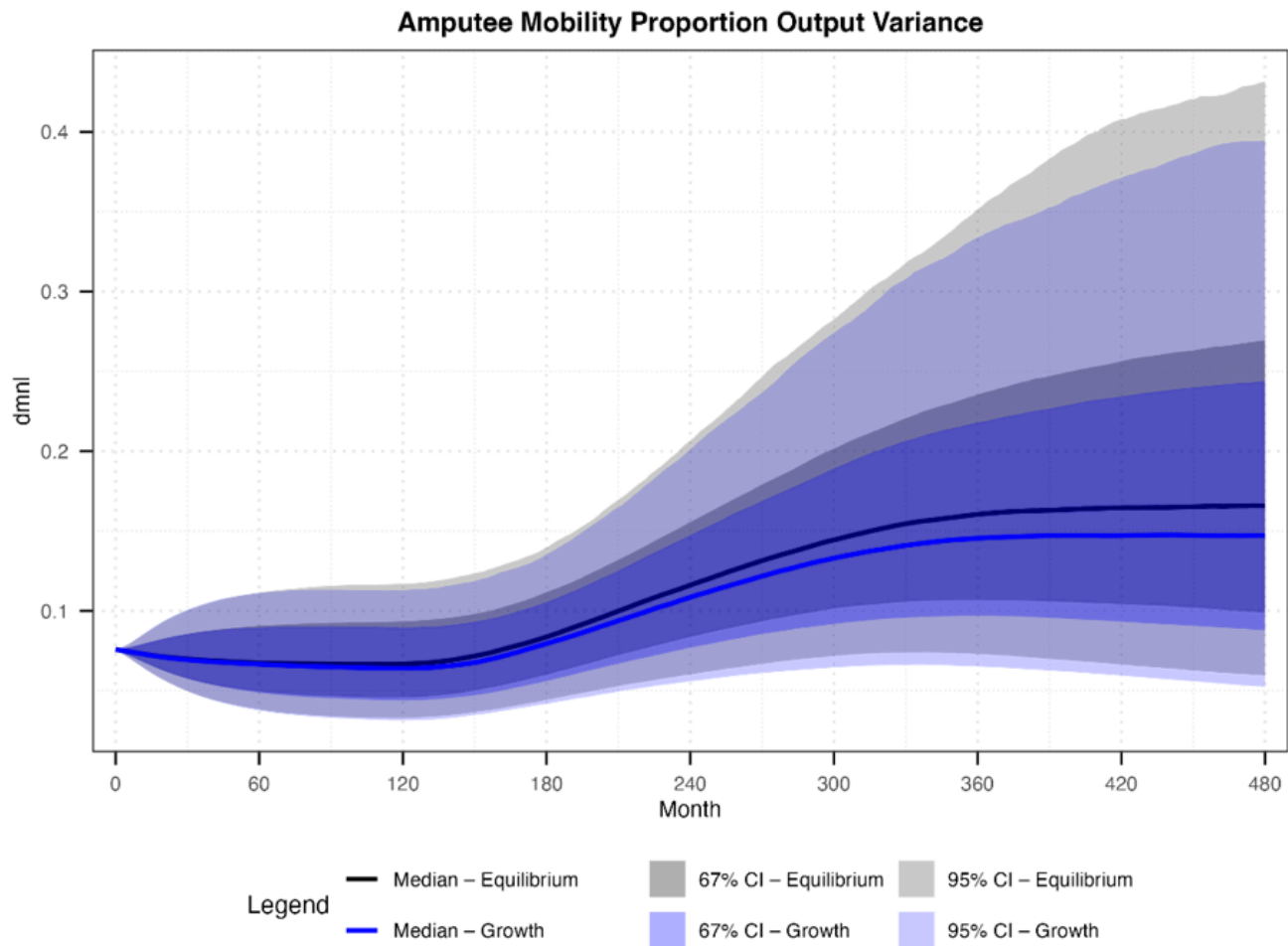


Figure 3

Simulation results of Amputee Mobility Proportion under two demographic scenario conditions: equilibrium (black) and growth (blue). Solid lines represent the median across uncertainty ensemble runs (94000 for equilibrium; 98000 for growth), while shaded region represent the 67% and 95% confidence intervals, illustrating output variance due to parametric uncertainty.



Figure 4

Sobol' sensitivity indices for Amputee Mobility Proportion under (a) equilibrium and (b) growth conditions in months 240 and 480.