АКТУАЛЬНІ ПРОБЛЕМИ МЕДИЦИНИ

UDC 616.314-089:005.8
DOI https://doi.org/10.32782/health-2025.2.31

THE STRATEGIC IMPORTANCE OF IN-HOUSE PRODUCT DEVELOPMENT IN MAXILLOFACIAL PRACTICE

Scorobogach Valeriia Serhiivna
Maxillofacial Surgeon, Private Clinic Free Smile Dentistry (USA)
ORCID: 0009-0001-0734-1751

The article explores the strategic importance of in-house product development in private maxillofacial practice to integrate clinical innovation with business sustainability. The study identifies that the traditional service-based healthcare model limits profitability due to dependence on chair-time, local competition, and operational costs. Conversely, developing proprietary, biocompatible products – particularly hydroxyapatite-based toothpaste and mouthwash – enhances revenue diversification, patient loyalty, and clinic brand value. This study aims to examine both the clinical and entrepreneurial rationale for in-house product creation and propose a practical framework for private dental and surgical clinics. The research applies a mixed-method approach combining literature review, international benchmarking, and a case study of a Ukrainian maxillofacial clinic introducing hydroxyapatite oral care products. Results demonstrate a 36% reduction in dentin hypersensitivity, a 72% increase in patient trust, and new B2B collaborations contributing up to 18% of total clinic revenue. The findings confirm that proprietary formulations improve clinical outcomes and transform private clinics into innovation-driven enterprises with sustainable business models. The study concludes that in-house product development represents a dual pathway for strengthening clinical quality and financial resilience, serving as a model for future-oriented private healthcare systems.

Key words: *hydroxyapatite, medical entrepreneurship, proprietary products, dental management, innovation in practice, biomimetic materials.*

Скоробогач Валерія. Стратегічна роль розробки внутрішніх продуктів для розвитку щелепно-лицевої практики

У статті розглянуто стратегічне значення розробки власних продуктів у приватній щелепно-лицевій практиці як інструменту поєднання клінічних інновацій та підприємницької стійкості. Встановлено, що традиційна сервісна модель медичних закладів обмежує прибутковість клінік через залежність від кількості прийомів, локальну конкуренцію та високу собівартість операційної діяльності. Натомість створення власних біосумісних продуктів – зокрема гідроксиапатитної зубної пасти та ополіскувача – забезпечує диверсифікацію доходів, підвищення лояльності пацієнтів і зміцнення бренду клініки. Метою дослідження є аналіз клінічних та бізнес-орієнтованих передумов внутрішньої розробки продуктів, а також розроблення практичної моделі для приватних стоматологічних і хірургічних закладів. Дослідження базується на поєднанні аналізу міжнародного досвіду медичного підприємництва, кейс-стаді української клініки, що розробила власні продукти на основі гідроксиапатиту, та порівнянні з практиками Японії, ЄС і США. Результати показали, що використання біоміметичних продуктів сприяє зменшенню чутливості зубів на 36 %, зростанню довіри пацієнтів на 72 % і формуванню нових бізнес-каналів через B2B-співпрацю. Застосування авторських формул дозволяє не лише підвищити якість лікування, а й перетворити клініку на інноваційний центр із власним виробничим потенціалом. У висновках обґрунтовано, що впровадження власних продуктів забезпечує двосторонній ефект – клінічне вдосконалення та фінансову стійкість – і може стати моделлю для сталого розвитку приватної медицини.

Ключові слова: *гідроксиапатит, клінічне підприємництво, власні продукти, стоматологічний менеджмент, інновації у практиці, біоміметичні матеріали.*

Formulation of the problem in general form and its relation to important scientific or practical tasks. In modern maxillofacial surgery, the strategic role of innovation extends beyond clinical practice and encompasses entrepreneurial dimensions of healthcare delivery. Traditionally, private clinics have relied almost exclusively on service-based revenue, where patient volume, high operational costs, and competitive saturation limit profitability. As studies in healthcare economics have demonstrated, such dependency creates vulnerability to market fluctuations and hinders long-term growth [22]. At the same time, global trends in personalized medicine and biomaterial development encourage medical institutions to shift toward hybrid business models that combine treatment services with proprietary product innovation.

The central problem addressed in this study is the lack of strategic frameworks enabling private surgical and dental clinics to develop and commercialize their medical or cosmetic products. While large corporations dominate the field of biomaterials, smaller private clinics increasingly possess the research potential and clinical data to design customized products aligned with patient needs. Integrating in-house product development into clinical operations can enhance competitiveness, strengthen brand identity, and generate diversified revenue streams. Thus, the problem under investigation lies at the intersection of clinical innovation, business strategy, and sustainable healthcare management.

Analysis of recent studies and publications. Recent research emphasizes the importance of medical entrepreneurship and innovation management in dentistry and maxillofacial surgery. According to Di Stefano et al. [6], clinical innovation, when combined with structured business planning, significantly increases the survival rate of healthcare startups. Similarly, Kim et al. [16] observed that dental clinics engaged in small-scale R&D and product testing achieved higher patient satisfaction and long-term profitability.

In-house development of biomimetic materials, particularly hydroxyapatite-based compounds, has received increasing attention due to their ability to restore enamel and improve oral health [26]. Empirical studies show that the introduction of such materials enhances not only therapeutic outcomes but also the clinic's market positioning as an innovator [9]. However, most research focuses on large manufacturers, leaving a gap in understanding how small, private clinics can successfully implement product innovation within limited resources.

Scholars such as Shrestha and Park [22] highlight the potential of strategic partnerships between clinics and academic institutions to accelerate product validation and reduce R&D costs. Moreover, studies in strategic management suggest that developing proprietary products within clinical settings can transform a service-oriented practice into a vertically integrated enterprise [10, 3]. Despite these findings, the literature still lacks detailed frameworks addressing how private maxillofacial practices can systematize product innovation while maintaining clinical quality.

This study aims to identify and substantiate the strategic value of in-house product development in private maxillofacial practice. The specific objectives are to:

1. Analyze the clinical, technological, and managerial factors that influence the feasibility of in-house product innovation.

2. Assess the impact of proprietary product development on patient satisfaction, clinic reputation, and financial sustainability.

3. Formulate a conceptual framework for integrating product innovation into private healthcare management.

Main resultates. Feasibility rests first on clinical plausibility: biomimetic hydroxyapatite (HAp) has a well-described capacity to occlude dentinal tubules and promote enamel remineralization, with randomized trials and systematic reviews showing reductions in dentin hypersensitivity and caries risk comparable to fluoride formulations when used consistently in daily care. This clinical signal lowers scientific risk for a clinic considering in-house innovation, because the active's mechanism of action, safety profile, and typical effect windows (≈ 4-6 weeks) are already documented across diverse patient groups. Recent syntheses report effective caries prevention with HAp in the absence of fluoride. At the same time, bench-to-chairside studies demonstrate surface repair, roughness reduction, and patient-reported sensitivity relief – evidence that allows clinics to anchor product claims to conservative, evidence-aligned language rather than speculative promises.

Regulatory and safety factors further support feasibility when approached with discipline. In the European Union, cosmetic products are governed by Regulation (EC) No 1223/2009; within that framework, the Scientific Committee on Consumer Safety has issued a recent opinion confirming nano-hydroxyapatite's safety up to 29.5 % in toothpastes and 10 % in mouthwashes, provided purity and particle specifications are met [7]. In the United States, feasibility depends on intended use and claims: if a dentifrice claims anticaries activity via fluoride, it falls under the FDA OTC anticaries monograph; if a clinic formulates an HAp product without drug claims (e.g., "cosmetic whitening," "smoothness," "supports enamel"), it generally sits in the cosmetic category, shifting the compliance burden toward accurate labeling and cosmetic GMP rather than drug approval [24]. These pathways are managerially attractive because they permit staged market entry – first with cosmetic claims, later, if desired, with formal drug pathways – while maintaining patient safety and regulatory alignment.

On the technological side, small-batch oral-care manufacturing is achievable with standard equipment (mixing, homogenization, pH control, filtration, filling) if the clinic partners with a contract manufacturer or sets up a compliant pilot line. What matters is process control rather than scale: ISO 22716 – Cos-

metics – Good Manufacturing Practices [14] and the FDA's GMP guidance under MoCRA specify documentation, equipment hygiene, personnel training, in-process checks, release criteria, and complaint handling. In practical terms, a clinic can de-risk technology adoption by creating a lightweight product dossier (formula, supplier COAs, stability data, labels, claims substantiation) and validating critical parameters on small engineering batches before widening distribution. This approach modifies capital intensity and allows rapid iteration in response to chairside feedback without compromising traceability or quality [14].

Managerial feasibility ultimately hinges on governance, positioning, and a realistic scope of claims. As studies show, HAp's evidence base enables conservative, patient-meaningful positioning – "relief of sensitivity," "supports remineralization," "smooth enamel feel" – that aligns with both clinical observations and literature, reducing reputational risk and easing staff adoption. At the same time, claim inflation (e.g., drug-like anticaries assertions without meeting monograph requirements) should be avoided; a clear "cosmetic first" roadmap mitigates regulatory exposure in early phases. Cross-functional routines are critical: clinicians define the use-case and inclusion criteria; operations run GMP-style checklists; marketing translates evidence into plain-language content; and compliance pre-screens labels for jurisdictional nuances. In our view, clinics that embed this loop and use telemedicine or follow-up calls to collect short PROMs create a virtuous cycle: real-world data refine the formula, educate patients, and substantiate conservative claims over time. Finally, because feasibility is contextual, it is wise to pre-screen ingredient lists against the latest EU notifications and align U.S. labels with FDA cosmetic GMP conventions to ensure consistent compliance [7, 24].

Assessing impact begins with patient satisfaction, which, as we understand from the biomaterials literature, is closely tied to symptom relief and perceived treatment value. Hydroxyapatite (HAp) dentifrices consistently reduce dentin hypersensitivity and improve surface quality within 4-8 weeks; randomized controlled trials, including long-term trials, demonstrate noninferiority to fluoride in preventing caries and reducing sensitivity [21, 18]. In our view, this direct, experiential benefit converts a clinic-developed product into a satisfaction driver.

Reputation effects flow from this satisfaction-based and signaling mechanisms: physician endorsement functions as a strong heuristic in medical decision-making, and visible expert branding correlates with improved online ratings and patient trust. In dental and oral surgery contexts, systematic reviews emphasize communication quality and trust as central reputation levers [8, 23]. When conservatively positioned and transparently supported, clinic-branded evidence-based products can strengthen this loop by extending touchpoints, enhancing authority, and sustaining referrals.

Financial sustainability emerges from diversified, non-chair-time revenue streams. Practice-management commentary suggests that adding retail lines or private-label products increases revenue per visit and stabilizes income [11]. For example, a Dental Economics article describes how clinics create additional value by building balanced mixes of products and services to reduce dependence on procedural volume [11]. A hybrid model (clinic dispensing + subscriptions + selective B2B distribution) balances margin and volume while lowering cash flow volatility.

A coherent conceptual framework for integrating product innovation into private healthcare management should link clinical evidence, compliant manufacturing, market fit, and continuous improvement within one governance system [3, 4]. At the core is a closed learning loop that moves from problem definition in the clinic (unmet needs observed chairside) to rapid formulation, controlled clinical use, compliant release, and post-market analytics, then cycles back to refine claims and composition. Governance anchors the loop through stage-gates, each with predefined go/no-go criteria on safety, efficacy signals, quality, and brand fit [4].

Idea → Feasibility → Pilot (chairside micro-trial with PROMs) → Compliance Review (claims, labeling, safety file) → Limited Launch → Scale

Process discipline is ensured by cosmetic-GMP playbooks for small-batch production (documentation, hygiene, in-process checks, release criteria, and complaint handling) so that even modest pilots meet traceability and quality norms [14,24]. Regulatory alignment is built in early: in the EU, nano-hydroxyapatite limits and specifications from the SCCS guide safe formula boundaries and labeling; in the U.S., a "cosmetic-first" path keeps claims within cosmetic scope until evidence and strategy warrant an OTC drug route [7, 24].

Strategically, the framework nests this loop inside a management scorecard that aligns four perspectives – clinical, patient/market, internal processes, and financial – so that innovation activity advances care quality, reputation, efficiency, and econom-

ics in parallel [15]. Clinically, product indications are tied to pathways (e.g., sensitivity management, early erosive wear) and monitored via short PROMs at 2-4 weeks; patient/market fit is validated through transparent education, conservative claims, and digital reputation metrics (conversion, review velocity, NPS); internal process excellence is tracked via batch yield, QC deviations, cycle times, and complaint resolution; and financial impact is assessed through revenue mix, reorder rate, contribution margin, and customer lifetime value. To keep patient value central, the framework uses a clear value proposition map – explicitly linking the product's biomimetic mechanism (e.g., hydroxyapatite tubule occlusion/remineralization) to jobs-to-be-done (comfort, recovery support, daily maintenance), pains relieved (thermal "zing," postoperative sensitivity), and gains created (smooth enamel feel, professional oversight) [20].

Operationally, the model specifies roles and handoffs so the clinic can execute at a small scale without friction: clinicians define the problem and inclusion criteria and review chairside outcomes; an operations lead owns GMP checklists, supplier COAs, stability data, and release documentation; marketing translates evidence into plain-language microcontent and manages online channels; and compliance pre-screens labels/claims by jurisdiction. Data systems connect the parts: EMR flags eligible patients; CRM automates education and follow-up surveys; an analytics dashboard integrates PROM/NPS, sell-through, QC, and complaint data for monthly reviews. Telemedicine touchpoints are built into the first 4–6 weeks of home use to reinforce instructions, collect PROMs, and triage issues quickly – closing the evidence loop while sustaining engagement. Channel strategy follows a balanced sequence—clinic dispensing for initiation and counseling, subscription reorders for convenience, and selective B2B for volume smoothing – each with guardrails that avoid incentive conflicts and maintain clinical integrity.

Implementation proceeds in three horizons. In Horizon 1 (0-3 months), the clinic codifies governance (stage-gates, SOPs, dossier templates), selects one use-case, and completes engineering batches with stability and label drafts aligned to SCCS/FDA conventions [14,7,24]. In Horizon 2 (3–9 months), it runs a chairside pilot with PROMs, executes a limited launch with conservative claims, and activates the scorecard dashboard; monthly reviews decide iterate/hold/scale. In Horizon 3 (9-18 months), it scales production, formalizes distributor agreements, and expands SKUs only after meeting thresholds on clinical signal (e.g., sensitivity reduction), quality (QC deviations below target), reputation (NPS above target), and finance (minimum contribution margin). In this way, product innovation becomes a managed capability – clinically anchored, quality-assured, market-validated, and economically transparent – rather than a one-off experiment. When clinics follow this framework, they convert clinical know-how into tangible, compliant offerings that reinforce patient satisfaction, strengthen brand authority, streamline operations, and diversify revenue – advancing the broader strategic agenda of sustainable, patient-centered private healthcare [15, 4, 14, 7, 24, 20].

Conclusion. This study substantiates that in-house product development represents a technical innovation and a strategic transformation for private maxillofacial practices. Clinics can evolve from service-oriented enterprises into hybrid medical-entrepreneurial ecosystems through the integration of clinical expertise, managerial discipline, and regulatory awareness. The analysis demonstrated that clinical feasibility depends on aligning biomimetic material research with evidence-based protocols, ensuring that innovation complements – rather than disrupts – therapeutic safety and efficacy. Technological adoption, particularly of hydroxyapatite-based compounds and digital modeling tools, enhances procedural precision while opening new opportunities for product differentiation and brand positioning.

As empirical and theoretical studies have shown, proprietary product development strengthens patient trust and satisfaction by visibly connecting the clinic's scientific credibility with tangible outcomes. When innovation is embedded in a transparent clinical pathway and supported by post-treatment feedback mechanisms, it becomes a key driver of loyalty, reputation, and long-term competitiveness. Financially, such internal R&D initiatives diversify revenue streams, mitigate supplier dependency, and promote operational resilience – mainly when supported by lean resource allocation, ethical marketing, and digital process management.

The conceptual framework formulated in this research offers a comprehensive guide for clinics seeking to institutionalize innovation. It links clinical discovery with compliant production, market feedback, and continuous improvement within a single governance system. In doing so, it provides a pragmatic blueprint for converting clinical knowledge into scalable, evidence-based products that reinforce medical integrity and business sustainability.

Ultimately, in-house innovation should not be viewed as a supplementary or experimental activity but as a core strategic function of modern healthcare

management. For maxillofacial practices, it represents an essential path toward independence, differentiation, and resilience in a competitive, patient-centered, and regulation-driven environment. Further studies may expand this model to other dental and surgical specialties, testing its long-term impact on profitability, patient outcomes, and the evolution of clinical entrepreneurship in private medicine.

REFERENCES

1. Amaechi, B. T., et al. (2021). Hydroxyapatite and its preventive effects on dental caries: A systematic review. *European Journal of Dentistry, 15*(1), 1–8. https://doi.org/10.1055/s-0040-1717001
2. Cardinal Health. (2023). Private-label healthcare products: Margins and growth trends. https://www.cardinalhealth.com
3. Christensen, C. M., Grossman, J. H., & Hwang, J. (2020). The innovator's prescription: A disruptive solution for health care. McGraw-Hill.
4. Cooper, R. G. (2019). Winning at new products: Creating value through innovation (5th ed.). Basic Books.
5. De Melo Alencar, C., et al. (2019). Clinical effectiveness of toothpastes containing nanohydroxyapatite for dentin hypersensitivity. *Scientific Reports, 9*, Article 16987. https://doi.org/10.1038/s41598-019-53511-3
6. Di Stefano, G., Peteraf, M., & Verona, G. (2020). Dynamic capabilities and the evolution of business model innovation in healthcare startups. *Long Range Planning, 53*(3), 101871. https://doi.org/10.1016/j.lrp.2020.101871
7. European Commission. (2025). Scientific Committee on Consumer Safety (SCCS) — Opinion on hydroxyapatite (nano). https://health.ec.europa.eu
8. Ferreira, X., et al. (2023). Determinants of patient satisfaction in dental services: A systematic review. *International Journal of Dental Research and Practice, 6*(4), 211–223.
9. Garcia-Godoy, F., & Hicks, M. J. (2020). Maintaining the integrity of enamel and dentin: The importance of hydroxyapatite-based materials. *Journal of Clinical Dentistry, 31*(S1), S1–S7.
10. Grant, R. M. (2019). *Contemporary strategy analysis: Text and cases edition* (10th ed.). Wiley.
11. Harris, B. (2024, August 19). Add value to your dental practice by adding revenue streams. *Dental Economics.*https://www.dentaleconomics.com/sponsored/article/55091910/add-value-to-your-dental-practice-by-adding-revenue-streams
12. Holland & Hart. (2023). Navigating anti-kickback and self-referral risks in private healthcare retail. https://www.hollandhart.com
13. Hsu, J. Y., Lin, S., & Tsai, C. H. (2022). Effects of physician online reputation and expertise cues on patient selection. *Health Marketing Quarterly, 39*(2), 150–166. https://doi.org/10.1080/07359683.2022.2039046
14. International Organization for Standardization. (2007). ISO 22716:2007 — Cosmetics — Good manufacturing practices (GMP) — Guidelines on good manufacturing practices. ISO.
15. Kaplan, R. S., & Norton, D. P. (2001). *The strategy-focused organization: How balanced scorecard companies thrive in the new business environment.* Harvard Business School Press.
16. Kim, H., Park, E., & Lee, J. (2021). Innovation management in dental care services: The impact of R&D and product testing on clinic performance. *Healthcare Management Review, 46*(4), 275–284. https://doi.org/10.1097/HMR.0000000000000271
17. Limeback, H., et al. (2023). Remineralization and dentin tubule occlusion effects of hydroxyapatite dentifrices: A meta-analysis. *Frontiers in Dental Medicine, 4*, Article 1065934. https://doi.org/10.3389/fdmed.2023.1065934
18. O'Hagan-Wong, K., et al. (2021). The use of hydroxyapatite toothpaste to prevent dental caries. *European Journal of Dentistry / PMC.* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8930857/
19. Ortiz, M. (2019). Trust and authority in healthcare decision-making: The role of professional endorsement. *Journal of Health Communication, 24*(6), 518–527. https://doi.org/10.1080/10810730.2019.1620278
20. Osterwalder, A., & Pigneur, Y. (2010). *Business model generation: A handbook for visionaries, game changers, and challengers.* Wiley.
21. Paszynska, E., Pawinska, M., Enax, J., Meyer, F., Schulze zur Wiesche, E., May, T. W., Amaechi, B. T., Limeback, H., Hernik, A., Otulakowska-Skrzynska, J., Krahel, A., Kaminska, I., Lapinska-Antonczuk, J., Stokowska, E., & Gawriolek, M. (2023). Caries-preventing effect of a hydroxyapatite toothpaste in adults: An 18-month double-blinded randomized clinical trial. *Frontiers in Public Health, 11*, Article 1199728. https://doi.org/10.3389/fpubh.2023.1199728
22. Porter, M. E., & Teisberg, E. O. (2007). Changing the Organization of Health Care—Reply. *JAMA, 298*(3), 286-288.
23. Shrestha, B., & Park, J. (2019). University-clinic collaboration for innovation in dental materials development. *Journal of Technology Transfer, 44*(5), 1381–1397. https://doi.org/10.1007/s10961-018-9701-7
24. Stanciu, A., et al. (2023). Online reputation management in oral and maxillofacial surgery: Systematic review. *BMC Oral Health, 23*, Article 754. https://doi.org/10.1186/s12903-023-03422-1
25. U.S. Food and Drug Administration. (2025). Guidelines for over-the-counter oral care products and cosmetic claims compliance. https://www.fda.gov
26. Zhang, L., Li, Y., & Chen, Z. (2025). Patient-reported outcome measures (PROMs) in dental care: Implications for satisfaction and engagement. *Journal of Dental Research and Practice, 8*(1), 34–46.
27. Zhang, Y., Zhou, X., & Chen, Y. (2022). Biomimetic hydroxyapatite in enamel restoration: Clinical applications and market trends. *Journal of Applied Oral Science, 30*, e20220145. https://doi.org/10.1590/1678-7757-2022-0145