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# Integration of medical device design training in clinical teaching - A case study

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#### I. INTRODUCTION

Dental practitioners often encounter situations that require customising the prosthesis to satisfy the needs of patients. Artificial devices called dental appliances or prosthesis is custom fabricated for the functional, aesthetic, and psychological wellbeing of patients (Chu et al. 2013). The patient's complaints may vary from missing natural teeth to extensive maxillofacial defects, and there is no single best rehabilitative therapy for these conditions. Designing our product is the choice, and this demands adaptive expertise, i.e., the ability to generate potential solutions (Mylopoulos et al. 2018). Maxillofacial Prosthodontics applies a variety of learning methods like systematic simulation laboratory exercises, See One, Do One, Teach One (SODOTO method), and supervised clinical practice to train the routine technical skills and clinical practice. To maximise the outcomes in the complex prosthetic treatment, the course specialists designed

"Interdisciplinary Device Development program (IDDP)"—a value-added course for the postgraduates in collaboration with the Biomedical Instrumentation Engineering Faculty of our Institution. IDDP is the first of its kind challenge-based learning model in Dentistry that uses innovations to deal with rehabilitation care beyond routine practice. This paper aims to present our IDDP model and programme outcomes.

#### **II. METHODS**

IDDP is structured in three stages referring to problem determination, design, and development. An abstract idea about the essential requirements and intellectual property protection is also included and is scheduled for 3 hours per week for 10 weeks' (Table 1). The IDDP concept and curriculum were presented in the College Council meeting and subsequently in the Board of Studies and Academic Council. The proposal was approved and permitted implementation.

Program period	Interdisciplinary	Training
	team Participants	
1 <sup>st</sup> week (3 Hours)	Maxillofacial Prosthodontics clinical teachers and Postgraduates	<b>Problem determination</b> This stage is framed with a series of questions to tackle the issue and needs to be addressed by thedevise designers
2 <sup>nd</sup> - 5 <sup>th</sup> week (12 Hours)	Maxillofacial Prosthodontics & Biomedical Instrumentation Engineering	<b>Device designing</b> 1. Setting product objectives (mockup, refinement, and design representation using bio- engineering principles) 2. Prototype development
6 <sup>th</sup> -8 <sup>th</sup> week (9 Hours)	Maxillofacial Prosthodontics & Biomedical Instrumentation Engineering	<b>Device development</b> This stage uses case studies to discuss how to develop new devices to deal with fresh problems through knowledge translation.

9<sup>th</sup> - 10<sup>th</sup> week (6 Hours)

**Regulatory affairs & IP rights** Introduction to regulatory compliances, device validation, risk management, and intellectual property rights.

Table 1: IDDP curriculum framework

Participation in IDDP is mandatory for all postgraduates (PGs) of Maxillofacial Prosthodontics, but knowledge translation into practice is expected only when patients present with unique/challenging conditions. Chances of treating these patients are given for all PGs, but priority is given to those who showed valuable accomplishments in their regular clinical works. Once get allotted with such cases, the PG needs to work with their faculty incharge, the primary consultant, a faculty member from biomedical engineering, and laboratory technicians.

The device designing demands advanced prosthodontic techniques and the attainment of competency depends on repeated practice. Skill assessment before accustoming it is not a safe practice hence the IDDP is not emphasising on assessments that reflect on summative grade, but performance assessment was made for the postgraduates who have undertaken the task to appraise their diligence, completeness, and problem-solving ability in a standard template, and supporting them to improve their learning.

#### **III. INVENTIONS IN THE CLINICAL GROUNDS**

#### A. Cheek Bumper

A Von Recklinghausen's disease patient reported with a nodule on the left buccal mucosa and chewing difficulty. The patient expected non-surgical management, and there was a need for invention. Relieving the contact between the mucosal nodule and teeth was suggested as a solution and one PG student turned out the novel idea as an acrylic cheek bumper, an intraoral device that separated the growth 5mm away from the teeth surface. Wearing this appliance at mealtime solved the patient's problem.

## B. Training Pad for Jaw Reposition

A patient has undergone hemimandibulectomy on the right side. After a month, he reported aesthetic concern because of the deviation of the lower third of the face during jaw movements. Denture rehabilitation with a flange is a routine treatment to improve aesthetics. In our discussion, a PG student proposed to reposition the jaws before denture treatment to achieve the jaw compatibility for receiving the denture, hence optimising the success. The team accepted to transform the vision into reality. A prototype was prepared, and an intraoral acrylic pad with retainers was developed. Later the patient was treated with a prosthesis and he expressed his happiness in gaining back the chewing efficiency and confidence

*C. Modified Impression Tray to Make Ear Prosthesis* To avoid the shape distortion and to get the adequate fine details in the replica, a postgraduate student in the existing tray pattern did a design modification and got an excellent result.

## D. Compression Stent

A patient was referred for the management of a hypertrophic scar following ear piercing. The literature search revealed a solution of stent fabrication to cover the affected ear completely and wearing it full time for a year. The drawbacks like patient discomfort and longtime follow-up were highlighted and a PG student suggested redesigning the compression sent to cover only the scar region using claw type hair clip model. The patient was instructed to wear the stent for 10 to 12 hours per day. At the end of the fifth month, the scar was completely disappeared and she regained the ear lobe shape.

The devices in the process include:

- i. Mouth opening assisting device to treat trismus.
- ii. Impression tray with size adjustable screws.

iii. Custom designed intraoral radio-productive device for patients receiving radiotherapy.

## IV. STRENGTHS AND LIMITATIONS

A supportive curriculum always opens an avenue for innovation. Integration of Biomedical engineering solved the clinical problem by applying engineering principles, formulas, and materials in device designing as the dental specialty lacks the potential to practice the engineering domain. IDDP inspired our postgraduates to take part actively in treatment planning sessions. There is a positive shift in their clinical reasoning skill, describing the treatment options with their pros and cons, and finally specifying the target device by solving the limitations on the existing model or developing an alternative model.

The unresolved factors of IDDP include the struggle to tap the inventive potential of graduate students, their level of commitment, and time allocation. Formal assessment, patient satisfaction survey, student perception, and feedback should be considered.

## V. MOVING FORWARD

Incorporating IDDP in the dental curriculum at the national level is the way forward.

## VI. CONCLUSION

Our experience in IDDP evidences the innovation that happened on academic grounds. The structured training

and opportunity to transform the learning into practice enhanced the confidence level of the clinicians to think out of the box, act as problem solvers, and shape the future health care industry.

#### Notes on Contributors

Dr. K. Anbarasi, MDS, PhD, devised the presented concept, framed the theoretical framework, wrote the manuscript, and agreed on its final form for submission.

Dr. Kasim Mohamed, MDS, involved in curriculum planning, conducted the programme, contributed to the final version of the manuscript, and agreed to its final form for submission.

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## Declaration of Interest

The authors have no conflict of interest.

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