

Cost-Utility Analysis of a Novel Poly-lactic Acid Dermal Matrix for the Closure of Diabetic Foot Ulcers

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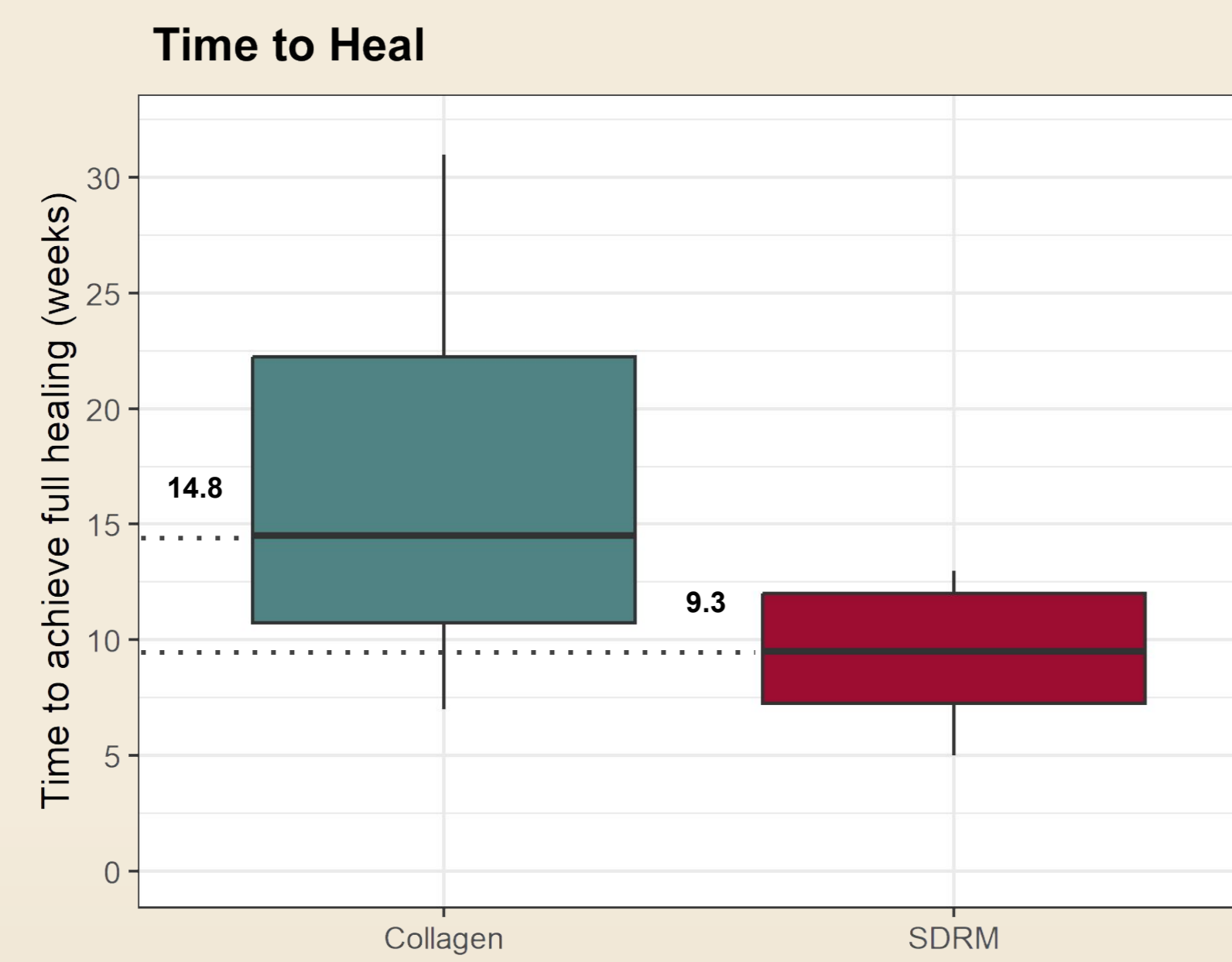
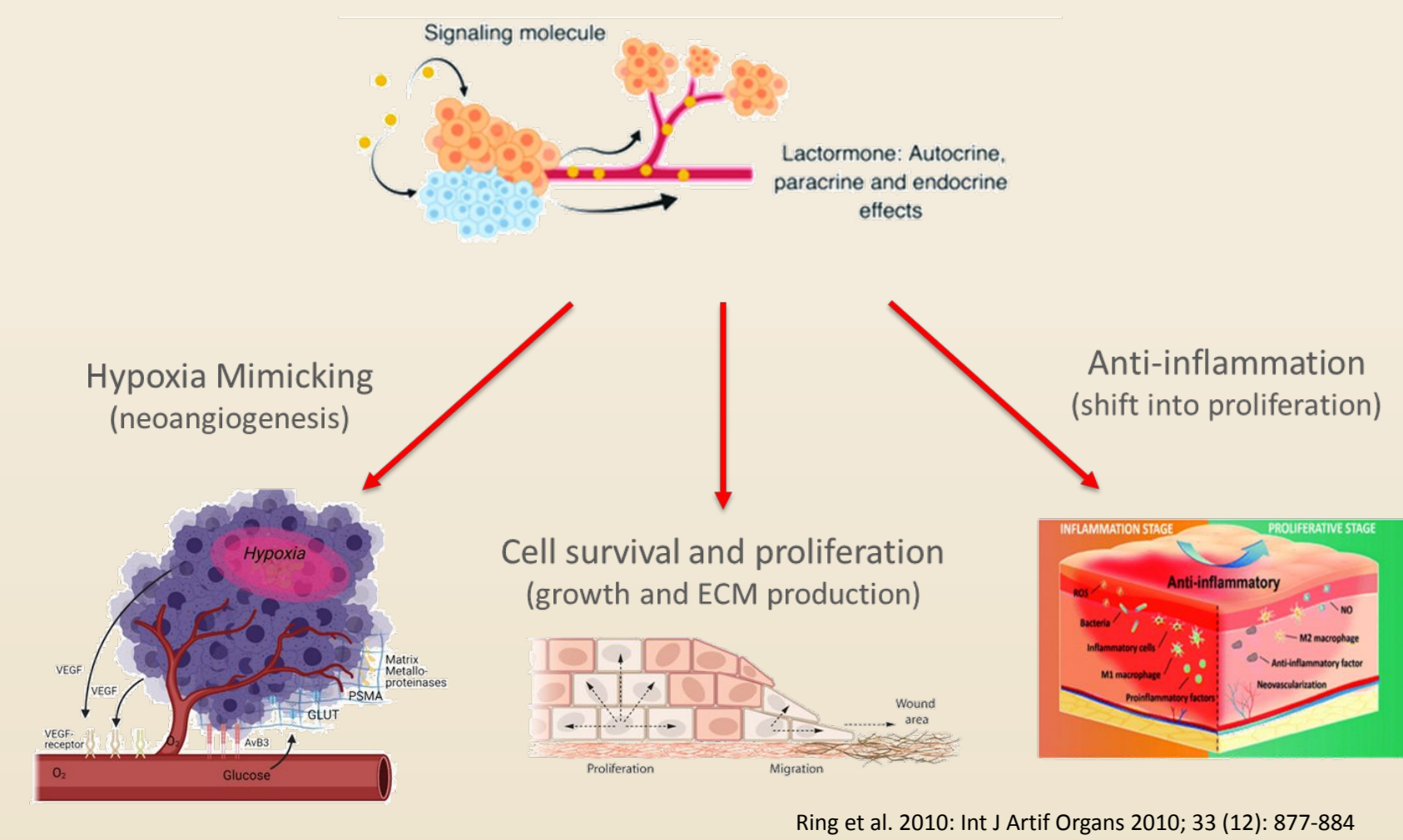
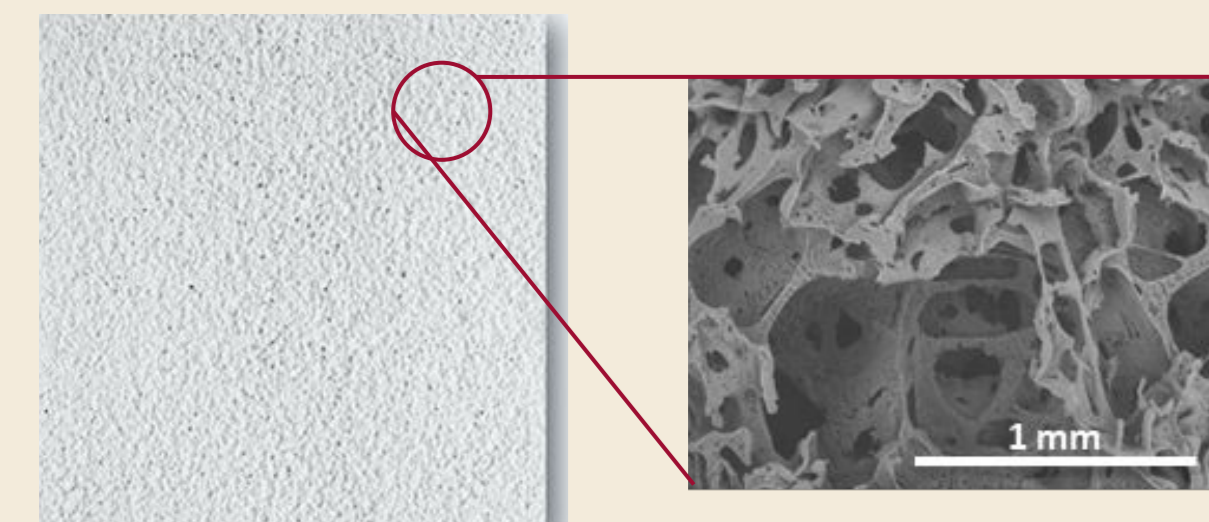
Background

Objective:

- To present a **cost-utility analysis** of a randomized-controlled trial (RCT) data to highlight the immediate economic advantages and the health outcomes of using **poly-lactic acid (PLA) wound closure matrices** in managing diabetic foot ulcers (DFUs).

Background:

- DFUs affect up to 35% of people with diabetes and represent a challenge for closure.
- We recently published an RCT demonstrating a **44% reduction in time** for achieving DFU healing when using a novel **PLA wound closure matrix** compared to standard of care (collagen dressings). ¹
- The **lactate** released by the PLA matrix acts as a paracrine agent (lactomone) with potent signaling effects that include:
 - Hypoxia mimicking** and triggering of **neo-angiogenesis**
 - Cell survival and proliferation**
 - Anti-inflammation**
- In addition, the lactate causes acidification of the wound bed and a **pH shift** to neutral values.
- While PLA wound closure matrices have demonstrated significant clinical benefits, to date, no analysis of whether they are cost effective has been performed.



Full healing of the wounds was achieved in 14.8 ± 8.1 vs. 9.3 ± 2.9 weeks (p=0.021) in the collagen vs. PLA group. This represents a **reduction of 44% of the time** needed to achieve full wound closure, compared to the standard of care.

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Methods

- Effectiveness data**, including weekly wound size, were derived from the primary RCT outputs. ¹
- Cost components**, including debridement and wound care, corresponding to Ohio State's cost listings for 2022, were sourced from the United States Centers for Medicare & Medicaid Services. Other costs were extracted from price lists of wound care product manufacturers.
- The **total and mean costs** associated with the wound healing process were calculated for the cost analysis.
- Health utilities** for a non-healed and healed DFU were obtained based on the literature. For the cost-utility analysis, the time frame assessed corresponded to one full episode of a DFU lasting 29 weeks.
- Health outcomes were calculated using **quality-adjusted life years (QALYs)**.

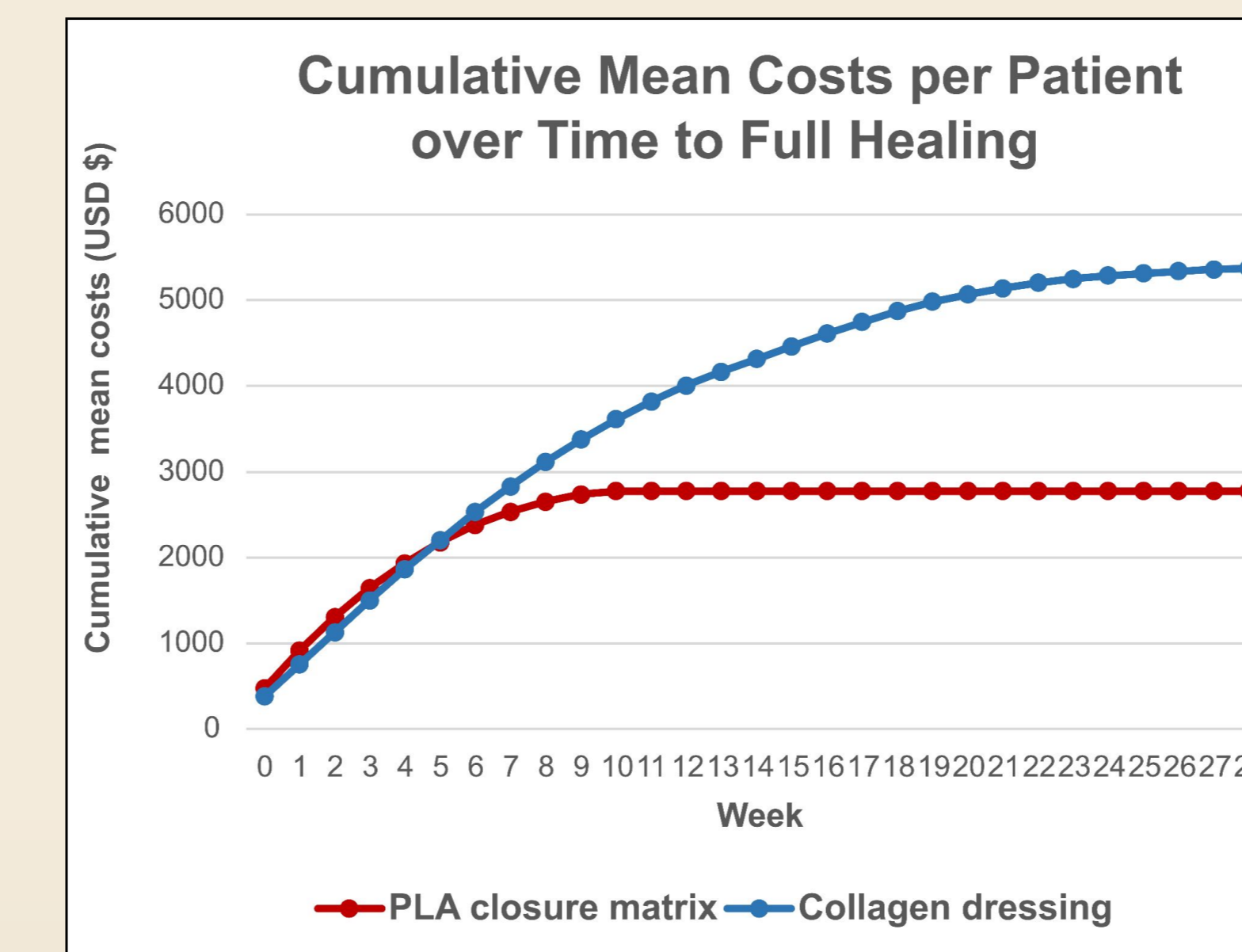
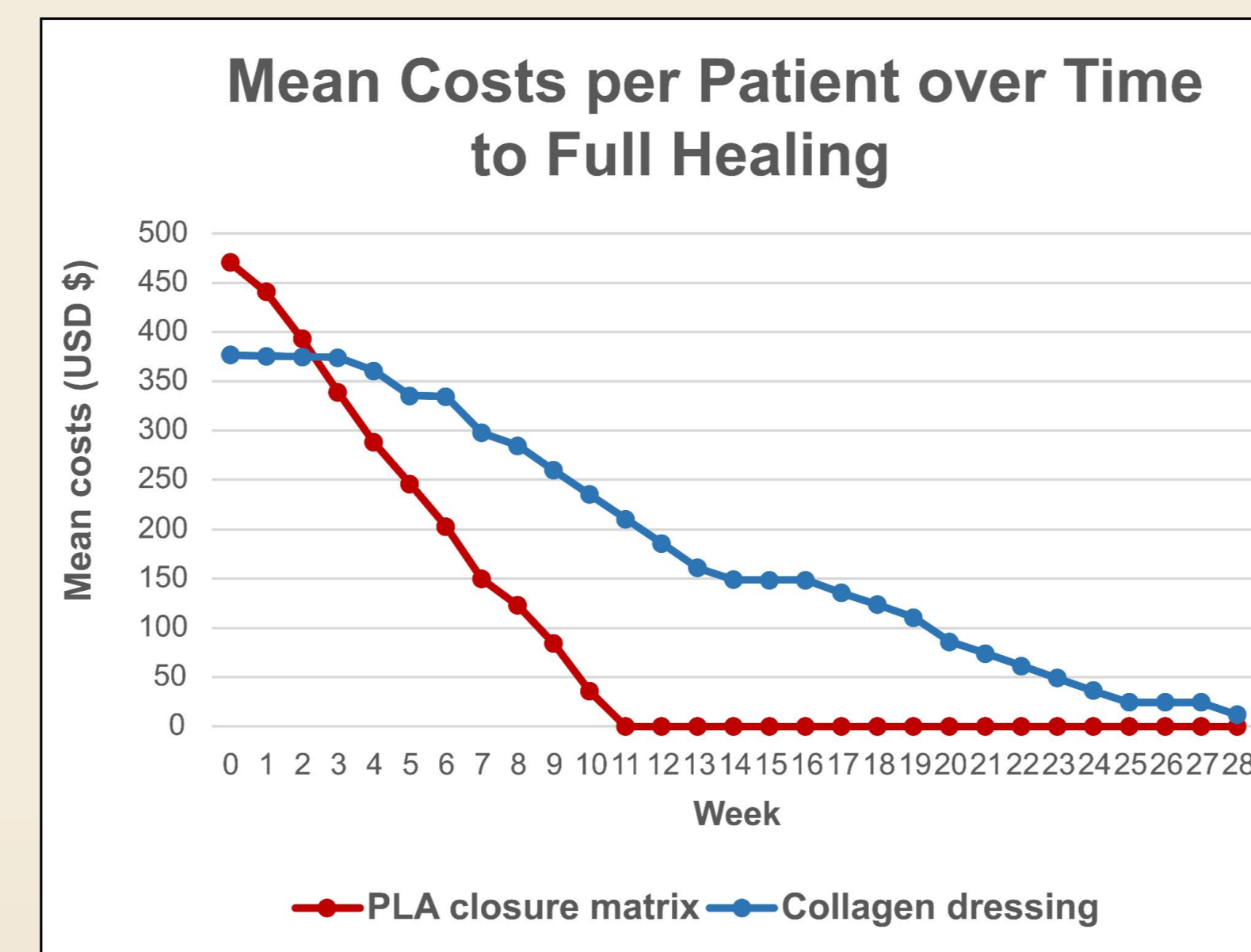
Results

- The cost components included in the model were the following:

HEALTHCARE SERVICES	CPT CODE	COST
PLA Matrix cost (per sqcm)	N/A	\$59.69
Collagen Dressing (per 4 cm ² piece)	N/A	\$10
Superabsorbent Dressing	N/A	\$10
Non-adherent Dressing	N/A	\$13.20
Debridement (only Collagen group)	11042 11045 add-on (if required)	\$126.07 \$40.30
Wound Care and CAMP application (only PLA group)	15275	\$156.84
Walking Boot	L4386	\$167.28
At-Home Nursing Care (Home health)	N/A	\$177.53

<https://www.cms.gov/medicare/physician-fee-schedule/search/overview>

- Cost over Time:**



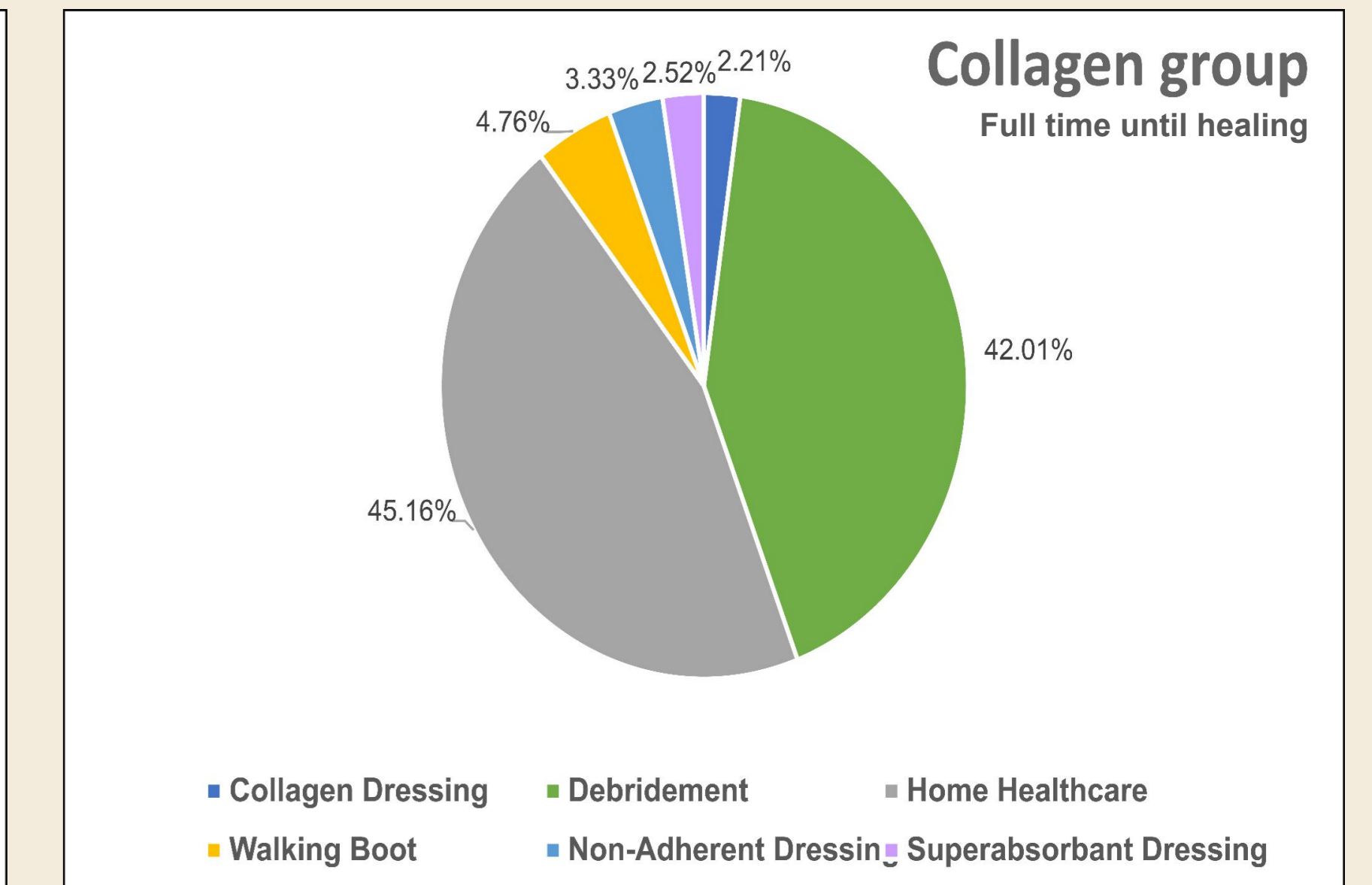
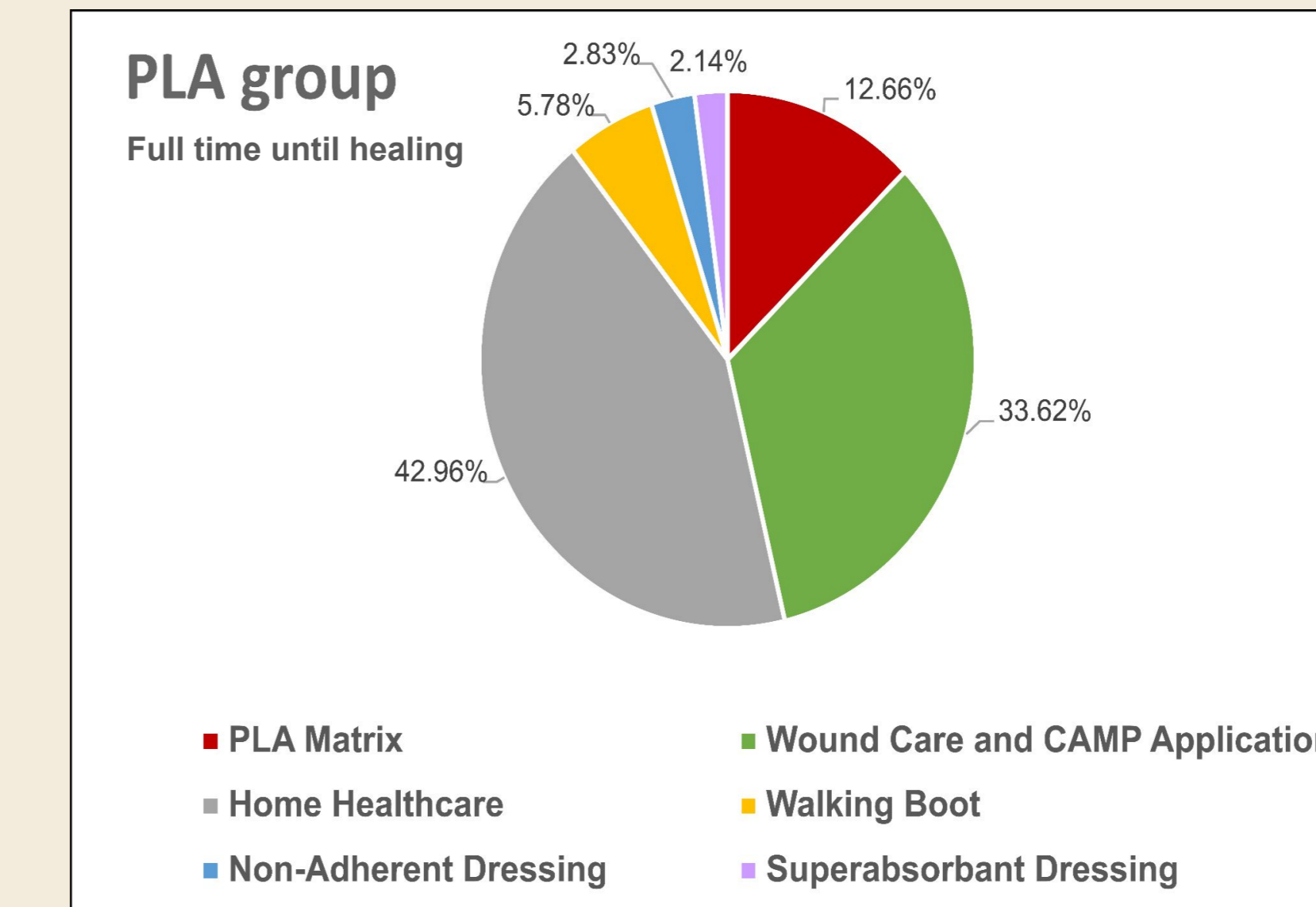
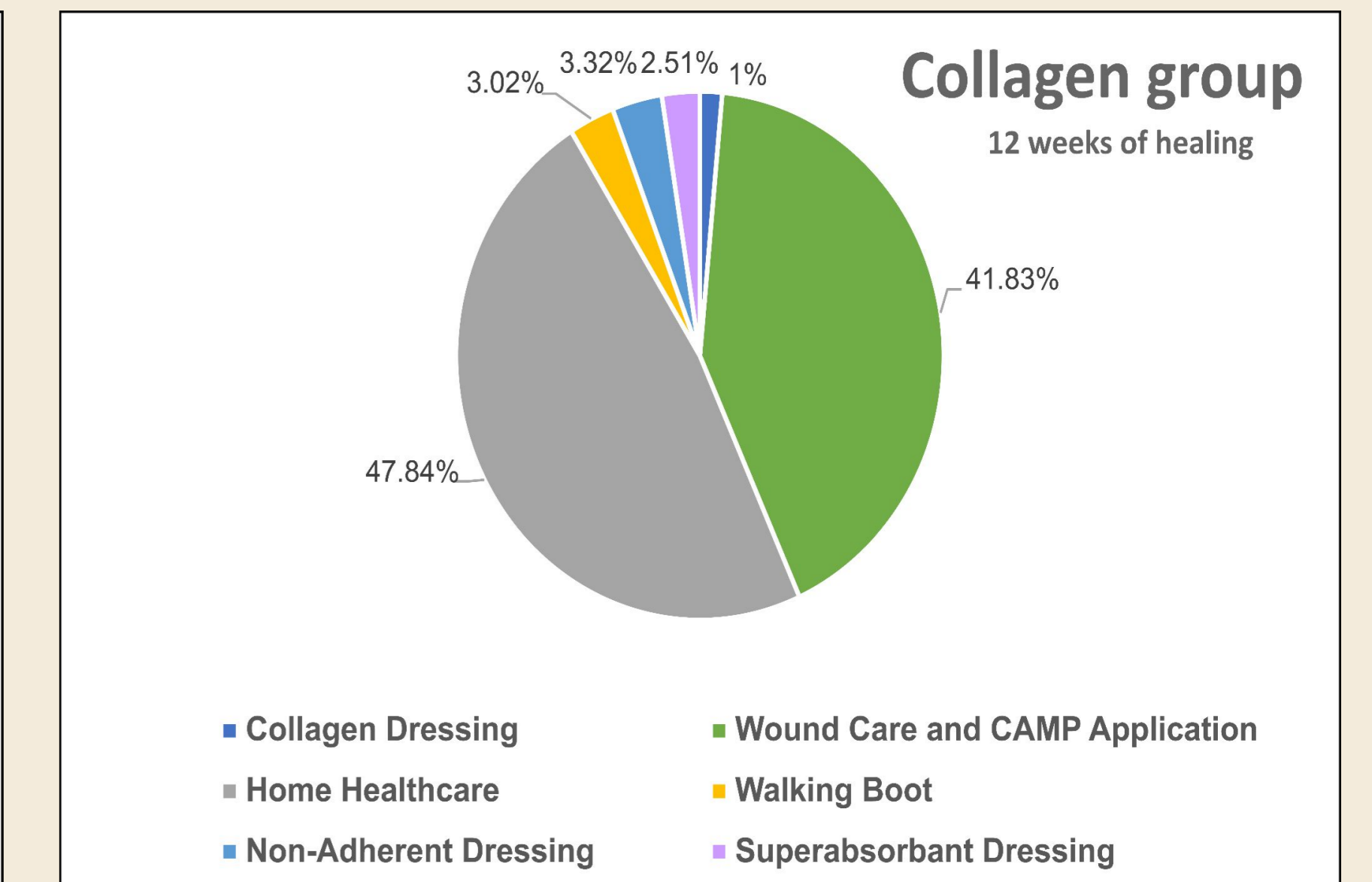
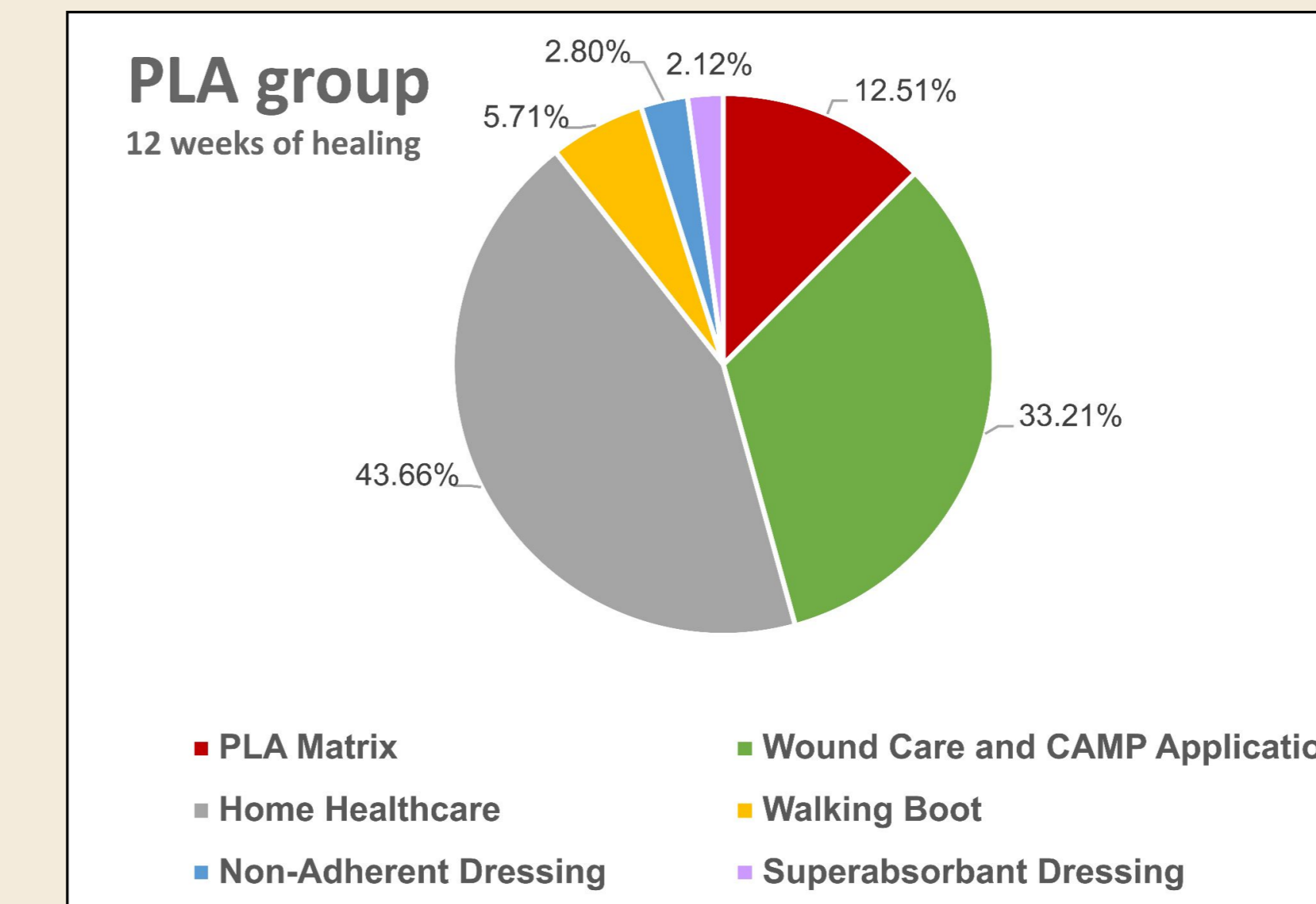
The **PLA intervention cost decreased gradually**, so patients did not incur any costs from the 13th week onwards because they were completely healed. In contrast, patients in the collagen group were treated until the 31st week, which resulted in a longer payment period. Therefore, **cumulative cost analysis showed a higher cost for the collagen group after the 8th week**. By the end of the trial, the total mean costs per patient to achieve closure of a DFU were almost twice as high in the collagen group than those in the PLA group.

- Health outcomes (QALY):**

- Health outcomes were calculated using **quality-adjusted life years (QALYs)**, which combine the impact of quality of life (utility) and quantity of life (time) associated with our intervention.
- The **time horizon** was 31 week. For this reason, QALYs were **converted to weeks**.
- The **utility value** was derived from other studies ^{2,3}:
 - Healed ulcer**; utility value = 0.8
 - Unhealed ulcer**; utility value = 0.6

INTERVENTION	Mean QALY (years)	Mean QALY (weeks)
PLA matrix	0.46	24
Collagen dressing	0.30	20

The results of our study showed that PLA dressing provides a higher quality of life index compared to collagen dressings. To put it another way, **PLA provided 4 more weeks of complete health, compared to collagen dressings**.



The most expensive part of the treatment was home-healthcare, followed by debridement or wound care and CAMP application. Remarkably, for the PLA group, the costs associated with the product were less than 15% of the total. In the case of collagen dressings, despite the costs being a minor fraction of the total, they increased by more than 100% when analyzed at 12 weeks of care vs. full healing. Therefore, it was concluded that **PLA had lower costs than collagen dressing at both 12-week and full healing time points**.

Discussion

- The **PLA group had a lower cost and higher QALY in comparison with the collagen group**.
- A sensitivity analysis (not shown) indicated that even after removing the home visit costs, the PLA group still had lower costs than the collagen group.
- Among both groups, home-healthcare and wound care accounted for the majority of costs, **not the products**.

In summary, the use of PLA is cost-effective in comparison to collagen dressings.

In addition to reducing the duration of treatment considerably, which improves the quality of life of patients, it also reduces the burden of costs on patients and for the Health Care system.

References

- Liden BA, Ramirez-Garcialuna JL. Efficacy of a poly-lactic acid matrix for the closure of Wagner grade 1 and 2 diabetic foot ulcers: a single-center, prospective randomized trial. Wounds. 2023 Aug;35(8):E257-60.
- Dougherty EJ. An evidence-based model comparing the cost-effectiveness of platelet-rich plasma gel to alternative therapies for patients with nonhealing diabetic foot ulcers. Advances in Skin & Wound Care. 2008 Dec 1;21(12):568-75.
- Carrington AL, Mawdsley SKV, Morley M, et al. Psychological status of diabetic people with or without lower limb disability. Diabetes Res Clin Pract 1996;32:19-25.
- Haller HL, Sander F, Popp D, Rapp M, Hartmann B, Demircan M, et al. Oxygen, pH, Lactate, and Metabolism—How Old Knowledge and New Insights Might Be Combined for New Wound Treatment. Medicina. 2021 Nov;57(11):1190.
- Certo M, Llibre A, Lee W, Mauro C. Understanding lactate sensing and signalling. Trends in Endocrinology & Metabolism. 2022 Oct 1;33(10):722-35.