Cost Comparison of Manufacturing Clear Aligners In-Office vs. Outsourcing

by

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DEDICATION

I dedicate this thesis to my dearest mom, Josephine Ginika Akpua, often referred to as Dr. J. This work is a testament to the unwavering love, endless support, and boundless sacrifices you have made for me. Your strength has been my anchor, your wisdom my guiding light, and your faith in God and in me my greatest inspiration. Thank you for your endless support and always believing in me.

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ABSTRACT

Introduction: The rising demand for clear aligners has prompted orthodontic practices to evaluate the economic feasibility of in-office manufacturing versus outsourcing. The purpose of this study was to calculate the per-aligner cost of manufacturing in an in-office setup, factoring in overhead, direct and indirect materials, and direct labor. In addition, it examines the break-even point, per-unit-cost where in-office manufacturing becomes more cost-effective than outsourcing to an established lab. That is, the break-even point signifies the point when all the initial investments have been paid off so any difference after that point is all profit towards the in-office manufacturing side, and it is measured in terms of individual aligners. By comparing the financial implications of these options, this research aims to provide orthodontic practices with data-driven formulas to make informed decisions about whether to outsource clear aligners production or manufacture them in-office.

Methods: Using established theoretical frameworks, the formula to calculate cost of manufacturing per-aligner, and the break-even point was obtained. Each variable was then obtained from vendor quotes for 3D printers, alcohol wash, and curing units, aligner materials, and software required for in-house manufacturing. Allowable depreciations were obtained from the federal government page. Operational costs, including labor, maintenance, and utilities, specific to in-office production in orthodontics offices were utilized. Average production volumes were based on the average that were obtained from offices that does mostly or only in-office manufacturing for clear aligners. Published product pricing rates for outsourcing aligners from industry-leading providers were used, and an assumption on the average amount of aligners used for each product pricing offers were made to ensure an

equivalent base to calculate the break-even point. Each variable was then plugged into an excel sheet to ensure consistency and reliability during calculations.

Results: Using Sprintray's Pro 2 3D printer, ProWash, and NanoCure, with a 7 year useful life and 12,000 annual model prints. In addition to zendura flx, Ulab software, 24.85% depreciation, an average orthodontic assistant salary of $21.98, and a facility cost that include a 9 sqft lab in a 1,500 sqft office, and $2 per sqft for utilities, the average cost to manufacture a single in-office aligner is $17.51. Using a weighted average and with the assumption that the average total aligners used is 90 aligners for invisalign comprehensive, 60 for invisalign moderate, 42 for Invisalign lite, and they are used 65%, 25%, and 10% of the time on average, the break-even point for Invisalign is 1,746 individual aligners or 873 pairs of aligners. Similarly for spark aligners, using a weighted average and average 90 for spark advanced, 70 for spark 20, and 30 for spark 10, and they are used 65%, 25%, and 10% respectively, the break-even point is 4,190 individual aligners or 2,095 pairs of aligners.

Conclusion: This study analyzed the cost to manufacture clear aligners in-office vs outsourcing using a detailed cost breakdown and break-even analysis. The findings highlight that although the cost per aligner is $17.51 and remains constant, the break-even point varies significantly based on the company that is being outsourced to, the selected product purchased from the company, the average total number of aligners used per patient. For example, with the assumptions made, In-office manufacturing becomes more cost-effective than Invisalign after 1,746 individual aligners or 873 pairs of aligners. When compared to spark aligners, the break-even is 4,190 individual or 2,095 pairs of aligners. Orthodontic practices should adopt in-office manufacturing for aligners if their production volume consistently exceeds the calculated break-even

points for their treatment plans. For lower-volume practices or those prioritizing upfront cost savings, outsourcing may remain the preferred option. Strategic planning and regular cost analysis will ensure the chosen production model aligns with the practice's financial goals and operational needs.

Review of Literature

Theoretical frameworks

To have a thorough and objective analysis of the cost-comparison between manufacturing aligners in-office or outsourcing to an established lab, certain frameworks and models must be established[1]. The theories and models that relevant for this cost-comparison study are Cost-Benefit Analysis (CBA), Break-Even Analysis BEA), and Production Economics (PE).

Cost-Benefit Analysis:

This is a financial analysis that involves the process of comparing the total projected or estimated costs in embarking on a project action to the anticipated benefits to determine if it is an action that is worthwhile[2]. It is useful in this case because the approach of manufacturing aligner in-office is being compared to outsourcing to an established lab.

The cost associated with manufacturing in-office aligners include the initial fixed investments for equipment such as 3D printers, alcohol wash machine, curing unit, and employee training, variable costs such as raw materials (aligners), indirect cost (overhead and maintenance), and labor that is directly proportional to the number of aligners produced [3]. The benefits of in-office manufacturing include faster turnaround time, increased flexibility and customization for the clinician, and typically less cost per unit ordered[14].

On the other hand, the costs associated with outsourcing to manufactured labs include the cost per unit produced, and administrative and shipping fees[4,5]. The benefits include significantly lower initial investments, the ability to scale and cutback promptly and efficiently, and benefiting from latest and greatest technology available because established labs typically budget extensively for research and developments[5].

Although one of the goals of CBA in this scenario is to help clinicians make objective decisions which will require quantifying the benefits to align with the costs, some of the drawbacks are that some of the benefits, especially the intangibles are hard to quantify, and different clinicians value different things. In addition, some variables such as market demands, cost of materials, and useful life of technology are unpredictable[2].

Break-Even Analysis:

Break-even analysis is a financial tool that helps companies realize the point at which taking one course of action will equal to the alternative, often referred to as the break-even point[6]. In this scenario, it will be to know the point at which manufacturing in-office aligners will equal the cost of outsourcing. Calculating the break-even point will allow clinicians to know the amount of patients that aligner-care services need to be rendered to before it becomes more cost effective to manufacture in-office aligners. Knowing this point and understanding the analysis can help dental offices with strategic decision making and market positioning [7].

There are five components to break even analysis: fixed costs, variable costs, revenue, contribution margin, and the break-even point [8]. When comparing two path of actions like in this scenario, the fixed cost refers to the initial investment required for in-office manufacturing, the variable cost is also for in-office manufacturing, the revenue refers to the cost of outsourcing per unit ordered, the contribution margin refers to the difference between the cost of outsourcing per unit and the variable cost per unit manufactured in-office, and the break-even point is when there is no net difference in the total costs associated with taking either routes[8].

Although the break-even point could help companies with market positioning and decision making, it has its limitations. One of its main drawbacks is that it assumes prices will remain constant. For example, in this case it assumes that the variable costs like overhead and labor, and outsourcing cost to remain fixed. Market volatility and the constant changes in prices of goods and services makes it extremely difficult to have an accurate real-time break-even point[9]. Another limitation is that it assumes that all costs will be fully classed into either fixed or variable but in reality, a few costs could be classified as semi-variable[9]. For example, in a case of in-office aligner manufacturing where the 3D printer is fixed and the resin used per model is variable, resin tank fits into neither category as it is a semi-variable cost. It does not have a linear direct correlation with the numbers of aligners produced but it needs to be replaced after prolonged usage. In addition, the break-even point sole focus is on quantitative analysis so making business decision solely based on that and not factor in qualitative measures such as customers experience and satisfaction, and competitive landscape could be a potential limitation to dental offices aiming to grow[9].

Production Economics:

The economics of production is a branch of economics that examines the relationship between input (labor, capital and raw materials) and output (good and services) in the production process[10]. Understanding production economics typically helps organizations maximize product/service efficiency with the minimum resource required. For example, in the scenario where the manufacturing of in-office aligners is being examined, the economics of production will consider the economies of scope, law of diminishing return, technology advancements, and economies of scale [10].

Economies of scope examines how the manufacturing of one good can indirectly reduce the cost of production of another one[11]. For example, the manufacturing of in-office aligners requiring initial investments to purchase 3D printers, wash station, etc., and equipments like these could also be used to manufacture other things such as a nightguard or other dental appliance which can help increase cost savings in offices where they would otherwise also outsource manufacturing of such dental appliances.

Law of diminishing returns states that if one keeps increasing a certain input (capital and resource) while other factors remain constant, as some point there will be minimal to no effect to the bottom line (outputs)[12]. In this scenario with aligner manufacturing, there could come a point where additional input does not have significant effects on the volume or quality of aligner produced.

Another aspect of production economics that plays a role in the decision of insource vs outsource is technology advancements. With advancements in artificial

intelligence and digital dentistry, orthodontic offices for example can produce dental appliances much faster and with more automation at lower marginal costs[13].

Furthermore, understanding economies of scale helps guide organizations on whether an input (investment) is worthwhile because in a manufacturing setting where there is a relatively high initial investment and fixed cost, the larger the volume produced, the lower the average cost per unit produced[14]. In context, the more aligners manufactured in-office, the orthodontic office will achieve economies of scale as the average cost of each aligner will decrease[15].

History and current practices in aligner production

The concept of using a series of removable appliance to move teeth was first introduced to the field of orthodontics in 1945 by Kesling[16] when he created a rubber-based tooth positioning appliance commonly referred to as the positioner. In the 1960s, Nahoum then introduced the first clear thermoplastic appliance as a new modality for orthodontics treatment[17]. It was commonly referred to as the dental contour appliance. The manufacturing process of this appliance involved making an impression of the dentition and creating a cast from that. This cast is then altered by sectioning the teeth with a jeweler's saw and using a baseplate wax to hold them in their new positions[18]. From this new position the appliance is formed, and this process could accommodate several materials such as polyethylene, and acetate, and was often fabricated in both clear and colored sheets[18]. In 1971, Ponitz then proposed the manufacturing of clear

aligners by preheating a clear plastic and then using a vacuum unit over the patient's cast model to transform the material into the form of the dental arch[19].

The evolution of the production of clear aligners took massive steps with the introduction of computer-aided design and computer-aided manufacturing (CAD-CAM) in the 1960s as this signified that orthodontics offices can overcome a major limitation of the current manual fabrication process which was limited to minor malocclusion[20]. Combining this with the development of additive manufacturing meant that clear aligner manufacturing is now ready for industrialization. i.e., it can be used to treat comprehensive cases and mass production is feasible[21,22].

In 1997, a key innovation in orthodontic treatment was discovered. Stanford University graduates Zia Chishti and Kelsey Wirth established Align Technology with the vision of using computer technology and 3D printing to create a personalized system of clear aligners for straightening teeth[23]. By 1999, Align Technology introduced Invisalign aligners to the market, and invisalign quickly became popular among consumers seeking a discreet and comfortable alternative to traditional orthodontic treatments[23]. As Invisalign's success grew, other companies such as Spark Aligners and ClearCorrect entered the market with their own clear aligner. In addition, some orthodontics offices decided to manufacture their own clear aligners rather than to outsource production. These systems not only do it provide comparable advantages and use similar treatment methods as Invisalign does, but their manufacturing processes are also similar[24]. In the following sections, we take a closer look at the key steps involved in current practices of clear aligners manufacturing by in-office and outsourcing to an established lab.

Current practice in in-office aligner manufacturing:

The first step of aligner manufacturing begins with the creation of an accurate digital representation of a patient's teeth[25]. Intraoral scanners have largely replaced traditional impression methods, offering greater accuracy and patient comfort[25]. These scanners capture detailed 3D images of the dental arches, which are then used to plan the treatment digitally.

The second step is involving computer-aided design. Once the digital scan is acquired, specialized orthodontic software is employed to create a detailed treatment plan. This plan specifies the targeted tooth movements and determines the sequential progression of aligners needed to achieve the desired results. The software generates a series of precise digital models, each representing an incremental stage of tooth movement, which are then utilized as templates for the fabrication of the aligners[26].

The third step is involving additive manufacturing (3D printing). In this step digital models that were manipulated are subsequently transformed back into physical prototypes using 3D printing technology. Stereolithography (SLA) and Digital Light Processing (DLP) are two of the most frequently utilized type of 3D printing due to their sound capability and excellent precision to produce smooth, detailed surface finishes[27]. The selection of 3D printing technology and materials is a critical factor, as it directly influences the accuracy of the printed models and, consequently, the overall quality of the final aligners. After the models have been 3D printed, it is usually engulfed with excess slimy resin which can then be removed by washing the models in a bowl or

bucket of isopropyl alcohol, usually 70% and then light curing the models afterwards so it could withstand extreme heat.

The fourth step after the models have been 3D printed and processed, they serve as molds for the thermoforming process. During this stage, a thermoplastic sheet which is commonly composed of materials such as polyethylene terephthalate glycol (PETG) is heated and vacuum-formed over each model to shape the aligner[28]. The choice of material is essential because that determines key properties of the aligner such as its strength, flexibility, and optical transparency, all of which are essential for its functionality and aesthetic appeal.

The fifth step of manufacturing involves trimming and polishing as the thermoformed aligners to achieve a precise fit and eliminate any excess material. Rigorous quality control measures are applied at this stage to ensure that each aligner meets the required specifications and is free of defects[29]. This step helps ensure the aligner's functionality, effectiveness, and overall comfort which could help increase patient’s satisfaction and achieve desired treatment outcomes.

The final step involved in aligner manufacturing is packaging and delivery. This is vital to ensuring the aligners reach patients in optimal condition and are ready for immediate use. These processes are designed with careful attention to practicality, hygiene, branding, and patient education[20]. Proper packaging safeguards the aligners against contamination and damage during transit, while also reflecting the brand's professionalism. Additionally, providing clear instructions and educational materials

alongside the aligners ensures that patients understand proper usage and maintenance, enhancing treatment outcomes and patient satisfaction.

Current practice in outsource aligner manufacturing:

The first step of outsourcing aligner manufacturing is identical to that of in-office production as clinician will need a digital representation of the patient's teeth, this is routinely achieved with a 3D intraoral scanner. The next step is then to upload the digital representation into the software or platform of the outsourced company to be able to manipulate the digital representation to the clinician and patient's comfort. After that, the lab will then handle the comprehensive production process, which includes creating 3D models, thermoforming the aligners, and performing the final trimming and polishing. All steps are carried out based on the data provided, ensuring the aligners are precisely tailored to the patient's treatment plan.

Cost component analysis

The cost structure associated with in-house aligner manufacturing compared to outsourcing encompasses distinct categories that significantly influence the financial and operational strategies of orthodontic practices. A comprehensive understanding of these cost components is essential for evaluating the long-term feasibility, cost-efficiency, and overall impact of each production method on practice sustainability and patient care outcomes.

Cost component of in-office production

Fixed cost:

One of the most notable costs when it comes to in-office aligner manufacturing is the initial start-up cost, often referred to as the fixed cost. Fixed costs are expenses that remain constant regardless of the production volume, whether no items are produced, or hundreds are manufactured[31]. These costs are incurred independently of output levels and typically include investments in equipment, and software licensing. In this case, the production process necessitates the use of high-quality equipment, including 3D printers, isopropyl alcohol (IPA) wash equipment, curing units, intraoral scanners, and thermoforming machines[41]. These tools are essential for ensuring precision, efficiency, and the consistent quality of the aligners produced. For this exercise, the cost of intraoral scanner was excluded because it is also used in the production of outsourced clear aligners. Sprint ray 3D printers, wash and curing units were used as reference because it is the most common 3D printers used amongst orthodontists in United States[42]. Ulab was used as the software of choice because it is the most used software for in-office aligner manufacturing[32] in the US and it has no initial cost for licensing.

Variable Costs:

Variable costs are expenses that fluctuate based on the number of appliances produced. These costs are directly tied to the volume of production[31]. These costs in this case include materials such as resin for 3D printing, thermoforming sheets, ongoing software use[32]. Variable costs are often subdivided into direct and indirect materials. The primary distinction between the two is in their role within the production process.

Direct materials are integral to the creation of a specific product or service and become a part of the final product, such as the thermoforming plastic sheets used to fabricate aligners. In contrast, indirect materials support the overall manufacturing process but do not directly form part of the final product, such as resin used to print the model of the patient's dentition[33]. For this exercise, zendura flx was used for thermoplastic aligners, sprintray model resins, and Ulab software to design the movement.

Labor cost:

The monetary compensation given to workers for their time, effort, and expertise in performing tasks to produce goods and services are widely regarded as labor cost. This includes wages, salaries, and other benefits that would help retain the worker[34]. Labor cost could be either a variable, fixed cost, or a combination of both as some workers are paid a set salary while others are paid based on the amount of time used to complete a given task[35]. For this exercise, labor cost will be classified as part of variable costs because hourly wages will be factored in rather than a standard salary, and it include the time dedicated towards the production process such as getting the models ready and cured, the thermoforming process, trimming and finishing of aligners, and packaging. What is not included is the time while the models are being printed, washed or cured as no actual labor is being used during that period. With tremendous variability in the average wage of an orthodontic assistant across state line, the national average will be used as a reference in this paper.

Opportunity Cost:

Opportunity cost is seen as the potential value of the next best alternative that is forgone when a particular decision is made, or an action carried. It represents the potential benefits or gains that could have been achieved by selecting a different course of action[36]. For example, assume 20 hours of labor time is spent weekly towards the manufacturing process and because the 20 hours is tied up, the worker cannot spend investing in other revenue generating service like marketing or patient's care. The opportunity cost in this sense would be the difference in whatever the profit from the other revenue-generating service minus the profit from manufacturing aligners in-office. This trade-off underscores the importance of evaluating opportunity costs when deciding whether to produce or outsource clear aligners. For this paper, there will be no quantification of opportunity cost.

Cost component of outsourcing production

Price-per-unit:

The most notable costs when it comes to outsourcing production for clear aligners is the price-per-unit cost[37]. Outsourcing providers typically charge a fixed fee per set of aligners with the freedom to keep the case open for a few years. These manufacturers typically charge a few hundred to just a little over $2000 for the complete set of aligners[38]. They also offer the option of limited set of aligners, single or dual arch for treatment, and options for treatment duration which starts after the first order has been placed. This fee generally covers models printing, aligner manufacturing, and packaging[39]. Then there is an additional charge for shipping and delivery[40]. For this paper, Align technology which charges from a low of $605 to a high of $2095 for dual

arch treatment[39], and SparkAligners with a range of $945 - $1730 for dual arch treatment[40] will be used as reference.

Shipping Cost:

Cost of shipping is the additional costs associated with outsourcing aligner manufacturing. These fees cover the transportation of digital impressions or physical models to the manufacturer, as well as the delivery of the finished aligners back to the practice [39,40]. This contributes to the overall cost of outsourcing and thus, is factored into the break-even analysis. There is also an additional charge for the expedited shipping option, and for replacement aligners so orthodontics offices that such should factor in the extra fees.

Break-even Formula and Calculation

To calculate the break-even point when manufacturing clear aligners in-office becomes more cost-effective than outsourcing to an established lab, both equations need to be set to equal to each other[41]. For instance, if Q is the break-even point in terms of the quantity of individual aligners, and it signifies when all the initial investments have been paid off so any difference after that point is all profit towards the in-office manufacturing side

Initial investments$_{make}$ + Cost per aligner (CPA)$_{make}$ x Q = Cost per aligner (CPA)$_{buy}$ x Q

Solving for Q, then gives:

$$Q = \frac{Initial\ investments\ (in-office)}{CPA\ (buy) - CPA(make)}$$

After solving for Q, then anything above that number will signify that manufacturing in-office is more cost effective. To solve for Q, first we must calculate each variable independently then plug into the equation.

Initial Investments$_{\text{in-office}}$:

Equipment (E)= Pro 2 3D Printer + ProWash + ProCure

= \$10,000[42] + \$3,000[43] + \$3,300[44]

E = \$16,300

CPA$_{\text{make}}$:

Sum of costs for Materials (M), Labor (L), and Software (S).

Materials:

a. Resin:

Resin cost per model = Resin used per model × Cost per mL

With the average resin used per model being 11.4 mL from a random sample of 300

Resin cost per model = 11.4 mL per model × Cost per mL

To then calculate the cost per mL. Cost per bottle is \$144 for 1kg of resin[55].

$$\text{Cost per mL} = \frac{cost\ per\ bottle}{Volume} = \frac{\$149}{V}$$

To then calculate the volume in mL, the density of the resin must be factored in[46]

$$Volume = \frac{Mass}{Density} = \frac{1000g}{1.1g/mL} = 909mL$$

Now that the volume in mL has been attained, incorporate it into the cost per mL formular

$$\text{Cost per mL} = \frac{cost\ per\ bottle}{Volume} = \frac{\$149}{909\ mL} = \$0.16/mL$$

With the cost per mL known, incorporate it into the original formular to obtain the resin cost per model. Therefore,

Resin cost per model = resin used per model × resin cost per mL

Then Resin cost per model = 11.4 mL × $\frac{\$0.16}{mL}$ = $1.83/model

b. Aligner sheet:

Cost per aligner = $\frac{Cost\ of\ box\ of\ aligner\ material}{total\ numer\ of\ sheets\ in\ the\ box}$

Cost per aligner[57] = $\frac{\$96.8}{20}$ = $4.84/sheet

c. Post-processing supply:

Isopropyl alcohol (IPA) = $30/gallon[48]

Average amount of models washed with 1 gallon of IPA = 200

Cost of IPA per model = $\frac{\$30}{200\ models}$ = $0.15/model

Material cost per aligner = Resin cost per model + Aligner cost per model + Cost of IPA per model

Material cost per aligner = ($1.83) + ($4.84) + ($0.15)

Material cost per aligner = $6.82

During manufacturing processes, there is often product defects or loss of some raw materials. The percentage of non-defective products produced in a manufacturing process is known as the production yield, and it is calculated by dividing the number of defect-free products by the total number of items initiated in production[49]. For example, in in-office aligner manufacturing, the production yield will be derived after accounting for resin loss from failed prints and post-print processing, and aligner loss from thermoforming process, etc., the combined percentage is the cost of production yield[4]. With developments in technology and more access to information in recent years, the percentage of cost of yield during aligner manufacturing has decreased significantly[50]. To adjust for these inefficiencies, 5% cost of yield is applied.

Therefore, True material cost = $6.82 $\times$ 1.05

True material cost = $7.16/aligner

Additional material costs:

- Aligner burs/miscellaneous = $\frac{\$30}{100\ models}$ = $0.3/aligner
- Polishers = $\frac{\$5\ per\ polisher}{10\ aligners} = \$0.5/aligner$

- Packaging = $\frac{\$1.20}{package} = \$0.6/aligner$

Total material cost per aligner = $7.16 + $0.3 + $0.5 + $0.6

Total material cost per aligner = $8.56

Labor cost per aligner (L):

Labor cost per aligner = Sum of labor time per aligner (in hrs) × hourly wage

National hourly rate for orthodontics assistant = $21.98/hour[51]

According to the IRS, employers are responsible to pay an additional 7.65% on employee's earnings for Federal Insurance Contributions Act (FICA), commonly referred to as payroll taxes[52].

Factor in employer's payroll taxes of 7.65% = $21.98 × 1.0765

= $23.66

Labor time for each step is:

d. Post-processing (PP) = 3 mins/4 aligners
e. Trimming and shaping (T&S)= 13.47 mins/4 aligners
f. Quality control and inspection (QC) = 8 mins/4 aligners
g. Packaging and labeling (P&L)= 12 mins/4 aligners

Sum of labor time = (PP) + (T&S) + (QC) + (P&L)

Sum of labor time = $\frac{3\ mins}{4\ aligners} + \frac{13.47\ mins}{4\ aligners} + \frac{8\ mins}{4\ aligners} + \frac{12\ mins}{4\ aligners}$

Sum of labor time = $\frac{9.12\ mins}{aligner}$

To account for inefficiencies such as fatigue and breaks, 20% buffer is added to the sum of labor time.

Sum of labor time = 9.12 mins/aligner × 1.2

Sum of labor time = 10.94 mins/aligner

To convert to hour:

$$\frac{10.94\ mins}{aligner} \times \frac{1\ hour}{60\ mins} = \frac{0.18\ hour}{aligner}$$

Going back to the formula.

Labor cost per aligner = Sum of labor time per aligner (in hours) × hourly wage

Therefore Labor cost per aligner = $\frac{0.18\ hour}{aligner} \times \frac{\$23.66}{hour}$

= $4.26/aligner

Software cost/aligner (S):

With Ulab being the most used software for designing in-office aligners[32], and they charge per stl files exported. Hence,

S = $4.50 per stl

Variable Costs $_{\text{in-office}}$ = M + L + S

= $8.56 + $4.26 + $4.50

= $17.32

CPA $_{buy}$:

For this paper, three product pricing of Align technology dual-arch treatment and three product pricing of Spark aligners dual arch treatment will be used. An assumption of the total average amount of aligners used for each product pricing, and the percentage of time that each product is used will be made. This assumption helps with the calculation of the weighted average. These values could be easily changed and plugged into the formula by clinicians to reflect the total average number of aligners used and the percentage of time that each product is used in his or her orthodontic office. Below are two tables with the said breakdown.

Table 1: Align Product Pricing and Average total aligners per unit

	Maximum Aligners per arch	Additional Aligners	Average total aligners per unit
Invisalign Comprehensive ($2,095)	Unspecified	Reasonable number	90

Invisalign Moderate ($1,795)	Up to 20	1 set of additional	50
Invisalign Lite ($1,349)	Up to 14	1 set of additional	30

Table 1: SparkAligners Product Pricing and Average total aligners per unit

	Maximum Aligners per arch	Additional Aligners	Average total aligners per unit
Spark Advanced ($1,730)	Unlimited	Unlimited	90
Spark 20 ($1,209)	Up to 20	2 set of additional	50
Spark 10 ($945)	Up to 10	1 set of additional	20

To get the total complete cost, add $15 shipping fee for every shipment. With the average additional sets of aligners ordered per treatment planned to be at 1.5[53], three total sets of shipment will be assumed for invisalign comprehensive and spark

advanced ($45 each), while two sets will be assumed for Invisalign moderate, spark 20, invisalign lite, and spark 10.

With the variable cost per in office aligner manufactured, and the average total amount of aligners needed for each case type known, multiply those two numbers to get the variable cost per unit of in-office aligner manufacturing. This ensures an equivalent basis for comparison. For example, if the average total aligners for invisalign moderate is 60 aligners per unit which costs $1,795 then the equivalent base comparison for in-office manufacturing is 60 x $17.32 ($CPA_{make}$) = $1,039. In this case for example, an extra $45 will be added for shipment to invisalign moderate unit cost to get the total cost to outsource. In this said example, the break-even point will be 20.35 units.

Cost Per-Aligner Formula and Calculation

To establish a versatile formula for calculating the cost of production per aligner, it is essential to consider the various factors contributing to the overall expense. These typically encompass fixed costs (e.g., equipment) and variable costs (e.g., materials, labor, and overhead). The general formula is.

$$\text{Manufacturing Cost} = \text{Overhead} + \text{Direct Labor} + \text{Direct Materials}^{54}$$

Overhead costs, also known as fixed costs, include all indirect costs related to production that cannot be directly attributed to a specific product such as equipments (E) and (S), rent and utilities (F), and machinery depreciation (D). Direct labor (L) are the wages paid to the workers directly involved in the production process. Direct materials are the materials that could be traced directly to the finished products[64]. In this

case, the aligner itself. M signifies both direct and indirect materials. Since equipment costs are spread over the total amount of aligner produced, production volume (V) must be factored in[55]. Hence, the formula is:

$$\text{Manufacturing Cost Formula} = \frac{E \times (1-D)}{UV} + \frac{F}{V} + S + M + L$$

- $E =$ Equipment cost = Printer + Wash + Cure = $16,300
- $U =$ equipment useful life = 6.85 years[56]
- F = Annual facility costs = $450

  Average space needed for in-office lab = 3ft by 3ft = 9sq ft[57]

  Average size of orthodontics office = 1500 sq ft[58]

  Percentage of cost contributed by lab = $\frac{9\ sq\ ft}{1500\ sq\ ft} \times\ 100 = 0.6\%$ Sum of cost for facility and utility = Rent + Utility

  a. Average monthly Rent = $6,000

     Therefore, annual rent = $6,000 $\times\ 12$ = $72,000

     Cost for rent = 0.6% of $72,000 = $432

  b. Average utility = $2 per sq ft[67]

     For 1,500 sq ft

     Average annual utility bill = $3,000

     Cost of utility = 0.6% of $3,000 = $18

- $M =$ Material cost per aligner = $8.56
- $L =$ Labor cost per aligner = $4.26 per aligner
- $S =$ Software cost/aligner = $4.50

- V = Number of aligners produced annually = 12,000
- D = 0.2485

  With the average orthodontics salary being at $309,000[59], the marginal tax rate is 35%. However, its effective tax rate is 24.85%[70].

Plug in all the variables back into the formula. Therefore,

$$\text{Manufacturing Cost} = \left(\frac{16{,}300 \times (1-0.2485)}{6.85 \times 12{,}000}\right) + \left(\frac{450}{12000}\right) + (4.50 + 8.56 + 4.26)$$

$$= (0.15) + (0.037) + (17.32)$$

Total Manufacturing Cost = $17.51 per aligner

Benefits and challenges of in-office manufacturing vs outsourcing

The decision as to whether clinicians should outsource, or manufacture aligners in-office goes beyond a direct quantitative analysis as there are other factors that play significant role. This section takes a deeper look at the advantages and disadvantages of outsourcing vs insource manufacturing.

<u>Benefits of insource manufacturing</u>

One of the advantages of in-office manufacturing is that it gives the clinician the opportunity to have faster turnaround times. With seamless integration of all the steps involved in manufacturing, dental offices can have aligners fabricated and ready for delivery within a few hours[61]. On the other hand, outsourcing can take a few weeks before the clinician can deliver aligners to the patient[61]. This faster turnaround time not

only does it apply during treatment initiation but can also be useful during refinement or midcourse corrections.

Another benefit is that in-office manufacturing allows for improved customization. Typically, outsourced lab operates on standardized workflow which makes it difficult and, in some cases, impossible for the clinician to accommodate for certain clinical needs of his or patient. For example, a clinician might want to add a hook on the aligner on a certain tooth that the standardized workflow of an outsourced lab does not permit. This level of personalized approach enables to clinician to fully customize his or her treatment plan and could help lead to more precise treatment outcomes[62].

Additionally, Smith et. al., 2022 shows that the cost of outsourcing a complete treatment plan can be as high as $2000 for a single patient while manufacturing in-office could be as low as $10 per aligner [4]. This suggests that there will be significant savings in terms of overhead when manufacturing is insourced vs outsourced. This reduction in overhead can help position the clinician strategically in a competitive aligner treatment modality market. i.e. the clinician could pass the savings to the patient, increase his or her profit margin, decrease cost of treatment, or a combination of any of those.

Furthermore, manufacturing in-office gives the dental clinics greater workflow and quality control. Manufacturing aligners in-office allows the dental clinic to select things like packaging designs, quality and color of materials used for aligners, and workflow. For example, a clinician might want to switch back and forth to a certain type of aligner material after every 6 stages, insource manufacturing allows for those.

Production issues can also be addressed and fixed in real time which could help minimize disruptions to the treatment timeline and processes[63].

Drawbacks of Insource Manufacturing

One of the main challenges of in-office manufacturing is the initial investments required. Unlike outsourcing that does not have any additional substantial investment, insourcing requires the purchase of things like 3D printer, alcohol wash, and curing units for the lab to be functional[74]. These additional initial investment makes it challenging to dental offices especially the ones that do not have the funds available.

Secondly, the demands of manufacturing aligners in-office while having similar clinical responsibilities would require extra care and time management. Unlike outsourcing that does not require much after the order has been placed, trying to balance both clinical and manufacturing needs could take away from patient care and could possibly cause inefficiencies in both departments[65].

Additionally, operational and staffing challenges makes it more difficult for companies that wants to opt for insource manufacturing. Trying to introduce aligner manufacturing in an office requires extensive training, and often new employees need to be sought after to ensure he or she oversee the new operations. With rising hourly wages of orthodontics assistant and offices facing staffing challenges, adding the need for addition employees is a drawback to insource manufacturing[65].

Furthermore, manufacturing of aligners whether in-office or outsource requires the lab to adhere to certain regulatory standards and quality assurance[66]. For example,

each step during manufacturing should be rigorously evaluated, from manipulating the bits on the software to post-processing wash and trimming the aligners to eliminate rough edges. In addition, appropriate measures for disposal and ventilation of the in-office labs and clinic must be taken. Maintaining these standards and quality assurance requires resource allocation and could be perceived as a potential drawback especially for dental offices that are not equipped to handle it.

Benefits of Outsource Manufacturing

One of the major advantages of outsourcing aligner manufacturing is that there is no additional initial investment. Unlike insource that requires the initial costs for equipment, for outsourcing the dental clinic only pay for the units being ordered and shipment. This is a huge benefit because it helps eliminate certain barrier of entry towards aligner care services. In addition to the substantial initial cost savings, dental clinics can leverage the economies of scale and expertise of outsourced manufacturers to minimize costs[15].

Another benefit to outsource is that allows dental offices to have flexibility and the ability to scale based on market demands. For example, if there is a surge or decline in clear aligners therapy, offices can adjust accordingly and not worry about either being overstaffed, accruing more unnecessary expense or understaffed which could put a strain clinical aspects and manufacturing endeavors [15]. This flexibility allows dental offices to meet patient's needs efficiently and promptly.

Furthermore, outsourcing to professional aligner manufacturers gives dental offices access to enhanced technology and innovations as these labs typically invest heavy into research and developments[77]. Dental offices having access to the latest and greatest technology without the need to invest heavily into it. In addition, these professional labs invest into ensuring the meet the highest quality standards and controls. Outsourcing allows the clinicians to benefit from that stringent quality standards without the burden of maintaining it in-office[78].

Drawbacks of Outsource Manufacturing

One of the main challenges of outsourcing manufacturing is the extended turnaround time. The process involves sending a digital or analog impression to the scan and then waiting a few weeks for it to be manufactured, packed, and shipped. This delay is a drawback compared to insource which could take a few hours as it could lead to treatment interruptions, potentially less motivated patient, and as a result, prolonged overall treatment time[77].

Although outsourcing manufacturing requires less initial investment to get started, the ongoing cost per unit ordered is typically more expensive than insourcing. This difference in cost, which is ongoing could reduce the dental practice's profit margin [9]. The decision on how to navigate the reduction in profit margin, either passing the expense on to the patient and increase treatment fees or taking the loss from the reduction is a challenge that orthodontics offices must deal with.

Additionally, outsourcing limits the clinician's ability to customize the treatment plan both in terms of treatment progression and sequencing, and alterations to the aligner materials. This limitation in customization and flexibility is also felt in cases where the clinician deems mid-course correction to be necessary because it will lead to delay in treatment and in some cases the desires of the clinician cannot be reached by the outsourced company.

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STATEMENT OF THESIS

Objective:

- Calculate the cost per aligner utilizing in-office manufacturing.
- Determine the break-even point for when in-office manufacturing becomes more cost effective that outsourcing.

Hypothesis:

- The cost to manufacture an aligner in-office will be $10 or less
- The break-even point will be at 800 individual aligners

Null hypothesis:

- The cost to manufacture an aligner in-office exceeds $10.
- The break-even point will exceed 800 individual aligners

MANUSCRIPT FOR PUBLICATION

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Cost Comparison of Manufacturing Clear Aligners In-Office vs. Outsourcing

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Abstract

This study conducts a cost comparison of manufacturing clear aligners in-office versus outsourcing, focusing on determining the break-even point at which in-house production becomes more cost-effective and calculating the average cost per aligner. Using a comprehensive cost analysis model, this research evaluates factors such as equipment depreciation, material costs, labor expenses, facility overhead, and treatment plan variability. Data were collected using Sprintray's Pro 2 3D printer, ProWash, NanoCure, and Zendura FLX material, Ulab software, united dtates government, and internal revenues service information.

The findings reveal that when using Sprintray's Pro 2 3D printer, ProWash, and NanoCure, with a 7 year useful life and 12,000 annual model prints. In addition to zendura flx, Ulab software, 24.85% depreciation, an average orthodontic assistant salary of $21.98, and a facility cost that include a 9 sqft lab in a 1,500 sqft office, and $2 per sqft for utilities, the average cost to manufacture a single in-office aligner is $17.51. Furthermore, using a weighted average and with the assumption that the average total aligners used is 90 aligners for invisalign comprehensive, 60 for invisalign moderate, 42 for Invisalign lite, and they are used 65%, 25%, and 10% of the time on average, the break-even point for Invisalign is 1,746 individual aligners or 873 pairs of aligners. Similarly for spark aligners, using a weighted average and average 90 for spark advanced, 70 for spark 20, and 30 for spark 10, and they are used 65%, 25%, and 10% respectively, the break-even point is 4,190 individual aligners or 2,095 pairs of aligners.

This study provides a decision-making framework for orthodontic practices, highlighting the financial advantages of in-office manufacturing for offices that treat a lot

more patients than the break-even for their respective category while underscoring the practicality of outsourcing for lower-volume treatments. By identifying the cost drivers and break-even thresholds, the research aids orthodontic practices in optimizing their aligner production strategies to balance cost efficiency and operational needs.

Introduction

In recent years, the field of orthodontics has seen significant advancements in the development and application of clear aligners, a modern alternative to traditional braces[1]. As demand for these aligners continues to rise, orthodontic practices face a critical decision: should they manufacture aligners in-office or outsource production to specialized companies[2]. This choice is pivotal, not only for operational logistics but also for financial outcomes[3].

The decision to manufacture in-office aligners or to outsource involves complex cost considerations that extend beyond simple comparisons of immediate expenditures[4]. For practices considering in-house production, the initial investment such as 3D printing technology, cure, and alcohol was equipment needs to be purchased or leased so the initial investment can be substantial[5]. Conversely, outsourcing the production of aligners, while potentially reducing upfront costs, might be less cost-effective in the long-term due to per-unit pricing and factors such as marketing expense that might affect the external suppliers[6].

The rationale as to why clinicians choose either route is: in-office manufacturing offers control over the entire production process, could cut the turnaround time by a

fraction and allows for more customization for patients[7]. On the other hand, outsourcing can alleviate the administrative burden and need for technical expertise. It can also reduce overhead, and consequently, the cost to the patient[8].

Given these considerations, this study aims to provide a comprehensive analysis of the costs associated with both approaches. By comparing the detailed expenses incurred from in-house production to those from outsourcing, this research aims to find the cost of manufacturing per aligner and to identify the break-even point where it is more cost-effective to outsource than manufacture in-office. This analysis is essential for orthodontic practices aiming to optimize their financial performance while maintaining good standards for patient care[9].

This research not only addresses a gap in the current orthodontic literature but also could be a guide for clinicians when considering adding aligner therapies into their service offerings. By taking a closer look at the factors that affects manufacturing, including fixed costs such as equipment, material cost, both direct and indirect, labor cost, and maintenance, this study provides valuable insights that can influence strategic decisions within the orthodontic community[10].

Materials and Methods

This analytical study was approved by the Case Western Reserve University (CWRU) Institutional Review Board (IRB) (Appendix 1) under the IRB-exempt status. This study was designed to compare the cost of manufacturing clear aligners in-office versus outsourcing, with a focus on determining the break-even point at which in-house production becomes more

cost-effective. The materials used to gather data were Rayware software to gather data on the amount of resin used to print per model. Three hundred random models in a horseshow shape were placed into the rayware software to determine the average amount of resin needed to print a model. Thirty consecutive production processes were then timed from 3D printing to post processing, thermoforming, trimming & finishing, and packaging to figure out the average time of direct labor spend during manufacturing.

To calculate the cost of in-office manufacturing per-aligner, fixed costs, which included the upfront investment in 3D printers, and post-processing equipment. Depreciation was calculated using a straight-line method over 7 years. Variable costs included the cost of Zendura FLX material, resin used, burs for trimming and brushed for finishing, alcohol for post-processing rinse, utilities, labor for the process of aligner manufacturing, and Ulab software cost to export stl files. Labor costs were estimated based on the average time required per aligner and the assistant's hourly wage. The total cost per aligner was calculated as:

$$\text{Manufacturing Cost per Aligner} = \frac{E \times (1-D)}{UV} + \frac{F}{V} + S + M + L$$

Where:

- E = Equipment
- D = Depreciation
- U = Useful life of equipment
- V = Number of aligners produced annually
- F = Facility cost
- M = direct material cost per-aligner

- $L =$ Labor cost per-aligner
- $S =$ Software cost/aligner = $4.50

The per-unit cost for outsourcing was sourced from the published market rates by the chosen aligner providers, invisalign and spark aligner including shipping fees.

The break-even was calculated using:

$$Q = \frac{Initial\ investments(in-office)}{CPA\ (buy) - CPA(make)}$$

Where:

- Q = number of patient treatment plans needed to break even

Break-even (Q) was then calculated by using a weighted average and with the assumption that the average total aligners used is 90 aligners for invisalign comprehensive, 60 for invisalign moderate, 42 for Invisalign lite, and they are used 65%, 25%, and 10% of the time on average. Similarly for spark aligners, using a weighted average and average 90 for spark advanced, 70 for spark 20, and 30 for spark 10, and they are used 65%, 25%, and 10% respectively.

To ensure accuracy, cost data were cross-verified orthodontic practice benchmarks, and industry reports. A sensitivity analysis was conducted to evaluate the impact of key variables, such as material costs, average total aligners required, and cost of outsourcing on the break-even point.

Microsoft Excel was used for cost modeling, break-even analysis, and data visualization. This methodology ensures a comprehensive, reproducible, and data-

driven approach to evaluating the financial viability of in-office aligner production compared to outsourcing.

Results

Using Sprintray's Pro 2 3D printer, ProWash, and NanoCure, with a 7 year useful life and 12,000 annual model prints. In addition to zendura flx, Ulab software, 24.85% depreciation, an average orthodontic assistant salary of $21.98, and a facility cost that include a 9 sqft lab in a 1,500 sqft office, and $2 per sqft for utilities, the average cost to manufacture a single in-office aligner is $17.51. With regards to the break-even point, using a weighted average and with the assumption that the average total aligners used is 90 aligners for invisalign comprehensive, 60 for invisalign moderate, 42 for Invisalign lite, and they are used 65%, 25%, and 10% of the time on average, the break-even point for Invisalign is 1,746 individual aligners or 873 pairs of aligners. Similarly for spark aligners, using a weighted average and average 90 for spark advanced, 70 for spark 20, and 30 for spark 10, and they are used 65%, 25%, and 10% respectively, the break-even point is 4,190 individual aligners or 2,095 pairs of aligners.

Discussion

The decision to manufacture aligners in-office or outsource to established providers such as Invisalign or Spark has profound implications for orthodontic practices in terms of cost, efficiency, and operational flexibility. This study aimed to evaluate and compare the financial and operational considerations associated with both approaches, providing insight into the cost-effectiveness of each option under various scenarios.

The cost to manufacture one in-office aligner is $17.51, this cost represents the total production expense per aligner when manufacturing is done in-office and accounts for all relevant variables, fixed and variable.

The break-even point when comparing in-office aligners to Invisalign is 1,746 individual aligners (or 873 pairs of aligners or 23.59 patients). This means that an orthodontic practice must manufacture 1,746 individual total aligners during the useful life of the equipment to be more cost-effective than outsourcing aligners to Invisalign. Practices with patient volumes lower than this break-even point would find outsourcing more financially viable due to the upfront costs of equipment, software, and labor involved in in-house manufacturing.

The break-even point when comparing in-office aligners to spark aligners is 4,195 individual aligners (or 2,095 pairs of aligners or 56.69 patients). This means that an orthodontic practice must manufacture 4,195 individual total aligners during the useful life of the equipment to be more cost-effective than outsourcing aligners to Invisalign. Practices with patient volumes lower than this break-even point would find outsourcing more financially viable due to the upfront costs of equipment, software, and labor involved in in-house manufacturing.

The findings reveal distinct differences in the cost structures of in-office manufacturing versus outsourcing:

For in-office manufacturing, initial investments in 3D printers, wash, and curing units, were identified as significant upfront expenditures for practices opting for in-office production. These costs must be amortized over a high volume of aligner cases to achieve cost-effectiveness, which may pose a barrier for smaller practices or those with

low case volumes. Additionally, maintenance and occasional replacement of equipment contribute to ongoing fixed costs. Variable costs of In-office manufacturing include material costs such as resin and aligner sheets, and labor expenses were found to contribute substantially to the per-unit cost. Practices with streamlined workflows and trained staff can reduce labor inefficiencies, but material costs remain relatively fixed.

On the other hand, outsourcing costs to providers like Invisalign and Spark aligners that operate on a per-unit pricing model. This eliminates upfront capital investment and allows for predictable costs. However, the higher cost per aligner compared to in-office production makes this approach less cost-effective for practices with high case volumes. Shipping fees and potential delays in delivery may add to the total cost and impact workflow efficiency.

Economies of scale play a critical role in determining the viability of in-office manufacturing. The break-even analysis indicates that practices need to achieve a certain case volume to offset the high fixed costs of in-office production. For high-volume practices, the cost per aligner decreases significantly with in-office manufacturing, making it the more financially viable option. Conversely, low-volume practices may find outsourcing more practical, as it avoids the financial risk associated with underutilized equipment.

One of the key advantages of in-office production is the ability to reduce turnaround time. Practices with in-office manufacturing capabilities can produce aligners within 24-48 hours, enabling faster initiation of treatment plans and improved patient satisfaction. In contrast, outsourcing involves shipping times and reliance on third-party schedules, which can delay treatment starts, particularly for adjustments or refinements.

Outsourcing to Invisalign or Spark offers the benefit of standardized, high-quality aligners with proven track records. These providers leverage advanced technology and research & developments to deliver precise aligners with consistent results. On the other hand, in-office manufacturing provides greater flexibility for customization, enabling orthodontists to tailor aligners for specific cases, particularly for complex movements or cases requiring frequent refinements.

Operational considerations is a major aspect that needs to be considered in this cost-comparison. While in-office manufacturing offers greater control over the production process, it also requires significant operational expertise. Practices must invest in staff training, quality control measures, and workflow optimization to ensure consistent results. Outsourcing shifts the burden of production to third-party providers, allowing orthodontists to focus on patient care and case management rather than production logistics. Another aspect of operational consideration is the limitation on labor. There could be instances where it is would be more cost effective to manufacture aligners in-office but due to limitation on labor because it takes a certain amount of time to manufacture an aligner, it might be better to opt for outsource rather than insource.

The choice between in-house production and outsourcing ultimately depends on the practice's strategic goals and operational model:

In-office manufacturing is best suited for high-volume practices with the capacity to absorb initial costs and maintain operational efficiency while outsourcing is ideal for smaller practices, those just starting aligner therapy, or those prioritizing simplicity and low operational risk.

In addition, the break-even point calculation is solely a function of production costs and is not influenced by the price charged to patients. While revenue determines profitability, the break-even point provides a clear understanding of when in-office aligner production becomes more cost-effective than outsourcing. This distinction is essential for making informed decisions about investment in in-office aligner manufacturing capabilities.

This study focused primarily on financial costs and did not account for other factors such as patient satisfaction, brand perception, or clinical outcomes. Future research and studies could explore the impact of emerging technologies, such as AI-assisted design and advanced resin materials, on the cost dynamics of in-office manufacturing. For example, the cost-comparison of manufacturing using direct printing of aligners. In addition, environmental implications of in-office vs. outsourced production could be examined. Broader comparisons across different aligner brands and technologies can also be studied.

Conclusion

This study analyzed the cost to manufacture clear aligners in-office vs outsourcing using a detailed cost breakdown and break-even analysis. The findings highlight that although the cost per aligner is $17.51 and remains constant, the break-even point varies significantly based on the type of treatment plan and the number of aligners required. For example, In-office manufacturing becomes more cost-effective after 1,746 individual aligners or 873 pairs of aligners when compared to invisalign. As for spark aligners, it becomes more cost-effective after 4,190 individual aligners or 2,095 pairs of aligners. Orthodontic practices should adopt in-office manufacturing for

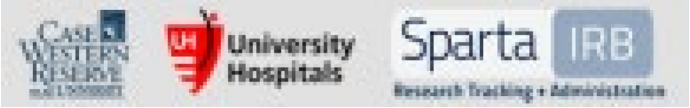
aligners if their production volume consistently exceeds the calculated break-even points for their treatment plans. For lower-volume practices or those prioritizing upfront cost savings, outsourcing may remain the preferred option. Strategic planning and regular cost analysis will ensure the chosen production model aligns with the practice's financial goals and operational needs.

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Title:	Cost! A deciding factor between manufacturing in office aligners and outsourcing to a lab
IRB Number:	STUDY20240456
IRB Office:	CWRU IRB
Determination Date:	4/26/2024
Type of Submission:	Initial Study
Type of Review:	Determination
Documents Reviewed:	• TAkpua_IRB protocol, Category: IRB Protocol;

The IRB determined that the proposed activity is not research involving human subjects. **IRB review and approval is not required.**

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please submit a new study to the IRB for a determination.