TUCK SCHOOL OF BUSINESS AT DARTMOUTH
GLASSMEYER/MCNAMEE CENTER FOR DIGITAL STRATEGIES
VINCENT L. LACORTE CASE SERIES

Case #6-0024

Aligning the Supply Chain

Introduction

Len Hedge, VP of Operations at Align Technology, paced his office, looking like an air traffic controller with his headphones strapped to his head and stacks of late order reports in each hand. He was on a phone conference with Dave Hunter[1], an orthodontist who had been an early adopter of Align's revolutionary products — transparent plastic aligners used to straighten teeth in adults. Dave had called Len regularly during the shipment crisis that had accompanied Align's implementation of an enterprise resource planning (ERP) system.

While Len always learned things by taking customers' calls, he had been happy not to hear from Dave for a while. But now Dave was upset again. This time, it was incorrect information on order status and promised ship date that had triggered Dave's ire. Len grimaced as he listened to Dave's tirade, lamenting to himself the unfortunate side effect of manufacturing a mass customization product. It was the highest-submitting customers, hence the best customers, that tended to be the most adversely affected by late shipments when production systems are deployed or changed. His unease turned to intrigue, however, when Dave started talking about a change he had perceived in the way Align's technicians were designing the treatment plans.

"I have a certain way that I like to define the treatment, and it had been working well with my assigned technician, Maria. I was getting treatment plans that matched the way I like to treat, but now, this most recent one doesn't look like Maria's work. I don't know who designed it, but it doesn't suit my approach to treatment, and it's different from the approach that I had been getting from Align in the past. …"

Hearing this, Len realized that this was not just a manufacturing and customer care issue, but involved treatment design as well. It turned out that Maria was on medical leave and the current manual method of assigning technicians to customers was not delivering the performance the customer came to expect from Align. And if Dave was noticing an inconsistency, other doctors must be noticing it as well. Len opened up a PowerPoint

[1] Customers are based on composites of individuals we interviewed, but do not represent any specific person. Any likeness to a specific individual is coincidental.

This case was written by CDS Research Fellow Laura Rock Kopczak and Professor M. Eric Johnson of the Tuck School of Business at Dartmouth. It was written as a basis for class discussion and not to illustrate effective or ineffective management practices. Version: June 6, 2006.

presentation he was working on with the VP of Information Technology (IT), for the upcoming board meeting. He and his IT partner were seeking approval for a $2M IT investment to address the growing complexity of managing Align's global manufacturing process. Perhaps the treatment design issue could also be addressed by the new system, making Len's business case for the IT investment even more compelling. Glancing at the clock, he realized that it was too late to call the Treat Operations General Manager, Ted Callaghan, in Costa Rica. Managing a global supply chain from the Santa Clara, California headquarters always presented time challenges. Together, they would have to address this design complaint immediately, as a step towards regaining the customer's trust. But perhaps Dave had provided a much larger clue to the value of automating the supply chain — and indeed improving Align's value proposition.

The Manufacturing Control Issue

Len joined Align in 1999 as VP of Manufacturing. He had been around for the first product shipment, the early penetration of the orthodontics market, the company's IPO, and the ramp-up of production at the company's three operations in Santa Clara, California; Juarez, Mexico; and San Jose, Costa Rica.

Now, in September 2003, the company was in the midst of a transition from a start-up venture to an established firm, capable of sustained growth and consistent profitability. As part of that transition, the company was struggling to formalize its business processes and implement robust enterprise information systems needed to support the anticipated sales growth. Throughout the changes, manufacturing control had remained stubbornly complex. As production volume had increased, it had become increasingly difficult to control the flow and quality of production using manual processes.

Len had been working for several years to implement a system to better track and control the flow of product through the multi-country manufacturing process. At this point, however, Align's top management was gun-shy about new systems. The FY 2001 implementation of an ERP system had not gone smoothly; the resulting chaos had contributed to a flat line growth for six months. Stung by the disruption, and unfulfilled expectations of detailed process and quality control with the new ERP system, they were forced to step back and determine if a better system existed for their manufacturing execution needs.

The manufacturing process depended on "human glue" to integrate the 28 different software applications and 75 data pools (databases, logs, spreadsheets, etc.). With a system that included more than 200 contact points per order, the likelihood that an order made it through without any problems was about 10%. Customers liked the product, but they were frustrated with inconsistent service levels! The imperative was clear, and yet the cost to implement and perceived risk were high. Len would have to make a well-defined case, as a first step. Then he would face the challenge of implementing the new system without impacting the thousands of orthodontists and dentists who already used Align's product.

Align Technology

Align Technology, headquartered in Santa Clara, California, manufactured and marketed a new proprietary treatment for malocclusion — the improper positioning of the teeth and jaws. The advantages of the new approach to orthodontics were aesthetics, comfort, and improved oral hygiene. The treatment time was also likely to be shorter than that of traditional braces. Marketed as Invisalign ™, the product had an average selling price of $1695 in 2003. It included a virtual treatment plan, approved by the submitting doctor, and a series of orthodontic plastic positioners that a patient wore for two weeks per stage. An average treatment included 19 stages, which took a little less than a year to complete (see Exhibit 1).

By 2003, Align had shipped more 155,000 treatments with 2003 sales totaling $122.7M and a net loss of $20.1M (see Exhibit 2). The new technology was catching on. To protect its rapidly growing business, Align had submitted 57 patent applications for the Invisalign™ product. It was expected that these patents would forestall competition.

The Market

More than 200 million individuals in the U.S. have some form of malocclusion. Annually, less than 1% of these individuals enter orthodontic treatment [2]. While Align sold its product worldwide, the bulk of its business was selling to the 8,000 orthodontists and 100,000 general practice dentists in North America. By 2003, nearly all of the orthodontists and a third of the dentists had gone through a two-day training course on Align's technology and products. Roughly 5,000 of these trained doctors had submitted cases to Align.

Traditionally, braces were fitted by orthodontists, and dentists referred their patients to orthodontists. Now, with the Invisalign™ product, dentists were taking on simple orthodontic cases themselves. The Invisalign™ marketing message outlined several benefits to the orthodontists who adopted the Invisalign™ product, including: ClinCheck, a web-based computer graphics interface that allowed doctors and patients to visualize the treatment; simple doctor training; patients' ease of use and satisfaction; expanded patient base; decreased chair and staff time; and resulting higher fees and margin.

While some orthodontists adopted readily, others resisted. Impediments to adoption included the need to retrain and to use computer technology, the frustration of long wait times while the ClinCheck files were downloaded, and the need to establish a second business process within the doctor's daily practice. In the words of one orthodontist, "I've been treating patients with existing technology for thirty years. I have a good reputation and a solid, profitable practice. Why should I switch to an unproven treatment method?"

Establishing and maintaining doctors' trust was a critical success factor for Align. Trust was based on Align performing and communicating with professionalism and high quality. The extent to which doctors would react favorably, and place further business with Align, depended on Align's ability to deliver sound treatment plans, manufacture and deliver the

[2] ADHA News, American Dental Hygienists' Association, May-June 2005.

product within promised lead times, and to provide timely, correct, and complete information on treatment and product delivery.

The Manufacturing Process

As Lance Aldrich, Production Systems Manager, put it, “No one does what we do!”

This was certainly the case. Align produced high volume, highly customized medical products with close tolerances. Product design, which was integrated with production, was done collaboratively with the doctor. No two Invisalign™ patients were alike — so every set of aligners was unique. Every customer had a different arch with differently shaped and configured teeth. Lance remarked, “When a new order arrives, we only know the customer has a patient with an upper and lower arch that wants to purchase the Invisalign™ product. There is no way to know what teeth we will move or how many aligners the treatment will take until we create the virtual treatment. Orders could be for patients with 32 to 10 teeth!”

Production was complicated by the fact that it involved both real and virtual operations, using proprietary technologies and information systems, and by the fact that manufacturing progressed through three manufacturing sites and one or more reviews by the doctor.

Overview

Exhibit 3 presents an overview of the manufacturing flow for orders that flowed straight through the process without backtracking or rework. These were the minority of orders. An order was a request for a set of aligners, which included on average 38 different aligners (19 upper and 19 lower). Typical cycle times and promised delivery times are shown in the figure. The “product” under manufacture initially took a physical form, then was converted to a virtual form for intermediate processing, and was later converted back to a physical form for final processing and shipment.

Manufacturing commenced with a review of the case by the dental lab in Santa Clara, California, to determine if the case was appropriate for treatment with the Invisalign™ product. Cases included a package of patient information submitted by the treating doctor to Align, including impressions, photos, and x-rays. If the case was complete and appropriate, it was passed to manufacturing (in Santa Clara) and an order was created. Manufacturing scanned the impressions, creating a rough 3D representation of the patient’s mouth. The data file was then sent to San Jose, Costa Rica, where it was manipulated and a treatment plan created. (A treatment plan consisted of a set of 3D images of the upper and lower jaws corresponding to each stage of the treatment.) A data file of the treatment plan was then sent to the doctor for review and approval.

Once approved by the customer, the treatment plan file was sent to Santa Clara, where a set of molds, one for each aligner, was fabricated using Stereolithography (SLA) technology. These molds were shipped to Juarez, Mexico, where one aligner was made from each mold in a painstakingly manual process. Finally, the set of aligners was shipped to the doctor.

While coordinating manufacturing across three sites was complex, Align had clear reasons for choosing these locations. Operations, which included direct customer interface (with the doctor) or involved expensive, proprietary, machine-based processing, were located in Santa Clara. This included the processes which made the initial physical-to-virtual conversion and the final virtual-to-physical conversion. Treatment operations, which involved skilled computer-aided design of treatment plans, were located in Costa Rica, which had an abundant supply of well-trained, relatively inexpensive, dental technicians. The labor-intensive aligner fabrication was located in Mexico where labor costs were lower.

Process Steps … and Production "Eddies"

The advantage of Align's approach, as described in the company's marketing literature, was that the Align product was "complex to make, easy to use." By taking on upfront design, done collaboratively with doctors, Align eliminated the need for later design adjustments — the chair time that doctors required to tighten and adjust traditional braces. This simplified the course of treatment.

On the other hand, as is often the case with design and first-run production processes, there were many points in the production process at which design or production corrections were made. The extent to which this occurred could be seen by looking at each step in the process and considering the potential for required rework.

Len viewed the flow of product through the production process as a river with many eddies in which product could get caught for varying amounts of time. Production control was currently based on trying to keep up with identifying eddies and prodding product back into the main flow of the river. A challenge for the future was to make product caught in eddies visible and eliminate rocks that caused product to flow into eddies in the first place.

Treatment Initiation Order Entry

Once a doctor determined that a patient could be treated with the Invisalign™ product, the doctor "ordered" the product by mailing a "submission kit" to Align. The submission kit was a 8" x 11" x 2" box that contained X-rays and photographs of the patient's mouth, PVS (polyvinyl siloxane) impressions of the patient's upper and lower set of teeth, a wax bite to register the alignment of the upper and lower dental arches, and an Invisalign™ treatment prescription form.

At the same time, the doctor could enter a sales order and the treatment prescription into Align's proprietary VIP (Virtual Invisalign™ Practice) web portal. About 30% of orders were entered by doctors. These orders did not, however, transfer automatically to the ERP system; Align personnel printed out the information from VIP, then re-keyed it into the ERP system. The case number (production order number) assigned by the ERP system had no correspondence to the order number in the VIP system.

While Align received submission kits every day, daily arrivals varied considerably, typically peaking on Monday with a daily swing in volume of 20-30%. The first step upon opening the box was to disinfect the PVS impressions. The impressions were then returned to the box. Align personnel entered a sales order into the ERP system. The order record would allow

Align to track, at a very high level, the progress through the supply chain. The sales order was the purchase order against which the product would be shipped. The order corresponded to a delivery of a set of aligners, the number of which was not yet determined.

Personnel then checked that the submission kit was complete. If not, the doctor was called, a hold code was entered into the ERP system, and the box was put on a shelf with other cases that were on hold. About 10% of submission kits were received incomplete. Completed kits were processed. X-rays and photographs were scanned. The teeth and bite impressions were scanned using a proprietary X-ray scanning process that created 3D images of the upper and lower dental arches and of the alignment of the upper and lower jaws. The 3D images looked like the impressions, with excess plastic included. With earlier scanning technologies, quality controls in place resulted in higher rejection of impression scans by Treat Operations in Costa Rica. This posed a problem for the ERP manufacturing module which did not have a mechanism for tracking rework between production facilities.

Dental technicians then reviewed the 3D images using the company's proprietary Treat software. If the impressions hadn't scanned well, they were rescanned. After the quality check, the order, with the Treat data file, was downloaded to Costa Rica.

Treat Operations

In San Jose, Costa Rica, dental technicians created treatment plans for each order, using the company's specialized software. A treatment plan included a 3D representation of tooth positions and alignment for each stage of the treatment. The treat process had four major steps, each done by a different group of technicians. First was the cutting process. Using the software, technicians refined scanned images of the impressions. They then individuated the teeth, removing gingival tissue and separating each tooth into individual geometric units so that each tooth could move separately. They also aligned the arch, adjusted the occlusal relationship using patient photos, and checked the bite to ensure the digital model exactly represented the anatomy of the patient. Next was the setup process. Here, a technician moved each tooth into alignment, following the doctor's prescription. This created a final setup of the patient's teeth. After the teeth were properly aligned, the technician reapplied the gingival tissue that was removed in the cutting process. Next, in the staging process, a technician created a plan for moving the teeth, stage by stage, from their starting positions to their final positions. Each stage represented the gradual tooth movement achieved with each aligner in the full series. The number of stages varied with the complexity of the treatment, with a typical treatment plan consisting of 19 stages. The outcome of the staging process was a digital animation showing the simulated movement of the teeth in each stage of treatment. Finally, in the last step, the treatment plan was inspected and reviewed by clinical staff to ensure it met with the doctor's prescription and Align's internal quality standards.

The typical technician processing time for designing a treatment plan was about 8 hours, with 50% of the time spent on Setup and Staging. However, the time varied by 100% or more, depending on the complexity of the treatment. The setup and staging processes were the main engine of the treatment process, requiring the most skilled technicians. Often these steps were the bottleneck in the process. GM Ted Callaghan carefully managed the workflow within the facility to build ahead of these steps so they would not be starved for work. Nevertheless, maintaining an even flow was challenging as technicians occasionally encountered problems causing cases to experience backtracking or delays. This could be a result of unworkable impressions (which might require that the impressions be rescanned or retaken by the doctor), or the technician might have a clinical question, which would be routed first to the head clinician and then escalated, if necessary, to orthodontists on staff in Costa Rica and Santa Clara. The technicians favored working on the less complex cases and would often choose to work on them first.

Several hundred dental technicians worked in San Jose. These were generally people who had been in school studying to become dental hygienists. Dental technicians went through extensive in-house lab-based training, and then began to work on simple cases and in lower skilled areas, such as the cutting process. New people worked closely with production leads and supervisors until they felt comfortable working on their own. Designing treatment was an art; while technicians followed design principles.

Doctor Review

The treatment plan file was transferred into the VIP portal and an e-mail notification containing the filename was sent to the doctor. At her convenience, the doctor downloaded the read-only file, and viewed the treatment plan using Align's ClinCheck software. The treatment plan was provided to doctors as a movie showing 3D-simulated movement of the teeth and alignment from starting to ending positions. For 50% of the orders, the doctor approved the treatment plan on the first pass. Orders requiring modification were passed through order processing in Santa Clara, and then were sent on to Costa Rica for modification. In most cases, the doctor approved the modifications.

The typical review time for an order that was approved on the first pass was 8 days. Orders requiring modification of the treatment plan typically took 2 to 5 days longer to process. Sometimes, however, difficult orders, or ones in which the technician were unsure about, could get stuck somewhere in the process.

Mold Fabrication

Data from the 3D virtual models generated in Costa Rica for the treatment plan were then used to guide stereolithography (SLA) equipment to manufacture the SLA molds. This was done in Santa Clara. As stated, each case required an average of 38 molds (19 upper and 19 lower) for the 19 treatment stages. SLA technology had been used historically for making plastic prototypes from CAD drawings. Align was one of the first companies to use the technology for high-volume production.

The SLA machine directed a laser beam over a pool of a liquid epoxy-based resin, hardening it to form the features of the mold. The molds were built up, layer by layer, in a process that took a couple hours. There were multiple SLA machines in Santa Clara. Upon completion, molds were packaged and shipped to Juarez, Mexico.

Aligner Fabrication and Shipment

In Juarez, Align employees manufactured aligners in a “shelter facility,” a facility which was provided by a contractor. The aligner, which was actually a negative of the mold, was made by using heat and pressure to form a thin thermo-plastic sheet over the mold. The aligner was allowed to cool, and then was pried off of the mold, trimmed, labeled, polished and disinfected.

For skilled workers, roughly 1% of the time, the plastic of the aligner tore when being separated from the mold. In these cases, the aligner and possibly the mold would have to be remanufactured. The completed set of 38 aligners was then packaged and shipped as a complete set to the doctor. The acceptance rate by the doctors was almost 100%.

Customer Care and Production Control

The small cadre of people in Customer Care and the production schedulers kept product moving through the process as best they could. The information they had available to them from the information systems was limited and not always up-to-date or correct. The four “move” transactions — into and out of Costa Rica and Mexico, along with the ship transaction — helped schedulers and customer care personnel determine where in the process (and where in the world) the orders were located. Since the systems did not include a production hold or rework status flag, there was no immediate visibility of which orders had flowed into eddies. The tool they used most often was an order aging report that indicated which orders had not moved in more than four days. On a typical day there were 20 orders on this report.

Customer Care interacted with doctors, providing status information to them, prompting them to take action on ClinCheck review, answering questions, and resolving problems. Customer Care notified doctors of materials not received, rejected impressions, clinical holds, and ClinChecks waiting to be reviewed. When a problem occurred, Customer Care called production control to determine the status and/or history of an order.

The order history in the ERP system included work order start and completion and move transactions into and out of Costa Rica and Mexico. Since there were no within-facility move transactions, it was difficult to track down the status and location of individual orders, beyond knowing at which facility they were being processed.

The ERP system was not capable of tracking who had worked on a job (except the person who signed off on the between-facility move transactions); this was done manually by shift supervisors. And there were no notes in ERP about issues that came up as production progressed.

Thus, production controllers spent their days using email and the phone, contacting people in the three facilities, to determine production status and to reconstruct what had happened to a particular order. Due to the lack of solid information, there was a tendency for people to place the responsibility of an aged order on upstream or downstream operations, rather than addressing the aged order. The bulk of their time was spent in information gathering and dispute resolution, rather than problem solving. All in all, it was a very stressful, but essential, job.

Information Systems at Align

Information systems had always been critical to Align's success. Align had chosen to develop its own systems for treatment design as part of the development of its unique design and production process. Align had also developed its customer-facing web portal (VIP) and the ClinCheck software in-house. The company maintained a staff of in-house IT developers and engineers in support of systems development and enhancement.

Production control at Align had some specific requirements, which could be difficult to accommodate with off-the-shelf software. First, since an order included the full set of aligners, it was important to track production at both the order and the aligner level. Second, it was important to maintain a Device History Record (DHR) for each mold and aligner. This was a Class 1 FDA requirement. Ideally, the DHR would include information on who worked on each aligner and when work was done for every process step. Third, it would be useful to store a version history for the treatment designs, so that when a doctor requested a modification, the designer could choose from previous versions to select an appropriate starting point for the redesign. Fourth, there were many rework paths for individual aligners and molds. Fifth, the order was sent out to the doctor for approval, and then reinserted into the production process. Last, production scheduling was done using forward scheduling from the order placement date, with a fixed lead time. This fit well with the build-to-order process.

Align set a strategy to use packaged software for its business applications, including order administration, accounting/finance, production control, and human resources. With this in mind, there had been several attempts at implementing a centralized automated production control system. An early attempt, based on an Access database, was made in 1999. This first attempt was not robust enough to supplement the paper-based tracking process in place at the time. There had been other attempts that did not meet all of manufacturing's requirements, the latest of which was an ERP system.

The ERP system had not met manufacturing's requirements in two ways: the negative impact of the implementation and the limited realized capabilities of the system. Align had set a very aggressive implementation schedule. During implementation, as Align began to oversee production using the ERP system's work orders, Align lost visibility of cases in process. The resulting late shipments, mix-ups in shipments, and misinformed and delayed customer communication led to customer dissatisfaction, a breakdown in trust, and eventually a six-month drop in new orders in FY 2001.

As the system was being implemented, it became obvious that the system was not capable of handling Align's complex production-routing requirements. Since the ERP system did not support dynamic routing, only forward movement through the process could be included in the work order routing. Backtracking and rework could be tracked only by opening a new work order. While fixed routings could work well in a batch environment, they did not work in Align's production environment, with its batch size of one, and its high incidence of backtracking and rework.

The other major deficiency in the ERP system's capabilities was that it did not force workers to enter transactions into the system before initiating the next step in the process. Product moved from facility to facility without accompanying system transactions. When this happened, system information on product location was wrong.

In the end, the ERP system was used for finance, sales order administration, and manufacturing for high level tracking between facilities. There was still a need for a system to control the manufacturing process, particularly a middle tiered system that would tie into shop floor controls and the corporate ERP system. In the meantime, Align continued to run with limited production tracking and without any central system to track product being internally held or reworked.

The MES Project

In March 2003 Len Hedge, now VP of Operations, reopened the production control issues and chartered a team to find a solution. Their intent had been to diagnose the problem and select a systems vendor by the end of the year, then implement in 2004. Align engaged an outside consultant to help the team determine the user needs and system requirements. The consultant interviewed 50 people from various departments. Based on these interviews, the team established a list of requirements and their relative priority (see Exhibit 4). The team concluded that a Manufacturing Execution System (MES) that would act as a middle tier software platform and was integrated with their existing systems would solve many of their production needs.

Manufacturing Execution Systems are a general category of software applications that focus on plant automation, quality, and application integration. The three main components of an MES are:

- A workflow engine that allows tracking and priority-based control of the flow of product through the production process;
- A quality system that includes document control, supplier quality, user certification and training, correction and preventative action, statistical process control and reporting; and
- An enterprise integration layer for integrating other enterprise applications and production machinery.

The team evaluated three MES vendors. Factors considered included software capabilities, personnel, projected implementation effort, and cost of development and implementation. Based on their evaluation, the team recommended that Align proceed with implementing an MES from Datasweep (excerpts from a Datasweep brochure are included in Exhibit 5).

With nearly nine months of work behind them, Len was almost ready to present the business case supporting the system investment to the executive management team and the board of directors.

As luck would have it, the MES project was one of several major IT initiatives competing for resources. Another project, sponsored by the CFO in response to Sarbanes-Oxley (SOX 404) requirements, was a major upgrade to the ERP system as well as interfaces between ERP and VIP. Both projects were needed and calendared to kick off at the same time. Would Align be capable of doing both? Simultaneously? A key consideration was "Had Align learned enough from a prior ERP project to guide its efforts for a successful implementation?" Len did not want to go through another sub-par ERP deployment.

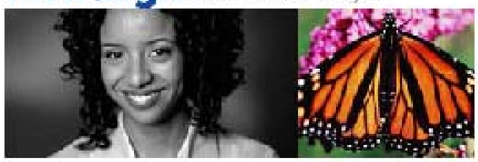
Looking Ahead

Len was sure that an MES would serve as a scalable repository for the product flow and quality information needed to make the production process more stable and robust. The task at hand was to create the business case for the Datasweep MES. This included a justification for the system — the projected benefits and ROI.

Len also had to develop a realistic implementation plan, assessing the cost of implementation, and the projected impact, during implementation, on operations. Align could not afford a repeat of the disruption that had occurred with the ERP implementation. And he had to convince the executive team and board of directors that it could be done this time. This would be a challenge, as trust in the organization's ability to implement was low, and fear of the downside risk was high.

Exhibit 1: Align brochure excerpt

invisalign Learn how to smile again.



Invisalign straightens your teeth with a series of clear, virtually invisible custom-molded aligners.

Invisalign. With breakthrough technology that lets you have the smile you've always wanted — without the hassle of braces.

The clear alternative to metal braces.

By using a series of clear, removable aligners, Invisalign straightens your teeth with results you'll notice sooner than you think. The course of treatment involves changing aligners approximately every two weeks, moving your teeth into straighter position step by step, until you have a more beautiful smile. And unlike braces, these clear aligners can be removed while you eat and brush your teeth as usual.

Less treatment time.

An average Invisalign course of treatment takes about a year. You'll see your Invisalign Certified Orthodontist or Dentist every 6 to 8 weeks for adjustments and to check progress. At regular intervals, you'll receive a new set of custom-molded clear aligners to continue the straightening process. The total number of clear aligners is specific to you, determined by your doctor for your course of treatment.

Clear. And comfortable.

Since Invisalign is practically invisible, there's no unwarranted attention to your mouth. In fact, very few people will notice at all - unless you tell them. They're comfortable to wear and remove easily when you eat, brush, and floss.

All across the country, people like you now have great smiles and straighter teeth, thanks to Invisalign. Why not join them? To find an Invisalign Certified Orthodontist or Dentist in your area, just click here. That gorgeous smile you want is just a click away.

What is Invisalign?

Quicktime Video
Low Bandwidth Version

Exhibit 2a: Financial Results — Income Statement

Annual Financials for Align Technology Inc All amounts in millions except per share amounts.	Fiscal Year End:12/31 2003	2002	2001
Net Sales	122.7	69.7	46.4
Cost Of Goods Sold	51.6	45	46.8
Gross Profit	**71.2**	**24.7**	**-0.4**
SG and A Expenses	78	84.7	83.7
R and D Expenditures	13.1	13	14.7
Depreciation and Amortization	-	-	-
Income Before Depreciation and Amortization	-19.9	-72.9	-98.8
Interest Expense	0.4	0.2	2
Investment Gains (Losses)	-	-	-
Total Operating Expenses	**91.5**	**97.8**	**100.4**
Non-Operating Income	0.3	0.3	3.4
Other Income	-	-	-
Income Before Tax	-20	-72.8	-97.5
Provision For Income Taxes	0.1	-	0
Income After Tax	-20.1	-72.8	-97.5
Minority Interest	-	-	-
Net Income Before Extra Items	-20.1	-72.8	-97.5
Extra Items Discontinued Operations	-	-	-
Net Income	**-20.1**	**-72.8**	**-97.5**

Exhibit 2b: Financial Results — Balance Sheet

Annual Financials for Align Technology Inc All amounts in millions except per share amounts.	Fiscal Year-End:12/31 2003	2002	2001
Cash	45.4	38.8	51.3
Marketable Securities	2.3	2.7	12.5
Receivables	21.3	16.8	11.6
Inventories	1.4	1.5	1.5
Raw Materials	0.9	0.9	1.1
Work In Progress	0.2	0.3	0.2
Finished Goods	0.3	0.3	0.2
Notes Receivable	-	-	-
Other Current Assets	6.8	6	4.7
Total Current Assets	**77.1**	**65.8**	**81.6**
Property, Plant, and Equipment, Gross	48.1	44.5	42.6
Accumulated Depreciation	25	19.4	10.6
Property, Plant, and Equipment, Net	23.1	25.1	32
Intangibles	-	-	-
Investment Advances To Subsidiaries	-	-	2.6
Deferred Charges	-	-	-
Deposits And Other Assets	2	1.9	2
Other Non-Current Assets	-	-	-
Total Non-Current Assets	**25.1**	**27**	**36.6**
Total Assets	**102.2**	**92.9**	**118.2**
Notes Payable	-	-	-
Accounts Payable	3.1	3.4	4.4
Current Long Term Debt	-	-	-
Current Portion Capital Leases	0.3	0.5	0.5
Accrued Expenses	19.2	9.7	11.4
Income Taxes	-	-	-
Other Current Liabilities	14.8	11.1	1.6
Total Current Liabilities	**37.4**	**24.7**	**17.8**
Mortgages	-	-	-
Deferred Charges To Income	-	-	-
Convertible Debt	-	-	-
Long Term Debt	1.7	3.3	-
Non-Current Portion Of Capital Leases	0.2	0.5	1
Minority Interest (Liabilities)	-	-	-
Other Long Term Liabilities	-	-	-
Total Non-Current Liabilities	**1.8**	**3.8**	**1**
Total Liabilities	**39.2**	**28.5**	**18.8**
Preferred Stock	-	-	-
Common Stock, Net	0	0	0
Capital Surplus	368.8	364.7	355.1
Retained Earnings	-300.6	-280.5	-206.1
Treasury Stock	-	-	-
Other Equity	-5.2	-19.9	-49.6
Total Shareholder Equity	**63**	**64.3**	**99.4**
Total Liabilities Shareholders Equity	**102.2**	**92.9**	**118.2**

Exhibit 3: Overview of Manufacturing Process

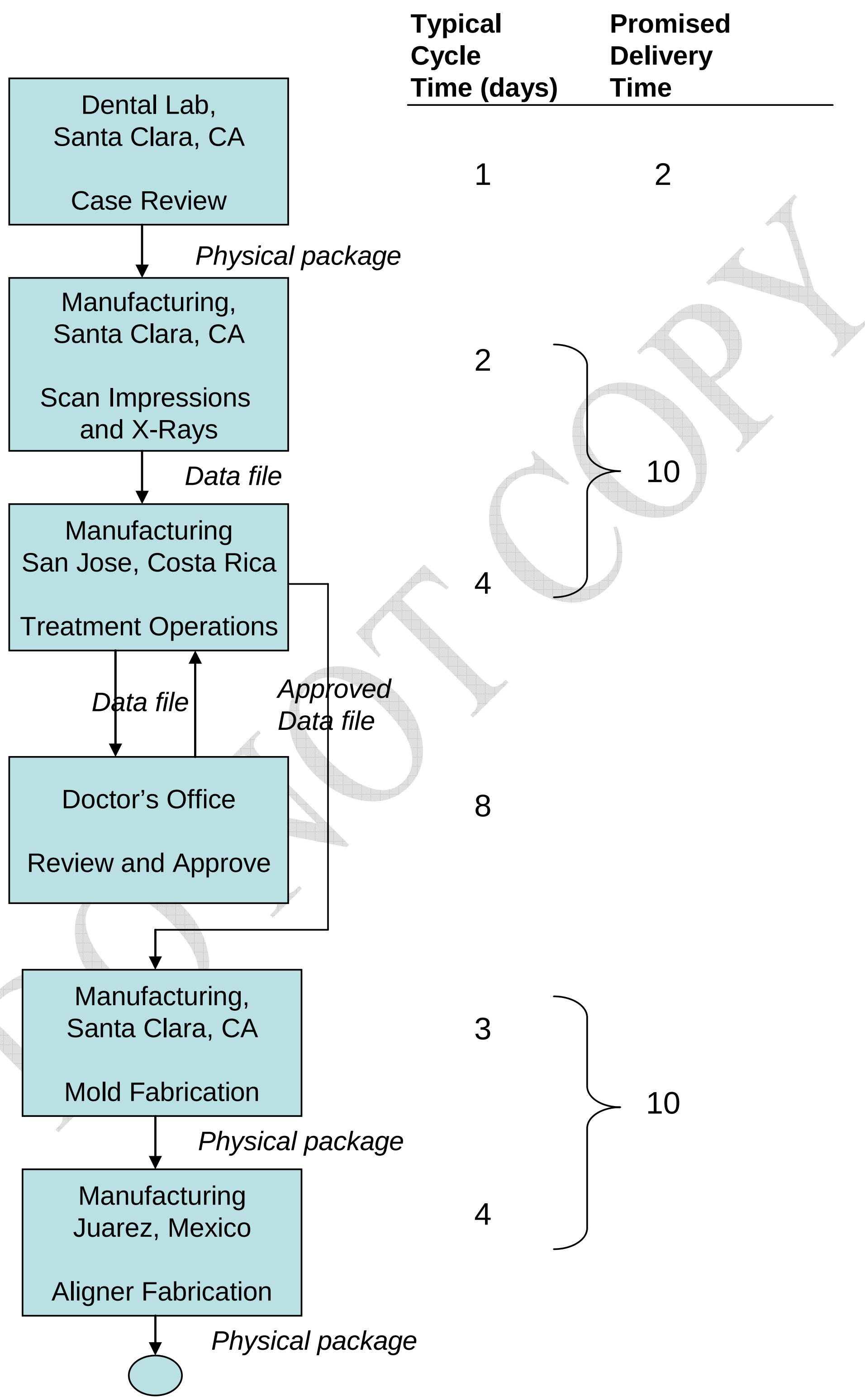


Exhibit 4: Relative Priority of Requirements

	Flexibility of Requirement		
Requirement	**Very**	**Moderate**	**Low**
Produce 35% more product			X
Increase gross margins 5-10%			X
Delight the customer			X
Automated workflow, programmable business logic			X
Dynamic routings, auto rework loops			X
Application integration			X
Real time data collection and reporting			X
Configurable database			X
Multi-site capable, independent, synchronized			X
SPC (statistical process control)		X	
Current view of product flow/load		X	
DFT (demand flow ---?)		X	
KPI dashboard (key performance indicator)		X	
Auto report distribution		X	
CAPA (---??---)		X	
FDA, ISO, CAMDCAS compliance		X	
Employee training and certification	X		
Automatic capture of labor actuals	X		
Make to order forward scheduling	X		
Real time resource planning	X		

Exhibit 5: Datasweep brochure excerpt

The Datasweep® Advantage™ Suite

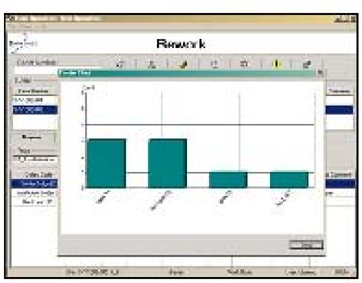
The Datasweep® Advantage™ suite of integrated software solutions complements and extends existing investment in ERP systems to deliver unprecedented control over and visibility into global manufacturing and repair operations. In addition to a set of standard applications, the integrated suite includes reporting and analysis, configuration tools, integration tools and full data management – all built using open-standard J2EE technology.

Applications

Datasweep applications provide functionality for effective management of supplier quality inspections, manufacturing shop floor and repair depot operations. Integrated quality management applications reduce time-to-quality and drive Six Sigma quality improvements.

Shop Operations

- Tracks WIP at serialized unit, lot (including splits and merges) or work-order level
- Provides and enforces dynamic workflow-based routings for rework loops



TRACK WIP ON THE SHOP FLOOR WITH PAPERLESS EXECUTION

- Enforces manufacturing processes, including routings and BOM
- Maintains complete electronic device and batch history records (DHR/BHR) including operations, operators, equipment, components, test results, defects and rework
- Supports RFID, bar-code scanning and direct integration with equipment
- Includes configurable screens for complex operations and user interface requirements

ECO Manager

- Enables importing of engineering change orders (ECOs) from ERP or PLM systems
- Supports creation and modification of ECOs, including temporary deviations
- Enables viewing, testing, and execution of ECOs during assembly, test failure and repair processing

Operator Certification

- Disciplined approach to ensuring 100% compliance with certification requirements
- Tracks and enforces operator and group certifications required for an operation
- Sets and enforces recurring certification time-frames and expiration dates by revision
- Provides supervisor/instructor signoffs and approvals on certification

"Datasweep provides us visibility and traceability across the entire manufacturing process to meet manufacturing goals, and thoroughly integrates with our ERP and CRM applications."

Network Engines

Manufacturing Operations