Nipendra (Nip) P. Singh
Consulting Partner
S&A Consulting Group, LLP

Investment Casting of Orthopaedic Implants

An Overview of Emerging Technology

Introduction
This overview briefly describes the strengths of, and areas of opportunity for improvement in, the investment casting manufacturing process as it relates to the manufacture of orthopaedic implants.

For over three decades, hundreds of thousands of patients have elected to have part of their skeletal system replaced by man-made implants. Industry experts project that by 2005, around 1,000,000 Americans will receive hip, knee or shoulder replacements annually (750,000 if partial and revision replacements are excluded).[1]

What will the number be in 2025? It may be too early to offer a projection, but it is apparent that the investment casting process is positioned to play an even more important role in the manufacture of orthopaedic devices in the future than it does today. Is the technology up to the challenge? Let's take a look.

Why Investment Casting?
In earlier years, joint replacement components were machined from forged/rolled bar stock; today, the majority of components are manufactured by the investment casting process.

Investment casting is the process of choice because it produces extremely complex and detailed components that possess exceptional dimensional accuracy, but at an overall cost that (in quantities) is far less than if each part were machined from a single block of metal. The "in quantities" qualification means that the process lends itself to the repetitive production of "standard" components.

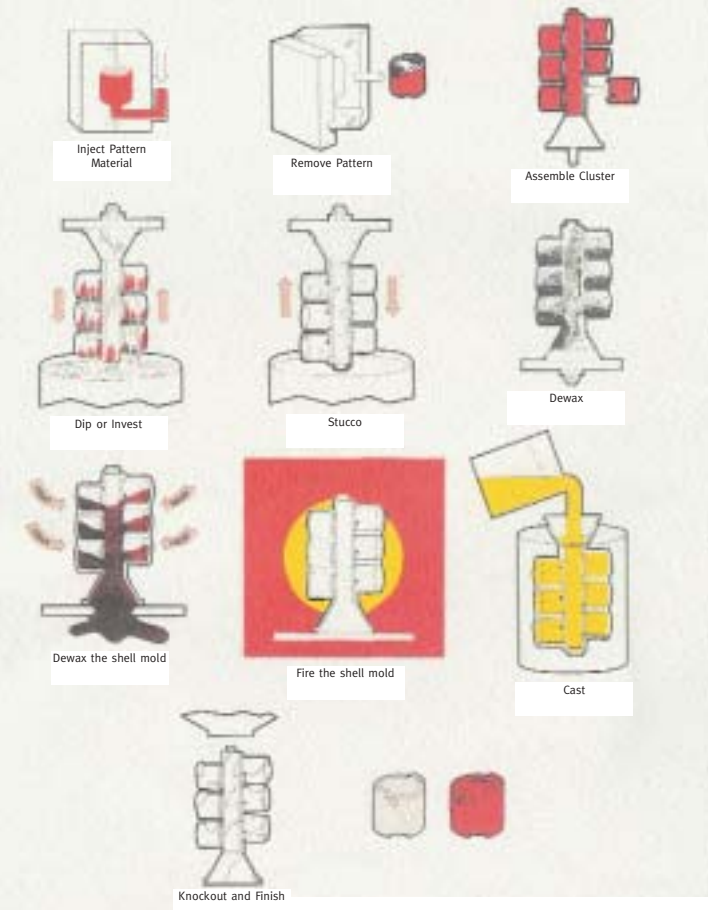
There are many advantages of investment cast components over other forming methods. Some of the advantages are:

- little machining is required (shape casting)
- holes and undercuts can be cast instead of machined
- tighter control of dimensions
- greater freedom of design options
- cost-effective casting shapes

What is Investment Casting?
The Investment Casting Process (Precision Casting, or Lost Wax Process) dates back to ancient Egyptian, Indian and Chinese cultures when many ornamental and commercial components were cast.

This process has been improved considerably in the last 50-60 years and is employed to produce high technology jet engine components, commercial components, jewelry and sports equipment (golf heads), as well as medical devices. A simplified depiction of the steps involved in traditional processes for casting of joint replacements is provided below.

Figure 1. Traditional Processes for Casting of Joint Replacement



continued on page 48

Investment Casting, continued from page 45

Several sizes of standard molds are machined. An investment casting wax is injected. The wax is then processed through a multi-stage ceramic shell-building process, which may take up to a week to make.

The shell is heated to melting point, and the wax pattern is then removed and fired to stabilize the ceramic for contact with the molten metal. The mold is filled with molten metal, the castings are cooled, and then they are separated from the "tree" for individual processing.

Full non-destructive testing is performed, depending upon the casting's intended usage. Numerous governmental agencies and/or commercial regulatory bodies (i.e., FAA for aerospace applications, FDA for medical device applications) are intimately involved with the manufacturing and certification aspects of casting.

During the past several decades, our technical understanding of the investment casting process has increased exponentially. Previously, the lead time for going from design to production and certification of aerospace and medical castings took more than a year. Today, mass-produced implant components require only a few months.

Non-destructive testing technology, and improvements and enhancements in computer technology, have enabled the casting industry to test, track and analyze individual castings for optimum performance.

Mass Production

Orthopaedic companies produce numerous series of standard joint replacement products. In the case of hip replacement surgery, manufacturers offer approximately 18 to 25 standard sizes for press-fit hip implants, and perhaps eight to ten standard sizes for cemented implants. This range of implant sizing typically allows the surgeon to match the bony dimensions for most patients within a tolerance of approximately one millimeter.

Even with so-called standard sizing, the investment casting process demands considerable time and expense. The wax pattern used in the lost wax process may be hand-sculpted or may be made by injecting melted wax into a metal die. Production of each such die typically takes one to three months of machining and, depending upon complexity, incurs a high cost. Once the die becomes available, the steps from "Make Wax Pattern" through "Casting" can represent an elapsed time of two weeks or more. Most of the processing steps require intervention by highly skilled workers who handle every part individually.

Rapid Prototyping

In the context of producing personalized surgical implants, Rapid Prototyping (RP) technology is being used by many device companies. However, RP processes are also predicated upon the use of a "wax" pattern. Although the cost and time associated with die production is reduced, a ceramic shell must still be created—a process that is slow and costly. Thus, although a wax pattern can be made by RP technology in only a few hours, production of a casting still requires a step for making a shell—a process that is time-consuming as well as expensive.

Producing surgical implants that are personalized for the needs of individual patients requires that the implants be made quickly, so that scheduling the operation becomes the pacing item in the surgery.

Concurrently, implants must be produced more economically so that personalized implants are compatible with cost constraints imposed by hospitals and insurance companies. These concerns are coupled with the need to replace worn-out joints as soon as practicable in order to avoid other detrimental changes to the patient's joint that might be caused by long delays between joint replacement design and actual implantation.

The Future

Investment casting processes have served patients reasonably well, given the existing state of the art.

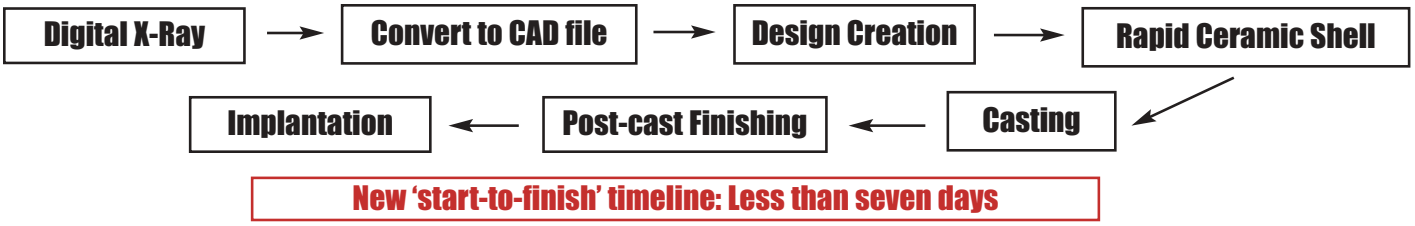
However, according to one leading surgeon (an internationally recognized authority on joint replacement), hip replacement surgeries have an 18% revision rate. This surgeon believes that the rate can be reduced by one-third by using mass customization and by creating personalized joints for virtually all patients. (Although providing "standard sizes" of implants is a serviceable option for many patients—even when considering variations in patient anatomy such as femoral neck/shaft lengths, neck-shaft angles, etc.—for some patients it is not.)

The surgeon also believes that the 82% of patients NOT requiring revision would have had a better post-operative experience (including less pain, shorter recovery time, fewer follow-up visits and a quicker return to normal activities) if they had received a custom implant. In his opinion, 90% of the revision surgeries are related NOT to the mechanical performance of the implant itself, but instead to difficulties arising from the implantation of the artificial joint itself.

It is believed that the prospects for successful post-operative results will improve if it becomes possible to provide implants designed specifically for each patient. Currently, customized or personalized implants are typically produced by machining blocks of alloy—a process that takes six to eight weeks at a cost several times that of a standard "production" implant.

A new technology process (see Figure 2.) is under development that takes advantage of recent advances in digital x-ray, rapid prototyping, ceramic shell and other related technologies.

Figure 2. Flow diagram: "process of the future" for personalized design and manufacture of implants.



Summary
This process will create opportunities for rapid delivery of custom joint replacement devices and promises to supply these components with improved accuracy, cost savings and reduction of lead times by eliminating many of the process steps inherent in conventional or conventional RP investment casting processes.

Not only will production times decrease but, with every step eliminated, dimensional accuracy will increase—providing truly personalized prostheses that will, hopefully, reduce the incidence of costly revision surgeries. This process is currently under development and is anticipated to be commercially available within two to five years.

Will this emerging technology live up to the expectation that boxes of boutique hip and knee prostheses will soon be delivered daily to the loading docks of hospitals around the world? Time will tell.

Editor: S&A Consulting, Inc. has been a global leader in technology, marketing and management consulting for over 15 years. Consulting Partner and Chief Executive Officer Nipendra (Nip) Singh has almost 30 years of experience in high-technology manufacturing businesses, and his team of consultants has more than 200 years of collective experience in investment casting. Mr. Singh holds a metallurgical engineering degree and completed postgraduate work in business at Case Western Reserve University.

The firm consults for commercial, medical, automotive, aerospace and IGT casting companies and their customers. Mr. Singh has also performed technical assessment of licensees and patents, led the preparation of strategic plans for new products, guided the turnaround of a business with heavy operating losses and troubleshooted process, equipment, material and design issues for clients in the United States, Europe and Asia.

S&A Consulting Group, LLP
Signature Square 1
25201 Chagrin Boulevard, Suite 180
Cleveland, OH 44122-5633
216-593-0050 (phone)
216-593-0053 (fax)
www.sa-consultinggroup
info@sa-consultinggroup.com

[1] Source: Knowledge Enterprises, Inc.