The ALLOFIT™ Insert: Clinical and Scientific Data

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Summary

The ALLOFIT Cup coupled with the Alpha type insert is a well-established system of acetabular components (Figure 1). The press-fit titanium cup has been sold worldwide since 1993. It functions with the clinically successful Alpha insert that has been used in several different acetabular cup systems since 1989. Testing has demonstrated that the ALLOFIT cup system offers numerous special characteristics. These include strong initial stability of the cup, which is enhanced by the nature of the press-fit as well as the macrostructure of the cup. In addition, the cup system provides excellent congruency between the shell and the insert, leading to more efficient transmission and distribution of loads. Two anti-rotation spikes on the inside of the shell enhance the rotational stability between the cup and insert. The spikes also aid in preventing micromotion between the cup and insert, thereby minimizing backside wear.

INSERT LOCKING MECHANISM

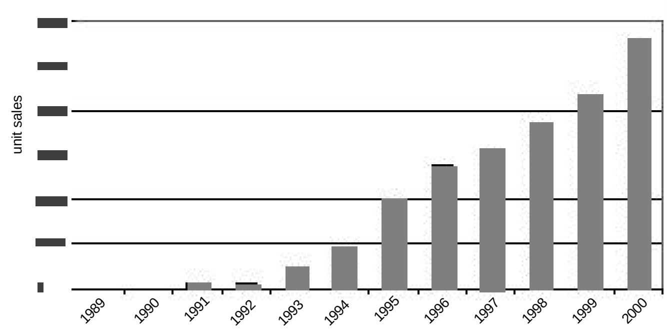
Clinical Experience

The ALLOFIT is a clinically successful cup system that has been sold worldwide since 1993. More than 40,000 Allofit shells have been implanted, with close to 12,000 sold in the year 2000. The ALLOFIT shell functions with the Alpha inserts that are compatible with various different cup systems.

Over 125,000 Alpha type inserts have been implanted since 1989 (Figure 2) with no reports of long-term failure of the insert/shell connection. Within this period of time, four cases (<0.003%) have been reported where the Alpha insert disassembled at a maximum of four weeks after implantation. It can be assumed that a potential reason for the failures was that these four liners were not fully engaged with the shell peri-operatively.

Figure 1 *Allofit Cup and Alpha Durasul and Metasul inserts*

Figure 2 *Alpha Type Insert Sales 1989 to 2000*

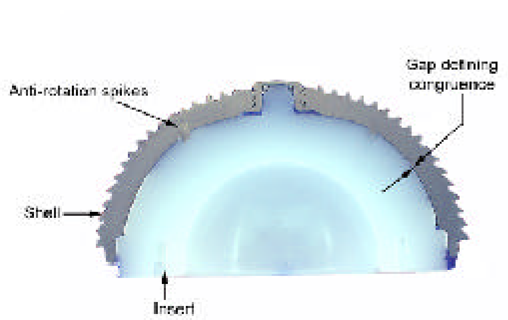


Congruency

A main concern with two-piece acetabular cup designs is the congruency between the cup and the insert.[1] A highly congruent cup/insert leads to large contact area of supported polyethylene. Larger contact area between the cup and insert is believed to yield a better distribution of stresses within the polyethylene insert as well as more efficient transmission of loads from the insert to the acetabular cup.[2] Loading of incongruent polyethylene is believed to lead to localized deformation and stresses that may be associated with wear of the insert and debris formation.[1]

Congruency of the ALLOFIT cup and Alpha insert was evaluated using a standard technique.[1] Liquid acrylic was poured into each titanium cup (sample size=2) immediately prior to fully seating the insert into the shell. After curing for 24 hours under a 10 lbf compressive load, each assembly was sectioned with a band saw (Figure 3). Subsequently, an optical microscope was used to measure the gap between the cup and insert at 5° increments around the hemispherical cup[3]. Gaps less than 0.2 mm were characterized as regions of contact[1] based on reasonable machining tolerances. The resulting congruent area corresponding to the gap measurements was calculated with 3D modeling software.

Figure 3 *Cross section of the ALLOFIT Cup size 54 (56mm) and Alpha Durasul insert. A gap between the cup and insert larger than 0.2mm indicates unsupported polyethylene. The gap was measured around the hemispherical cup at 5° increments.[3]*



The ALLOFIT cup system had excellent congruency between the cup and insert.[3] The average area of supported polyethylene was 30.3cm^2 and 29.1cm^2 for the shell with 1 and 3 screw holes respectively (Figure 4). The congruency or average percentage of supported polyethylene was 82.5% and 79.3% for the 1 and 3 screw hole shells, respectively (Figure 5). In conclusion, the ALLOFIT cup system ranked high in both total area of supported polyethylene and percentage of supported polyethylene compared with other acetabular designs. The excellent congruency is expected to result in better force distribution and transmission of loads to the cup, thereby minimizing deformation and subsequent wear of the polyethylene insert.

Figure 4 *Contact area of supported polyethylene for a number of acetabular shells on the market. All shells have an outer diameter of 52mm or 53mm unless otherwise noted.[1,3,4] For comparison reasons, the theoretical contact area of supported polyethylene was calculated for 1 and 3 screw holes.*

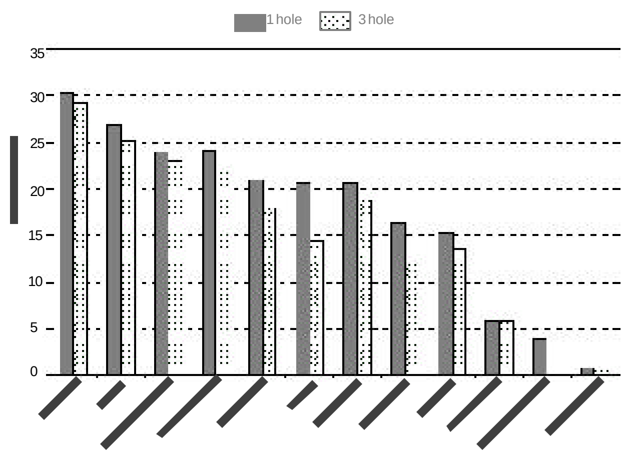
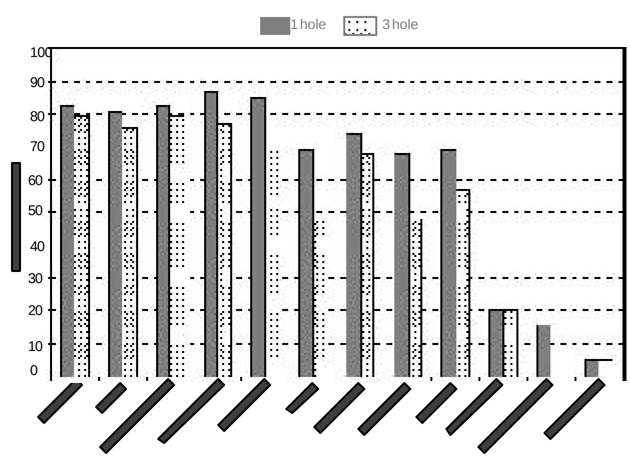


Figure 5 *Congruency or the percent of supported polyethylene for a number of acetabular shells on the market. All shells have an outer diameter of 52mm or 53mm unless otherwise noted.[1,3,4]*



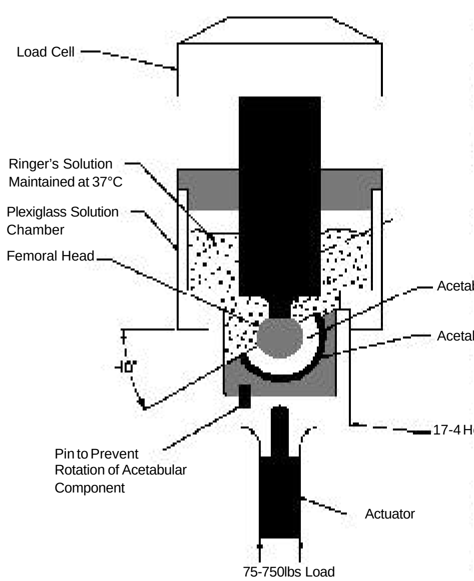
Connection strength

The strength of the connection between the cup and insert is important in preventing insert separation. The ALLOFIT system has two anti-rotation spikes on the inside of the cup designed to increase the rotational stability between the cup and insert. Results from both rotational stability and fatigue tests demonstrate the strength of the connection between the titanium shell and the insert.

To evaluate the rotational stability of the ALLOFIT system, the torque necessary to release the insert from the shell was measured (sample size: 2 cups, 7 inserts).[5] The torque was applied at 0.44°/sec without any axial load. A mean torque of 87.7in-lb was required to release the Alpha insert. In comparison to a version without spikes, the internal spikes increased the strength of the connection by almost 40%.

The fatigue performance of the ALLOFIT system was evaluated under cyclic loads and torques (sample size: 6 cups, 6 inserts).[6] Extreme physiological loads of between 750lb and 75lb (5 times body weight) and torques between 22 in-lb and 2.2in-lb were applied sinusoidally (Figure 6). Loads were applied at 6 Hz for 10 million cycles, simulating approximately 10 years *in vivo*. Testing took place at *in vivo* load angles and in Ringer's solution at 98.6°F to simulate a physiological environment. None of the acetabular assemblies experienced any adverse effects when exposed to the extreme physiological loads and torques. All of the anti-rotation spikes remained rigidly secured to the cup. Inspection under the microscope revealed no evidence of gross polyethylene creep. No polyethylene cracking was detected at the anti-rotation spikes, or in the body of the insert.

Figure 6 *Schematic diagram of the fatigue test of an acetabular system.[6]*

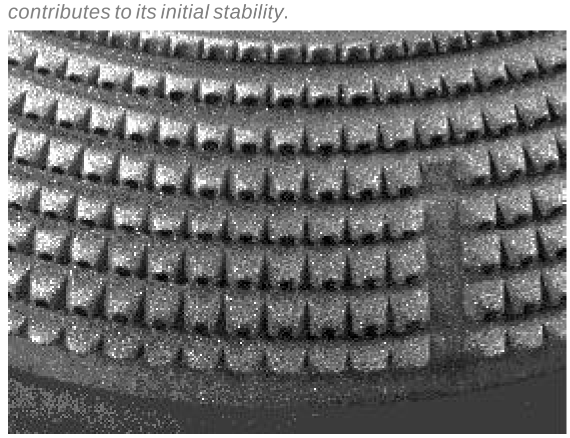


PRIMARY STABILITY

Initial stability of the cup in the acetabulum is vital to the success of the implant. Lack of initial fixation may lead to poor bone growth into the shell and subsequent loosening of the implant.[7] Previous studies have shown that the amount of contact between the shell and bone, particularly at the equatorial rim, is an important factor in determining the initial stability of the shell.[8]

Initial stability of the ALLOFIT cup is achieved by a 2mm press-fit and the macrostructure of the shell. The hemispherical design of the ALLOFIT imitates the original shape of the acetabulum, leading to close contact between the bone and implant. In addition, the flattened pole and oversized equator should promote more physiologic load transmission in the equatorial region of the shell. The unique macrostructured surface (RIDGELOCK technology) is made up of fine barb-shaped teeth up to 1mm in height. This grit-blasted roughened surface increases the surface contact with the bone to ultimately increase stability of the implant (Figure 7).

Figure 7 *The 3D macrostructure of the ALLOFIT cup contributes to its initial stability.*



The initial stability of the ALLOFIT cup was evaluated by measuring the torque required to lever the acetabular cups (sample size=6) out of PVC-foam blocks, which simulate cancellous bone.[9] Three sizes of under-reamed hemispherical holes were machined to provide 1mm, 2mm, and 3mm of press-fit. The average torque required to lever out the acetabular cups for 1mm, 2mm, and 3mm of press-fit was 61.9in-lb, 174.4in-lb, 307.2in-lb, respectively. Note that as press-fit increases, the average force required to assemble the cup into the acetabulum also increases, making it more difficult to impact the cup. An optimum of 2mm press-fit was chosen for the design of the ALLOFIT cup system.

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