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MP-1™ Polyimide for Medical Devices: 1. Pre Clinical Studies

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Abstract: Due to constant increase in human life expectancy, more people require primary and revision total hip replacement surgeries, costing billions of US$ per year. Currently used ceramic on X-linked Polyethylene appears to be the best choice by default, but it still wears. The wear particles generated, are the major cause of osteolysis and joint failure. During 2011-14, leading orthopedic companies suffered global recalls of their MoM hip systems resulting in thousands of revision surgeries. The search continues for new and more durable materials bearing materials. Developments in medical technology have increased the demand for advanced materials due to aging population, advanced medical procedures and contagious diseases. Metals and ceramics are prevalent in the medical industry. However, the unique properties of polymeric materials exhibit potential as better replacements for conventional materials. MMATECH Ltd. has developed a new articulation liner made of a revolutionary material of the Polyimide family, MP-1™, a spin-off of the Aerospace industry. MP-1™ has proved to be biocompatible, heat-resistant, highly crosslinked, combining unusual strength, toughness, self-lubrication, excellent friction and wear durability, as well as resistance to fatigue, creep, impacts and chemicals. These properties lead to longer life span and safer articulating implanted components. MMATECH received the CE and ISO certificates for its MP-1™ Acetabular liner of hip implant based on a pilot clinical study conducted in New-Zealand with excellent 13y follow-up results. Ethical Committee approval was granted for a clinical study of 100 patients in New Zealand. The results of the first 82 surgeries follow-up demonstrated normal blood parameters, no osteolysis, and improved quality of life. The performance of MP-1™ even at 13 years is very promising and is now being applied to younger patients (~ 40 Y old) in view of the retrieval data. Part 1 of this research will summarize the pre-clinical studies while Part 2 will deal with the clinical studies.

Keywords: Polyimide, Wear, Hip Replacement, Implants, Mechanical Behavior, Physical Chemical Properties, Clinical Trial, Biocompatibility

1. Introduction

Due to constant increase in human life expectancy, more people require primary and revision total hip replacement surgeries (Figure 1). Significant advancements in surgical treatment have provided effective options to reduce the pain and disability associated with certain musculoskeletal conditions. Total joint replacement has become a widely accepted treatment for many destructive joint diseases including osteoarthritis, rheumatoid arthritis, osteonecrosis and very severe pathologic fractures of total joint replacements. The two most common replaced joints and most successful ones are the knee and the hip. Joint replacement surgery (hip and knee replacement) is considered the most effective intervention for severe osteoarthritis, reducing pain and disability and restoring some patients to near normal function.

Ostheoarthritis is one of the ten most disabling diseases in

developed countries. Worldwide estimates are that 9.6% of men and 18.0% of women aged over 60 years have symptomatic osteoarthritis, including moderate and severe forms [1]. Age is the strongest predictor of the development and progression of osteoarthritis. It is more common in women, increasing after the age of 50 especially in the hip and knee. Other risk factors include obesity, physical inactivity, smoking, excess alcohol and injuries (European Commission, 2008b). While joint replacement surgery is mainly carried out among people aged 65 and over, it can also be performed among people at younger ages.

Hip replacement is a surgical procedure in which the hip joint is replaced by a prosthetic implant. Hip replacement surgery can be performed as a total replacement or a hemi (half) replacement. Such joint replacement orthopedic surgery generally is conducted to relieve arthritis pain or fix severe physical joint damage as part of hip fracture treatment. A total hip replacement (total hip arthroplasty) consists of replacing both the acetabulum and the femoral head with an implant consisting of four major parts: Acetabular shell, liner and femoral head coupled to the hip implant (stem). Hemi-arthroplasty generally only replaces the femoral head. Out of the four parts only the liner and the femoral head are under constant articulation while the shell and the stem are fixed to the bone without movement.

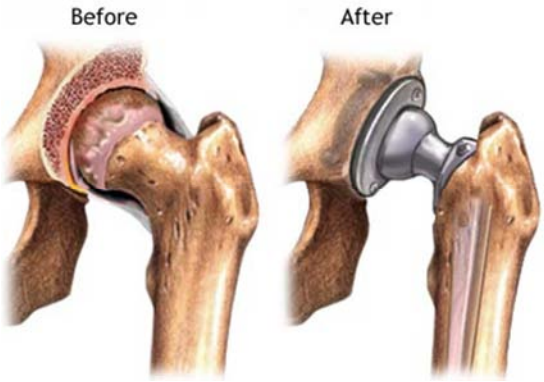

Figure 1. *Total hip replacement (by Adams).*

The most common problem that may arise soon after hip replacement surgery is hip dislocation. Because the artificial ball and socket are smaller than the normal ones, the ball can become dislodged from the socket if the hip is placed in certain positions[12]. The most common later complication of hip replacement surgery is an inflammatory reaction due to tiny (sub-micron) particles that gradually wear off the artificial joint surfaces and are absorbed by the surrounding tissues [2]. The inflammation may trigger the action of resorption of the bone matrix called osteolysis, causing the implant to loosen and may cause pain. To treat this complication, the doctor may use anti-inflammatory medications or recommend revision surgery (replacement of the artificial joint). Medical scientists are experimenting new materials with improved wear resistance that last longer and cause less inflammation.

Currently used ceramics, X-linked Polyethylene, and metal have various disadvantages and wear with time [2, 4-6, 14]. Metal on Metal (MoM) was abandoned due to metal ion release and pseudo-tumor production [3]. The wear particles generated of bearing systems, are the major cause of osteolysis and joint failure. The search continues for new and more durable materials bearing materials in articulating joints, such as hip and knee joints. Statistics indicate that today's commonly used materials are not performing well enough. More than 650,000 total hip arthroplasties were performed in 2017 in the US alone, but it is estimated that by 2025 as many as 21% of all hip arthroplasty procedures will be surgical revisions of the implant. Such a high revision rate means better implant material is needed. Traditionally, an artificial hip consists of a metallic or ceramic femoral ball, a metallic acetabular cup with a liner usually made of ultra-high molecular weight Polyethylene (UHMWPE) and a metallic stem. UHMWPE was used clinically for over 40 years. Several studies have concluded that the primary cause of implant loosening is osteolysis (bone resorption) caused by wear debris generated at the articulating surface of the polyethylene acetabular liner. The goal therefore is to develop an alternative material for use in orthopedics that does not generate wear debris of a type that induces osteolysis. This article presents the alternative using the polymer polyimide (MP-1™) as a replacement for UHMWPE in orthopedic application.

Traditional metallic implants can result in a phenomenon called "stress shielding". Stress shielding occurs when a stiff metallic implant tends to carry the majority of the load rather than the preferred load sharing where the bone and the implant share the load carrying duties. When the metallic implant carries the majority of the load, the adjacent bone weakens over time. To achieve the desired load sharing for structural orthopedic implants, it is critical to use an implant material with similar modulus of that bone. Cortical bone has a modulus of 14 GPa, Titanium implants have a modulus of 110 GPa and MP-1™ has a modulus of 3.7 GPa. Metallic articulating implants tend to release sub-micron wear particles from the surface, which tend to invade the tissues surrounding the implant causing poisoning and tumor growth [7-9]. Metallic articulating implants are thus scarcely in use anymore since the recall of De-Pue's hip implants in 2011.

Another approach reviewed in the paper [10] concentrates on various newly developed plasma-sprayed and sintered of advanced articulating coatings for implant applications. A great effort was made to improve the coating adherence and reduce stresses by minimizing coefficient of thermal expansion mismatch between the coating and the implant's substrate, but still the effect of peeling and cracking cannot be totally avoided. Efforts were also made to improve mechanical properties by depositing bilayers on the implant material to improve wear resistance and adhesive strength using ceramic composites, nano-graphens and bio-glasses.

Poly ether-ether Ketone (PEEK) implants – a high temperature resisting thermoplastic polymer, has varying locations of crystallinity in the structure due to variable cooling rates in areas of different cross sectional thickness.

Moreover, PEEK's crystallinity changes with aging time. This varying crystallinity affects the material properties of the implant with time causing the material to become more brittle. No hip liner or knee tibia made of PEEK has ever succeeded [11].

Ceramic implants are brittle or spall therefore the implant must have thick walls, thus limiting the range of motion of the hip or knee. When breaking the ceramic implant is shuddering and the breakage is considered a catastrophic failure [12]. Ceramic implants usually impose continuous squeaking after implant. Moreover, a phenomenon of stress corrosion is well known in ceramics in a wet environment causing crack evolution and sudden break. Ceramic implants, due to their complex production process, are most expensive and thus occupy only about 10% of the total market of hip implants and less than 2% of the knee implants.

Other studies ranked alternative materials according to their biocompatibility and mechanical properties for use as an acetabular bearing surface in an artificial hip prosthesis but scarcely reached the market [17].

The team of MMATECH Ltd. determined that an advanced polyimide MP-1™ appeared to be the most promising solution. MP-1 is a high temperature thermosetic polymer, consisting of an aromatic backbone molecular chain which is interconnected by ether functional groups. This chemical structure confers stability at very high temperatures (exceeding 400°C), resistance to chemicals and radiation damage, and durability to creep and fatigue. Historically, the availability of poly-aromatic polymers arrived at a time when there was growing interest in the development of “wear free” hip acetabular liners and femoral balls, with stiffness comparable to bone [13, 16]. The evolution of polyimide MP-1™ has been studied extensively for bio-medical applications resulting from excellent biocompatibility and mechanical properties. MP-1™ is the first generation of polyimides used in medical devices. The special chemical composition of the MP-1™ polyimide enables it to be used for long-term implants because of significant hydrolytic resistivity and long term durability. MP-1™ is totally inert and is not prone to oxidation or solvent's attack or any degradation.

In article [13] the pre-clinical testing of MP-1™ was described revealing the chemical, physical and mechanical properties of the material including creep and fatigue. A full series of biocompatibility tests was executed and described as well. The results have proved that MP-1™ is totally biocompatible, has better fracture toughness than ceramics, better wear resistance than polyethylene, minimal friction coefficient, it is self-lubricating, and has chemical inertness and high durability in fatigue and creep resulting in dimensional stability and high endurance limit.

In this part more specific tests were conducted aiming at articulating joints. These included Hip simulator, catastrophic impact test, stability tests and aging stability. All these tests were needed to prove safety of the material before approaching clinical trials.

2. Experimental

The pre-clinical experiments regarding the THR acetabular liner included specific tests conducting on the articulating joint devices. The experiments included Hip simulator of MP-1™ liner, catastrophic impact test on MP-1™ liner and stability tests on the acetabular MP-1™ liner and metallic cup. All these tests were needed to prove safety of the material before approaching clinical trials.

2.1. Experimental – Hip Simulator

The next step of the pre-clinical tests was Hip Simulator examining the biotribology of MP-1™ liner devices. Hip simulator dynamic machine tests a joint replacement device under conditions and forces approximating those occurring in the human body while walking. The test was performed in Script laboratory in San Diego (La Jolla), according to ISO 14242 Implants for surgery — Wear of total hip-joint prostheses.

The MP-1™ acetabular hip liners (MMATECH product) for wear testing were produced by compression molding of PI powder to a block and then CNC machined to liners. The test system included 12 acetabular liners of 28 mm inner diameter in CoCr metal shells. All liners were Gamma air sterilized.

Marathon (Cross Linked UHMWPE) liners were evaluated as controls.

CoCr heads and zirconia ceramic heads were used as the counter faces.

Bovine calf serum was used as the lubricant test fluid in which the liners were soaked.

The hip simulator experiment ran for 5 Million cycles (representing 5 years life time), while stopping at each 500,000 cycles for cleaning and weighing. Test temperature was 37 C and the frequency was 1 Hz.

The hip joint simulator performs 2x3 simultaneous tests (and two soaked controls) Figure 2. The specimens are oriented in an anatomically correct position; the resulting hip joint force was applied on the liner via the cup. Consequently, the direction of the force vector was constant relative to the cup and moved relative to the head. All three in-vivo angular displacements were simulated: Flexion / extension, abduction / adduction and internal / external rotation. The specimens were assembled under laminar flow conditions and sealed by capsulated single test chambers to exclude contamination. The temperature of the test fluid as well as the fluid level was controlled throughout the testing. The wear of the components was determined gravimetrically and calculated volumetrically.

Following the hip simulator test the fluid analysis of wear particles was done,

The objective of this analysis was to characterize the shape and size of wear particles generated in the hip simulator wear test conducted on MP-1™ material. Particles from three different test stations were evaluated and compared. This entailed retrieving the particles from the bovine serum solutions, imaging them using scanning electron microscopy

and then utilizing a custom image analysis software (developed specifically for wear particle analysis) to characterize their size and morphology as per ASTM standard 1877.

Figure 2. *Hip simulator testing*

2.2. Experimental - Lever out, Push out and Torsion Test

The MP-1™ acetabular liner is inserted into the acetabular cup without cement. The stability of this couple must be tested before implanting in the body. Three tests were conducted in order to assure the safety of the device.

23 liners were produced, according to CNC drawings, by compression molding of MP-1™ powder to blocks and machining the blocks to final liner shape (Figure 3). Every design of total hip arthroplasty system has usually three sizes; Small, Medium and Large (Table 1).

Since dislocation continues to be a common complication of total hip arthroplasty (THA) [4], their stability must be tested. Many factors are known contributors to THA stability. Intraoperative stability tests have been used to assess range of motion (ROM) using two critical positions: 90° flexion plus internal rotation and extension plus external rotation, and higher intraoperative range of motion (ROM) is believed to minimize dislocation risk. An example of instability is the phenomena of impingement. Impingement is a mechanical abutment conflict between the bone of the femur and the pelvis; in a total hip replacement, it is contact between the metal femoral neck and the cup liner or bone-to-bone contact such as between the greater trochanter and the pelvis. In the clinical setting, some causes of failure such as wear or dislocation infer to impingement. The consequences include limited motion and function; increased stress on the liner rim, accelerated loosening of the implant; liberation of metal debris from the femoral neck; generation of rim wear, potentially increasing the risk of osteolysis; subluxation and dislocation, pain and need of revision surgery. In order to test the stability of the system three tests were performed: Evaluation of Push out stability under ASTM F 1820 requirements, evaluate the Lever out and Torsional stability of MP-1™ liners with Delta TT cups.

2.2.1. Push out Test

The test determines the Axial Disassembly Force of a Modular Acetabular Device in push out test. Push Out Test six MP-1™ liners (MMATECH) were assembled into Delta TT shells featuring an 18-degree tapered internal geometry. Liners are pressed into the cup by means of a ceramic head at 2000±50 N maximum load (according to Ceramtec procedure). The whole system of cup and liner are subsequently put on a metallic ring which fully supports the cup but not the liner (Figures 4, 5).

The liner is pushed-out pressing on the polar protrusion with a 6 mm metallic plunge. The applied disassembly load is recorded by means of the load cell.

2.2.2. Lever out Test [11]

Lever out test is performed by disarticulating liner from cup by means of a lever arm (Figures 6, 7), lever is joined to MP-1™ liner by a hole in 5 mm diameter. The liner is pressed into the cup in with a force 2000±50 N.

The parameter considered to evaluate stability is the bending moment calculated by multiplication of applied force and the lever arm for the cosine of the inclination angle (α).

Force is applied till insert-cup disassembly. The lever bar is loaded at a rate of 5mm/ min. at the external side at 58,5 mm (b) from the fulcrum (Figure 6). The length of the lever arm from the fulcrum to its insertion point into the liner is 86,0 mm (a). The inclination angle (α) 25°. A force-displacement curve is recorded. The maximum lever out torque, (calculated by the maximum force multiplied by the lever arm length(b)) is presented as a further measure of the locking mechanism strength.

Six liner-shell assemblies were subjected to a lever out.

Table 1. *List of liners tested.*

INSERT SIZE	ARTICULATION	No. of PARTS
SMALL	32(40)	4
MEDIUM	36(44)	15
LARGE	40(48)	4

2.2.3. Torsional Test

Torsional stability test is performed using servo-hydraulic testing machine.

Torque application: Torque is applied at constant speed of 1° per sec.

Locking mechanism strength was evaluated by measuring the torque required to axially twist the MP-1™ liner. The acetabular shell is rigidly fixed to the base of the machine and the liner not axially loaded. The liner is driven at a constant 6 rpm via a Polyurethane embedded, steel coupling nut (Figure 8). The maximum initial axial torque, averaged for three new components, is presented as a measure of the axial locking mechanism strength.

Test parameters:

Liner insertion into cup, Preloading 2000 ± 50 N

Load removal, Test load applying 0 N

Six MP-1™ liners (MMATECH) were assembled into shells and tested. which were, in turn, glued into cylindrical fixtures. Ceramic femoral heads were glued to the inside of the ceramic liners. Femoral heads were assembled onto

titanium tapered spigots representing femoral stem tapers. The spigots and cylindrical fixtures were firmly fixed in the test machine, and were subjected to torsional load until failure.

All three tests are performed at room temperature T°= 23±2°C

Figure 3. *Cup and liner for testing.*

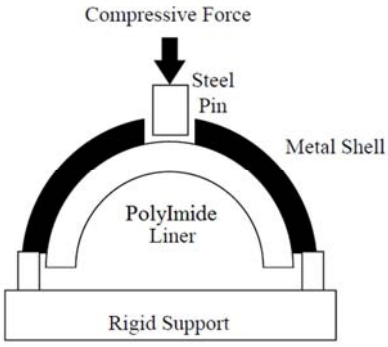

Figure 4. *Push-out test.*

Figure 5. *Push-out test.*

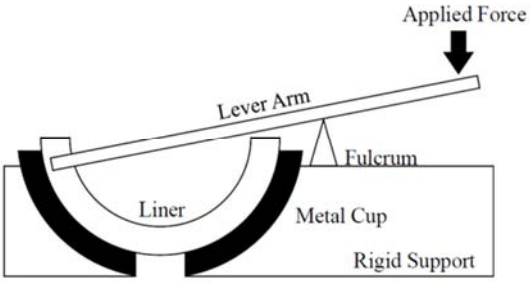

Figure 6. *Lever-out test.*

Figure 7. *Lever-out test.*

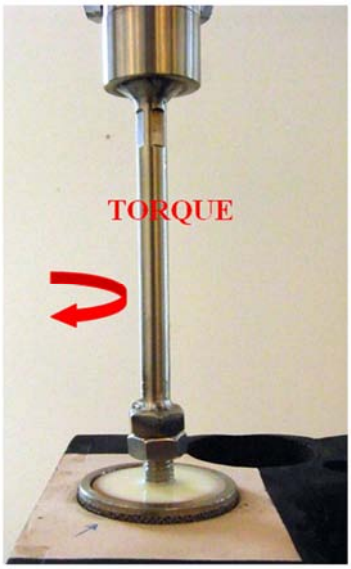

Figure 8. *Torsional stability test.*

2.3. Catastrophic Impact Test –Experimental

The aim of the Catastrophic Loading Test is to find out if the tested materials MP-1™ can withstand loads at the range of 10 times body weight and hammering of the implant during surgery.

Six (6) MP-1™ samples were tested. Each sample was machined into hemispheres with a 38mm outer diameter and 2 mm thick (Figure 9). The parts were immersed in bovine serum, diluted 25% with buffer solution, to mimic the part's environment and friction conditions in the body.

The load used in this study was a ball impacting at a load of 730 kg. This load represents an individual who weighs 73 kg and accidentally stumbles, causing a 10 times body weight impact on the hip joint. The 73 Kg weight was selected as the maximum weight of a person having 38 mm diameter acetabulum. A cycle of 0.1 Hz was selected to allow the piston to fill with air.

The Technion (ITT) developed the Impact Loading Machine. The machine has one air piston with 125 mm

internal diameter, and a pressure gauge for indication of the loading value.

The parts were placed in the concave station of the loading machine with the apex of the shell oriented downward (Figure 10). The Bovine Serum was poured into the test article such that the serum reached the top mark on the station's metal cup.

A pneumatically driven mechanism pressed a metal head against the test article in a vertical axis. The diameter of the metal head was 1 mm smaller than the internal diameter of the test article, causing a 0.5 mm clearance, which represents a typical clinical clearance scenario.

The test articles was cyclically loaded at 0.1Hz for 100 impacts.

At the end of the test each test article was returned to its labeled container to be stored for the possibility of further examination.

Figure 9. *Test samples made of MP-1™ for impact test.*

Figure 10. *Impact test machine.*

2.4. Stability Test of Liner

Liners made of polyimide MP-1™ have unlimited storage time at room temperature since they are produced from Polyimide.

Usually machining of plastic articles induces residual stresses, which may cause change of dimensions with time as the stresses are relieved.

Since the liners are produced with high precision so they will suit the outer metal cup and the inner ceramic femoral ball dimensions it is very important that their sizes won't change with time.

Typical example of residual stresses is given in Figure 11. If the outer stresses are tensile the machined part is sensitive to fatigue. If the stresses are of compression, the part is less sensitive to fatigue..

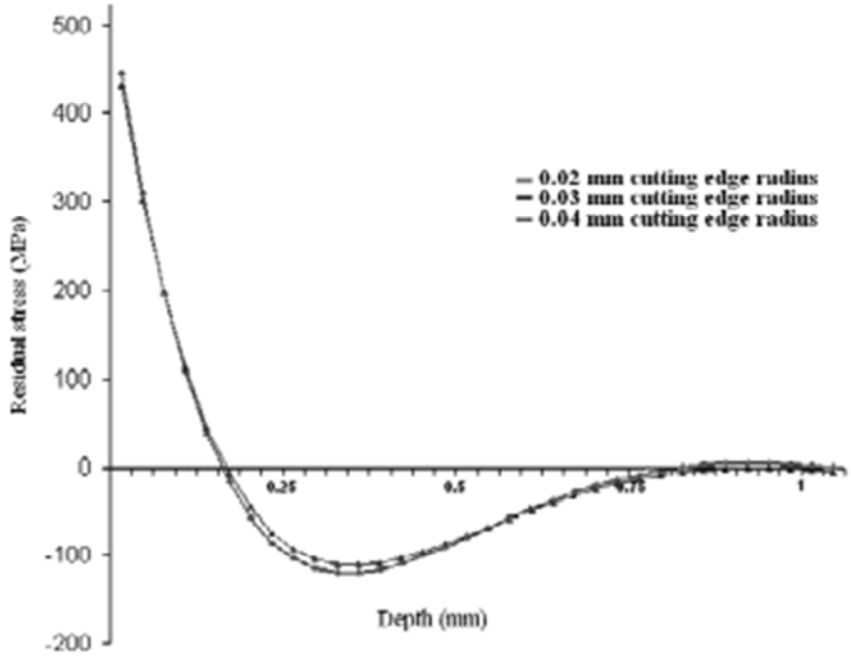

Figure 11. *Residual stresses with depth Experimental.*

A liner No. 307 machined by PPD (Canada) on 7/2012 was measured and the results were reordered by PPD. Ario (Israel) also measured this same liner in 4/13.

Ario measured the same liner No. 307 again in 6/2016. All measurements were done on an X-Y-Z measuring machine.

3. Results and Discussion

3.1. Results – Hip Simulator

Figure 13 shows the volumetric results for the MP-1™ wear test of the hip simulator. These results resemble the wear after 5M cycles.

Table 2 shows the very low wear rate of MP-1™ against Ceramic compared to other pair of materials used in hip simulator.

The results present MP-1™ against DELTA Ceramic heads. Microscopic pictures of the wear surface showed a totally smooth surface highly polished with no scratches or pits (Figure 12). The volumetric wear rate of the MP-1™ against CoCr is higher than that for the UHMWPE against CoCr. The volumetric wear rate of the MP-1™ against Ceramic is considerably smaller than that for the UHMWPE against Ceramic head. (Figure 13)

MP-1™ picked up more fluid in the load soak compared to UHMWPE.

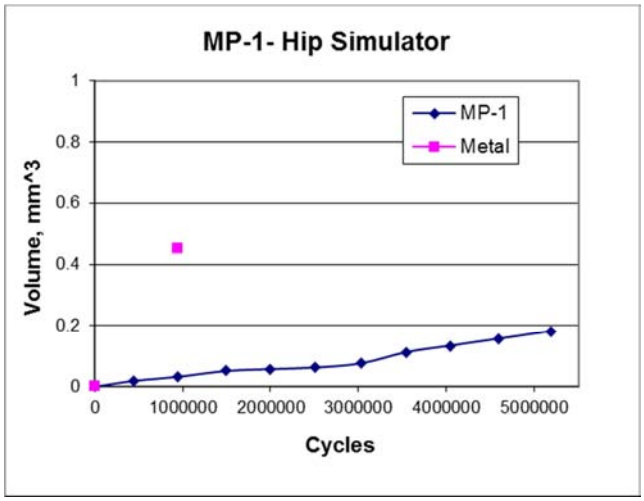

Figure 12. *Hip simulator results of MP-1™ vs. Ceramic and metal vs. metal.*

Under these conditions, the MP-1™ exhibited an order of magnitude less wear than the control.

Table 2. *Comparable Wear Rates Results.*

BEARING COUPLE (28MM)	Wear rate (mm^3 per year)
Traditional PE on Metal[2]	50
Traditional PE on Alumina Ceramic	40
Moderate x-linked PE on Metal	35
Highly x- linked PE on Metal	20
MP-1™ on Metal- I	0[4]
MP-1™ on Metal- II	0.18[6]
MP-1™ on Delta Ceramic	0.044[6]
Traditional PE on Zirconia[1]	6.3[5]
Metal on Metal[1]	0.45

[1]A. A. Goldsmith et al, Proc. Inst. Mech. Eng. 214(1), 39 (2000) [2] CoCrMo [3] Alumina [4] From the fluid analysis from Hip simulator test after 1.9 Mc 213 particles of MP-1™ had been counted. Their mean diameter was about 1.7 micrometer. The total volume of these particles is about 8 x 10-6 mm3 - tends to zero! [5] 9000 implants made of Zirconia had been recalled by the supplier because of degradation and powdering. [6] After 5M cycles (estimate of 5 years)

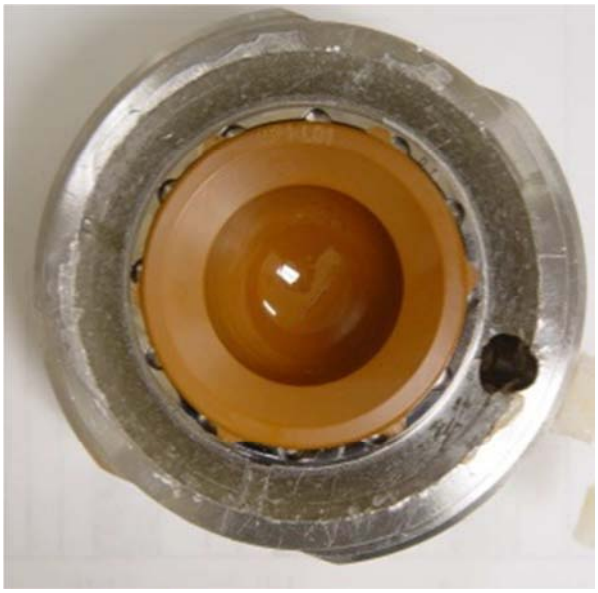

Figure 13. *Smooth surface after 5M cycles.*

Fluid analysis showed that the number of particles from the MP-1™ material were significantly less than those obtained from retrieved human tissue. The particle number was significantly lower than what is usually observed in crosslinked UHMWPE retrievals. The size (ECD) of the MP-1™ particles was almost two-fold larger than particles generated by hip joints (crosslinked UHMWPE). Particles from UHMWPE hip joints have a mean ECD of approximately 0.694 micrometer (sub-micron), MP-1™ material yielded particles with a mean of 1.881micrometer (with some large particles up to 23.154 Microns) Figure 14. The MP-1™ particles are also larger than the UHMWPE particles retrieved from knees and shoulders. Since none of the particles was sub-micron these particles cannot be swallowed by macrophages thus not causing any infection.

The aspect ratio was slightly smaller than observed from crosslinked UHMWPE hip retrievals thus more rounded and less fibril-like. (Figure 15).

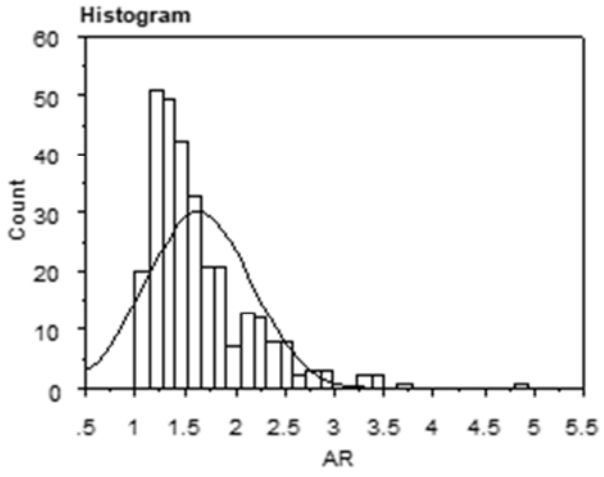

Figure 14. *MP-1™ size distribution of wear particles.*

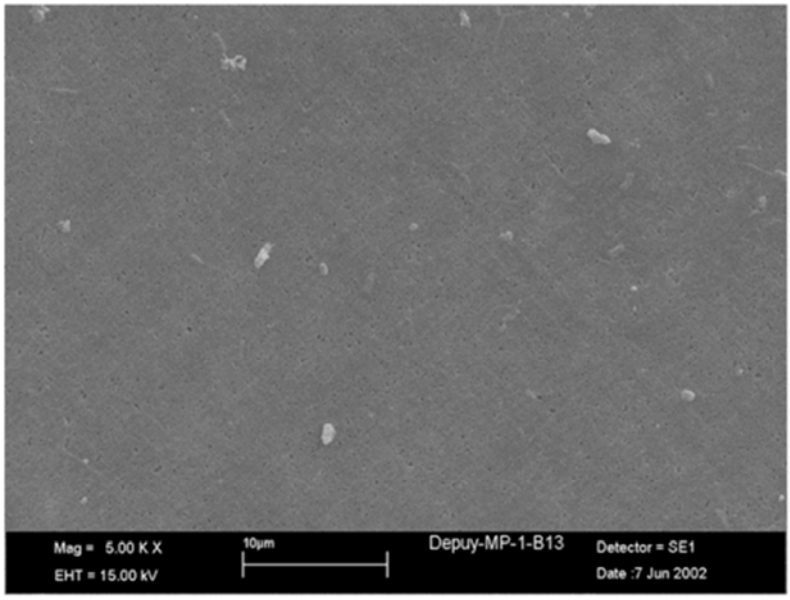

Figure 15. *SEM picture of MP-1™ wear debris.*

3.2. Results - Lever out, Push out and Torsion Test

3.2.1. Requirement Criteria

Acceptable push-out, lever out and torsion stability load values are defined according to the existing test reports considering different liner materials already marketed and clinically proved.

Push-out test - Minimum acceptable Push-out load value for Medium 36mm MP-1™ Liner is > 200N

Lever-out test - Minimum acceptable Lever-out load value for Medium 36mm MP-1™ Liner is > 20 Nm

Torsion stability test - Minimum acceptable Torsion stability load value for

Medium 36mm MP-1™ Liner is > 4Nm

3.2.2. Results Push out Test

Table 3 shows the outcome of the push-out test.

Table 3. *Push out results.*

Serial number Liner	Note	Load (N)	Average, STD deviation
S/N 201100204	Pressed to 2000 N	455	376.7 ±98.9 N
S/N 201100205	Pressed to 2000 N	325	
S/N 201100206	Pressed to 2000 N	257	
S/N 201100207	Pressed to 2000 N	315	
S/N 201100208	Pressed to 2000 N	529	
S/N 201100209	Pressed to 2000 N	339	
S/N 201100102	Impacted to 2000 N	307	
S/N 201100101	Impacted to 2000 N	487	

3.2.3. Results Lever out Test

Table 4 shows the outcome of the lever-out test.

Table 4. *lever out torque results.*

Serial number Liner	Note	Torque (Nm)	Average, STD deviation
S/N 201100301	Pressed with 2000 N	29.2	28.9 ±2.6 Nm
S/N 201100302	Pressed with 2000 N	25.6	
S/N 201100304	Pressed with 2000 N	30.6	
S/N 201100305	Pressed with 2000 N	32.2	
S/N 201100306	Pressed with 2000 N	29.8	
S/N 201100307	Pressed with 2000 N	25.9	

3.2.4. Results of Torsional Stability

Table 5 shows the outcome of torsional stability test.

Table 5. *stability torque results.*

Serial number Liner	Torque (Nm)	Average, STD deviation
S/N 201100103	12.04	12.86 ± 0.86
S/N 201100104	13.75	
S/N 201100105	12.80	

Push out test, Lever out test and Torsional stability test of MP-1™ Liner coupled with Delta TT cup (50 diameter medium liner) showed higher values than the required criteria.

Following confirmation of its biocompatibility tests, hip simulator, lever and push out and stability tests, the polyimide MP-1™ was employed as a biomaterial for orthopedic implants.

3.3. Catastrophic Impact Test – Results

The results for all the tests were evaluated as pass/fail where pass means no visible damage of the part and fail means any visible damage of the part. The results showed that all six parts stayed intact after the test. No visible sign or marking or wear on the parts was observed.

3.4. Aging Stability Test – Results

The results of the two measurements of the same liner as is and stored on the shelf for 4 years were compared in Figure 16.

The results show that the liner is stable and did not change its dimensions within 4 years of storing on the shelf at room temperature.

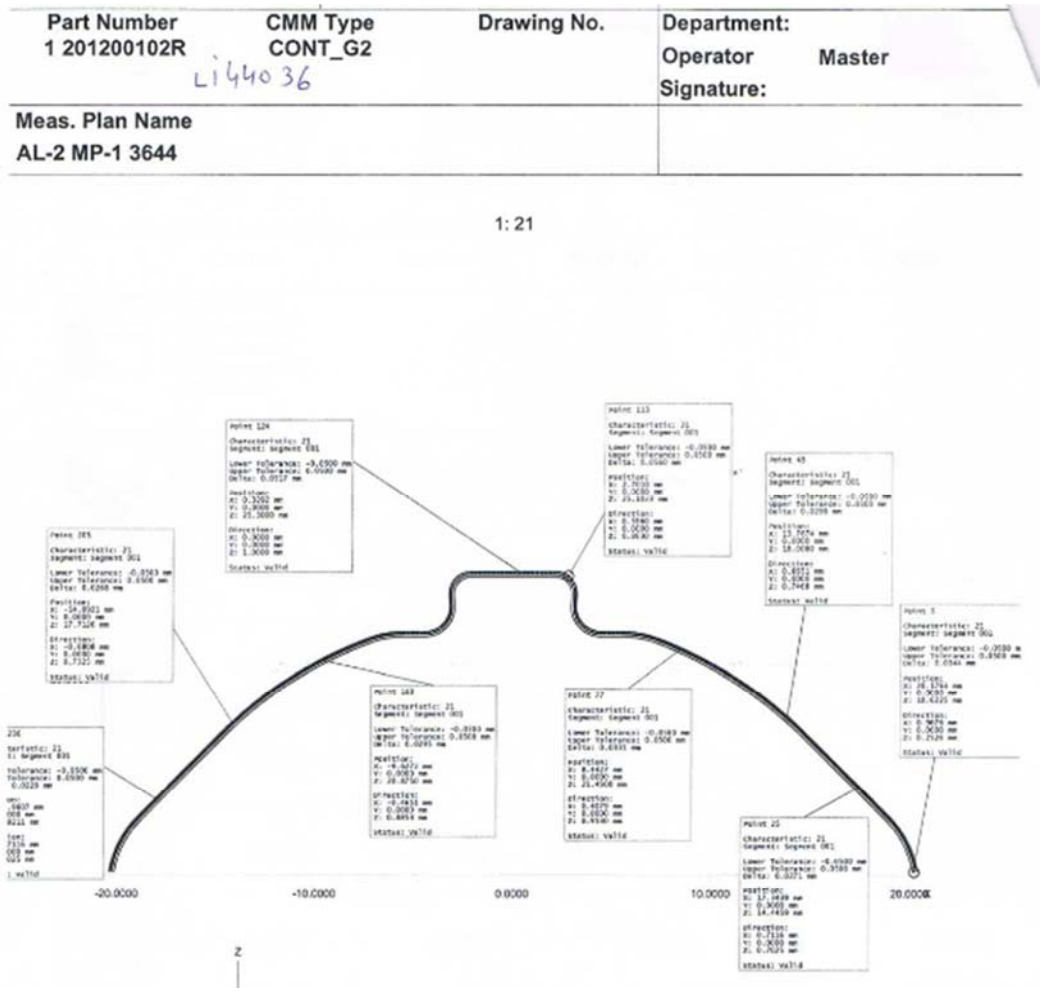

Figure 16. *Measurements of the same liner: as received and after 4 years storage on the shelf.*

4. Conclusions

The widespread adoption of a new biomaterial is necessarily a slow and careful process.

In an effort to initiate clinical trials with MP-1™ biomaterial an extensive polymer science literature survey was done and mechanical and physical properties, and chemical resistance of MP-1™ biomaterials in creep and fatigue was investigated [13]. Due to the excellent results, an advanced pre-clinical research was done testing the acetabular liner as a device in various tests including hip simulator, lever out push out and torsional stability and catastrophic impact as well as testing the dimensional stability in a long time storage.

Hip simulator results proved that MP-1™ has very low wear, lower than all other couples used in articulating joints in orthopedics (Metal, Ceramic and X-UHMWPE). Moreover, the wear debris of MP-1™ are larger than 1 μ thus are not able to be swallowed by microphages thus not causing inflammation. All other materials used to date produce sub-micron wear debris thus causing inflammation in the surrounding tissues when wear particles are exposed. The hip simulator results prove excellent safety of MP-1™.

Lever out push out and torsional stability tests were all high above the requirement limits showing that the liner will not be pushed out from the cup, will not dislocate while walking and will adjust well to the cup with high stability.

Catastrophic impact proved the excellent resistance of MP-1™ to impact in the event of implanting, jumping, fall from the standing position and walking on steps.

The results proved that this family of polymers (polyimides) will be inherently strong, inert, and biocompatible, more than other currently used biomaterials that have been clinically tested for the last few decades. Due to its high inertness, MP-1™ biomaterials may be an attractive platform to develop many different novel bioactive devices. MP-1™ will be an alternative to metallic biomaterials in the orthopedic community for implantation and fracture fixation implants.

MMATECH Ltd manufactured hip acetabular liners to perfectly fit into the external metallic shell of three main sizes (Small, Medium and Large) to be used are used against ceramic femoral heads (Biolox Delta or other) [15]. The clinical results as well as post-marketing results will be published as part II of this article.

Although MP-1™ polyimide is currently only offered by

one international producer, growing demand for this material may stimulated great interest in MP-1™ biomaterial development.

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