Surface Damage in Machined Ram-Extruded and Net-Shape Molded Retrieved Polyethylene Tibial Inserts of Total Knee Replacements

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Background: Polyethylene wear has emerged as a major determining factor in the long-term clinical performance of total knee replacements. This study addresses the in vivo wear performance of two types of polyethylene tibial inserts used in similar total knee arthroplasty designs.

Methods: A surface damage assessment of retrieved specimens was performed for twenty-six net-shape molded tibial inserts manufactured from H1900 resin without calcium stearate additive (Miller-Galante) and forty-three machined ram-extruded tibial inserts manufactured from GUR 4150 resin with calcium stearate additive (Miller-Galante II). Stereomicroscopic inspection and digital image analysis were used to quantify the extent and severity of pitting, dimensional change, and delamination.

Results: Pitting and dimensional change were the most common modes of damage in both groups, with the prevalence ranging from 77% to 92% for pitting and from 51% to 81% for dimensional change. Delamination was the least common mode of damage, with the prevalence ranging from 21% to 35%. The severity of pitting was higher in association with the cemented implant-bone interface. The extent and severity of delamination increased with implantation time. No severe delamination was observed before sixty months after implantation in the net-shape molded group, whereas severe delamination was present as early as ten months after implantation in the machined ram-extruded group. The time between surgery and the discovery of damage was longer in the net-shape molded group for all modes of damage except for medial dimensional change.

Conclusions: On the basis of the components available in our implant retrieval pool, we found that at equivalent levels of surface damage, the net-shape molded H1900 resin tibial inserts demonstrated longer service life than did the machined ram-extruded GUR 4150 components. The superior performance of the net-shape molded components may be related to the resin type, the absence of calcium stearate, the consolidation method, or the method of final geometry shaping. This superior damage resistance is expected to contribute to superior long-term clinical performance of net-shape molded ultra-high molecular weight polyethylene in total knee arthroplasty.

Wear of prosthetic implants has been increasingly recognized as a limiting factor in the longevity of total joint replacements. Release of particulate wear debris may result in periprosthetic bone loss and loosening of the implant[1-3]. Several studies of the material properties of prosthetic implants have suggested that the wear resistance of ultra-high molecular weight polyethylene components can be affected by the method of sterilization, the presence of additives, the type of resin, and the method of fabrication[4,5]. Machining from ram-extruded bar stock or net-shape molding are two alternative methods that have been used to manufacture components. Net-shape compression-molding allows the control of polymer resin consolidation at the level of an individual component. Ram-extrusion and subsequent machining

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produce implants with mechanical properties derived from the precursor bar properties. Radiographic wear studies have indicated that net-shape molded polyethylene acetabular components are associated with lower wear rates in comparison with machined components[6]. Retrieved compression-molded components of different geometries have been associated with lower wear rates[7]. Laboratory studies on retrieved Insall-Burstein and Insall-Burstein II tibial inserts (Zimmer, Warsaw, Indiana) have demonstrated that molded components are associated with less surface damage and higher oxidation resistance than are machined components[8,9]. Reports on the long-term clinical survivorship of total knee designs that made use of net-shape molded tibial inserts have suggested that this method of fabrication has possible advantages compared with the machining method[10].

The purpose of the present study was to test the hypothesis that net-shape molded tibial inserts undergo less surface damage than ram-extruded machined inserts. This was accomplished by analyzing retrieved net-shape molded and machined ram-extruded components of a similar unconstrained design.

Materials and Methods

Sixty-nine retrieved tibial inserts from posterior cruciate-retaining unconstrained total knee replacements were studied. The components were fully conforming in the coronal plane and nonconforming in the sagittal plane.

The tibial implants fell into one of two groups: net-shape molded components and machined ram-extruded components. The net-shape molded components consisted of Miller-Galante total knee arthroplasty polyethylene inserts (Zimmer) made from Himont 1900 resin (H1900) (Himont, Wilmington, Delaware) conforming to the polyethylene standard ASTM F 648 type 3. The H1900 resin is currently in use and is manufactured by Montell (Wilmington, Delaware). This material was consolidated by uniaxial compression-molding without the addition of calcium stearate. The final implant geometry was determined by the molding process. The machined ram-extruded components were Miller-Galante II total knee arthroplasty polyethylene inserts (Zimmer) made from GUR 4150 resin conforming to the polyethylene standard ASTM F 648 type 2. GUR 4150 was widely used until the last few years, at which time most implant manufacturers switched to the stearate-free resin GUR 1050 (Ticona, Summit, New Jersey). This material was consolidated by ram-extrusion with the addition of approximately 0.05% calcium stearate. The ram-extruded bar was then machined to form the final implant geometry. Thus, the major differences between the two fabrication processes were the method of final geometry shaping and the method of consolidation of the base resin. For both fabrication processes, the final components were sterilized with gamma irradiation in air and were packaged in air. The corresponding metal trays for both types of tibial inserts were made of Ti-6Al-4V alloy with either a polymethylmethacrylate precoat for cement fixation or a commercially pure titanium fiber-metal porous coating for cementless fixation. The Miller-Galante and Miller-Galante II trays had similar geometry and design features, including a peripheral containment rim and a dovetail locking mechanism to hold the polyethylene insert. The counterfacing femoral component was made either from Ti-6Al-4V alloy or from cobalt-chromium alloy. Data on the material of the counterfacing femoral component were available for sixty-eight retrieved implants. There was no significant difference (at the $p < 0.05$ level) in the composition of the counterfacing femoral component between the two groups of tibial polyethylene inserts.

The net-shape molded H1900 group consisted of twenty-six polyethylene inserts that were retrieved after six to 144 months of implantation (Table I). Of these, fourteen components had been implanted for longer than five years. Nine tibial trays were associated with a cemented implant-bone interface, and ten were associated with a cementless implant-bone interface. The type of interface was not recorded for seven retrieved implants. The average age of the patients at the time of the index arthroplasty was 68.2 years (range, forty-seven to ninety-one years). There were ten men and sixteen women. Twenty-one of the components in this group were retrieved at the time of revision surgery, and five were retrieved post mortem. The most common reason for revision surgery for patients with this insert was a complication related to the patellar component (Table II), followed by infection and then by loosening and instability.

The ram-extruded machined GUR 4150 group consisted of forty-three polyethylene inserts that were retrieved after one to 106 months of implantation, with ten compo-

TABLE I Data on the Groups

Group	Total Number of Explants	Implantation Time *(mo)**	Gender (M, F) *(no. of patients)*	Patient Age at Surgery *(yr)**	Type of Retrieval (Revision, Post Mortem) *(no. of implants)*	Type of Implant-Bone Interface†	Material of Counterfacing Component†
Net-shape molded	26	61 (6 to 144)‡	10 (38%), 16 (62%)	68.2 (47 to 91)	21 (81%), 5 (19%)	9 cemented, 10 cementless	13 Ti-6Al-4V, 13 cobalt-chromium
Machined ram-extruded	43	33 (1 to 106)‡	17 (40%), 26 (60%)	67.7 (40 to 94)	34 (79%), 9 (21%)	29 cemented, 9 cementless	15 Ti-6Al-4V, 27 cobalt-chromium

*The data are given as the mean, with the range in parentheses. †Data were not recorded for all specimens. ‡The difference between the groups was significant (p = 0.007).

TABLE II Reason for Removal of Failed Components at Revision

Group	Total Number of Failed Components	Reason for Removal					
		Infection	Loosening	Instability	Fracture	Patellar Problems	Other
Net-shape molded	21	4 (19%)	3 (14%)	3 (14%)	1 (5%)	8 (38%)	2* (10%)
Machined ram-extruded	34	7 (21%)	7 (21%)	6 (18%)	3 (9%)	7 (21%)	4† (12%)

*One component was removed because of excessive polyethylene wear, and one was removed for an unknown reason. †One component was removed because of arthrofibrosis; one, because of hemorrhagic synovitis; one, for screw removal; and one, for an unknown reason.

nents having been implanted for longer than five years (Table I). Twenty-nine tibial trays were associated with a cemented implant-bone interface, and nine were associated with a cementless interface. In five cases, the type of interface was not recorded. The average age of the patients at the time of the index arthroplasty was 67.7 years (range, forty to ninety-four years). There were seventeen men and twenty-six women. Thirty-four components were retrieved at the time of revision surgery, and nine were retrieved post mortem. The most common reasons for revision surgery in this group was a complication related to the patellar component, infection, and loosening (Table II).

There were no significant demographic differences (at the $p < 0.05$ level) between the two groups with regard to age, gender, or reason for revision surgery. The mean time from the index arthroplasty to the retrieval of the implant was shorter for the machined ram-extruded components than for the net-shape molded components ($p = 0.007$). There were more cemented interfaces in the ram-extruded machined GUR 4150 group than in the net-shape molded H1900 group ($p = 0.039$).

The medial and lateral articulating surfaces of the inserts were inspected with use of a stereo microscope at 18-power magnification. Digital images of the components were then captured with use of a Panasonic WV-CD50 camera (Panasonic USA, Secaucus, New Jersey) with a DT2851 frame grabber (Data Translation, Marlboro, Massachusetts). An earlier established system of damage identification[11,12] was adopted for this study after restricting the number of damage modes to three. We addressed the two types of surface damage that are most likely to be responsible for a large amount of debris generation: pitting and delamination. In addition, the articulating surface was examined for dimensional change because of its potential to accelerate the other modes of surface damage by affecting joint kinematics. The term "dimensional change," rather than "deformation," was used to describe a permanent change in surface shape because of the difficulty in distinguishing between deformation due to creep and actual loss of the material. Thus, the components were first inspected for the presence or absence of pitting, dimensional change, and delamination. Separate scores for the extent and the severity of surface damage were then assigned to the medial and lateral compartment of each insert.

The extent of each type of damage was assessed with use of Image-Pro image-analysis software (Media Cybernetics, Silver Spring, Maryland) and was expressed as a percentage of the surface occupied by the specific mode of damage. Severity scores were assigned on the basis of the intensity of surface damage. The severity of pitting was expressed as the median size (in mm) of the observed pits. The severity of dimensional change was assigned a score of 1 if the surface damage could only be detected visually on the basis of its reflective properties, a score of 2 if the same type of surface damage was palpable, and a score of 3 if there was a change in gross surface shape. The severity of delamination was quantified on the basis of previously described criteria[7]. Visible delamination with discoloration at the subsurface level without propagation into the surface was assigned a severity score of 1, more advanced delamination with surface involvement but without removal of the material was assigned a score of 2, and damage with removal of a layer of material from the surface was assigned a score of 3.

Multiple linear regression was used to test for the effects of several variables (duration of implantation, age, gender, component thickness, type of implant-bone interface, and type of counterfacing component material) on the continuous descriptors of polyethylene damage, such as the extent of all three modes of damage and the severity of pitting. The Spearman rank correlation coefficient was used to test the relationship between the same variables and the discrete descriptors of polyethylene damage reflecting the severity of dimensional change and the severity of delamination. Chi-square tests were used to assess the effects of individual factors on the presence of specific modes of damage. Paired sign tests were used to test for medial-lateral differences. As a way of examining the two groups in terms of the time distribution between the initial surgery and the discovery of the particular mode of damage, Kaplan-Meier curves and the log-rank test were used to compare implant types with respect to the time from the initial surgery to the discovery of damage. This method was also used to compare potential differences due to the type of implant-bone interface, the type of counterfacing component material, the type of retrieval (during revision surgery or post mortem), and gender. The Cox proportional-hazards model was used to perform multivariate analysis of additional factors that independently affected the time from the initial surgery to the discovery of damage, including the operating surgeon, the thickness of the component, and the age of the patient.

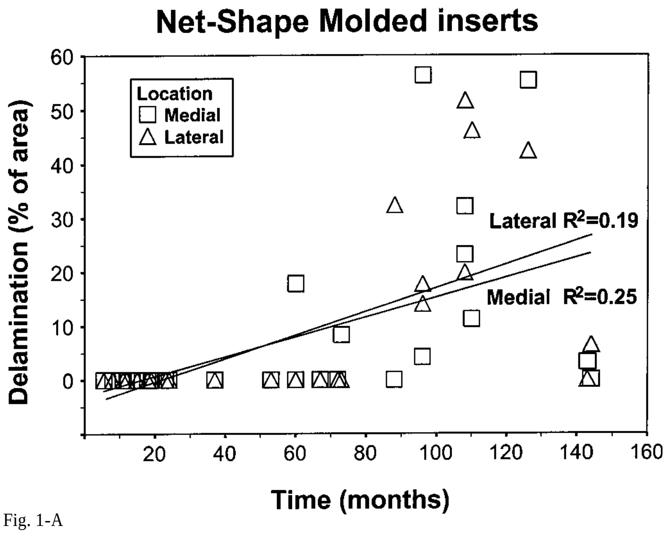

Fig. 1-A

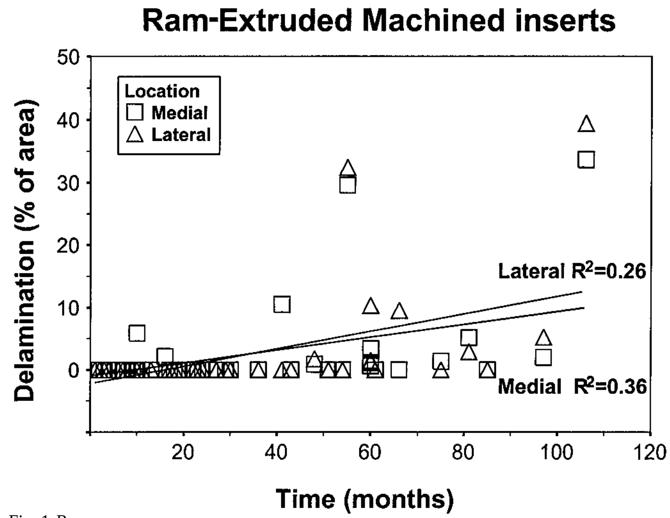

Fig. 1-B

Illustrations depicting the extent of delamination versus implantation time in the net-shape molded group (Fig. 1-A) and the machined ram-extruded group (Fig. 1-B).

Results

Pitting and dimensional change were the most common modes of surface damage observed in both the net-shape molded group and the ram-extruded machined group. In the net-shape molded group, pitting was present on twenty-two (85%) of the components medially and on twenty-four (92%) of the components laterally. Similarly, in the machined ram-extruded group, pitting was observed on thirty-three (77%) of the components medially and on thirty-five (81%) of the components laterally. There was higher prevalence of pitting on the components associated with a cemented interface than on those associated with a cementless interface in both implant groups ($p = 0.001$ medially, and $p = 0.013$ laterally). In the net-shape molded group, dimensional change was present in twenty-one (81%) of the components medially and in twenty (77%) of the components laterally. In the machined ram-extruded group, dimensional change was present in twenty-two (51%) of the components medially and in twenty-five (58%) of the components laterally. Delamination was the least common mode of damage, with nine (35%) of the components affected medially and eight (31%) of the components affected laterally in the net-shape molded group and with twelve (28%) of the components affected medially and nine (21%) of the components affected laterally in the machined ram-extruded group. On the basis of numbers available, medial-lateral differences in the extent of the damage were not significant for any of the damage modes.

The extent of damage varied widely across both groups. The extent of pitting ranged from 0.02% to 68%, the extent of dimensional change ranged from 0.93% to 75%, and the extent of delamination ranged from 0.63% to 56%. The extent of delamination increased with implantation time in both the net-shape molded group and the machined ram-extruded group (Figs. 1-A and 1-B) ($R^2 = 0.25$ medially and $R^2 = 0.19$ laterally in the net-shape molded group, and $R^2 = 0.36$ medially and $R^2 = 0.26$ laterally in the machined ram-extruded group; $p < 0.0005$ for all). Interestingly, no severe delamination was observed before sixty months after implantation in the net-shape molded group, whereas severe delamination was observed as early as ten months after implantation in the machined ram-extruded group (Figs. 1-A and 1-B). There was a significant increase in dimensional change over time, both medially and laterally, in the machined ram-extruded group only (Fig. 2) ($R^2 = 0.16$ medially and $R^2 = 0.30$ laterally; $p < 0.0005$ for both).

The severity of pitting, expressed as the median size of the pits, was between 0.2 and 1.5 mm in the machined ram-extruded group and between 0.25 and 7.0 mm in the net-shape molded group. The severity of lateral pitting was greater than

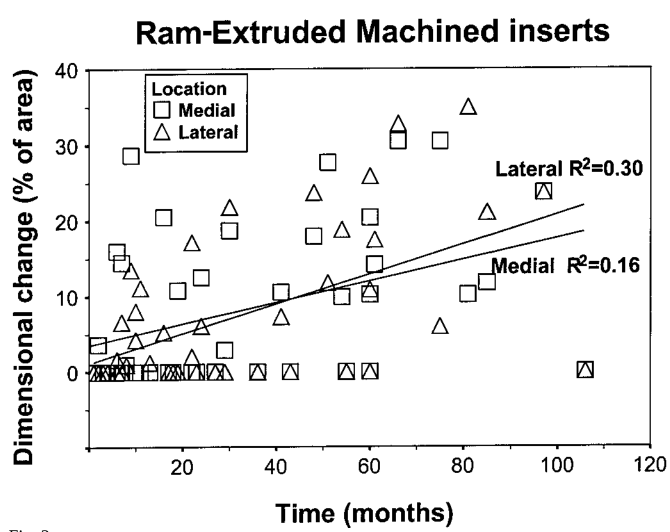

Fig. 2

Illustration depicting the increase in the extent of dimensional change in the machined ram-extruded group.

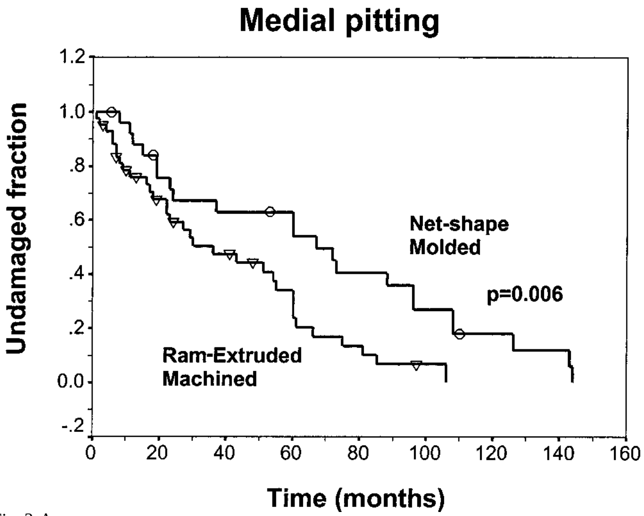

Fig. 3-A

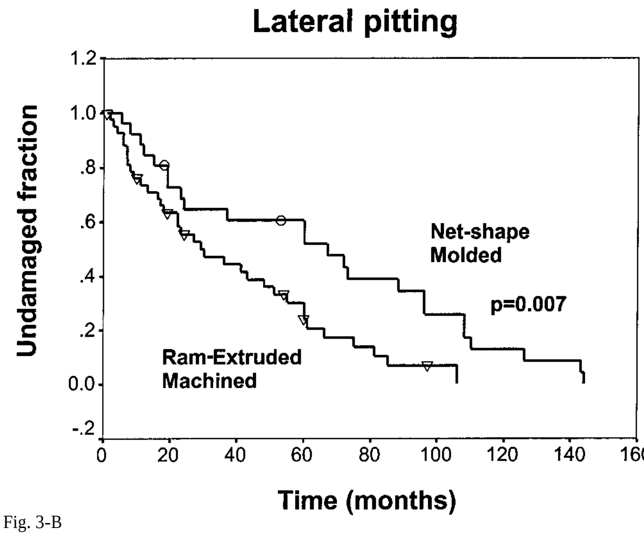

Fig. 3-B

Illustrations depicting the time distribution between the initial surgery and the discovery of medial pitting (Fig. 3-A) and lateral pitting (Fig. 3-B).

that of a medial pitting in the net-shape molded group ($p = 0.049$). The severity of pitting on either side was higher in association with a cemented interface (rho = 0.448 medially and 0.357 laterally; $p < 0.001$). All three delamination grades were present in both groups. The severity of delamination increased with time medially and laterally in both groups (rho = 0.66 medially and 0.70 laterally in the net-shape molded group, and rho = 0.52 medially and 0.61 laterally in the machined ram-extruded group; $p < 0.0005$ for all). The observed dimensional change never exceeded a severity score of 2 (a palpable in the change surface shape), indicating that gross surface change was not present in the polyethylene inserts that were studied.

On the basis of the numbers available, no other significant correlations were observed among the variables of implantation time, age, gender, component thickness, type of retrieval (during revision or post mortem), counterface material, and surface damage.

Analysis of the time distribution between the initial surgery and the discovery of damage by pitting, dimensional change, or delamination revealed that the interval was longer for the net-shape molded group than for the machined ram-extruded group for all three modes of damage (Figs. 3-A through 5-B). With the exception of medial dimensional change, these differences were all significant ($p = 0.006$ for medial pitting, $p = 0.007$ for lateral pitting, $p = 0.027$ for lateral dimensional change, $p = 0.001$ for medial delamination, and $p = 0.001$ for lateral delamination). Since pitting was more often observed in association with a cemented implant-bone interface, we applied the Cox proportional-hazards model to distinguish the effects of implant type and bone-implant interface type on the time to the onset of pitting. This analysis showed that the type of implant rather than the type of implant-bone interface had an effect on the time distribution ($p = 0.009$ medially and $p = 0.016$ laterally). The rest of the tested variables, including the type of counterfacing component material, the operating surgeon, the type of retrieval (during revision or post mortem), gender, and component thickness, did not affect the time from the initial surgery to the discovery of damage.

Discussion

Pitting was the most extensive mode of damage observed on the articulating surface of the retrieved tibial polyethylene inserts in both the net-shape molded group and the machined ram-extruded group, followed by dimensional change and delamination. With the exception of the extent of dimensional change in the machined ram-extruded group, the descriptors of pitting and dimensional change did not increase with implantation time. We did not observe that wear was being initi-

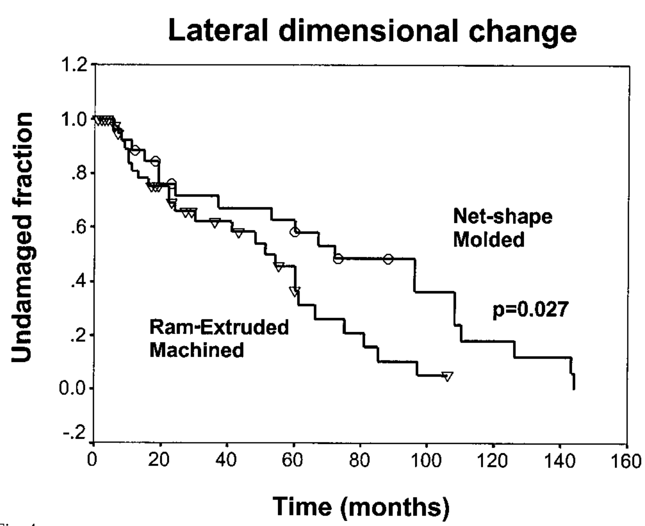

Fig. 4

Illustration depicting the time distribution between the initial surgery and the discovery of lateral dimensional change.

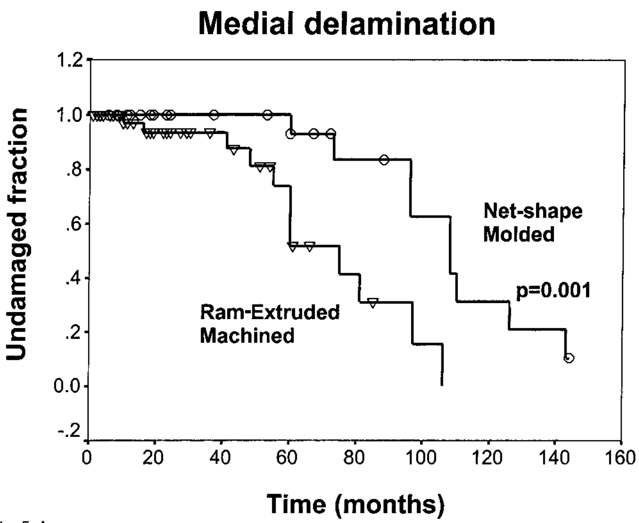

Fig. 5-A

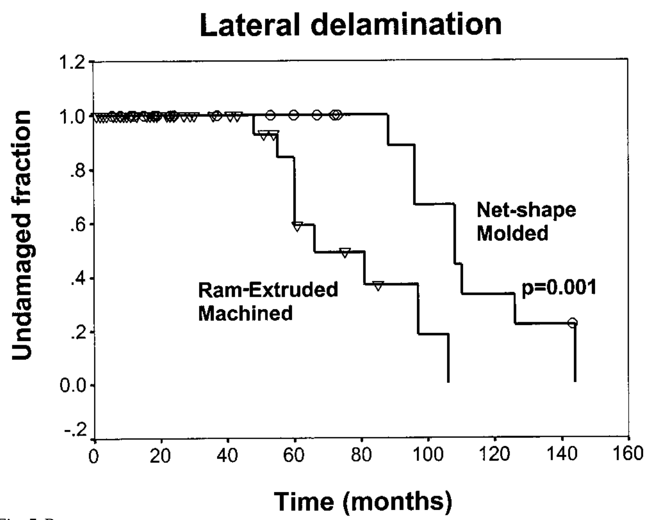

Fig. 5-B

Illustrations depicting the time distribution between the initial surgery and the discovery of medial delamination (Fig. 5-A) and lateral delamination (Fig. 5-B).

ated by posteromedial dimensional change as was reported in a previous study of similar semiconstrained tibial inserts[13]. Although delamination was the least common of the observed modes of damage, its extent and severity were the only damage descriptors that increased with implantation time in both groups. This finding suggests that the delamination process, which has often been associated with the production of large amounts of debris and component failure[14,15], may be caused by a subsurface fatigue process[16] that is directly related to material aging with a resultant loss of shear strength[17]. The present study demonstrates that net-shape molded and machined ram-extruded inserts have a different time-course for the onset of severe delamination. In contrast with the findings in the machined ram-extruded group, no severe delamination was observed before sixty months after implantation in the net-shape molded group. This finding is consistent with reports that net-shape molded components have a greater resistance to oxidation[9] and therefore a slower loss of subsurface strength.

The absence of direct time-related changes in either the extent or the severity of the other two modes of damage suggests that other factors, such as third-body wear, surgical technique (for example, alignment, ligament-balancing, and so on), or activity level may have contributed to the presence of pitting and dimensional change. Since the present study did not distinguish between pits that were formed by the ejection of material due to locally high stresses at the surface[18] and pits that were formed through indentation, we suspect that some of the pitting could be explained by the presence of harder third-body particles, possibly bone cement. This supposition is consistent with our findings of a higher prevalence of pitting and increased pit size in association with the cemented implant-bone interface. This mechanism of pitting would have taken place early in the implantation period, thus weakening the relationship between this type of surface damage and implantation time. If higher activity levels result in higher material stresses within the liner, one would expect a larger magnitude of dimensional change due to cold flow in younger patients. The fact that patient age was not correlated with any of the modes of damage suggests that, in our study population, age may not have been a sufficient descriptor of patient activity. The lack of medial-lateral differences in surface damage indicates that physiologically higher joint-reaction forces acting across the medial compartment of a knee joint[19] may not necessarily result in asymmetric surface damage of the tibial liner. The only medial-lateral difference that was detected was for pitting in the net-shape molded group, in which more damage was observed laterally.

It should be pointed out that the findings of this study are strictly applicable only to components that are sterilized by gamma irradiation in air and packaged in air. The impact of other factors known to affect polyethylene wear, such as shelf life, patient activity, patient weight, and implant alignment could not be ascertained in this retrieval study as data were not available on a sufficient number of patients to allow for statistically meaningful conclusions.

In summary, the improved performance of the net-shape molded tibial articular surface (as indicated by later onset of all modes of damage except for medial dimensional change) may be related to the polyethylene resin, the exclusion of calcium stearate, the method of consolidation, or the method of final geometry shaping. In this particular implant application, the calcium-stearate-free net-shape molded H1900 resin components demonstrated better in vivo function. ■

NOTE: The lead author of this paper, Aivars Berzins, M.D., who was a first-year resident in Orthopaedic Surgery at Rush-Presbyterian-St. Luke's Medical Center, died suddenly and tragically on April 4, 2002, amidst his colleagues and friends. Dr. Berzins was pursuing his dream of being an orthopaedic surgeon/basic science investigator after many years of hard work in the Biomaterials Research Laboratories at Rush. He was a clear-thinking scientist who possessed a remarkably intuitive understanding of biomechanics and consistently displayed ingenuity in the conduct of his research. He was just beginning to apply these gifts in the clinics, hospital wards, and operating room when his life was cut short. Dr. Berzins was a kind, loyal, and compassionate man who is survived by his wife, Ilze, and his daughters, Kristine and Elina. The orthopaedic surgery community has lost a young man with a great potential to make important and long-lasting contributions to our field. He will be sorely missed by his friends and colleagues at Rush. Our hearts go out to his loved ones who will feel his loss most profoundly.

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