EPM — Endo-Plant-Müller Vertriebsgesellschaft mbH

The new EPM MUELLER® modular Hollow Rasp

- Reduction of possible complications and a minimization of the FES-risk through lower developed pressure inside the cavity during rasping
- Exact fit of the implants, higher precision
- Depending on the rasp-philosophy of the user, a higher or lower permeability of liquids and solid materials into the inside of the rasp can be achieved. A change in the cutting geometry modifies the cortical cutting or the spongiest compacting properties of the rasp without increasing the developed pressure.
- After rasping, bone grafting material can be easily earned from the inside of the modular rasp, if needed.
- Easy cleaning because of the modularity
- Through the rasp shaft, the rasp can be connected to the slide hammer, pneumatic device or used only with a hammer

EPM MUELLER® modular Hollow rasp with shaft and slide hammer, with adaptor for pneumatic device

Low - Impact - Rasping

New Hollow Rasp System

BONE MARROW RASP: EP 0 745 352 A2, US 5,681,315

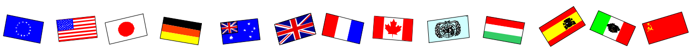

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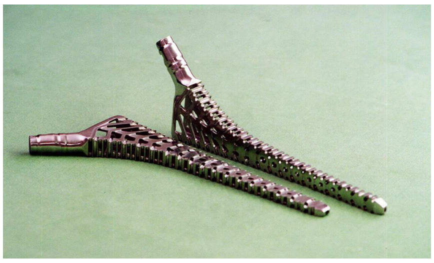
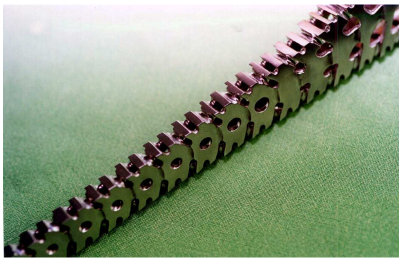
Table of Contents





1. Management of Innovation

The research and the preparation for the patent application began in August 1993 on the initiative of the doctors' team of the prosthetic department at the Garmisch-Parten-Kirchen hospital. Since then, a complete modular system of instruments in the field of hip prosthetics has been developed that is protected by several patents .

The promotion the project received from the Ministry of Trade and Commerce has also contributed to completing the first stage in the development of the hollow rasp system in September 1997.

At present, our hollow rasp system is the only patent in the field of endoprosthetics with a rasp design that has been put into practice and that was declared "clinical mature for testing" by the users.

2. The development of Hollow Rasp

2.1Medical and Scientific Aspects

Implantation technology currently uses full metal rasps for the preparation of the bone marrow area, i.e. for the preparation of the marrow area before inserting the endoprosthesis. One disadvantage of the existing rasp method are the enormous forces, which may lead to an inaccurate bone treatment and even to bone fractures, because the full rasp is driven into the bone cavity like a wedge. Another shortcoming of this method is seen in the pressure increase in the bone marrow area that occurs while driving in the rasp. The severe consequences of this have been proved. Intra-osseous pressure points (IMD-points) may occur while driving in the conventional rasp, that lead to the so called "Fat embolic syndrome" (FES). The complications may be fatal as has been repeatedly proven. *(Der Orthopäde, volume 24, book 2, April 1995).*
As these operations are optional interventions, any further complication must be seen as an additional risk. The conventional rasps also require a considerable physical input from the operator, which may have a negative impact on the efficiency, accuracy and security, when several prostheses have to be implanted in one day.

Conventional rasp technology is "high impact surgery" which does not come up to the high technical standard in the other fields of endoprosthetics.

"Experts in the subject have hardly been able to understand for a long time that the highly developed technologies used for the production of prostheses are confronted with implantation techniques that seem to come from the stone-age. Thus, even today in most of the cases the preparation of the marrow area is still done by forming rasps that are driven into the sawn-off shaft of the thigh with the help of a heavy hammer. Apart from the feeling of the operator, this is done in a relatively uncontrolled manner, which may, in some, fortunately only rare cases, lead to the fracture of the thigh shaft. As far as driving in the forming rasps is concerned, or speaking more generally, as far as the modeling of the prosthesis bearing is concerned, an innovation seems to be long overdue ..."

(Extract from: Expert opinion No. 973 by Dr. med. Dipl.-Ing. H. Heindl, dated April 7,1997 - commissioned by the Bavarian Ministry of Trade, Commerce and Technology)

Against this background, the novelty of the system lies in the practical use of the hollow rasp on the one hand and thus in the avoidance of such problems as the ones mentioned above. On the other hand, a complete system has been extended in such a way that a newly developed pneumatic rasp may now be used. Such meaningful combination has not been known before. It corresponds to the modern idea of: ***„Low impact surgery".***

2.2. Product Description

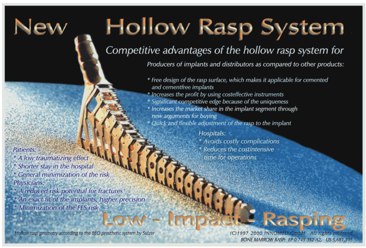


Fig.4 Hollow rasp - geometry according to the BEO prosthetic system by Sulzer

The new hollow rasp can be applied with different types of the cutting geometry both in the cemented and the cement-free hip prosthetics.

The new hollow marrow area rasp makes it possible to reduce the radial and axial bone tension because of its new cutting properties and thus allows to implant endoprosthetic shafts more smoothly.

Figure 5 show the so-called "cycle pump effect" as a comparison between the full and the hollow rasp, resulting in an adverse intramedullar increase of the pressure.

The volume reduction that occurs when inserting the full rasp into the femur (thigh bone) generates an increase of pressure inside the bone. This cannot happen in the case of a hollow rasp (Fig. 5) as there is atmospheric pressure inside the bone at any time.

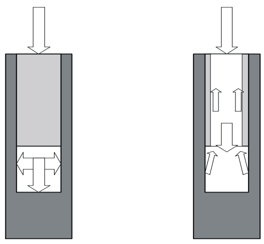


Fig.5

2.3. The Advantages of the Raspsystem

- In its advance direction, the surface of the rasp is open at about 75 % as a result of its specifically defined cutting geometry and its thin wall thickness, so that the material can be entered. This reduces the amount of displaced bone marrow considerably.

- While the rasp has the same surface, the volume of the material is reduced by 50-70% in comparison with conventional full rasps, which improves the handling essentially.

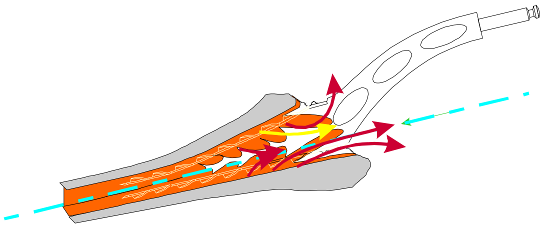


Fig.6

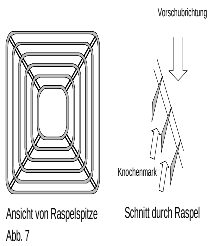


Fig.7

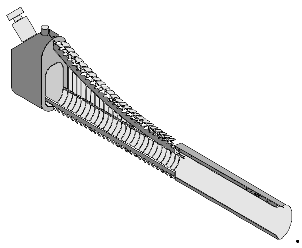


Fig.8

- Because of a special design of the opening geometry in the rasp, it is mainly liquids which are conducted into the inside of the rasp so that the desired compression effect of the spongiosa itself is retained.

- The rasps can be produced in any shape, i.e. both rasps for all kinds of straight-shaft prostheses and rasps for anatomically formed implants. Furthermore, different types of the cutting geometry may be executed exclusively in the proximal and in distal part of the rasp. The hard and tenacious alloy ensures that the rasps can be used several times.

- Liquid suction devices can be integrated.

- Cleaning/maintenance: by ultra-sound and steam pressure cleaning devices.

3. Scientific Comparison

EFFECT ON INTRAMEDULLAR FEMORAL PRESSURE BY A NEW HOLLOW RASP SYSTEM VS. STANDARD RASPS

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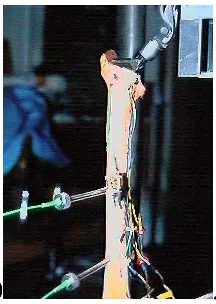
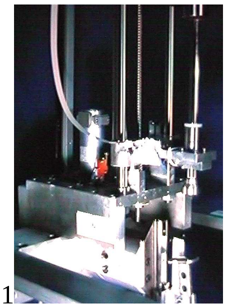
Introduction:

Fat embolic syndrome is a well known life threatening risk in total hip arthroplasty. One of the most important pathogenetic factors for the bone marrow intravasation are any manipulations, which lead to increased intramedullar pressure. So fat embolic phenomena documented by transoesophageal echocardiography occur - beside stem insertion - also during the preparation of the proximal femur with awls and rasps (Hofmann 1999, Schmidt 2000). Therefore the reduction of intramedullar pressure for this preparation step is an essential aim to minimize the fat embolic risks.
The objective of the present study was to evaluate the effect of a new developed hollow rasp system on the intramedullar femoral pressure in comparison to the conventional rasp system with the identical geometry.

Materials and Methods:

12 fresh frozen human femora (6 pairs) with a mean age of 55.8 years (23-69 yrs) were used for this study. The macroscopic and radiographic examination revealed no pathologic changes. Using an oscillating saw the proximal osteotomy was performed. For an identical starting position of the rasps a central 9 mm hole was drilled in the cancellous bone along the axis of the proximal femur with a depth of 40 mm. According to the x-rays the final rasp size and there distal tip position was determined. 1 cm and 11 cm below this assessed distal tip position two 5 mm holes where drilled through the anterior cortex of the femora.

Two pressure transducers were threaded through the predrilled holes to reach into the medullary canal proximally (P1) and distally (P2) (Fig.9). A special testing device was constructed to hold the femur and the rasp in a standardized position (Fig.10).

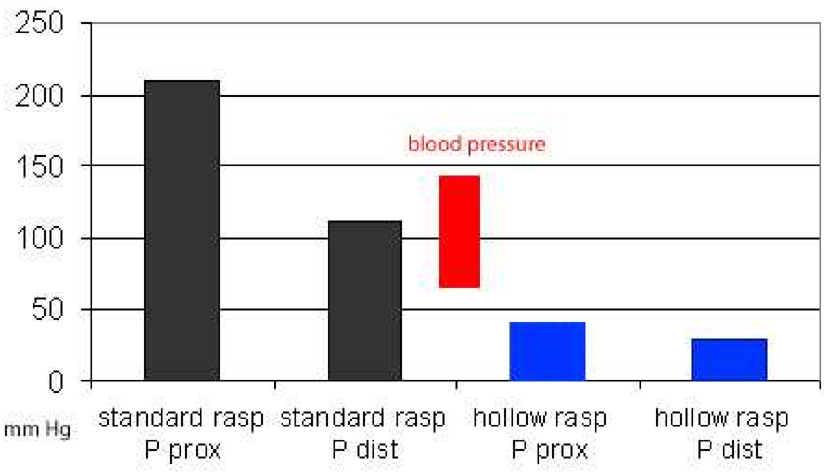
Fig.9  .Fig.10  Fig.11 

With a precision gliding mechanism a modified mallet (1.2 kg, similar to mallet weights used in surgery) hit the rasp always from an equidistant altitude in respect to the actual rasp position (acceleration distance 1.05 m) to guarantee identical impact forces (Fig.11).
Before testing low viscosity mineral oil , similar to the properties of the fatty liquid phase of the bone marrow (e.g. released after drilling the cortical holes), was filled in the femoral cavity since all air was removed. After calibration of the pressure transducers the insertion of the smallest rasp started and the data were continuos digital documented in 0.2 s intervals. Before the insertion of the next rasp size always a recalibration was performed.
For statistical analysis of the paired data the Wilcoxon Signed Rank Test was applied.

Results:

From each rasping procedure of a single rasp size the maximum intramedullar pressure was determined.
In the six femora prepared with the standard rasps the maximum pressure values ranged for the proximal location (P1) from 11.3 to 1035.3 mmHg with a mean of 208.6 mmHg (SD $\pm$ 256.6). At the distal measurement point (P2) the values were significantly smaller ($p<0.005$) compared to proximally with a range from 4.5 to 527.4 mmHg and a mean of 111.0 mmHg (SD $\pm$ 111.0).
In the six opposite femora prepared with a new developed hollow rasp system the maximum intramedullar pressures for P1 ranged from 3.0 to 152.3 mmHg with a mean of 40.5 mmHg (SD $\pm$ 33.8). For the hollow rasps no statistical difference was found for the proximal values compared to the distal ones, for which a range of 4.5 to 45.0 mmHg with a mean of 29.3 mmHg (SD $\pm$ 13.5) was found.

Table 1: Comparison of intramedullar pressures caused by the standard solid rasps vs. the new developed hollow rasp system of identical geometry. The intramedullar pressures caused by the standard rasps are significantly higher vs. the hollow rasp system.
$p < 0.0001$; ** $p < 0.005$; n. s. = not significant



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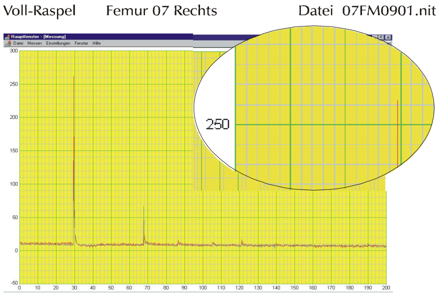

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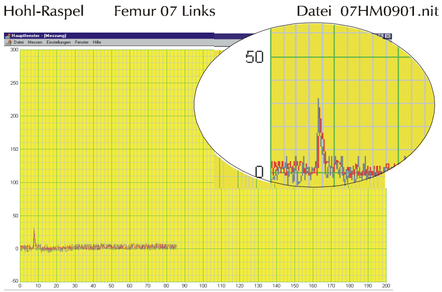


Table 1

The comparison of the pressure data between the standard rasp vs. the hollow rasp group demonstrated a high statistical difference. So proximally as well as distally the intramedullar pressures in the femora prepared by the standard solid rasps were significantly higher than in the hollow rasp group ($p<0.0001$ proximal and distal) (Tab. 1, Fig.12).

Discussion:

We constructed a special testing device to hold the femur and the rasp in a standardized position and with a precision gliding mechanism a modified mallet hit the rasp always from an equidistant altitude in respect to the actual rasp position to guarantee identical impact forces. With high sensitive transducers the intramedullar pressure was measured 1 and 11 cm below the final position of the distal tip of the rasp. Under these standardized conditions 12 paired femora were analyzed.

The data of this study demonstrate that the used standard solid rasps caused around the distal tip of the rasp mean intramedullar pressures of 209 mmHg with a maximum of 1035 mmHg. These values are obvious above the physiological systolic pressure of a human being. And even the distal measurements with a mean of 111 mmHg are higher than the normal diastolic blood pressure. This data suggest a high potential risk for bone marrow intravasation and consecutive embolic phenomena.

Fig.13

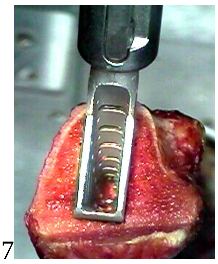
Fig.14

Fig.15

In contrast the new developed hollow rasp system of identical geometry caused proximally as well as distally highly significant lower intramedullar pressures than the standard solid rasps. The mean values in both measured locations are smaller than 45 mmHg with only a single value above 90 mmHg. The macroscopic evaluation of the rasps, removed after the rasping procedure, already indicate one of the most important factors for the pressure differences. Whereas the ”teeth” of the solid rasps were almost completely filled with compacted bony debris (Fig.13+14) the hollow rasps always had remaining open areas to the hollow center of the tool (Fig.15).

Fig.16

Fig.17



(Fig.16, at the left the smallest rasp, Fig.17).

Therefore – especially in the smallest rasp size – a lot of bone marrow debris was found in the ”core” of the hollow rasps

The present study proves the significant effect of different rasp designs on the intramedullar femoral pressure. On the other hand in vivo studies demonstrated that the rise of the intramedullar pressure in the femur is the most important pathogenetic factor of pulmonary embolism during total hip arthroplasty (Pitto 1998).

Therefore a rasp design as the new developed hollow rasp system with a significant reduction of intramedullar pressure is of very high clinical relevance.

So in addition to other important rules as careful preparation techniques (Hofmann 1999, Wenda 1993) the tested hollow rasp design can get a simple, but important tool to minimize the risk of bone marrow intravasation and to subsequently prevent fat embolism with cardiorespiratory deterioration.

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4. Application

Competitive advantages of the hollow rasp system for

Producers of implants and distributors as compared to other products:

- Free design of the rasp surface, which makes it applicable for cemented and cement-free implants
- Depending on the rasp-philosophy of the user, a higher or lower permeability of liquids and solid materials into the insi of the rasp can be achieved. A change in the cutting geometry modifies the cutting or the compacting properties of the rasp.
- Retains the tried and tested implant system
- Increases the profit by using cost-effective instruments
- Significant competitive edge because of the uniqueness
- Increases the market share in the implant segment through new arguments for buying

Quick and flexible adjustment of the rasp to the implant

Physicians:

- Better and easier handling
- Less physical input for the operator
- A reduced risk potential for fractures
- An exact fit of the implants, higher precision
- A reduction of possible complications and a minimization of the FES-risk
- No costly adaptation of the operational technology

Hospitals:

- Economic efficiency for hospitals:
- Avoids costly complications
- Reduces the cost-intensive time for operations
- Low investment costs

Patients:

- A low traumatizing effect
- Shorter stay in the hospital
- General minimization of the risk which comes along with a hip operation, in particular with an FES which might be fatal
- Makes a decision for a hip prosthesis easier

High - Impact - Rasping

Low - Impact – Rasping

Fig.18

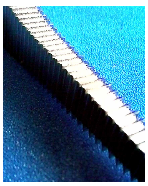

Fig.19

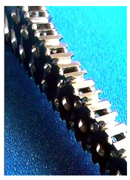

Fig.20

- **yesterday** **today** **tomorrow**

5. Annex.

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